

Original research

Walrus large bore guide catheter impact on recanalization first pass effect and outcomes: the WICKED study

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ABSTRACT

Background The use of a balloon-guide catheter (BGC) in acute stroke treatment has been widely adopted after demonstrating optimized procedure metrics and outcomes. Initial technical constraints of previous devices included catheter stiffness and smaller inner diameters. We aim to evaluate the performance and safety of the Walrus BGC, a variable stiffness catheter with a large bore 0.087 inch inner diameter (ID), via the the WICKED study (Walrus Large Bore guide Catheter Impact on reCanalization first pass Effect and Outcomes).

Methods This is a retrospective, site adjudicated, multicenter study on consecutive patients with large vessel occlusion treated with the Walrus BGC. Baseline characteristics, procedural outcomes and functional outcomes were analyzed.

Results A total of 338 patients met the inclusion criteria. The Walrus was successfully tracked into distal vasculature and allowed therapeutic device delivery in all but 3 cases (0.9%). Large aspiration catheters ≥ 0.070 inch ID were used in 71.9% of cases. Stent retriever thrombectomy was used as the first-line modality in 59.2% and thromboaspiration in 40.8% of cases. The successful recanalization rate (modified treatment in cerebral ischemia (mTICI) 2b/3) was 94.4%, with 64.8% of the patients achieving mTICI 2b/3 after the first pass. The Walrus-related adverse event rate was 0.6%, corresponding to two vessel dissections. Functional independence was 50% (126/252) and mortality 25% (63/252). Unfavorable outcomes were more likely in older patients, who had unsuccessful reperfusion, longer procedure times, and a higher mean number of passes.

Conclusion In acute ischemic stroke patients presenting with large vessel occlusion, the Walrus BGC demonstrated excellent navigability and safety profile, allowed the accommodation of leading large bore aspiration catheters, and demonstrated high vessel recanalization rates.

INTRODUCTION

Over the past years, efforts have been made to improve the treatment of patients with acute ischemic stroke due to large vessel occlusion, from workflow optimization to refinement and development of new therapies.^{1–3} Evolving comprehension of the factors involved in thrombectomy and

their implications in procedure success and patient outcomes allowed the development and optimization of devices aiming to mitigate adverse events and increase efficacy. The use of balloon guide catheters (BGCs) during thrombectomy facilitates proximal flow arrest, minimizing the risk of clot fragmentation and propagation of distal emboli during its retrieval.⁴ When used as an adjunct technique during thrombectomy, BGCs have demonstrated increased rates of successful recanalization, first-pass effect, and decreased procedural times.⁵ The potential benefits of BGCs were demonstrated with *both* contact-aspiration and stent-retriever first-line modalities.⁶

Numerous in vitro and animal studies have elucidated the hemodynamic mechanisms associated with the use of BGCs. Initial technical constraints such as increased stiffness and small inner diameter (ID) had limited the disseminated use of previous BGCs. The Walrus Balloon Guided System Catheter (QApel Medical Inc, Fremont, CA) is a variable stiffness, large bore catheter that allows accommodation of market-leading aspiration catheters. The catheter obtained Food and Drug Administration (FDA) clearance in mid July 2019. The purpose of our study was to retrospectively investigate the performance and safety of the Walrus BGC in the recanalization of emergent large vessel occlusion (ELVO).

METHODS

The WICKED study is an investigator-led post-market surveillance study that aims to document the outcomes associated with the use of the Walrus BGC system. It comprises a retrospective review of five comprehensive stroke centers between August 2019 and December 2020. Local ethics committees and/or institutional review boards at each institution approved the retrospective analysis of de-identified patient data, which did not require informed consent. The cohort consisted of all *consecutive* patients with acute ischemic stroke due to ELVO undergoing thrombectomy using the Walrus Balloon Guide Catheter System. FDA approved mechanisms of thrombectomy were allowed, including aspiration and/or stent-retriever. Exclusion criteria included spontaneous recanalization

before the intervention and Walrus catheter usage for non-acute stroke conditions.

