Balloon guide catheter versus non-balloon guide catheter: a MR CLEAN registry analysis

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Stroke: Vascular and Interventional Neurology

ORIGINAL RESEARCH

Balloon Guide Catheter Versus Non–Balloon Guide Catheter: A MR CLEAN Registry Analysis

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BACKGROUND: Balloon guide catheters (BGCs) are used to prevent distal emboli during endovascular treatment for acute ischemic stroke. Although literature reports benefit of BGC, these are not universally used, and randomized head-to-head comparisons are lacking. This study compared functional, safety, and technical outcomes between patients treated with non-BGC and with BGC during endovascular treatment in a nationwide prospective multicenter registry.

METHODS: Patients from the MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands) Registry, 2014 to 2018), who underwent endovascular treatment with a non-BGC or BGC, were included. Primary outcome was the modified Rankin Scale score at 90 days, and secondary outcomes included procedure time and first-attempt successful reperfusion (extended Thrombolysis in Cerebral Infarction ≥2C). Treatment-effect modification and subgroups were analyzed according to first-line thrombectomy technique and different sizes of non-BGC.

RESULTS: In total 2808 patients were included, and 1671 (60%) were treated with BGC. No differences in the modified Rankin Scale score at 90 days were seen between non-BGC and BGC groups (adjusted common odds ratio [OR], 0.98 [95% CI, 0.82–1.10]). The non-BGC was associated with faster procedure times compared with BGC (adjusted β: −2.99 [95% CI, −5.58 to −0.40]). A significant treatment effect was found between BGC use and thrombectomy technique. In subgroup analyses with stent retriever as first-line technique, 90-day modified Rankin Scale scores were significantly higher (more disability) in the non-BGC group compared with the BGC group (adjusted common OR, 0.79 [95% CI, 0.65–0.96]). Direct aspiration combined with non-BGC resulted in higher first-attempt rates compared with BGC (adjusted OR, 1.55 [95% CI, 1.06–2.28]).

CONCLUSIONS: This large prospective multicenter registry showed no differences in clinical outcome between patients treated with non-BGC and BGC. Subgroup analyses suggest that BGC outperforms the non-BGC when stent retriever is used as first-line technique, whereas non-BGC outperforms the BGC when aspiration is used.

The use of a balloon guide catheter (BGC) during endovascular treatment (EVT) of acute ischemic stroke is a well-known technique for achieving flow arrest, to avoid potential clot fragmentation with distal emboli.[1] The use of BGC is associated with shorter procedure time, higher successful reperfusion rates, and better functional outcomes when compared with a non-BGC approach; most of these studies are based on anterior circulation occlusions.[2–5]

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Two studies compared, in addition, the use of a non-BGC and BGC in combination with stent retriever thrombectomy. The Solitaire or Trevo stent retriever showed higher functional outcomes and higher reperfusion rates when a BGC was used.[6,7] Still, many procedures are performed without a BGC. A survey questionnaire showed that only 25% of treating physicians routinely used a BGC.[8] Arguments against BGC are higher costs, its rigidity, and the need for larger sheaths. On the other side, BGCs are rapidly evolving, and the additional costs are low compared with the overall costs.[9]

The primary aim of this study is to investigate clinical, technical, and safety outcomes between a non-BGC and BGC approach in a nationwide registry of patients with acute ischemic stroke treated with EVT. The secondary aim is to compare clinical and technical outcome between the guide catheters for occlusion location, first-line thrombectomy technique, and different non-BGC sizes.

Nonstandard Abbreviations and Acronyms

BGC	balloon guide catheter
eTICI	extended Thrombolysis in Cerebral Infarction
EVT	endovascular treatment
mRS	modified Rankin Scale
NIHSS	National Institutes of Health Stroke Scale

CLINICAL PERSPECTIVE

- This study found similar clinical outcomes between stroke patients treated with balloon guide catheter (BGC) or non-BGC in the MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands) Registry, a large prospective nationwide multicenter registry.
- Subgroup analysis suggest benefit of BGC in stroke patients when stent retriever thrombectomy is the first-line thrombectomy technique, whereas non-BGC outperforms BGC when direct aspiration is the first-line technique.

METHODS

Design

On reasonable request to the corresponding author, detailed statistical analyses will be made available. For this study, we used data from the MR CLEAN (Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands) Registry. All patients with acute ischemic stroke, who underwent EVT because of an intracranial large-vessel occlusion between March 2014 and December 2018, were included in this registry. The MR CLEAN Registry study protocol was granted with the permission to perform the study as a registry after evaluation by the medical ethics committee of the Erasmus University Medical Center (MEC-2014-235). The committee waived the need for obtaining informed consent.

