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Distal Access Catheter Improves Balloon Guide and Stent Retriever Thrombectomy Outcomes in Nonagenarians

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ABSTRACT

Background and Purpose: The safety and effectiveness of endovascular techniques in elderly patients with large vessel occlusion (LVO) remain controversial. We investigated the angiographic and clinical outcomes of nonagenarians treated with different endovascular techniques using a balloon guide catheter (BGC), distal aspiration catheter (DAC), and/or stent retriever (SR).

Methods: We analyzed the data from the Registry of Combined versus Single Thrombectomy Techniques (ROSSETTI) of consecutive nonagenarian patients with anterior circulation LVO and compared the outcomes of those treated with BGC+noDAC+SR (101-group), BGC+DAC+SR (111-group), and noBGC+DAC+SR (011-group). Demographic, clinical, angiographic, and clinical outcome data (National Institute of Health Stroke Scale score at 24 h [24h-NIHSS] and modified Rankin Scale score at 3 months) were compared. Predictors of the first-pass effect (FPE), defining Modified Treatment In Cerebral Ischemia 2c-3 (mTICI 2c-3) after one pass, were explored.

Results: Of the 4111 patients from the ROSSETTI registry, 243 nonagenarians (68.7% female) were included in the analysis. The distribution of endovascular techniques was 101-group (61.4%), 111-group (15.6%), and 011-group (23%). The 101-group and 111-group had significantly shorter procedural times than the 011-group. The 111-group had a higher FPE rate, a lower number of passes, and a higher rate of final mTICI ≥2c than the other groups. The 24h-NIHSS score was significantly lower in the 111-group.

In multivariate analysis, the only independent predictor for FPE was the BGC+DAC+SR endovascular technique (odds ratio 2.74 [confidence interval 1.16–6.47]; $p = 0.021$).
Conclusions: The addition of a DAC to a BGC increases the likelihood of FPE in nonagenarians with anterior circulation LVO SR-based thrombectomy for acute stroke.

1 | Introduction

The percentage of the population over 80 years increases by approximately 1.5 times every 10 years [1]. Considering that the incidence of vascular disease increases with age, the elderly population in need of mechanical thrombectomy (MT) is likely to increase. The principal techniques of MT implemented clinically include (i) the use of a stent retriever (SR) by incorporating the clot through it and withdrawal of the device under flow arrest by a balloon guide catheter (BGC) (BGC+SR), (ii) direct aspiration thrombectomy with a large-bore distal aspiration catheter (DAC), and (iii) a combination of both, where the SR is usually withdrawn into an intracranially placed aspiration catheter (BGC+DAC+SR) [2].

Despite the severe impact of acute ischemic stroke on the elderly in terms of morbidity, mortality, and cost, data to guide treatment decisions for this group are scarce, particularly regarding the most effective endovascular approach. Growing evidence has shown encouraging results in elderly populations who suffer from large vessel occlusion (LVO) stroke, with an emphasis on the benefits of revascularization therapy [3–22]; however, no studies have compared endovascular techniques from MT, mainly in nonagenarians. The ultimate goal of MT is to achieve fast and complete recanalization (Modified Treatment In Cerebral Ischemia [mTICI] 2c/3), ideally with a single device pass (referred to as first-pass effect [FPE]), which is associated with good clinical outcomes [23].

Tortuous vasculature, prevalent in older patients [24–26], often leads to failed MT due to SRs collapsing during retrieval and reduced contact between the aspiration catheter and clot [27], impairing both SR thrombectomy [28] and contact aspiration efficacy [29]. Extracranial and intracranial internal cerebral artery (ICA) tortuosity significantly lowers rates of FPE and final mTICI 2c-3 [24]. Combining SRs and contact aspiration increases FPE rates in patients without ICA tortuosity but not in those with tortuosity [24]. Selecting an effective and safe endovascular technique for nonagenarians is crucial to reducing thromboembolic complications and comorbidities, which can be achieved through rapid MT techniques that minimize iodinated contrast administration.

