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Impact of Balloon Guide Catheters in Elderly Patients Treated with Mechanical Thrombectomy: Insights from the ROSSETTI Registry

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ABSTRACT

BACKGROUND AND PURPOSE: Several nonrandomized studies have demonstrated the effectiveness of balloon guide catheters in treating patients with anterior circulation large-vessel occlusion. However, their impact on the elderly populations has been underreported. We aimed to analyze the effect of balloon guide catheters in a cohort of elderly patients (80 years of age or older) with anterior circulation large-vessel occlusion.

MATERIALS AND METHODS: Consecutive patients from June 2019 to June 2022 were collected from the ROSSETTI Registry. Demographic and clinical data, angiographic endovascular technique, and clinical outcome were compared between balloon guide catheter and non-balloon guide catheter groups. We studied the association between balloon guide catheters and the rate of complete recanalization after a single first-pass effect modified TIC1 2c–3, as well as their association with functional independence at 3 months.

RESULTS: A total of 808 patients were included during this period, 465 (57.5%) of whom were treated with balloon guide catheters. Patients treated with balloon guide catheters were older, had more neurologic severity at admission and lower baseline ASPECTS, and were less likely to receive IV fibrinolytics. No differences were observed in terms of the modified first-pass effect between groups (45.8 versus 39.9%, $P = .096$). In the multivariable regression analysis, balloon guide catheter use was not independently associated with a modified first-pass effect or the final modified TIC1 2c–3, or with functional independence at 3 months.

CONCLUSIONS: In our study, balloon guide catheter use during endovascular treatment of anterior circulation large-vessel occlusion in elderly patients did not predict the first-pass effect, near-complete final recanalization, or functional independence at 3 months. Further studies, including randomized clinical trials, are needed to confirm these results.

ABBREVIATIONS: BGC = balloon guide catheter; ET = endovascular thrombectomy; EVT = endovascular treatment; GPTFR = groin puncture to first run; GTR = groin puncture to revascularization time; LVO = large-vessel occlusion; mFPE = modified first-pass effect; mTICI = modified TIC1; sICH = symptomatic intracranial hemorrhage

The efficacy of endovascular treatment (EVT) in elderly patients with anterior circulation large-vessel occlusion (LVO) has been proven in several studies,^{1–5} though the proportion of elderly patients included in clinical trials (around 15%)

has been low and likely unrepresentative of the real-life situation.⁶

Additionally, the use of the balloon guide catheter (BGC) has been widely associated with higher reperfusion rates in anterior

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circulation LVO and better clinical outcomes.⁷⁻¹¹ However, the efficacy of the BGC in the elderly population is uncertain and poorly reported; consequently, its potential benefit in this population has yet to be proven.

The aim of the study was to determine the effect of BGC use on the rates of modified first-pass effect (mFPE) in a large cohort of elderly patients with anterior circulation LVO, due to the paucity of available data and the ongoing debate over the optimal endovascular approach to achieve complete reperfusion.

MATERIALS AND METHODS

The Registry of Combined vs Single Thrombectomy Techniques (ROSSETTI) (ClinicalTrials.gov Identifier: NCT04886687) is an ongoing investigator-initiated prospective study recruiting deidentified consecutive patients with acute ischemic stroke secondary to anterior circulation LVO treated with endovascular thrombectomy (ET) across 15 comprehensive stroke centers in Spain.

For this study, conducted according to the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) guidelines, we included patients treated from June 2019 to June 2022. The study inclusion criteria were the following: 80 years of age or older with confirmed LVO in the anterior circulation (intracranial ICA, M1, proximal M2); time from last seen well to treatment up to 24 hours; baseline NIHSS score ≥ 2 ; and a premorbid mRS score ≤ 2 . The presence of multiterritory arterial embolisms and tandem occlusions was the main exclusion criterion for this study. The type of ET approach and technique was at the discretion of the operator, including the use of BGC or conventional guide catheters.