The data collected at each center were predefined by a study protocol and entered into a standardized data form. Data included patient demographics, National Institutes of Health Stroke Scale (NIHSS), modified Rankin Scale (mRS), intravenous alteplase (IV-tPA), procedural details and metrics, intraoperative and postoperative adverse events, and 90 day follow-up. Angiographic outcomes, clinical outcomes, and the relation of adverse events with the investigated device were adjudicated by the treating physician. The primary efficacy outcome was defined as successful navigation to the target supra-aortic vessel with the Walrus BGC. The primary safety outcome was defined by the occurrence of vascular injuries (eg, dissection, perforation) at the site of the Walrus BGC or any injury attributable to the Walrus BGC.

Device

The Walrus 087 Balloon Guide Catheter System is a variable stiffness, single-wall catheter designed with the intent of providing proximal support, while maintaining distal flexibility and trackability. The tangential port at the proximal bifurcated dual port Luer allows a distal balloon’s inflation to provide distal support combined with flow control. The Walrus BGC is indicated to facilitate the insertion and guidance of an intravascular catheter and serve as a conduit for retrieval devices. The ID is 0.087 inches to accommodate newer larger therapeutic device delivery.

Procedure detail

All procedures were performed by experienced neurointerventionalists. Patients received intravenous thrombolytic therapy (tissue plasminogen activator, tPA) according to institutional standard of care. Stent-retriever and aspiration thrombectomies

were performed according to the treating physician’s preference. The Walrus BGC was positioned in the internal carotid artery, between the proximal cervical and cavernous segments, or in the vertebral artery, followed by the advancement of therapeutic devices. The Walrus BGC was inflated before clot extraction under constant aspiration through a manual syringe, active pump, or both. With the exception of the preferred first-line approach and devices used, thrombectomy technique was similar across all participating centers.

Secondary analysis

Prespecified secondary analyses included: (1) successful final vessel recanalization; (2) the rate of modified first-pass effect, defined as achieving successful recanalization (modified treatment in cerebral ischemia (mTICI) $\geq 2b$) after a single pass; (3) number of passes; (4) puncture-to-recanalization time; (5) use of adjunct therapy, including angioplasty, stent deployment, and drug therapies (cangrelor, eptifibatide, and intra-arterial tPA); (6) occurrence of symptomatic intracranial hemorrhage, defined as PH2 based on the ECASS (European Cooperative Acute Stroke Study) II classification; and (7) functional outcomes, with favorable outcome defined as an mRS score of 0 to 2 at 3 months post-intervention.

Statistical analysis

Demographic baseline and procedural characteristics were summarized and reported as mean \pm SD and median (IQR). Categorical data were summarized using rates and percentages. In univariable analysis, variables were compared using the χ^2 test, Mann-Whitney U test, and Fisher’s exact test. A p value <0.05 was considered statistically significant. All statistical analyses were performed using JMP (SAS, Cary, NC, USA).