This study was conducted using the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. The corresponding author takes responsibility for its integrity and data analysis and had full access to all study data. Because of legislative issues on patient privacy, source data will not be made available.

Participants

For this study, we included patients aged >18 years and treated with EVT within 6.5 hours after the start of stroke symptoms attributable to an intracranial large-vessel occlusion in the anterior circulation (intracranial carotid artery and middle cerebral artery). When insufficient data were available on the used (balloon) guide catheter, patients were excluded.

Treatment

A BGC was registered when an 8F to 9F guide catheter and a balloon were registered on the intervention form. The choice of a BGC and whether the balloon was inflated or not was made by the local treating physician. These data were not registered, and information on the achievement of flow reversal was also lacking.

Outcomes

The primary outcome was the modified Rankin Scale (mRS) score at 90 days of follow-up, ranging from 0 (no symptoms) to 6 (death). Secondary functional outcome measurements were excellent (defined as mRS score 0–1) and favorable (defined as mRS score 0–2) functional outcome, and National Institutes of Health Stroke Scale (NIHSS) score 24 to 48 hours after EVT. Technical outcomes included procedure duration, reperfusion grade, and first-attempt successful reperfusion, whereas safety outcomes included ischemic stroke progression and occurrence of symptomatic intracranial hemorrhage.

Reperfusion grade was based on the extended Thrombolysis in Cerebral Infarction (eTICI), a scale

ranging from 0 (no reperfusion) to 3 (complete reperfusion). Successful reperfusion was defined by eTICI≥2B, excellent reperfusion by eTICI≥2C, and complete reperfusion by eTICI 3. First-attempt excellent reperfusion was defined as eTICI≥2C after 1 attempt. Thrombus in another territory was defined as a remaining occlusion that did not match the target occlusion and had changed to another territory or changed to a more proximal location. A distal thrombus was defined as a remaining occlusion, different from the primary and secondary target, but in the same flow territory. An independent core laboratory, which consisted of 2 neuroradiologists and 6 interventional (neuro)radiologists, assessed all the imaging separately, while they were blinded for all clinical findings or findings on other imaging modalities. Stroke progression was defined when a patient scored at least 4 points higher on the NIHSS. Symptomatic intracranial hemorrhage was defined as an intracranial hemorrhage related to the clinical deterioration according to the Heidelberg criteria in combination with a neurologic deterioration of an increase of ≥4 points on the NIHSS. An adverse events committee scored the symptomatic intracranial hemorrhages.

Statistical Analysis

Baseline characteristics were presented with standard statistics. To compare patients treated with different guide catheters, we used a χ^2 test for binary or ordinal outcomes, whereas an independent-sample *t*-test was used for continuous parameters, after checking for normality of distribution using plots and Shapiro-Wilk test.

For the primary outcome, multiple ordinal regression analysis was used to compare the effect of the non-BGC on the mRS score at 90 days of follow-up with BGC as comparator. Secondary outcomes were analyzed with multiple ordinal, binary, or linear regression analyses, as appropriate. Odds ratios (ORs) or β estimates with 95% CIs were used to present the regression model results. Variables for adjusting the regression models were chosen on the basis of literature and baseline characteristic differences. These variables were age, sex, baseline NIHSS score, prestroke mRS score, intravenous thrombolysis before EVT, time between start symptoms and start EVT, baseline collateral score, atrial fibrillation, Alberta Stroke Program Early CT [Computed Tomography] Score, and location of the occlusion. Because of the exploratory and observational aspect of this study, no corrections were made for multiple testing.

Rc(Version 4.1.2) was used to perform all statistics. The level of significance was set at 0.05.

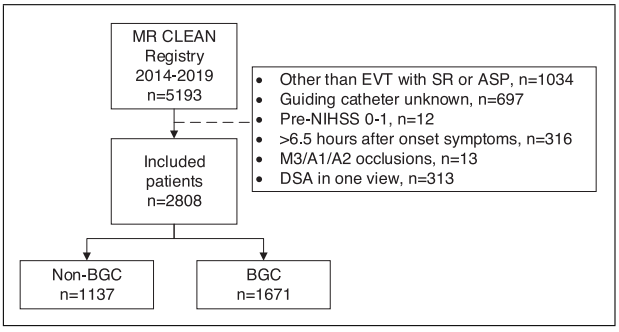

Figure 1. Flowchart of included patients. ASP indicates aspiration; BGC, balloon guide catheter; DSA, digital subtraction angiography; EVT, endovascular treatment; MR CLEAN, Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands; NIHSS, National Institutes of Health Stroke Scale; and SR, stent retriever.