We aimed to investigate the angiographic and clinical outcomes in nonagenarians with acute ischemic stroke treated with different endovascular techniques who presented with anterior circulation LVO as a substudy of the Registry of Combined versus Single Thrombectomy Techniques (ROSSETTI).

2 | Methods

2.1 | Study Design

The ROSSETTI registry is an ongoing investigator-initiated prospective study that collects de-identified demographic, clinical presentation, and site-adjudicated angiographic, procedural, and outcome data of consecutive patients with AIS treated with MT across 16 Comprehensive Stroke Centers in Spain. The registry began in June 2019 and has incorporated more recent device technologies. The study inclusion criteria are as follows: age ≥90 years, confirmed anterior LVO, time from last seen well to treatment <24 h, baseline National Institutes of Health Stroke Scale (NIHSS) score ≥2, and premorbid 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 forms. Therefore, this study has been performed by the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Exclusion criteria involved patients with additional intracranial LVO in the anterior or posterior circulation. The study data were prospectively collected using an online questionnaire. The type of SR, as long as it was approved by the Ethical Committee, was at the discretion of the operator. At the time of the current analysis, 274 patients met the inclusion and exclusion criteria of the 4111 patients included in the ROSSETTI registry. The patients were categorized according to the following endovascular techniques: BGC+noDAC+SR (101-group), BGC+DAC+SR (111-group), and noBGC+DAC+SR (011-group). FPE was defined as the achievement of mTICI2c-3 after a single device pass. The numerical classification has been used to make different techniques more understandable: the first number corresponds to the use (1) or nonuse (0) of the BGC, the second number indicates the use or nonuse of the intermediate catheter, and the third number reflects the use or nonuse of an SR.

2.2 | Outcomes

The primary angiographic outcomes were the rate of vessel recanalization after the FPE (mTICI 2c-3, achieved after the first attempt) and modified first-pass effect (mFPE) (mTICI 2b-3, achieved after the first attempt). Distal embolism as a procedure-related complication has also been documented. The treating neurointerventionalist had discretion over the selection of endovascular technique.

The primary clinical outcome was the rate of favorable clinical outcome, defined as an mRS score ≤2 at 3 months. Secondary outcomes included the 24h-NIHSS score, symptomatic intracranial hemorrhage (sICH) according to the European Co-operative Acute Stroke Study-II definition, final rates of mTICI 2b-3 and mTICI 2c-3 reperfusion, and 90-day mortality. The time frames from groin puncture to first run, first run to final revascularization (MT time), and groin puncture to revascularization were also compared between the groups. Reperfusion scores, symptomatic intracranial hemorrhage (defined as a documented hemorrhage associated with a decline of four or more points in the NIHSS score), and clinical outcomes were center-adjudicated by experienced neurointerventionalists.

2.3 | Statistical Analysis

Demographic and clinical data, procedural details, angiographic outcomes, and clinical outcomes were compared among the three groups. Chi-square and Fisher's exact tests were used for categorical variables, while Student's *t*-test or *F*-test was used for continuous variables. Univariate Cox proportional hazard regression was used to identify independent predictors of FPE, and variables with *p*-values of <0.05 were selected to generate prognostic models. Odds ratios and their corresponding 95% confidence intervals were calculated, and a *p*-value of <0.05 was considered statistically significant. All statistical analyses were performed using R (version 3.6.1, R Foundation for Statistical Computing, Vienna, Austria, https://www.R-project.org).

3 | Results

Of the 4111 patients included in the ROSSETTI registry, 274 (6.6%) were nonagenarians. Thirty-one patients were excluded because they were treated using endovascular techniques that included a few patients (21 for 010, 4 for 110, and 6 for 001). Therefore, a total of 243 nonagenarian patients, 68.7% females, with a median age of 92 years (interquartile range [IQR], 91–94) were finally analyzed. The median NIHSS score at admission and Alberta Stroke Program Early CT Score (ASPECTS) were 17 (IQR, 13–21) and 9 (IQR, 8–10), respectively. Recombinant tissue plasminogen activator was administered to 60 patients (21.9%) before undergoing MT. Table 1 shows the characteristics of the entire cohort.

