Original Paper

Endovascular Acute Ischemic Stroke Treatment with FlowGate Balloon Guide Catheter: A Single-Center Observational Study of FlowGate Balloon Guide Catheter Use

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Keywords

Balloon guide catheter · Acute stroke · Thrombectomy · Stent · First pass

Abstract

Background: Treatment of large vessel occlusion acute ischemic stroke with mechanical thrombectomy has become the standard of care after recent clinical trials. However, the degree of recanalization with stent retrievers remains very important in overall outcomes. We sought to review the utility of a new balloon guide catheter (BGC) in improving the degree of recanalization in conjunction with mechanical thrombectomy. **Methods:** The medical records of a prospectively collected endovascular ischemic stroke database were reviewed. All consecutive strokes when a FlowGate BGC was used with a thrombectomy stent retriever were identified. Use of a FlowGate BGC, number of passes, final Thrombolysis in Cerebral Infarction (TICI) score, trackability, and use of adjunct devices were all collected and analyzed. **Results:** Use of a FlowGate BGC resulted in 64% (33/52) first-pass effect (FPE) of TICI 2b/3, and specifically 46% (24/52) TICI 3 FPE (true FPE). A total of 52/62 (84%) of thrombectomy cases were treated with BGCs. In the remaining 10, the BGC was not inflated or used due to the clot not being visualized or the lesions being distal and BGC use thus not deemed appropriate. Adjunct use of an aspiration catheter was seen in 12% (6/52) of cases. The overall success with FlowGate BGCs with one or more passes of TICI 2b/3 was 94% (49/52). Trackability was achieved in 92% (57/62) of cases. **Conclusions:** Use of the FlowGate BGC as an adjunct to mechanical thrombectomy was associated with good FPE and an overall recanalization of TICI 2b/3 of 94%.

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Introduction

Acute ischemic stroke due to large artery occlusion has been established as a cause of severe disability. Recently, multiple studies have demonstrated the benefit of timely and complete recanalization using mechanical thrombectomy in changing the outcomes of these patients [1–5]. Outcomes are related to the degree and rate of recanalization as well as time [6]. The STRATIS and NASA registries also demonstrated better outcomes with one pass of the device, now called the first-pass effect (FPE) [7, 8].

Adjunct devices, such as balloon guide catheters (BGCs), were associated with better outcomes in the NASA registry and with less emboli in new territories in other retrospective single-center articles [9, 10], even when compared to direct aspiration with and without stent retrievers. However, some in vitro models have shown BGCs to be inferior in improving recanalization when compared to direct aspiration and direct aspiration with stent retrievers [11]. In addition, results from the ADAPT technique papers suggest that use of direct aspiration is faster with fewer emboli in new territories [12]. We address these issues with our current analysis.

FlowGate is a new and unique BGC. It is easy to use, less stiff, and has improved trackability from bench testing that could possibly allow smoother delivery into the distal cervical and proximal petrous segment of the internal carotid artery (ICA). This feature allows it to possibly work more effectively and more completely, resulting in more reversal of flow given its more distal location. The 8-F model has a 0.084-inch inner lumen allowing for more aggressive aspiration as well as concomitant use of intermediate large-bore aspiration catheters for salvage techniques as needed (Fig. 1).

The aim of this single-center study was to report the times to recanalization (groin puncture to recanalization, first angiography to recanalization), the percentage of one pass (first pass), overall recanalization rates, and complications. These data were compared to other published techniques such as direct aspiration as well as older registries and recently published retrospective and prospective studies with BGCs to demonstrate the performance and adverse events associated with the use of the FlowGate BGC.

Methods

A retrospective data analysis of a prospective database of large vessel occlusion acute ischemic stroke patients was conducted. Data including baseline demographics (age and sex), clinical data (baseline NIHSS score), angiographic data, procedure complications, along with time of groin puncture to recanalization and time of first angiogram to recanalization, were collected and reviewed from consecutive patients treated with the FlowGate BGC and stent retriever device. Use of the FlowGate BGC, number of passes, final Thrombolysis in Cerebral Infarction (TICI) score, trackability, and adjunct device use were also collected and analyzed. Trackability was defined as the ability to track the FlowGate BGC into the cervical or petrous ICA with no herniation or need to use another device system.

Angiographic recanalization was scored using the TICI score defined as follows: 0 = no perfusion; 1 = penetration, but no distal branch filling; 2a = perfusion with incomplete (<50%) distal branch filling; 2b = perfusion with incomplete (>50%) distal branch filling; 2c = near complete recanalization with small distal emboli; and 3 = full perfusion with filling of all distal branches [13].

First angiogram to recanalization was defined as the time stamp of first angiogram whether cervical or cerebral to time of complete recanalization. We defines this as pure thrombectomy time. This is done to analyze the time to get to the carotid, which can change from operator to operator. In addition, new catheters and techniques such as direct carotid access or radial access can be compared.

Inclusion Criteria

Any patient in whom the FlowGate BGC and stent retriever device were used as the first-choice device to restore blood flow and were deployed at least once was included.