Subgroup Analyses

We studied 3 predefined subgroups: depending on location of the occlusion, which first-line technique was used, and the size of the non-BGC (5–7F versus 8–9F). The interaction with effect was estimated for the location of the occlusion and first-line technique subgroups. Here, 2 interaction terms were added, one between the location of the occlusion and the guide catheter, and 1 between the first-line technique (stent retriever thrombectomy or direct aspiration thrombectomy) and the guide catheter. Patients treated with stent retriever combined with direct aspiration thrombectomy as first-line technique were classified as treated with stent retriever thrombectomy. When treatment interaction was significant, subgroup analyses were performed to evaluate the effect on the mRS score; otherwise, exploratory subgroup analyses were given. Additionally, we performed a sensitivity analysis with data after June 2016. Regardless of the sample size, the same adjustments were made as for the regression analyses.

Missing Data

All descriptive analyses were performed with original data. For the regression analyses, missing data were replaced with data obtained from multiple imputations. Multiple imputations were performed with predefined variables as predictors; for the complete list, see Appendix 1.

RESULTS

A total of 2808 patients (cohort March 2014 to December 2018) were included in this study, of whom 1671 (60%) were treated with a BGC (Figure 1). At

Table 1. Baseline Characteristics of the Patients Treated With a BGC Compared With Patients Treated With a Non-BGC

Characteristic	Non-BGC (n = 1137)		BGC 8F–9F (n = 1671)		*P* value	Missing, %
Age, mean (SD), y	70	(14)	70	(14)	0.260	0.0
Male sex, n (%)	595	(52)	885	(53)	0.771	0.0
NIHSS score, mean (SD)	16	(6.0)	15	(6.1)	0.213	1.2
IVT given, n (%)	833	(74)	1183	(71)	0.076	0.4
Systolic blood pressure, mean (SD), mm Hg	150	(26)	149	(25)	0.351	2.6
Medical history, n (%)						
Pre-mRS score					0.199	3.1
0	706	(65)	1055	(65)		
1	147	(13)	252	(16)		
2	98	(9.0)	117	(7.2)		
>2	143	(13)	203	(13)		
Ischemic stroke	187	(17)	310	(19)	0.188	0.9
Atrial fibrillation	242	(22)	444	(27)	**0.002**	1.4
Hypertension	601	(54)	867	(53)	0.597	2.0
Hypercholesterolemia	349	(32)	503	(31)	0.678	3.7
Diabetes	188	(17)	282	(17)	0.875	0.6
Current smoking	230	(28)	349	(27)	0.577	24.2
Use of coumarin	128	(11)	229	(14)	0.061	1.0
Use of NOAC	52	(4.6)	91	(5.5)	0.338	1.2
Use of antiplatelet	352	(31)	522	(32)	0.958	1.3
Imaging, n (%)						
Collaterals					0.208	4.8
Grade 0	73	(6.7)	92	(5.8)		
Grade 1	419	(39)	562	(36)		
Grade 2	408	(38)	619	(39)		
Grade 3	189	(17)	310	(20)		
ASPECTS					0.112	2.5
0–4	54	(4.9)	70	(4.3)		
5–7	240	(22)	304	(19)		
8–10	817	(74)	1254	(77)		
Occlusion location on CTA					0.233	3.3
ICA	50	(4.6)	76	(4.7)		
ICA-T	238	(22)	310	(19)		
MCA segment M1	647	(59)	952	(59)		
MCA segment M2	163	(15)	278	(17)		
Workflow						
Transfer from primary stroke center, n (%)	628	(55)	902	(54)	0.560	0.1
Onset-to-groin time, mean (SD), min	197	(71)	194	(77)	0.241	1.1

ASPECTS indicates Alberta Stroke Program Early CT [Computed Tomography] Score; BGC, balloon guide catheter; CTA, CT angiography; ICA, internal carotid artery; ICA-T, ICA terminus; IVT, intravenous thrombolysis; MCA, middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and NOAC, new oral anticoagulant.

baseline, patients treated using a BGC more often had atrial fibrillation compared with the non-BGC groups. All baseline characteristics are described in Table 1.

Functional Outcome

There was no significant difference in outcome according to the 90-day mRS score between the BGC and the non-BGC group (adjusted common OR [acOR], 0.98 [95% CI, 0.82–1.10]; Figure 2).

Regression analyses showed no differences between BGC and non-BGC in favorable functional outcome (adjusted OR [aOR], 1.17 [95% CI, 0.96–1.42]) and in NIHSS improvement with ≥4 points after 24 to 48 hours (aOR, 1.01 [95% CI, 0.85–1.21]; Table 2).