The distribution of endovascular techniques was 149 (61.4%) patients in the 101-group, 38 (15.6%) in the 111-group, and 56 (23%) in the 011-group. Globally, the FPE 2c-3 rate was 44% (Table 2). The 101-group and 111-group had significantly shorter procedural time (30 min [19–54] and 30.5 min [19–52 min], respectively) than the 011-group (50 min [29–65 min]). FPE 2c-3 rate was higher in the 111-group (57.9%) than in the 011-group (32.1%) (p = 0.013). The 111-group had a lower number of passes and a higher rate of final mTICI ≥2b or final mTICI ≥2c (Table 1). The 111-group and 101-group showed a significantly higher rate of final mTICI ≥2c than the 011-group. The rates of sICH and mortality were similar among the three groups. Additionally, the NIHSS score at 24 h was significantly lower in the 111-group than in the 011-group. There were no significant differences in effectiveness, safety, or clinical outcomes between the 101-group and the 111-group.

In the multivariate analysis, the only independent predictor for FPE 2c-3 was the BGC+DAC+SR endovascular technique (OR 2.74 [CI 1.16–6.47]; p = 0.021) (Table 3). On the other hand, BGC+SR modality and ASPECTS were other variables that bordered on statistical significance (1.85 [0.96–3.56]; p = 0.066 and 1.2 [0.99–1.45]; p = 0.057, respectively).

4 | Discussion

Although advancements in thrombectomy technologies have led to higher recanalization rates and better functional outcomes in acute stroke patients with LVO, the optimal endovascular strategies for elderly patients, particularly octogenarians and nonagenarians, remain unclear. These age groups are underrepresented in randomized clinical trials and meta-analyses, comprising less than 5% of the sample size [21], in contrast to approximately one third of mechanical thrombectomies performed among elderly patients in current clinical practice.

Tortuous vascular anatomy, which is associated with older age [24–26], is a common cause of failed MT [27]. SRs in curved vessels may stretch and collapse during retrieval, resulting in a loss of interaction with the clot [28]. On the other hand, vessel tortuosity also reduces the contact between the tip of the aspiration catheter and the clot and impairs clot aspiration [29]. Tortuosity impairs the effectiveness of both SR thrombectomy and contact aspiration catheters, necessitating more device passes and reducing the likelihood of complete reperfusion. Both extracranial and intracranial ICA tortuosity can significantly complicate the endovascular technique. Significantly lower rates of FPE and final mTICI 2c-3 have been reported in patients with ICA tortuosity than in those without [24]. In patients without ICA tortuosity, the combined use of SRs and aspiration is associated with a higher FPE rate than SR thrombectomy or aspiration alone but not in patients with ICA tortuosity. Choosing an effective and safe technique for nonagenarian patients is crucial due to the risk of thromboembolic complications. Faster MT techniques might reduce complications and comorbidities, such as by lowering the dose of iodinated contrast administered.

Our study found that the addition of a DAC to a BGC in anterior LVO SR-based thrombectomy significantly increased the likelihood of FPE in nonagenarian patients. This endovascular approach resulted in better technical outcomes, including a lower number of passes and a higher rate of FPE 2c-3, as well as improved clinical outcomes, such as a lower 24h-NIHSS score. Although aging can make proximal catheter access more time-consuming [14, 20], procedural times are shorter for BGC techniques, and BGC was associated with successful recanalization at the end of the procedure. According to our findings, the final mTICI 2c-3 was attained in two thirds or more of the patients when BGC techniques were applied, in contrast to slightly over half of the patients who were treated with DAC+SR without BGC. In addition, a final mTICI ≥2b was achieved in 97.4% of patients treated with BGC+DAC+SR, which is comparable to the recanalization rates reported in younger patients, with rates of up to 95% [30]. Our results align with a substantial body of research, though it is yet to be conclusively demonstrated in nonagenarians, which indicates that BGC leads to improved clinical outcomes and reperfusion scores when compared to non-BGC techniques [31–

TABLE 1 | Sample characteristics and comparison of endovascular techniques for nonagenarians with anterior large-vessel occlusion.