Qualifying patients were categorized according to whether BGC was used. The primary outcome was the rate of mFPE defined as achieving near-complete/complete revascularization (modified mTICI 2c-3j) after a single-device and single-pass approach.

The secondary outcome was the rate of near-complete reperfusion at the end of the procedure. We also analyzed the association between BGC use and the rate of functional independence, defined as an mRS score of 0-2 at 3-month follow-up.

Demographic and clinical data, the mTICI reperfusion scores, symptomatic intracranial hemorrhage (sICH) (according to the Second European Cooperative Acute Stroke Study [ECASS-II] definition), rates of mFPE defined as achieving mTICI 2b-3 after a single-device and single-pass approach, final rates of successful (mTICI 2b-3) and near-complete (mTICI 2c-3) reperfusion, and rates of functional independence at 3 months were assessed for the BGC and non-BGC subgroups. Groin puncture to revascularization time (GTR) was subcategorized into groin puncture to first run (GPTFR) and first run to final revascularization (ET time) and was also compared between the 2 groups. Reperfusion scores and sICH evaluation were center-adjudicated by experienced interventionists and neuroradiologists, and functional outcome at 3 months was assessed by stroke neurologists blinded to the imaging data.

Statistical Analysis

Demographic and clinical data, procedural details, and angiographic and clinical outcomes were compared in non-BGC-treated versus BGC-treated patients, FPE versus non-FPE events, and independent (mRS ≤ 2) versus dependent functional outcome (mRS > 2) at 3 months. χ^2 and Fisher exact tests were used for categorical variables; the Student *t* test/*F*-test, for continuous variables; and the χ^2 test, for categorical variables. Continuous variables are shown as mean (SD) or median (interquartile intervals) and were compared using the Student *t* test, ANOVA, Mann-Whitney, or Kruskal-Wallis tests as appropriate. Categorical variables were reported as proportions. Variables with a *P* value $< .1$ in the univariate analyses were entered into the multivariable models. Using binary logistic regression models in multivariate analysis, we evaluated the use of BGC as an independent factor contributing to first-pass effect and/or final near-complete recanalization.

All statistical analyses were performed using R statistical and computing software (Version 3.6.1; <http://www.r-project.org/>).

Ethics

All participating centers received institutional review board approval from their respective ethical committees and patients or their representatives signed the corresponding informed consent. The ROSSETTI Registry has been approved by the Independent Ethics Committee of the Hospital (Clinic of Barcelona HCB/2019/0152).

RESULTS

From 1728 patients included in the registry, a total of 808 patients met the inclusion criteria. The median age was 85 years, 521 (64.5%) were women, and 303 patients (37.5%) achieved functional independence at 3 months (Table 1). Patients treated with BGC (465 patients, 57.5%) were significantly older (86 versus 85 years of age, $P < .001$), had better ASPECTS at baseline (9 versus 8, $P < .008$), and had better neurologic status at admission (NIHSS 16 versus 18, $P = .035$).

The primary outcome (mFPE) was achieved in 45.8% of patients in the BGC group and in 39.9% of patients in the non-BGC group, with no statistical differences ($P = .096$). Furthermore, the rates of FPE were also similar between groups (55.9% versus 51%, $P = .168$).

Both successful and near-complete recanalizations were significantly higher in patients treated with BGC (93.8% versus 89.8%, $P = .039$, and 77.4% versus 66.2%, $P = .001$, respectively), with no statistical differences observed in the number of passes, final mTICI 0, or emboli to a new territory. Technical modification was less frequent in the BGC group (21.9% versus 35.4%, $P = .001$), and procedural times were shorter in this group (30 minutes versus 42 minutes, $P = .001$). Figure 1 summarizes the results of the final mTICI by BGC use. NIHSS score at 24 hours was significantly lower (7 versus 10.5, $P = .002$), but no differences

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Table 1: Demographics, clinical and neurologic characteristics by BGC use