Technical Outcome

The non-BGC and the BGC did not differ in excellent and complete reperfusion rates (aOR, 1.10 [95% CI,

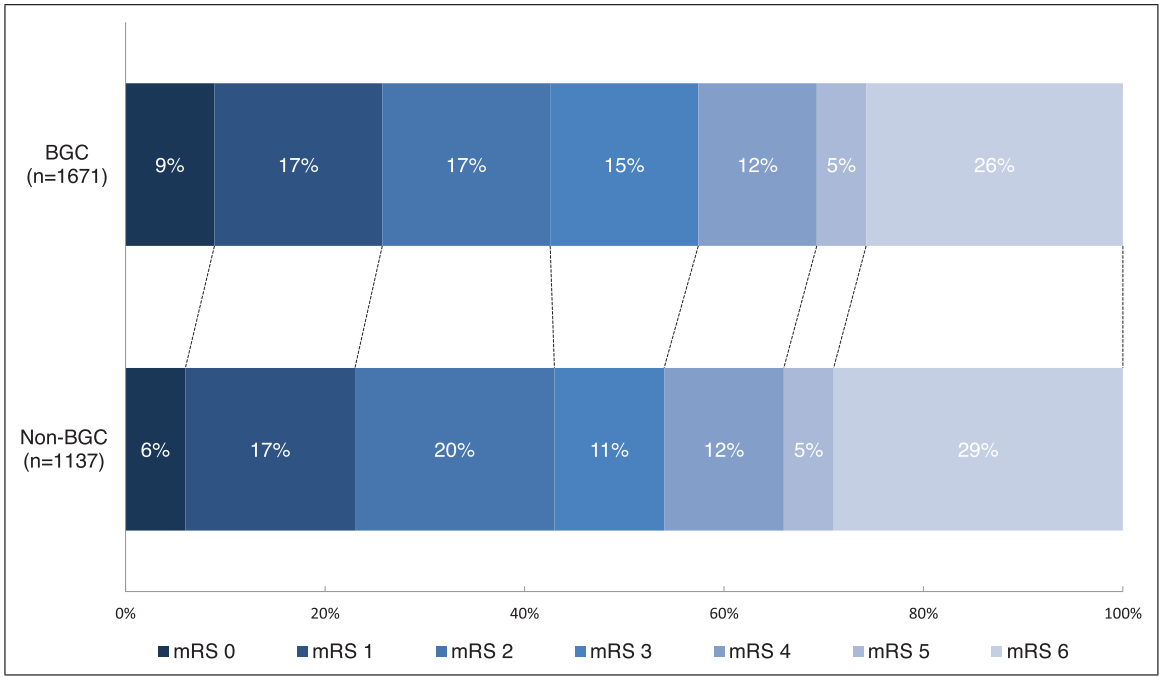

Figure 2. Distribution of the modified Rankin Scale (mRS) between the use of a non–balloon guide catheter (BGC) and a BGC. Multiple logistic regression with BGC as comparator with adjustment showed no significant difference in mRS score after 90 days (adjusted common odds ratio, 0.98 [95% CI, 0.82–1.10]).

Table 2. Associations Between Primary and Secondary Outcomes and the Use of a BGC

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.89 (0.78 to1.02)	0.100	0.98 (0.82 to1.10)	0.509
mRS 0–1 at 90 d	OR	0.89 (0.74 to1.07)	0.222	0.97 (0.78 to1.19)	0.749
mRS 0–2 at 90 d	OR	1.01 (0.86 to1.18)	0.896	1.17 (0.96 to1.42)	0.119
Excellent reperfusion (eTICI≥2C)	OR	1.05 (0.90 to1.22)	0.535	1.10 (0.94 to1.30)	0.244
Complete reperfusion (eTICI = 3)	OR	1.08 (0.93 to1.27)	0.308	1.11 (0.94 to1.31)	0.212
Symptomatic ICH	OR	0.89 (0.64 to1.23)	0.470	0.83 (0.59 to1.18)	0.307
Ischemic stroke progression	OR	1.03 (0.78 to1.35)	0.838	0.96 (0.72 to1.29)	0.796
Pneumonia	OR	0.75 (0.58 to 0.97)†	0.031†	0.75 (0.57 to 0.99)†	0.040†
Mortality at 90 d	OR	1.18 (0.99 to1.40)	0.069	1.06 (0.85 to1.31)	0.600
NIHSS score postintervention	β	0.53 (−0.20 to1.27)	0.156	−0.28 (−0.93 to0.37)	0.398
Improvement on the NIHSS with ≥4 points	OR	0.98 (0.82 to1.16)	0.798	1.01 (0.85 to1.21)	0.872
Procedure time	β	−1.78 (−4.28 to0.72)	0.163	−2.99 (−5.58 to to 0.40)†	0.024†
First-attempt excellent (eTICI≥2C)	OR	0.99 (0.83 to1.18)	0.891	1.00 (0.82 to1.20)	0.966
Thrombus in new territory	OR	1.19 (0.84 to1.67)	0.325	1.17 (0.81 to1.69)	0.397
Distal thrombus	OR	1.10 (0.87 to1.40)	0.412	1.10 (0.86–1.41)	0.445

