

Balloon Guide Catheter Improves Revascularization and Clinical Outcomes With the Solitaire Device

Analysis of the North American Solitaire Acute Stroke Registry

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Background and Purpose—Efficient and timely recanalization is an important goal in acute stroke endovascular therapy. Several studies demonstrated improved recanalization and clinical outcomes with the stent retriever devices compared with the Merci device. The goal of this study was to evaluate the role of the balloon guide catheter (BGC) and recanalization success in a substudy of the North American Solitaire Acute Stroke (NASA) registry.

Methods—The investigator-initiated NASA registry recruited 24 clinical sites within North America to submit demographic, clinical, site-adjudicated angiographic, and clinical outcome data on consecutive patients treated with the Solitaire Flow Restoration device. BGC use was at the discretion of the treating physicians.

Results—There were 354 patients included in the NASA registry. BGC data were reported in 338 of 354 patients in this subanalysis, of which 149 (44%) had placement of a BGC. Mean age was 67.3 ± 15.2 years, and median National Institutes of Health Stroke Scale score was 18. Patients with BGC had more hypertension (82.4% versus 72.5%; $P=0.05$), atrial fibrillation (50.3% versus 32.8%; $P=0.001$), and were more commonly administered tissue plasminogen activator (51.6% versus 38.8%; $P=0.02$) compared with patients without BGC. Time from symptom onset to groin puncture and number of passes were similar between the 2 groups. Procedure time was shorter in patients with BGC (120 ± 28.5 versus 161 ± 35.6 minutes; $P=0.02$), and less adjunctive therapy was used in patients with BGC (20% versus 28.6%; $P=0.05$). Thrombolysis in cerebral infarction 3 reperfusion scores were higher in patients with BGC (53.7% versus 32.5%; $P<0.001$). Distal emboli and emboli in new territory were similar between the 2 groups. Discharge National Institutes of Health Stroke Scale score (mean, 12 ± 14.5 versus 17.5 ± 16 ; $P=0.002$) and good clinical outcome at 3 months were superior in patients with BGC compared with patients without (51.6% versus 35.8%; $P=0.02$). Multivariate analysis demonstrated that the use of BGC was an independent predictor of good clinical outcome (odds ratio, 2.5; 95% confidence interval, 1.2–4.9).

Conclusions—Use of a BGC with the Solitaire Flow Restoration device resulted in superior revascularization results, faster procedure times, decreased need for adjunctive therapy, and improved clinical outcome. (*Stroke*. 2014;45:141-145.)

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The recent results of the Interventional Management of Stroke (IMS) III, Mechanical Retrieval and Recanalization of Stroke Clots Using Embolectomy (MR RESCUE), and Synthesis Expansion trials have generated interest in evaluating technical and procedural factors that can improve recanalization success, clinical outcomes, and optimize procedural efficiency.¹⁻³ The stent retrievers recently emerged as promising devices for acute ischemic stroke treatment, shown to be superior to the Merci retriever device in achieving better recanalization and clinical outcome in patients with acute ischemic stroke in 2 randomized trials.^{4,5}

The Solitaire Flow Restoration (FR) device is one example of a stent retriever that recanalizes vessels in patients with ischemic stroke attributable to large vessel occlusion. One important component of this procedure is the use of a balloon guide catheter (BGC), which is a supporting catheter placed in the neck. When the Solitaire device is retrieved with the clot, the balloon at the tip of the guide catheter is inflated to arrest antegrade flow from the carotid artery. Aspiration is also performed at the guide catheter tip to capture clot. Animal ischemic stroke models have shown an association between use of the BGC with inflation of the balloon on the distal guide catheter and decreased rate of distal emboli⁶; however, this corollary has not been demonstrated in human studies with the stent-retriever devices.

The present study aims to evaluate whether the use of a BGC influences clinical outcome, recanalization success, and reduces emboli to new territory in patients treated with the Solitaire device within the North American Solitaire Acute Stroke (NASA) registry. We hypothesize that recanalization of the primary target vessel would be superior with use of a BGC and thus lead to improved clinical outcomes.