	Overall Patients ≥80 Years (n = 808)	Non-BGC Use (n = 343, 42.5%)	BGC Use (n = 465, 57.5%)	P Value
Age (median) (IQR) (yr)	85 (83–88)	85 (82–88)	86 (83–89)	.001
Female sex (No.) (%)	521 (64.5)	217 (63.3)	304 (65.4)	.535
NIHSS score at admission (median) (IQR)	17 (12–21)	18 (13–21)	16 (11–21)	.035
ASPECTS at admission (median) (IQR)	9 (7–10)	8 (7–10)	9 (8–10)	.008
Time from stroke onset to diagnosis (median) (IQR) (min)	280 (180.75–589.25)	300 (196.5–564)	261 (172–609)	.069
IV tPA administered (No.) (%)	212 (26.2)	114 (33.2)	98 (21.1)	<.001
General anesthesia during EVT (No.) (%)	262 (32.4)	120 (35)	142 (30.5)	.142
Right-sided occlusion (No.) (%)	388 (48)	157 (45.8)	231 (49.7)	.272
Level of vessel occlusion (No.) (%)				.002
Carotid terminus	157 (19.5)	79 (23)	78 (16.8)	
MCA-M1	425 (52.7)	189 (55.1)	236 (50.9)	
MCA-M2	225 (27.9)	75 (21.9)	150 (32.3)	
GPTFR (median) (IQR) (min)	7 (5–12)	9 (5–16)	6 (4–10)	<.001
ET time (median) (IQR) (min)	25 (12–43)	30 (16–49)	22 (11–39)	<.001
GTR (median) (IQR) (min)	35 (22–57)	42 (27–66.5)	30 (19–49.25)	<.001
SR use	790 (97.8)	335 (97.7)	455 (97.8)	.863
Distal aspiration catheter use (No.) (%)	422 (52.2)	406 (51.4)	16 (88.9)	.002
Combined technique use (CA + SR)	406 (50.2)	292 (85.1)	114 (24.5)	<.001
FPE (mTICI 3) (No.) (%)	293 (36.3)	112 (32.7)	181 (38.9)	.067
mFPE (mTICI 2c–3) (No.) (%)	350 (43.3)	137 (39.9)	213 (45.8)	.096
FPE (mTICI 2b–3) (No.) (%)	435 (53.8)	175 (51)	260 (55.9)	.168
Final No. of passes (No.) (%)				.991
1	380 (47)	161 (46.9)	219 (47.1)	
2	192 (23.8)	81 (23.6)	111 (23.9)	
>2	236 (29.2)	101 (29.4)	135 (29)	
Technique modification	134 (27.9)	75 (35.4)	59 (21.9)	.001
mTICI 0 after first pass	256 (31.7)	118 (34.4)	138 (29.7)	.154
Final mTICI 0	29 (3.6)	17 (5)	12 (2.6)	.073
Final mTICI ≥ 2b (No.) (%)	744 (92.1)	308 (89.8)	436 (93.8)	.039
Final mTICI ≥ 2c (No.) (%)	587 (72.6)	227 (66.2)	360 (77.4)	<.001
Emboli to new territory	129 (16)	59 (17.2)	70 (15.1)	.410
sICH (No.) (%)	53 (6.6)	36 (10.5)	17 (3.7)	<.001
Complications				.692
Perforation	11 (29.7)	5 (29.4)	6 (30)	
Dissection	15 (40.5)	8 (47.1)	7 (35)	
NIHSS score at 24 hr (median) (IQR)	8 (3–16)	10.5 (4–17)	7 (2–15)	.002
Early neurologic deterioration (No.) (%)	52 (6.4)	26 (7.5)	26 (5.6)	.071
mRS 0–1 at 3 mo	191 (23.6)	81 (23.6)	110 (23.7)	.989
mRS 0–2 at 3 mo	303 (37.5)	136 (39.7)	167 (35.9)	.278
Mortality at 3 mo (No.) (%)	225 (27.8)	107 (31.2)	118 (25.4)	.068

Note:—IQR indicates interquartile range; SR, stent retriever; CA, contact aspiration.

were observed in functional independence or mortality at 3 months (Table 1 and Fig 2).