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; ICH, intracranial hemorrhage; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

0.94–1.30] and aOR, 1.11 [95% CI, 0.94–1.31], respectively; Table 2). The use of non-BGC resulted in slightly shorter procedure time (mean: 55 versus 57 minutes; adjusted β, −2.99 [95% CI, −5.58 to −0.40]; Table 2) compared with the BGC group. First-attempt reperfusion rate was comparable in both groups (non-BGC versus BGC: 27% versus 28%; aOR, 1.00 [95% CI, 0.82–1.20]; Tables 2, 3).

Table 3. Outcomes Between Patients Treated With a BGC and Patients Treated With a Non-BGC

Outcome	Non-BGC (n = 1137)		BGC (n = 1671)		*P* value
mRS score at 90 d, n/total (%)					0.010‡
0	63/1016	(6.0)	132/1544	(8.6)	
1	172/1016	(16)	267/1544	(17)	
2	199/1016	(21)	269/1544	(17)	
3	109/1016	(11)	226/1544	(15)	
4	124/1016	(11)	182/1544	(12)	
5	51/1016	(4.1)	75/1544	(4.9)	
6	298/1016	(29)	383/1544	(26)	
mRS score 0–1, n/total (%)	235/1016	(23)	399/1544	(26)	0.131
mRS score 0–2, n/total (%)	434/1016	(43)	668/1544	(43)	0.816
Successful reperfusion (eTICI≥2B), n/total (%)	843/1098	(77)	1263/1633	(77)	0.765
Excellent reperfusion (eTICI≥2C), n/total (%)	594/1098	(54)	865/1633	(53)	0.589
Complete reperfusion (eTICI = 3), n/total (%)	456/1098	(42)	647/1633	(40)	0.338
Symptomatic ICH, n (%)	62	(5.5)	102	(6.1)	0.522
Ischemic stroke progression, n (%)	95	(8.4)	136	(8.1)	0.893
Mortality at 90 d, n/total (%)	298/1016	(29)	393/1544	(26)	0.034‡
Pneumonia, n (%)	95	(8.4)	181	(11)	0.036‡
NIHSS score postintervention, mean (SD)*	12	(9.6)	11	(9.5)	0.100
Procedure time, mean (SD), min†	55	(33)	57	(33)	0.154
First-attempt excellent (eTICI≥2C), n/total (%)	268/986	(27)	409/1463	(28)	0.708
Thrombus in new territory, n/total (%)	61/1044	(5.8)	81/1558	(5.2)	0.535
Distal thrombus, n/total (%)	137/1083	(13)	183/1569	(12)	0.480

BGC indicates balloon guide catheter; eTICI, extended Thrombolysis in Cerebral Infarction; ICH, intracranial hemorrhage; mRS, modified Rankin Scale; and NIHSS, National Institutes of Health Stroke Scale.

*n = 2639, missing in 169 patients.

†n = 2723, missing in 85 patients.

‡Significant (*p* value < 0.05).

Safety Outcome

Symptomatic intracranial hemorrhage was seen in 62 patients (5.5%) in the non-BGC group and in 102 patients (6.1%) in the BGC group (*P* = 0.52; Table 3). The proportion of patients with pneumonia was lower after the use of a non-BGC (aOR, 0.75 [95% CI, 0.57–0.99]; Table 2). Thrombus in new territory and the rate of distal thrombus did not differ between the non-BGC and BGC groups (aOR, 1.17 [95% CI, 0.81–1.69] and aOR, 1.10 [95% CI, 0.86–1.41], respectively; Table 2).

Subgroup Analyses

Location of Occlusion

There was no significant interaction between location of the occlusion and effect of the guide catheter on the mRS score (*P* = 0.60). Figure S1 shows an exploratory graph of the effect of the guide catheters on the mRS score based on occlusion location.

First-Line Technique

The first-line used technique did interact with the effect of the guide catheter on the mRS score (*P*<0.01). Patients treated with stent retriever thrombectomy as first-line technique (n = 1990) in combination with a non-BGC had lower chances of better mRS scores compared with the BGC with stent retriever approach (acOR, 0.79 [95% CI, 0.65–0.96]), and lower first-attempt excellent reperfusion rates (aOR, 0.68 [95% CI, 0.52–0.88]; Table 4).