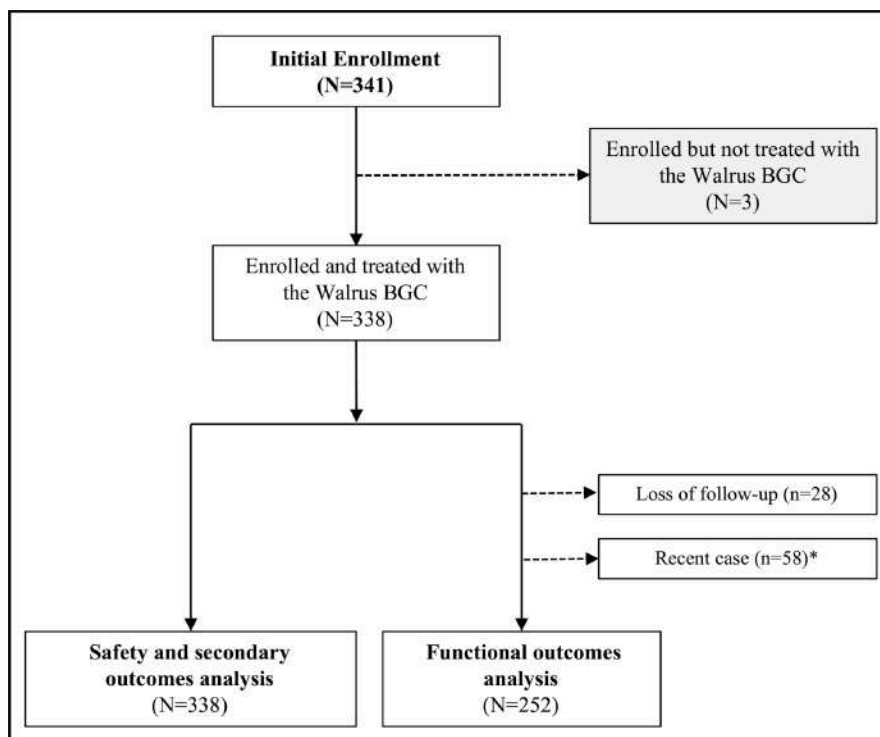


Figure 1 Patient flow diagram of thrombectomy through the Walrus balloon-guide catheter in acute ischemic stroke.

Table 1 Baseline characteristics

Variable	N (%)
Age (years)	68.3±15.1
Female	178 (52.6)
NIHSS	15 (11–21)
IV-tPA	126 (37.3)
Baseline mRS*	
0	223 (66.0)
1	38 (11.2)
2	31 (9.1)
3	26 (7.7)
4	10 (3.0)
5	1 (0.3)
Clot location	
M1	150 (44.4)
M2	88 (26.0)
M3	5 (1.5)
ICA	83 (24.6)
Basilar	9 (2.7)
PCA	3 (0.9)
Tandem occlusion	43 (11.2)
Anesthesia	
Conscious sedation	244 (72.2)
General	94 (27.8)
Access site	
Femoral	337 (99.7)
Radial	1 (0.3)

Values are presented as mean±SD, median (IQR) or n (%).

*Not available in nine cases.

ICA, internal carotid artery; IV-tPA, intravenous alteplase; M1-3, middle cerebral artery first, second, and third segments; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; PCA, posterior cerebral artery.

RESULTS

Baseline characteristics

A total of 338 consecutive patients met the inclusion criteria and were included in the study (figure 1). The mean age was 68.3±15.1

years, and the majority were female (178/338, 52.5%). The median NIHSS at presentation was 15 (IQR 11–21), and 86.4% were functionally independent (mRS ≤0–2) at baseline. Intravenous alteplase was given to 37.3% (126/338) of the patients. The occlusion site was the anterior circulation in 96.4% (326/338) of cases, with 11.2% (43/338) of the patients presenting with tandem occlusion. Baseline characteristics are detailed in table 1.

Procedure details

The majority of interventions occurred under conscious sedation (244/338, 72.2%), and access was through the femoral artery in all but one case. First-line approach included the use of a stent-retriever in 59.2% (200/338) of the cases, and aspiration in the remaining 138 cases (40.8%). There was no statistical difference between stent-retriever or aspiration modalities in first pass TICI 2b/3 (62.5% vs 68.1%, p=0.34) and final recanalization rates (95.5% vs 92.7%, p=0.39). Twenty-two different aspiration catheters were accommodated into the Walrus and allowed successful therapeutic delivery (figure 2), with the large ID ≥0.070 inch aspiration catheter accounting for 71.9% of cases. The most commonly used aspiration catheters were LBC (72/338, 21.3%; Cerenovus, Miami, FL), Zoom 71 (59/338, 17.4%; Imperative Care, Campbell, CA), Jet 7 (56/338, 16.6%; Penumbra, Alameda, CA), and React 71 (36/338, 10.6%; Medtronic, Irvine, CA).

An adjunct therapeutic device was used in 48 cases (14.2%), corresponding to 38 extracranial and 10 intracranial stentings. Angioplasty was performed in eight (2.4%) additional cases. Adjunct pharmacological antiplatelet/thrombolytic therapy was used in 34 (10%) cases, 29 (8.6%) of which were related to stent placement and five (1.5%) with vessel reocclusion or distal embolization. Verapamil was used, whether prophylactically or as a result of local vasospasm, in 8.6% (29/338) of the cases. Procedural details are available in table 2.

Outcomes

The Walrus BGC was successfully tracked to the target vasculature and allowed the delivery of different therapeutic devices in all but three cases (0.9%), related to kinking due to vessel tortuosity that precluded adequate therapeutic device delivery. Primary safety outcome events were noted in two patients (0.6%), both related to vessel dissection at the region where the Walrus balloon was inflated. In one case, flow-limitation required stent placement to secure the lesion and ensure vessel patency.