No endovascular technique, including BGC use, was associated with higher rates of mFPE (Table 2). Baseline ASPECTS, BGC use, distal aspiration catheter use, IV recombinant tPA, GTR, and endovascular time were statistically associated with final mTICI 2c–3. However, in the multivariate analysis, BGC use was not identified as an independent predictor of mFPE or final mTICI 2c–3 (Table 3). The univariate analyses for final mTICI 2c–3 and endovascular techniques are available in the Online Supplemental Data. Finally, no differences were observed in functional outcome by BGC use (Fig 2).

DISCUSSION

Our study shows that in a large cohort of consecutive elderly patients treated endovascularly, there was no evidence of benefit of BGC use in terms of early near-complete reperfusion (mFPE TICI 2c–3) or final near-complete reperfusion (mTICI 2c–3) compared with classic guide catheters or on clinical outcome.

Despite the low representation of elderly patients in clinical trials, several nonrandomized studies have demonstrated the benefit of EVT in elderly patients with anterior circulation LVO stroke. Although the efficacy is likely lower than in younger patients, it remains cost-effective for patients older than 80 years of age.^{1–5} A subanalysis of the Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke Trials (HERMES) meta-analysis showed a benefit of EVT in patients 85 years of age or older compared with conservative treatment (adjusted OR, 0.20 [95% CI, 0.13–0.33]).¹¹ Likewise, in the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN) Registry, an association between successful recanalization and good clinical outcome was also observed in patients 80 years of age or older.¹²

The reported rates of successful recanalization in the elderly population range from 75% to 88%, whereas functional independence at 3 months (defined by the presence of mRS 0–2) ranges from 18.2% to 27%, depending on the series,^{1,4,11} considerably