	Overall patients ≥90 years (*n* = 243)	**101 (*n* = 149, 61.4%)**	**111 (*n* = 38, 15.6%)**	**011 (*n* = 56, 23%)**	**101 vs. 111**	**111 vs. 011**	**101 vs. 011**
Age [years], median (IQR)	92 (91–94)	92 (91–94)	91 (90–94)	91 (90–93)	0.143	0.564	0.008*
Female gender, *n* (%)	167 (68.7)	103 (69.1)	25 (65.8)	39 (69.6)	0.693	0.694	0.943
NIHSS score at admission, median (IQR)	17 (13–21)	17 (13–21)	19 (16–21)	16 (13–20)	0.264	0.174	0.476
Alberta Stroke Program Early CT Score at admission, median (IQR)	9 (8–10)	9 (7–10)	9 (8–10)	9 (8–10)	0.012*	0.293	0.154
Last time seen well [min], median (IQR)	270 (180–618)	260 (187–563)	204 (143.5–277)	375 (210–825)	0.013*	0.001*	0.051
Intravenous thrombolysis, *n* (%)	60 (21.9)	19 (12.7)	21 (55.2)	20 (35.7)	<0.001*	0.008*	<0.001*
General anesthesia during MT, *n* (%)	51 (20.9)	44 (29.5)	2 (5.3)	5 (8.9)	<0.001*	0.039*	<0.001*
Left site occlusion, *n* (%)	123 (50.6)	76 (51)	21 (55.2)	26 (46.4)	0.346	0.271	0.553
Level of vessel occlusion, *n* (%)					0.231	0.862	0.242
Carotid terminus	42 (17.2)	25 (16.8)	6 (15.8)	11 (19.6)			
Segment M1 of MCA	136 (55.9)	77 (51.7)	25 (65.8)	34 (60.7)			
Segment M2 of MCA	65 (26.7)	47 (31.5)	7 (18.4)	11 (19.6)			
MT time [min], median (IQR)	21.5 (11–41.25)	21 (10–37)	19 (12–36)	34 (18–48)	0.663	0.045*	0.004*
Groin to recanalization time [min], median (IQR)	34 (21–60)	30 (19–54)	30.5 (19–52)	50 (29–65)	0.766	0.018*	0.001*
FPE (mTICI 3), *n* (%)	84 (34.5)	57 (38.2)	10 (26.3)	17 (30.4)	0.162	0.671	0.280
FPE (mTICI 2c-3), *n* (%)	107 (44)	67 (44.9)	22 (57.9)	18 (32.1)	0.165	0.013*	0.090
mFPE (mTICI 2b-3), *n* (%)	140 (57.6)	86 (57.7)	27 (71.1)	27 (48.2)	0.145	0.028*	0.205
Final number of passes, *n* (%)					0.306	0.042*	0.239

(Continues)

TABLE 1 | (Continued)