Fig. 1. Comparison of the inner lumen of the 8-F FlowGate balloon guide catheter versus that of other 8-F balloon guide catheters.

Table 1. Baseline characteristics and results ($N = 52$)

Mean age, years	69
Sex	
Male	24/52 (46%)
Female	28/52 (54%)
Intravenous tissue plasminogen activator	48/52 (92%)
Average time from groin puncture to TICI 2b/3, min	38.7 (30.1 for first pass)
Average time from first angiography to TICI 2b/3, min	29 (19.4 for first pass)
Site of occlusion	
Internal carotid artery	6/52 (12%), first pass (2/6) 33%
M1	38/52 (73%), first pass (25/38) 66%
M2	8/52 (15%), first pass (6/8) 75%

TICI, Thrombolysis in Cerebral Infarction.

Exclusion Criteria

Any patient in whom the FlowGate BGC may have been introduced but was not inflated was excluded.

Analysis

Standard descriptive statistics were calculated for all study variables. The baseline variables were compared between this FlowGate study and previous balloon guide and direct aspiration use publications. Due to the small size of both this study and previous ones, comparative statistics could not be done.

Results

A total of 88 acute ischemic stroke procedures were reviewed. Posterior circulation strokes, acute cervical occlusion or dissection with hemodynamic failure without distal clot, and severely tortuous or unfavorable anatomy were all excluded. It should be noted that BGCs were not used in the treatment of any posterior circulation strokes. With these stated exclusions, FlowGate was used in 62 cases but not inflated or used due to either nonvisualized clots (as seen when comparing computed tomography angiography to angiography-suite images), distal A2 clots, and M3 clots where the BGC was not used.

The FlowGate BGC was used in 52 cases. The overall success with the FlowGate BGC with one or more passes of TICI 2b/3 was 94% (49/52), and use of the FlowGate BGC resulted in 64% (33/52) first-pass rates of TICI 2b/3. Of these first-pass rates, 73% (24/33) were TICI 3, giving a true first-pass rate of 46% (24/52) (Table 1). Adjunct device use with an aspiration

Table 2. Technical tips

Tip	Possible benefit
Long sheath	adds proximal support
Stiff guidewire	helps to track the system higher up in the carotid to add stability
Use triaxial system	avoid any exchanges
Review computed tomography angiography of the head and neck	allows you to pick the most appropriate long catheter (VTK, Simmons, Vert)
Place clot in proximal third of stent retriever	clot will not slip away
Place balloon guide catheter as high up as possible	adds support and more suction
Fluff stent retriever	integrate clot more
Have a backup system	nothing works 100% of the time

catheter was seen in 12% (6/52) of cases. Trackability was achieved in 92% (57/62) of cases. Again, these 10 additional cases either had nonvisualized clots or distal lesions (including A2 and M3) where BGCs were not used. The safety profile had no carotid dissections or any other complications from BGCs. There were three stent-related procedural bleeds with one being symptomatic, one with no change, and one with complete resolution of symptoms.

For the first-pass cases, the average angiogram to recanalization time, which is considered the pure thrombectomy time, was 19.4 min, whereas it was 30.1 min from groin puncture to recanalization. The average angiogram to recanalization time was 29 min and the groin puncture to recanalization time 38.7 min for the entire cohort. The longest times were seen in the multiple-pass patients, with an average angiogram to recanalization time (pure thrombectomy time) of 47.9 min and a groin puncture to recanalization time of 55 min.

There were a total of 8 M2 clots, 6 ICA clots, and 38 M1 clots. The first-pass rates were 75% (6/8) for M2 clots, only 33% (2/6) for ICA clots, and 66% (25/38) for M1 clots. The average number of passes if the first pass not successful was 2 for M2 clots, 3 for ICA clots, and 3 for M1 clots.

Technical Notes

All procedures except for the first two used a long sheath ≥ 45 cm. A triaxial system using a 0.035-inch stiff guidewire, a diagnostic catheter of 125 cm or longer (Vert, Simmons 2, or VTK), and the 8-F FlowGate BGC (85 or 95 cm depending on patient anatomy and height) was used for all procedures. The wire and the diagnostic catheter were anchored in the distal petrous segment and the BGC was taken as distally as possible in the cervical segment or petrous ICA if feasible. At this time a baseline angiogram was performed. A 0.021 or 0.027 microcatheter with a 0.014 Synchro 2 microwire were then advanced past the clot. The wire was then removed, and the stent retriever was advanced and unsheathed with the goal to capture the clot in the proximal third of the device. A bypass angiogram was then obtained. The stent retriever was left in place for 5 min, and after 5 min, the BGC balloon was inflated with a 1-mL syringe under fluoroscopic guidance. Aspiration via extension tubing connected to a three-way stopcock attached to two 60-mL locking syringes was used as the stent retriever was slowly retracted (Table 2). After flushing the BGC, the post-pass angiogram was obtained. This was repeated two more times as needed. If, after the third pass, the clot remained, a distal aspiration catheter was used with the stent retriever. The stent was positioned again with the