When direct aspiration thrombectomy as first-line technique of treatment was used (n = 818), no differences were observed between the BGC and the non-BGC groups on clinical outcomes. In this subgroup, the use of a non-BGC had higher chances of mRS 0 to 2 scores (aOR, 1.49 [95% CI, 1.02–2.20]) and first-attempt excellent reperfusion rates compared with a BGC (aOR, 1.55 [95% CI, 1.06–2.28]; Table 5).

Different Non-BGC Sizes

Of 1137 patients treated with non-BGC, 660 (58%) were treated with 5F to 7F non-BGC. No differences were seen between the 5F to 7F non-BGC, 8F to 9F non-BGC, and 8F to 9F BGC (comparator) on mRS score at 90 days of follow-up (acOR, 0.94 [95% CI, 0.79–1.13] and acOR, 0.96 [95% CI, 0.79–1.17], respectively; Table 6). Favorable functional

Table 4. Associations Between Primary and Secondary Outcomes and the Use of a BGC When Stent Retriever Thrombectomy Is the First Choice of Treatment

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.74 (0.62–0.89)†	0.001†	0.79 (0.65–0.96)†	0.016†
mRS 0–1 at 90 d	OR	0.73 (0.57–0.93)†	0.012†	0.83 (0.63–1.10)	0.194
mRS 0–2 at 90 d	OR	0.86 (0.70–1.06)	0.162	0.99 (0.77–1.28)	0.938
Improvement on the NIHSS with ≥4 points	OR	0.97 (0.78–1.21)	0.811	1.02 (0.81–1.28)	0.869
First-attempt excellent (eTICI≥2C)	OR	0.66 (0.52–0.85)†	0.001†	0.68 (0.52–0.88)†	0.003†

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

Table 5. Associations Between Primary and Secondary Outcomes and the Use of a BGC When Direct Aspiration Thrombectomy Is the First Choice of Treatment

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	1.03 (0.79–1.34)	0.835	1.11 (0.83–1.49)	0.480
mRS 0–1 at 90 d	OR	1.06 (0.75–1.50)	0.752	1.13 (0.76–1.68)	0.756
mRS 0–2 at 90 d	OR	1.19 (0.87–1.61)	0.276	1.49 (1.02–2.20)†	0.041†
Improvement on the NIHSS with ≥4 points	OR	1.15 (0.81–1.62)	0.432	1.21 (0.83–1.76)	0.321
First-attempt excellent (eTICI≥2C)	OR	1.54 (1.07–2.21)†	0.020†	1.55 (1.06–2.28)†	0.025†

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

Table 6. Associations Between Primary and Secondary Outcomes and the Use of a 5F to 7F Non-BGC, 8F to 9F Non-BGC, and 8F to 9F BGC (Comparator)

8F–9F BGC as first modality		5F–7F non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.89 (0.76–1.05)	0.178	0.94 (0.79–1.13)	0.524
mRS 0–1 at 90 d	OR	0.85 (0.68–1.07)	0.167	0.93 (0.72–1.20)	0.576
mRS 0–2 at 90 d	OR	1.05 (0.86–1.27)	0.642	1.23 (0.97–1.56)	0.092
Improvement on the NIHSS with ≥4 points	OR	1.10 (0.90–1.34)	0.358	1.14 (0.93–1.41)	0.212
First-attempt excellent (eTICI≥2C)	OR	1.21 (0.998–1.47)	0.127	1.18 (0.95–1.46)	0.143
8F–9F BGC as first modality		**8F–9F non-BGC**			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.89 (0.74–1.07)	0.209	0.96 (0.79–1.17)	0.698
mRS 0–1 at 90 d	OR	0.94 (0.74–1.20)	0.642	1.02 (0.77–1.34)	0.912
mRS 0–2 at 90 d	OR	0.97 (0.78–1.19)	0.741	1.10 (0.85–1.42)	0.485
Improvement on the NIHSS with ≥4 points	OR	0.83 (0.65–1.05)	0.112	0.86 (0.67–1.10)	0.220
First-attempt excellent (eTICI≥2C)	OR	0.76 (0.58–0.98)†	0.034†	0.77 (0.59–1.02)	0.066

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

outcome and first-attempt excellent rate are comparable between the groups (Table 6).