	Overall patients ≥90 years (n = 243)	101 (n = 149, 61.4%)	111 (n = 38, 15.6%)	011 (n = 56, 23%)	101 vs. 111	111 vs. 011	101 vs. 011
1	123 (50.6)	76 (51)	25 (65.8)	22 (39.3)			
2	48 (19.7)	30 (20.1)	5 (13.2)	13 (23.2)			
>2	69 (28.3)	40 (26.8)	8 (21.1)	21 (37.5)			
Final mTICI ≥2b, n (%)	223 (91.7)	136 (91.2)	37 (97.4)	50 (89.3)	0.238	0.143	0.558
Final mTICI ≥2c, n (%)	171 (70.3)	111 (74.4)	30 (78.9)	30 (53.6)	0.612	0.012*	0.003*
NIHSS score at 24 h, median (IQR)	10.5 (4–18)	11 (4–18)	6 (2–16)	14 (6–17.5)	0.175	0.040*	0.351
Complications, n (%)	9 (3.7)	5 (3.3)	2 (5.2)	2 (3.5)	0.678	0.702	0.495
Type of complication, n (%)							
Dissection	3 (1.2)	2 (1.3)	1 (2.6)	1 (1.7)	0.743	0.822	0.645
Perforation	4 (1.6)	1 (0.6)	2 (5.2)	2 (3.5)	0.829	0.763	0.726
Other	2 (0.8)	0 (0)	1 (2.6)	1 (1.7)	0.746	0.634	0.897
Distal embolism to new territory, n (%)	4 (1.6)	2 (1.3)	1 (2.6)	1 (1.7)	0.642	0.709	0.841
Distal embolism to same territory, n (%)	20 (8.2)	12 (8)	3 (7.8)	3 (5.3)	0.877	0.720	0.863
Symptomatic intracerebral hemorrhage, n (%)	7 (2.8)	5 (3.3)	0 (0)	2 (3.6)	0.197	0.245	0.810
Modified Rankin Scale score 0–2 at 3 months, n (%)	46 (18.9)	19 (12.7)	9 (23.6)	18 (32.1)	0.159	0.385	0.005*
Mortality at 3 months, n (%)	83 (34.1)	53 (35.5)	10 (26.3)	20 (35.7)	0.106	0.346	0.510

Abbreviations: FPE, first-pass effect; IQR, interquartile range; M1, horizontal segment; M2, insular segment; MCA, middle cerebral artery; mFPE, modified first-pass effect; MT, mechanical thrombectomy; mTICI, modified Treatment In Cerebral Infarction; n, number of participants; NIHSS, National institute of Health Stroke Scale.

*Statistically significant contrast.

TABLE 2 | Comparison between the groups for first-pass (2c-3) effect in nonagenarians.

	Non-FPE (n = 136, 56%)	FPE (2c-3) (n = 107, 44%)	p-value
Age [years], median (IQR)	92 (90–94)	92 (91–93)	0.936
Female gender, n (%)	96 (70.5)	75 (70.1)	0.891
NIHSS score at admission, median (IQR)	17 (13–21)	17 (14–21)	0.872
Alberta Stroke Program Early CT Score at admission, median (IQR)	9 (7–10)	9 (8–10)	0.008*
Last time seen well [min], median (IQR)	270 (187–618)	270 (178–614)	0.853
Intravenous thrombolysis, n (%)	38 (27.9)	22 (20.5)	0.148
General anesthesia during MT, n (%)	29 (21.3)	22 (20.5)	0.625
Left site occlusion, n (%)	67 (49.2)	56 (52.3)	0.244
Level of vessel occlusion, n (%)			0.344
Carotid terminus	28 (20.5)	14 (13)	
Segment M1 of MCA	78 (57.3)	58 (54.2)	
Segment M1 of MCA	34 (25)	31 (28.9)	
MT time [min], median (IQR)	35 (21–52)	11 (8–19)	<0.001*
Groin to recanalization time [min], median (IQR)	49 (31–70)	21 (13.75–32.25)	<0.001*
Balloon guide catheter use, n (%)	87 (63.9)	81 (75.7)	0.032*
Stent retriever use, n (%)	122 (89.7)	96 (89.7)	0.859
Aspiration catheter use, n (%)	66 (48)	43 (40.1)	0.457
Final mTICI ≥2b, n (%)	116 (85.2)	107 (100)	<0.001*
Final mTICI ≥2c, n (%)	64 (47)	107 (100)	<0.001*
NIHSS score at 24 h, median (IQR)	13 (6–20)	6.5 (2–16)	<0.001*
Symptomatic intracerebral hemorrhage, n (%)	6 (4.4)	1 (0.9)	0.024*
Modified Rankin Scale score 0–2 at 3 months, n (%)	24 (17.6)	22 (20.5)	0.397
Mortality at 3 months, n (%)	69 (50.7)	14 (13)	0.003*

Abbreviations: FPE, first-pass effect; IQR, interquartile range; M1, horizontal segment; M2, insular segment; MCA, middle cerebral artery; MT, mechanical thrombectomy; mTICI, modified Treatment In Cerebral Infarction; n, number of participants; NIHSS, National institute of Health Stroke Scale.
*Statistically significant contrast.