Methods

The investigator-initiated NASA registry recruited 24 clinical sites within North America to submit retrospective demographic, clinical presentation, site-adjudicated angiographic, procedural, and clinical outcome data (modified Rankin scale) on consecutive patients treated with the Solitaire device from March 2012 to February 2013. BGC was used at the discretion of the treating physician. The time interval from symptom onset to groin puncture or first angiographic image was recorded, as well as total procedural time. If reperfusion failed, time at the end of procedure was recorded as the ending time.

Patients presenting within 8 hours from symptom onset of an anterior circulation large vessel occlusion or within 12 hours of a posterior circulation large vessel occlusion were included in the study. Thrombolysis in myocardial infarction and thrombolysis in cerebral infarction (TICI) recanalization were defined according to the Solitaire With the Intention for Thrombectomy (SWIFT) and Trevo versus Merci retrievers for thrombectomy revascularization of larger vessel occlusions in acute ischemic stroke (TREVO 2) clinical trial definitions.^{4,5} Symptomatic intracranial hemorrhage was defined as any parenchymal hematoma, subarachnoid hemorrhage, or intraventricular hemorrhage associated with a worsening of the National Institutes of Health Stroke Scale (NIHSS) score by ≥ 4 within 24 hours. Adjuvant therapy was defined as any additional drug (ie, intra-arterial lytic) or mechanical device modality used other than a stent retriever. Reperfusion, angiographic data, hemorrhage type, and clinical outcome were adjudicated by each individual center.

The data were stored and analyzed by the central coordinating site: the Medical College of Wisconsin. This NASA registry was performed without industry sponsorship or funding. Institutional review board approval was obtained from each institution's review board; only deidentified information was submitted for this analysis.

Statistical Analysis

Baseline characteristics were compared between patients with and without BGC placement using the Fisher exact or χ^2 tests for categorical variables and Student *t* test for continuous variables. Variables with a *P* value of <0.10 were entered into the multivariate binary logistic regression model to determine predictors of a good clinical outcome and successful reperfusion. Statistical analyses were performed using JMP version 10 (SAS Institute, Inc, Cary, NC).

Results

BGC data were reported in 338 of 354 patients. Of the 338 patients, 149 (44%) had placement of a BGC. Baseline demographics are presented and compared by univariate analysis (Table 1). The BGC group had more hypertension (82.4% versus 72.5%; *P*=0.05), atrial fibrillation (50.3% versus 32.8%; *P*=0.001), and were more commonly administered intravenous tissue plasminogen activator (IV tPA; 51.6% versus 38.8%; *P*=0.02) compared with patients without BGC. Admission NIHSS score was similar between the 2 groups. The site of occlusion was middle cerebral artery/M1 63.1%, M2 11.5%, internal carotid artery terminus 21%, and vertebrobasilar 4.7% in the BGC group versus 49.7%, 11.1%, 24.3%, and 14.8% in the non-BGC group, respectively. There was higher use of BGC in the anterior compared with posterior circulation (142/303, 46.9% versus 7/35, 20%; *P*=0.002; Table 1). Time

Table 1. Univariate Comparison of the BGC Group vs Non-BGC Group

Variable	BGC (n=149), n (%)	No BGC (n=189), n (%)	<i>P</i> Value
Demographics			
Age, y, mean (SD)	68.5 (14)	66.1 (16.2)	0.16
Women	73 (49)	90 (48)	0.9
Black	28 (19)	31 (16)	0.3
Vascular risk factors			
Hypertension	122 (82)	137 (72.5)	0.05
Atrial fibrillation	75 (50)	62 (33)	0.001
Diabetes mellitus	34 (23)	50 (26)	0.5
Hyperlipidemia	80 (54)	89 (47)	0.2
Smoking	44 (30)	62 (33)	0.6
Coronary artery disease	53 (36)	51 (27)	0.1
Clinical presentation			
Hospital transfer	58 (39)	100 (53)	0.1
NIHSS score, mean (SD)	17.6 (6.5)	18.3 (6.9)	0.3
NIHSS score, median (IQR)	17 (13–22)	18 (14–23)	
IV tPA administered	77 (52)	73 (39)	0.02
Location thrombus			
Anterior circulation			
M1 MCA	94 (63.1)	94 (49.7)	0.02
M2 MCA	17 (11.5)	21 (11.1)	1
Carotid terminus	31 (21)	46 (24.3)	0.5
Posterior circulation			
Basilar artery	7 (4.7)	28 (14.8)	0.002