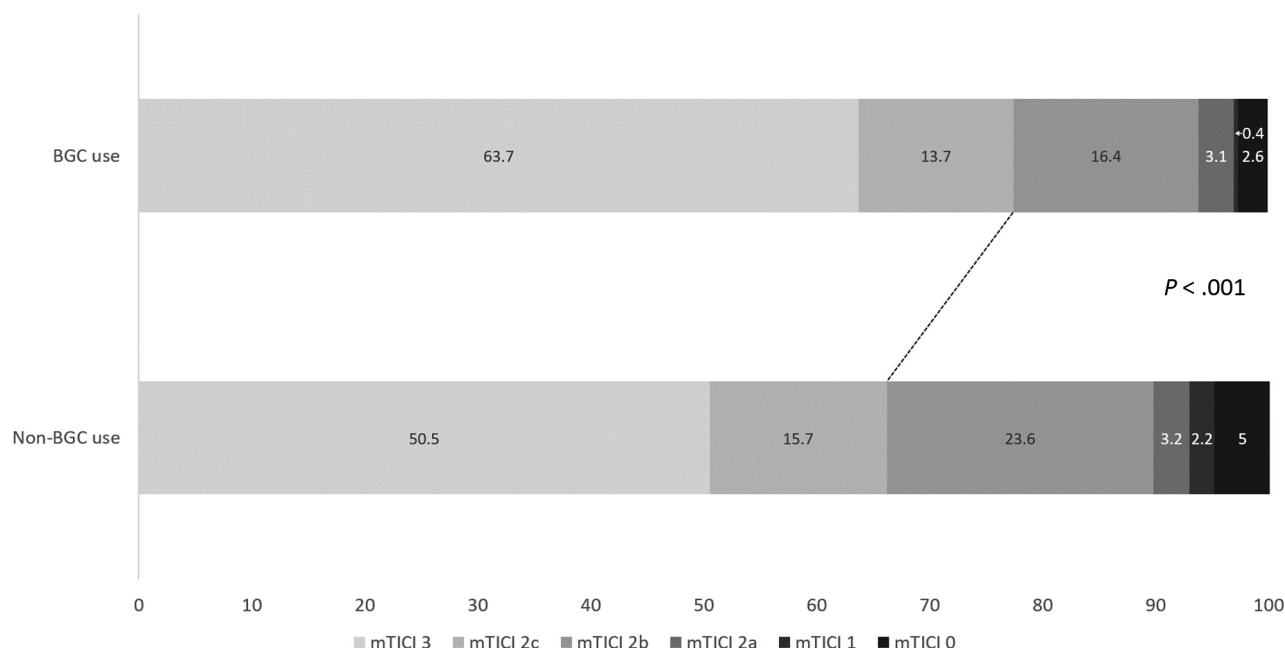


FIG 1. Distribution of the final mTICI according to BGC versus non-BGC use.

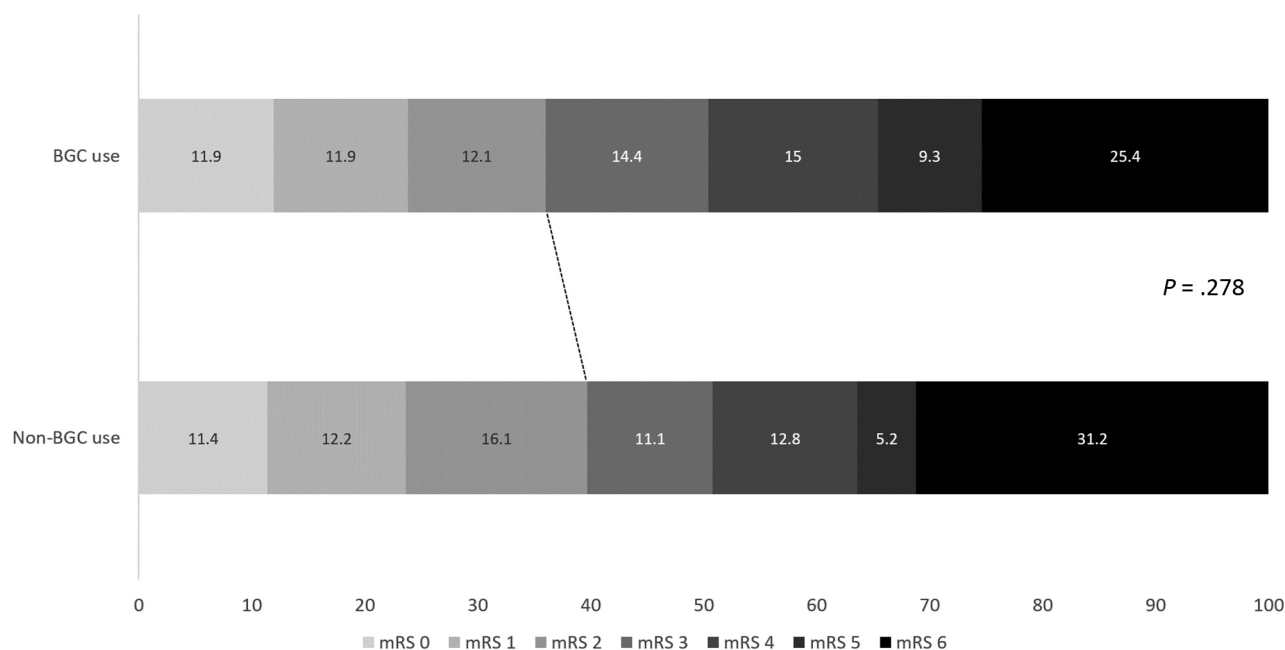


FIG 2. Distribution of mRS at 3 months according to BGC versus non-BGC use.

lower than that reported in the overall population of the HERMES meta-analysis (46%). Mehta et al¹³ published what may be the largest series from a nationwide sample with 1547 elderly patients (80 years of age or older) admitted between 2014 and 2016 without ET and a functional independence at 3 months of 9%.