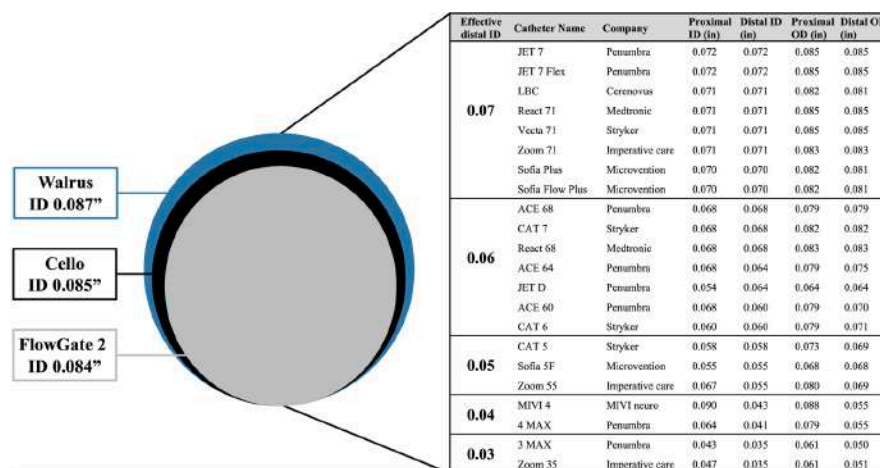


Figure 2 Aspiration catheters accommodated within the Walrus balloon-guide catheter system in the first pass. ID, inner diameter; OD, outer diameter.

Table 2 Procedure details

Variable	N (%)
First-pass approach	
Stent-retriever	200 (59.2)
Aspiration-only	138 (40.8)
Second-pass approach*	
Stent-retriever	83 (53.2)
Aspiration-only	73 (46.8)
Mean number of passes	2.1±1.8
Adjunct therapy	59 (17.4)
Adjunct procedure therapy	
Extracranial stenting ± angioplasty	38 (11.4)
Intracranial stenting ± angioplasty	10 (2.9)
Adjunct drug therapy	
Eptifibatide	30 (8.8)
Intra-arterial tPA	2 (0.6)
Cangrelor	2 (0.6)
Verapamil	29 (8.6)
Number of passes to mTICI ≥2b	
1	219 (64.8)
2	51 (15.1)
3	23 (6.8)
≥4	22 (6.5)
Final mTICI score	
3	159 (47.1)
2c	68 (20.1)
2b	92 (27.2)
2a	13 (3.8)
1	1 (0.3)
0	5 (1.5)
Final mTICI ≥2b	319 (94.4)
Final mTICI ≥2c	227 (67.1)
Mean puncture-to-mTICI ≥2b, min	30.8±21.0
Mean puncture-to-recanalization, min	37.5±25.4
Adverse events	
Emboli to new territory	7 (2.1)
Downstream emboli	5 (1.5)
Vessel dissection	4 (1.2)
Vessel perforation	2 (0.6)
Groin hematoma/pseudoaneurysm	5 (1.5)

Values are presented as mean±SD or n (%).

*Denominator=156.

mTICI, modified treatment in cerebral ischemia; tPA, tissue plasminogen activator.

Successful vessel recanalization (TICI 2b/3) was achieved in 94.4% (319/338), with a rate of first-pass TICI 2b/3 of 64.8% (219/338). The overall mean time from puncture-to-recanalization was 37.5±2 min, with a median number of passes of 1 (IQR 1–2). Median NIHSS decreased from 15 (IQR 11–21) at presentation to 5 (IQR 2–14, $p<0.001$) 24 hours after the thrombectomy. Intracranial cerebral hemorrhage occurred in 13 cases (3.8%).

Favorable functional outcome at 90 days was achieved in 50.0% (126/252) of the patients, and mortality was 25% (63/252). On univariate analysis, patients with unfavorable outcome were more likely to be 80 years or older ($p<0.001$), have unsuccessful reperfusion ($p=0.02$), longer procedure times ($p<0.001$), and higher mean

number of passes ($p<0.001$), and were less likely to have achieved TICI 2b/3 after the first pass (35.5% vs 58.0%, $p<0.001$). These same factors were also associated with mortality ($p<0.001$).