Sensitivity Analysis

After excluding patients treated before June 2016 (n = 806), no differences were seen in clinical outcomes between patients treated with and without a BGC (Table 7). Patients treated with a non-BGC and stent retriever as first-line thrombectomy technique had lower chances of better mRS scores (acOR, 0.72 [95% CI, 0.56–0.92]) and first-attempt reperfusion (aOR, 0.70 [95% CI, 0.51–0.97]) compared with those treated with BGC (Table 8). When patients were treated with direct

Table 7. Associations Between Primary and Secondary Outcomes and the Use of a BGC After June 2016

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.91 (0.77–1.07)	0.236	0.95 (0.80–1.13)	0.558
mRS 0–1 at 90 d	OR	0.88 (0.71–1.09)	0.243	0.90 (0.71–1.15)	0.404
mRS 0–2 at 90 d	OR	1.01 (0.84–1.21)	0.955	1.14 (0.91–1.44)	0.263
Improvement on the NIHSS with ≥4 points	OR	1.03 (0.84–1.26)	0.759	1.11 (0.90–1.37)	0.343
First-attempt excellent (eTICI≥2C)	OR	1.03 (0.83–1.27)	0.814	1.05 (0.84–1.31)	0.688

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

Table 8. Associations Between Primary and Secondary Outcomes and the Use of a BGC After June 2016 in Combination With Stent Retriever Thrombectomy as First-Line Technique

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	0.73 (0.58–0.91)†	0.005†	0.72 (0.56–0.92)†	0.008†
mRS 0–1 at 90 d	OR	0.69 (0.51–0.93)†	0.015†	0.70 (0.50–0.99)†	0.046†
mRS 0–2 at 90 d	OR	0.82 (0.64–1.06)	0.139	0.86 (0.62–1.18)	0.354
Improvement on the NIHSS with ≥4 points	OR	1.04 (0.79–1.35)	0.800	1.11 (0.83–1.47)	0.492
First-attempt excellent (eTICI≥2C)	OR	0.68 (0.50–0.92)†	0.013†	0.70 (0.51–0.97)†	0.031†

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

Table 9. Associations Between Primary and Secondary Outcomes and the Use of a BGC After June 2016 in Combination With Direct Aspiration Thrombectomy as First-Line Technique

BGC as first modality		Non-BGC			
	EE	Unadjusted	*P* value	Adjusted	*P* value
mRS at 90 d*	cOR	1.06 (0.80–1.41)	0.671	1.21 (0.89–1.65)	0.231
mRS 0–1 at 90 d	OR	1.13 (0.79–1.63)	0.499	1.19 (0.78–1.81)	0.419
mRS 0–2 at 90 d	OR	1.20 (0.86–1.66)	0.278	1.63 (1.07–2.48)†	0.023†
Improvement on the NIHSS with ≥4 points	OR	1.14 (0.79–1.64)	0.495	1.29 (0.86–1.93)	0.219
First-attempt excellent (eTICI≥2C)	OR	1.50 (1.02–2.20)†	0.037†	1.49 (0.99–2.25)	0.053

Data in parentheses are 95% CIs. BGC indicates balloon guide catheter; cOR, common OR; EE, effect estimate; eTICI, expanded Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

*cOR for improved mRS score.

†Significant (p value < 0.05).

aspiration as first-line technique, non-BGC treated patients had more often favorable mRS scores (aOR, 1.63 [95% CI, 1.07–2.48]; Table 9).

DISCUSSION

In this analysis, there was no overall benefit of the use of a BGC over non-BGC during EVT on functional outcome. However, subgroup analysis may suggest higher chances of better functional outcome when a BGC is used in patients treated with stent retriever thrombectomy as first-line technique. Conversely, shorter procedure times and lower pneumonia rates were in favor of the non-BGC compared with the BGC.

A recent meta-analysis showed technical, safety, and clinical benefits of BGC, including higher first-attempt successful reperfusion rates, lower distal thrombus rates, and higher mRS 0 to 2 scores.[3] These results were partly confirmed by our study, because lower first-attempt excellent reperfusion rates and lower chances of better mRS scores were seen in patients treated with non-BGC combined with stent retriever thrombectomy as first-line technique (Table 4). Contrarily, Table 5 shows higher first-attempt excellent reperfusion rates and higher chances of favorable functional outcomes when using a non-BGC combined with direct aspiration thrombectomy as first-line technique. Overall, no differences were observed in mRS score or distal thrombus rates between the different guide catheters.

An explanation for this difference might lie in the fact that our study adjusted for important confounders and used data from 2014 to 2019, whereas the meta-analysis did not adjust and used data before 2014. In a previous MR CLEAN Registry study, similar analyses were performed on data registered between 2014 and June 2016. These analyses showed higher reperfusion rates and early improvement of neurologic deficits when using a BGC compared with a non-BGC.[10] With our larger data set with more recent data, we were not able to show a clear benefit of a BGC, suggesting that thrombectomy techniques have changed over the past years. Especially, the growing use of intermediate catheters has probably mitigated the "protective" effect of the BGC. This is in line with findings described in Table 7, showing no differences in clinical and reperfusion rates when only data of patients treated after June 2016 are analyzed. However, when we take the first-line thrombectomy technique into account, we still see a benefit of BGC in combination with stent retriever thrombectomy, and when looking at direct aspiration as the first-line technique, the combination with a non-BGC results in a higher chance of an mRS score of 0 to 2.