BGC indicates balloon guide catheter; IQR, interquartile range; IV tPA, intravenous tissue plasminogen activator; MCA, middle cerebral artery; and NIHSS, National Institutes of Health Stroke Scale.

from symptom onset to groin puncture and mean number of passes were similar between the 2 groups (Table 2). Adjuvant therapy was used less frequently (20% versus 28.6%; $P=0.05$) and procedure time was shorter (120 ± 28.5 versus 161 ± 35.6 minutes; $P=0.02$) in the BGC group.

TICI 3 reperfusion was higher in the BGC group compared with the non-BGC (TICI 3, 53.7% versus 32.5%; $P<0.0001$), whereas TICI 2b/3 was similar (TICI 2b/3, 76% versus 71%;

$P=0.3$; Table 2). Distal emboli and emboli in new territory were similar between the 2 groups. Discharge NIHSS score (mean, 12 ± 14.5 versus 17.5 ± 16 ; $P=0.002$) and good clinical outcome (modified Rankin Scale ≤ 2) at 3 months were superior in patients with BGC compared with patients without (51.6% versus 35.8%; $P=0.02$).

The multivariate analysis (adjusting for age, hypertension, atrial fibrillation, initial NIHSS score, IV tPA, general anesthesia, BGC, time from onset to groin puncture, procedure time, recanalization, vessel location) demonstrated that the use of BGC remained as an independent predictor of good clinical outcome (odds ratio, 2.5; 95% confidence interval, 1.2–4.9; Table 3).

A separate analysis was performed removing IV tPA patients ($n=200$), of which modified Rankin scale at 3 months was available in 168 patients, 62 had BGC, and 106 without BGC. Patients in the BGC group had improved clinical outcome (45.2% versus 30.2%; $P=0.05$), lower discharge mean NIHSS scores (12 ± 13.6 versus 18 ± 18 ; $P=0.02$), and similar mortality (27.4% versus 35.9%; $P=0.3$) compared with the non-BGC group. In the IV tPA only group ($n=154$), the impact of BGC on positive outcomes was less robust, with favorable trends toward lower discharge mean NIHSS score (12.8 ± 15.4 versus 16.7 ± 15.8 ; $P=0.2$) and clinical outcome at 3 months (57.8% versus 44.8%; $P=0.1$).

Excluding patients with posterior circulation (35 patients) and restricting the analysis to anterior circulation did not affect the results and showed good clinical outcome in the BGC group compared with non-BGC group (52.1% versus 35.4%; $P=0.01$). Multivariate analysis in the anterior circulation only group (adjusting for the same variables as for overall analysis) showed use of BGC as an independent predictor of good clinical outcome. When analyzing the posterior circulation only (35 patients total, 7 with BGC), there was no relation to the use of BGC and good clinical outcome ($P=1$).

Table 2. Imaging, Procedural, and Clinical Results in the BGC Group vs Non-BGC Group