Table 3. Comparison of other first-pass balloon guide data and other techniques

	FlowGate	NASA	STRATIS	TRACK	ADAPT FAST
First-pass recanalization	47% TICI 3, 64% TICI 2b/3	25% TICI 3	62% TICI 2b/3 ^a	25% TICI 3	
Overall TICI 3	64%			44.5%	51%
Overall TICI 2b/3	94%	72.5%	91.9% ^a	77%	95%
Time from groin puncture to recanalization, min	38.7 (30.1 for first pass)	NR	NR	67	37
Time from first angiography to recanalization, min	29 (19.4 for first pass)	50 ^b	NR	NR	NR
Adjunct device use	12%	NR	NR	NR	22%

NR, not reported; TICI, Thrombolysis in Cerebral Infarction. ^a Data for use with Balloon Guide Catheter, not overall STRATIS results. ^b Guide Catheter Placement to Recanalization.

clot within the proximal third of the stent and used to anchor the aspiration catheter to the edge of the clot. Aspiration via the aspiration catheter was then started, and the stent was pulled slowly as the aspiration catheter was advanced until no flow was seen and the clot was trapped between the stent and the aspiration catheter. The entire system was pulled as one, but without pulling the stent into the aspiration catheter. The BGC was then flushed and the post-pass angiogram conducted.

Discussion

The FlowGate BGC demonstrated acceptable recanalization rates, first-pass recanalization, and time to recanalization when compared to previous publications. The first-pass effect (FPE) is an observation that patients with one-pass thrombectomies had better clinical outcomes. First-pass good clinical outcomes of mRS 0–2 at 90 days from the NASA registry were 61.3, 52.4, 44.7, and 39.1% with FPE-TICI 3, FPE-TICI 2b, none-FPE-TICI 3, and none-FPE-TICI 2b, respectively [7]. Use of the FlowGate BGC resulted in 64% (33/52) first pass of TICI 2b/3 and overall TICI 2b/3 of 94%, with more passes and adjunct aspiration catheter use in 12% of cases. The true FPE of TICI 3 was 46% for our cohort. The recently published TRACK registry true FPE was 25%, but this cohort included all thrombectomies, not just those with M1 or M2 clots [14]. The previously published TRACK abstract only had patients with M1 and M2 clots, reporting a true FPE TICI 3 revascularization after the first pass with the TREVO device compared to those with M1 occlusions (55.8 vs. 40.4%) [15]. In addition, the TRACK FPE included not just BGC use but overall FPE. Just like the NASA registry, TRACK also showed better overall good clinical outcomes at 54.3 versus 48% for the rest of the TRACK cohort [14]. We unfortunately did not have outcomes because of loss of follow-up due to insurance or snowbird population (patients leaving for their summer homes) effect and do not have 30- and 90-day outcomes. Our higher rates are comparable to STRATIS 62% FPE of TICI 2b/3, but this was a cohort of BGC patients only. Perhaps the flow arrest and reversal of flow, shown to reduce overall emboli in vitro, could explain the better recanalization and outcomes in other studies [16].

The overall TIC1 3 was 64%, which is higher than previously reported by ADAPT FAST and other stent retriever registries [12]. This could be due to single-operator use or the newer technology of BGCs, stent retrievers, and even aspiration catheters, which are now larger in diameter and more trackable (Table 3).

Some users have reported trackability issues with FlowGate, but this was not observed in this study, which might be due to our routine use of longer sheaths. For us, the catheter was easily trackable in 92% of cases. One advantage that operators consistently appreciated was the ability to use distal access catheters due to its larger inner diameter. The time from groin puncture to recanalization was similar to that reported by ADAPT FAST, perhaps due to a higher FPE, a less complex patient population, or use of only one standard approach, which has been reported by McTaggart et al. [17] to improve procedure times.

There are many limitations to this case series review and analysis. It is a single-center, single-operator report. Although the data were collected prospectively in real time during the procedures, the design is retrospective in nature. There was no central core lab for adjudication of TIC1 score. This was based on the final dictated report. In addition, the new FlowGate2 is now available and offers more support, so some of these data are limited and may be outdated.

Conclusion

Use of the FlowGate BGC was associated with a good true FPE of TIC1 3 of 46% and a FPE of 64% for TIC1 2b/3 and an overall recanalization rate of 94% TIC1 2b/3. The high success rate makes the device a very good alternative to other BGCs that are stiffer, less trackable, and have a smaller inner lumen diameter.

Statement of Ethics

This study was an observational retrospective study approved by the hospital institutional review board. The research presented in this paper was ethically conducted in accordance with the World Medical Association Declaration of Helsinki and the appropriate guidelines for human studies as well as according to animal welfare regulations, including the Animal Research: Reporting of in vivo Experiments (ARRIVE) guidelines, and was approved by the appropriate institutional review bodies.

Disclosure Statement

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Author Contributions

M.S. Teleb made substantial contributions to the conception of the study, the acquisition, analysis, and interpretation of data for the work, participated in drafting the work or revising it critically for important intellectual content, approved the final version to be published, and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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