The effect of changing techniques is further underlined by our observations of comparable rates of thrombi in another territory and distal thrombi between the BGC and non-BGC group. Literature showing lower distal thrombus rates, with most included patients before 2018, which substantiated our potential explanation.[2–4,11]

Multiple studies report high first-pass excellent reperfusion rates, especially when using a BGC: Zaidat et al reported 47.9% and Blasco et al reported 45.8%.[7,12] We reported 36% with non-BGC and 37% with BGC. Differences can be partly explained by the used technique during EVT. Zaidat et al and Blasco et al studied BGC combined with stent retriever thrombectomy, whereas we included patients treated with either direct aspiration or stent retriever thrombectomy.[7,12] Overall excellent reperfusion rates, however, did not differ.

Di Maria et al showed that first-line technique is a potential predictor for first-attempt successful reperfusion, however, without differentiating in guide catheter use.[13] We see in our subgroup analyses comparable results for the first-line technique as potential predictor, showing an interaction between guide catheter and first-line technique. These subgroup analyses might suggest a specific role for a BGC with stent retriever thrombectomy and a non-BGC with aspiration; however, interpretation needs to be done with caution.

Another potential explanation for different rates of first-attempt excellent reperfusion is the use of different BGCs. One study showed higher first-attempt excellent reperfusion rates after using a FlowGate^2 catheter compared with a Merci BGC.[14] The treating physicians in the MR CLEAN Registry were free to choose the materials of their preference, and type or brand of the BGC was not registered.

It is assumed that the use of a BGC is particularly beneficial during thrombectomies of proximal occlusions compared with distal occlusions, as the aspiration force is higher around the tip of the BGC compared with distal from the BGC.[15] When looking at the occlusion location, we observed no (trend toward) better mRS scores when using an 8F to 9F BGC compared with an 8F to 9F non-BGC for internal carotid artery occlusions (Figure S1). We also found no significant interaction between the location of the occlusion and the use of a BGC on clinical outcome ($P = 0.53$). A recent study may substantiate this theory, because no benefits were shown in clinical outcome in patients with a medium vessel occlusion treated with a BGC, regardless of first-line thrombectomy technique.[16] However, this study included not only patients with M2 up to M4 occlusions, but also those with anterior cerebral artery and posterior circulation occlusions, which were excluded in our study. This makes a direct comparison difficult.

Some limitations need to be mentioned. First, this was an observational, nonrandomized study, with risk of biases, especially because treating physicians were free to choose the guide catheter, the first-line thrombectomy technique, and all other materials. The fact that we studied large sample sizes and many treating physicians from all stroke centers in the Netherlands may minimize this effect, but a certain selection bias cannot be ruled out. Second, no distinction could be made between BGCs with and without an inflated balloon and the duration of inflation. It is known that heterogeneity on the decision (not) to inflate the balloon during the procedure exists. For example, when the BGC caused flow arrest already without inflation, physicians may decide not to inflate it. On the other hand, some physicians only inflate the balloon in specific situations (eg, in carotid stent placement or when a dissection is observed). In a situation when the balloon is not inflated, the BGC acts as a (smaller diameter) non-BGC. The Effect of Proximal Blood Flow Arrest During Endovascular Thrombectomy (ProFATE) trial is an ongoing trial, which randomized the use of a BGC with and without inflating the balloon in patients with acute ischemic stroke.[17] We expect this trial to provide more insight in the use of a BGC with and without inflated balloon. Third, although we analyzed the differences between stent retriever and direct aspiration thrombectomy, the combined use of a distal access catheter when using a stent retriever was not registered and is a definite source of heterogeneity in the stent retriever group. Fourth, no proper

differentiation was made between short and long sheaths; these data were not reliably registered in the MR CLEAN Registry. Fifth, we made no corrections for multiple testing because of the exploratory and observational aspect of the MR CLEAN Registry; therefore, there is a need for confirmatory studies.

CONCLUSIONS

This large prospective multicenter registry showed no differences in clinical outcome between patients treated with non-BGC and BGC. Subgroup analyses suggest that BGC outperforms the non-BGC when stent retriever is used as first-line technique, whereas non-BGC outperforms the BGC when aspiration is used.

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Supplemental Materials

Appendix 1
Figure S1

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