Unfortunately, there is a lack of data regarding endovascular approaches in elderly patients, and there is no evidence regarding the efficacy of BGC due to the absence of specific studies in this population.

Since Nguyen et al¹⁴ reported, in 2014, the benefit of BGC in revascularization and outcome results for the first time, several

studies have confirmed the efficacy of BGC in anterior circulation LVO as an independent factor associated with successful recanalization and functional independence.^{7-11,15-19}

On the other hand, a small number of studies found that BGC did not improve angiographic or clinical outcomes compared with conventional guide catheters. A recent meta-analysis involving 2091 patients reported no benefit of BGC use in terms of near-complete recanalization, FPE, or functional independence at 3 months. In addition, the authors concluded that the combined technique (contact aspiration plus stent retriever) did not improve reperfusion rates.²⁰ Bourcier et al²¹ published their experience with

Table 2: Univariate analysis for mFPE (TICI 2c–3)

	Overall Patients ≥80 Years (n = 808)	No mFPE (n = 458, 56.7%)	mFPE (n = 350, 43.3%)	P Value
Age (median) (IQR) (yr)	85 (83–88)	85 (83–88)	85 (83–88.75)	.294
Female sex (No.) (%)	521 (64.5)	293 (56.2)	228 (43.8)	.731
NIHSS score at admission (median) (IQR)	17 (12–21)	17 (12–21)	17 (12–20)	.323
ASPECTS at admission (median) (IQR)	9 (7–10)	9 (7–10)	9 (8–10)	.002
Last time seen well (median) (IQR) (min)	280 (180.75–589.25)	280 (183–608)	280 (178–568.5)	.478
IV tPA administered (No.) (%)	212 (26.2)	125 (27.3)	87 (24.9)	.459
General anesthesia (No.) (%)	262 (32.4)	138 (30.1)	124 (35.4)	.123
Local anesthesia (No.) (%)	160 (19.8)	87 (19)	73 (20.9)	
Conscious sedation (No.) (%)	386 (47.8)	233 (50.9)	153 (43.7)	
Right-sided occlusion (No.) (%)	388 (48)	226 (49.3)	162 (46.3)	.388
Level of vessel occlusion (No.) (%)				.564
Carotid terminus	157 (19.5)	94 (20.6)	63 (18)	
MCA-M1	425 (52.7)	234 (51.2)	191 (54.6)	
MCA-M2	225 (27.9)	129 (28.2)	96 (27.4)	
GPTFR (median) (IQR) (min)	7 (5–12)	7 (5–13)	7 (5–12)	.202
ET time (median) (IQR) (min)	25 (12–43)	37 (25–54.5)	12 (8–20)	<.001
GTR (median) (IQR) (min)	35 (22–57)	48 (35–71)	22 (15–31)	<.001
BGC use (No.) (%)	465 (57.5)	252 (55)	213 (60.9)	.096
SR (No.) (%)	790 (97.8)	446 (97.4)	344 (98.3)	.387
Combined technique use (CA + SR)	406 (50.2)	241 (52.6)	165 (47.1)	.123
Distal aspiration catheter use (No.) (%)	422 (52.2)	251 (54.8)	171 (48.9)	.094
Technique modification	134 (27.9)	130 (31.1)	4 (6.3)	<.001
sICH (No.) (%)	53 (6.6)	37 (8.1)	16 (4.6)	.134
Complications				.548
Perforation	11 (29.7)	10 (33.3)	1 (14.3)	
Dissection	15 (40.5)	12 (40)	3 (42.9)	
NIHSS score at 24 hr (median) (IQR)	8 (3–16)	12 (5–18)	5 (2–12)	<.001
mRS score 0–2 at 3 mo (No.) (%)	303 (37.5)	146 (31.9)	157 (44.9)	<.001
Mortality at 3 mo (No.) (%)	225 (27.8)	154 (33.6)	71 (20.3)	<.001

Note:—SR indicates stent retriever; CA, contact aspiration.