TABLE 3 | Predictors for first-pass (2c-3) effect in nonagenarians.

Univariate analysis	Odds ratio	95% confidence interval	p-value
ASPECTS	1.20	(1.00, 1.45)	0.046*
BGC + SR	1.74	(0.91, 3.33)	0.092
BGC + DAC + SR	2.90	(1.23, 6.81)	0.014*
Multivariate analysis			
ASPECTS	1.20	(0.99, 1.45)	0.057
BGC + SR	1.85	(0.96, 3.56)	0.066
BGC + DAC + SR	2.74	(1.16, 6.47)	0.021*

Abbreviations: ASPECTS, Alberta Stroke Program Early CT Score; BGC, balloon guide catheter; DAC, distal access catheter; SR, stent retriever.
*Statistically significant contrast.

34]. BGC has also been linked to shorter reperfusion times [33–35], and it has been proposed as an independent predictor of FPE [34, 36–40]. Experimental studies have demonstrated the potential of the balloon guide for clot retrieval and its ability to reduce clot migration [35]. The addition of continuous and localized suction and the mechanical "pinning" effect provided by the DAC may enhance clot engagement, easing the access and improving the stability of the system while performing SR-mediated MT, optimizing retrieval forces by aligning the vector of movement to a more desirable angle. Our data indicate that the use of new thrombectomy devices may enhance the rates of recanalization and ultimately lead to better outcomes, a finding also observed as a 24h-NIHSS decrease in the nonagenarian population.

In our recent study, octogenarian patients with anterior circulation LVO treated with BGC had higher rates of successful and near-complete recanalization [17]. There was a trend toward statistical significance for mFPE, but there were no statistical differences in terms of safety and mRS scores at 3 months. The use of BGC was not independently associated with improved recanalization rates after adjusting for confounder effects. However, Velasco Gonzalez et al. [36] studied the impact of arterial tortuosity on FPE in 200 patients treated with BGC and found that the BGC distal position was independently associated with FPE, highlighting the importance of optimizing the BGC technique. It has been recently reported that successful advancement of the DAC to the proximal end of the thrombus might be a key component for successful reperfusion in MT [41]. Higher baseline ASPECTS has been identified as a predictor of FPE mTICI 2c-3 for anterior circulation LVO [42, 43].

Although BGC techniques have been shown to result in shorter procedure times and a higher rate of successful recanalization, these technical outcomes do not appear to correspond with functional improvements at 3 months, as evidenced by similar mRS values in the non-BGC nonagenarian cohort. A meta-analysis of observational studies and randomized clinical trials found that only one quarter of patients over 80 years of age achieved good functional outcomes 90 days after MT, while one third of patients died [40], showing the more fragile clinical background of this subgroup. However, these results suggest that MT still provides substantial benefits to a significant proportion of octogenarians. Additionally, a medicoeconomic model demonstrated that MT reduces direct and indirect lifetime costs in both octogenarians and nonagenarians [44].

With a sample size of 243 nonagenarian patients, our study is one of the largest in the field and unique in comparing different endovascular techniques in this subgroup of patients in a real-life scenario. However, the nonrandomized nature of the registry and the lack of independent adjudication of clinical outcomes and angiographic results for each patient are potential limitations. The use of different types and sizes of SRs and DACs at different positions, as well as imbalances between the groups regarding intravenous thrombolysis (IVT) and general anesthesia use, may introduce bias. For anterior circulation LVO, IVT has been demonstrated to be a predictor of FPE in some studies but not in meta-analyses [45, 46]. The operator's proficiency with different endovascular techniques might also have served as a confounder. Moreover, the absence of imaging data and thrombus histology data prevents further characterization of the relationship between reperfusion and thrombus characteristics.

In conclusion, the addition of a DAC to a BGC increases the likelihood of FPE in nonagenarians with LVO anterior circulation acute ischemic stroke in real-world practice associated with a higher rate of early clinical improvements.

Conflicts of Interest

The authors declare no conflicts of interest.

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