	BGC (n=149), n (%)	No BGC (n=189), n (%)	P Value
Imaging results			
Distal emboli	26 (18.2)	29 (16)	0.7
Emboli in new territory	8 (5)	10 (5.2)	0.9
Recanalization TICI 3	80 (53.7)	61 (32.5)	<0.0001
Recanalization TICI 2b–3	113 (76)	133 (71)	0.3
Recanalization TIMI 2/3	128 (86)	158 (84)	0.6
Recanalization TICI 2a–3	131 (87.9)	166 (87.8)	1
Successful reperfusion TICI			
0	8.7	10.6	<0.001
1	3.4	1.6	
2a	12.1	18.6	
2b	22.2	38.3	
3	53	32.5	
Successful reperfusion TIMI			
0	10.1	12.8	<0.001
1	4	3.7	
2	26.9	50	
3	59.1	33.5	
Procedural factors			
Procedure time (SD)	120 (28.5)	161 (35.6)	0.02
Time onset to groin or first angio (SD)	348 (230.7)	375 (252.7)	0.3
General anesthesia	97 (84.4)	99 (60)	<0.001
No. of passes			
Mean (SD)	1.8 (1.2)	1.9 (1)	0.3
Median (IQR)	1 (1–2)	2 (1–3)	
IA tPA	40 (26.9)	60 (31.8)	0.3
Simultaneous Penumbra and Solitaire	18 (12.1)	34 (18.1)	0.1
Adjuvant therapy	29 (20)	54 (28.6)	0.05
Clinical outcome			
Discharge NIHSS score			
Mean (SD)	12 (14.5)	17.5 (16)	0.002
Median (IQR)	6 (1–18)	11 (4–42)	
Good clinical outcome (1 mo)	55 (49.1)	32 (24.2)	0.002
Good clinical outcome (3 mo)	65 (51.6)	62 (35.8)	0.02
Symptomatic hemorrhage	18 (12.2)	17 (9)	0.4
Mortality	33 (26.2)	55 (31.8)	0.3

BGC indicates balloon guide catheter; IA tPA, intra-arterial tissue plasminogen activator; IQR, interquartile range; NIHSS, National Institutes of Health Stroke Scale; TICI, thrombolysis in cerebral infarction; and TIMI, thrombolysis in myocardial infarction.

Discussion

This substudy compared the revascularization efficacy of adjunctive use of the BGC with the Solitaire stent retriever in a

Table 3. Independent Predictors of Clinical Outcome With Solitaire Treatment for Acute Ischemic Stroke

Variable	Nparm	DF	χ^2	P Value > χ^2
Age, y	2	1	94.54	<0.001*
Hypertension	2	1	3.93	0.0476
Atrial fibrillation	2	1	16.8	<0.0001*
Initial NIHSS score	2	2	9.47	0.0088*
Site	8	5	9.85	0.08
IV tPA	2	1	128.46	<0.0001*
TOG	2	1	0.58	0.45
TIMI success	2	2	2.75	0.25
BGC	2	1	66.66	<0.0001*
General anesthesia	2	2	5.56	0.026
Procedure time	2	2	5.56	0.06

BGC indicates balloon guide catheter; DF, degrees of freedom; IV tPA, intravenous tissue plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; Nparm, number of parameters; TIMI, thrombolysis in myocardial infarction; and TOG, time of onset to groin puncture.

*Statistically significant.

large patient series of acute ischemic stroke (338 patients). The study revealed improved recanalization rates for TICI 3 scoring, shorter procedure time, decreased need for adjuvant therapy, and better clinical outcome among patients treated with the BGC. In this study, there was no significant effect of use of the BGC with regards to presence of emboli in new territory.

The successful reperfusion results in our study comparing the BGC versus non-BGC groups were better than expected, the magnitude of difference largely driven by the TICI 3 category of reperfusion. The additional component of antegrade flow arrest with use of BGC is likely an important element that reduces migration of the entrapped thrombus or fragmented clots extracted by the stent retriever. The importance of the BGC with successful recanalization has also been observed in early case series of patients with acute ischemic stroke treated with other devices such as Neuronet and microsnares.^{7,8} In our study, higher use of IV tPA and lower rate of carotid T occlusions in the BGC group may have also contributed to better recanalization and clinical outcome. In separate subanalysis, the impact of BGC on good clinical outcome was more robust in the non-IV tPA group compared with the tPA group. This is likely because use of IV tPA confers additional advantages in recanalization and good outcome as has been shown in other studies such as IMS III.¹

The findings related to reduced embolic events with use of a BGC have been demonstrated in animal models^{9,10} and in vitro modeling.⁶ In an experimental ischemic stroke model, proximal aspiration devices were compared with distal basket-like devices (Catch, Balt), and thrombus–device interactions were analyzed. The number of embolic events was significantly higher with distal devices without proximal balloon occlusion compared with use of distal devices with proximal balloon occlusion (5/12, 42% versus 1/11, 9%; odds ratio, 7.1; 95% confidence interval, 0.7–75.2).⁹ Proximal aspiration devices showed a lower risk of thromboembolic events. Use of a BGC did not affect the rate of recanalization nor distal embolization for proximal aspiration devices. In another swine model testing the Solitaire device, Jahan¹⁰ noted that in many cases, the clot would be engaged within the struts and would shear off the device during retrieval into the tip of the BGC. It was possible to aspirate the clot into the guide catheter and prevent distal emboli.