Table 3: Multivariate analysis for FPE (mTICI 2c–3) and final mTICI 2c–3

Variable	P Value	aOR	95% CI
Model 1: mFPE (mTICI 2c–3) ^a			
AUC = 0.845			
BGC use	.459	0.851	0.556–1.303
Distal aspiration catheter use	.333	1.230	0.809–1.872
ASPECTS	.102	0.981	0.981–1.236
Model 2: final mTICI 2c–3 ^b			
AUC = 0.765			
BGC use	.772	0.938	0.607–1.449
Distal aspiration catheter use	.013	0.570	0.366–0.888
SR use	.004	1.225	1.282–1.619
GTR	<.001	0.979	0.974–0.984
ASPECTS	.004	1.190	1.057–1.340
NIHSS admission	.549	.991	0.961–1.022
IV tPA administered	.014	.494	0.281–0.869
Right-sided occlusion	.020	0.652	0.456–0.934

Note:—BGC indicates balloon guide catheter and distal aspiration catheter use; aOR, adjusted OR; SR, stent retriever.

^a Variables included in model 1 with a *P* value < .1 in the univariate analysis for FPE (mTICI2c–3).

^b Variables included in model 2 with *P* value < .1 in the univariate analysis for final mTICI 2c–3.

607 patients recorded in the Endovascular Treatment of Ischemic Stroke (ETIS) Registry, including an analysis of 190 matched pairs. After adjusting for potential confounders, the use of BGC did not improve reperfusion and clinical outcomes when the combined technique was used. In addition, a recent propensity score corresponded to analyses that reached similar conclusions.²² Unfortunately, no randomized clinical trials have been conducted

to date to explore the benefit of BGC use over conventional guide catheters, so observational studies provide the only available data at this time.

In our study, patients treated with BGC had higher rates of successful (mTICI 2b–3) and near-complete recanalization (mTICI 2c–3) on concluding EVT. There was a trend towards statistical significance in terms of mFPE (mTICI 2c–3) (45.8 versus 39.9%, *P* = .096), but there were no statistical differences in terms of safety and clinical outcomes at 3 months. However, the use of BGC was not independently associated with improved early or final recanalization rates after adjusting by confounder effects. Our results are consistent with those already published in the recent meta-analysis²⁰ and with the propensity score matching analysis published by Chen et al,²² in which no differences in recanalization, favorable outcome, or complications were observed between patients treated with or without BGC independent of age.

In our recently published global cohort of 426 patients, from the ROSSETTI Registry, with a median age of 76 years, BGC use was identified as an independent factor associated with FPE and functional outcome at 3 months.⁸ On the basis of this result, we can hypothesize that the age of patients undergoing ET may have a significant impact on angiographic and clinical outcomes. In these patients, arterial tortuosity may play an important role. In elderly patients, arterial tortuosity and the difficulty in reaching the target location to inflate the balloon and achieve flow arrest may compromise the efficacy of the BGC in terms of successful recanalization.^{23,24} Velasco Gonzalez et al²⁴ studied the impact of

arterial tortuosity in the FPE in 200 consecutive patients treated endovascularly with BGC. FPE can range from 30% to 70%, depending on anatomic factors, and the BGC distal position was independently associated with FPE, highlighting the importance of optimizing the BGC technique.

Limitations and Strengths

Our study has several limitations. As an observational study, the use of BGC or other techniques was not randomized because operator preference was respected. Moreover, there was no independent evaluation of the angiographic results for each patient, but blinded investigators reported functional outcome at 3 months and NIHSS scores at 24 hours.

On the other hand, this is the largest cohort of elderly patients studied in a multicenter prospective registry with a maintained database exploring the effect of BGC use.

CONCLUSIONS

In our study, the use of BGC during endovascular treatment of elderly patients with anterior circulation LVO did not predict FPE or near-complete recanalization. Further studies and randomized trials are needed to confirm these results.

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Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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