More recently, Dávalos et al¹¹ retrospectively reported their results of 141 patients treated at 6 European Centers with Solitaire FR device as first-line therapy and evaluated the impact of the BGC on collateral infarction. Data on BGC use were available in 123 patients. The investigators found that there were more infarctions in the collateral circulation in non-BGC–treated patients compared with patients treated with a BGC (6/28, 21% versus 4/95, 6%; $P=0.01$).

In addition to antegrade flow arrest with the BGC, thrombus aspiration likely plays an important role in the successful retrieval of clot, even with the stent-retriever technique. Several proceduralists are concomitantly applying aspiration at the site of the microcatheter while retrieving the stent retriever. Furthermore, it is likely that aspiration applied at the microcatheter middle cerebral artery clot interface, for example, generates higher suction than aspiration at the guide catheter parked in the cervical carotid artery. With the latter,

distance from clot to guide catheter is separated not only by a longer length of vessel susceptible to collapse, but also by the ophthalmic, anterior choroidal, posterior communicating arteries which may reverse flow, reduce suction effect, and lead to unintended embolization of the distal circulation or emboli in new territory. Further exploration of the role of aspiration at the site of the guide catheter versus microcatheter and larger catheter inner diameter versus standard inner diameter lumen should be addressed in subsequent studies.

Limitations

Our study had several limitations. Adjudication of reperfusion and clinical outcome was performed locally at each site, without a core laboratory or requirement of an independent adjudicator. This adjudication may be biased toward better angiographic results in favor of the Solitaire stent-retriever device. Some investigators may also consistently assign a TICI score of 3 to an angiographic result that other investigators would assign a score of 2b. There is also a chance that investigators using BGC were more likely to score TICI 3 than non-BGC investigators, overestimating the benefit of BGC. However, the initial primary objective of this study was evaluation of real-world performance of Solitaire device compared with the SWIFT and TREVO trials.¹² The BGC subanalysis was a secondary post hoc analysis, and hence we do not think this would have biased investigators to report higher recanalization rates with the knowledge that a BGC was used.

Use of a BGC was not randomized in this study, but was used at the discretion of the treating operator. Access difficulty or tortuosity may have precluded use of BGC in several cases, which may have increased procedural time, decreased probability for successful recanalization, and translate to less good clinical outcome. Variability in retrospective reporting of aspiration technique, whether at the guide catheter in the neck or microcatheter proximal to the clot, could be another variable influencing recanalization results in the BGC or non-BGC group. Another limitation is that even with a BGC present, we are not certain from this retrospective cohort that the balloon was inflated with every retrieval pass for flow arrest.

Conclusions

Use of a BGC with Solitaire stent-retriever device is associated with superior revascularization results, decreased use of adjuvant therapy, shorter procedure time, and improved clinical outcome. Confirmation of these findings may be important, along with the role of aspiration, preferably in the context of a randomized clinical trial.

Disclosures

Dr Zaidat is a consultant/advisory board member of Covidien, Stryker. Dr Gupta is a consultant/advisory board member of Covidien, Stryker Neurovascular. Dr Malisch is a member of DSMB SWIFT Trial. Dr Linfante is a consultant for Covidien. Dr Rai is a consultant/advisory board member of Stryker Neurovascular. Dr Nogueira is a consultant/advisory board member of Covidien, Stryker Neurovascular. Dr English is a consultant for Stryker Neurovascular. Dr Abraham is a consultant of Stryker Neurovascular and on the speaker's bureau for Boehringer Ingelheim. The other authors report no conflicts.

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