DISCUSSION

The WICKED consecutive case, multicenter study suggests the Walrus BGC is efficacious in therapeutic device delivery during ELVO thrombectomy, with an appropriate safety profile (0.6%). The Walrus BGC also demonstrated a consistent ability to deliver large-bore aspiration catheters with ID ≥0.070 inch in 71.9% of the reported cases. Notably, successful recanalization and first pass TICI 2b/3 were achieved in 94.4% and 64.8% of cases, respectively, which compares well with the available literature on balloon guides usage in thrombectomy procedures.

In vitro and animal models had been used to investigate the mechanisms surrounding the potential benefits of BGCs, eventually supporting their incorporation into clinical practice and leveraging new devices' advancement.^{7–11} The ability to control external factors and allow reproducible simulations with such models refined our knowledge on clot extraction and fragmentation dynamics.⁹ A partial thrombus embedment within the stent-retriever metal structure and limited distal clot control with contact aspiration techniques were proposed factors that could facilitate clot dislocation and fragmentation in the presence of ongoing flow. Besides, large clot extraction into the catheter tip has been demonstrated to be a determinant step in clot shearing and generation of distal emboli. Proximal flow arrest using BGCs and large sized guide-catheters emerged as potential instruments to reduce thrombus shearing.^{10–11} Chueh *et al*⁷ elucidated a significant decrease of clot fragments after balloon inflation, especially with hard clots, and additional flow reversal in the middle cerebral artery territory when applying concomitant continuous aspiration.⁷ The use of BGC proved to be a feasible strategy for preventing distal embolism in vitro for both stent-retriever or aspiration-only techniques.⁸

Despite the evolving design, one of the limitations of BGC use was the increased stiffness associated with their design, which occasionally might prevent adequate trackability and hamper distal access. The ability to navigate tortuous anatomy and achieve the desired position in the cervical or intracranial vasculature is an essential feature for any guide catheter. A few retrospective studies have detailed this limitation of BGCs, in which they were unable to navigate into the desired location due to angulation and tortuosity of the vessels, with an overall described trackability around 90–98%.^{12–15} These numbers are reinforced by the Aspiration vs Stent Retriever for Successful Revascularization (ASTER) trial, in which BGC use was mandatory for the stent-retriever arm but demonstrated successful placement in only 92% of the cases.¹⁶ The Walrus has a specially designed monolithic wall, with a variable stiffness, intended to facilitate navigability overcoming the conventional technical constraints associated with other BGCs.

Regarding the access site, a femoral approach was used in all but one of our cases. Radial access has been proposed as an alternative approach for treating large vessel occlusions, with a safe and efficient profile in well-selected patients.¹⁷ Despite this approach's potential benefits, large-caliber catheter use commonly needs to be forsaken due to the smaller caliber of the radial artery.¹⁸ The Walrus BGC is typically used inside a 9 French (9F) sheath, allowing for closure with an 8F Angioseal (Terumo, New Jersey, USA). In our series, the Walrus BGC has been used for a direct approach via VTK or SIM 2 125 cm catheters, occasionally using exchange maneuvers when a direct approach was not obtainable. The system performs better with an inner catheter to decrease the 'lip effect'. Therefore, when exchange maneuvers are needed, a 5F 125 cm length Vert catheter can be used. Balloon preparation is done in a typical fashion,

with the aspiration of the balloon with a syringe using a solution of contrast saline 50/50. Inflation and deflation times are noted to be fast, and no cases of balloon rupture were reported in the present series.

The use of catheters with larger IDs (~0.070 inch and 0.060 inch) through the Walrus BGC occurred in 71.9% and 14.2% of the cases, respectively. The preference for a large catheter size is based on mounting evidence demonstrating an increased likelihood of obtaining higher technical success and better clinical outcomes.^{19 20} Larger size catheters are able to generate higher aspiration forces, frequently regarded as a determinant factor for aspiration success.²¹ Although most recent studies have evaluated the influence of size over modern aspiration techniques, reduced aspiration force in stent-retriever first-line modality, due to the competing presence of microcatheter and thrombectomy devices, may also be improved by applying large-size catheters.

The numerous studies support a correlation between the use of BGC with improved recanalization rates (from 74.6% to 94.1%) and successful single-pass TICI 2b/3 reperfusion (from 24.2% to 63.7%).^{4 6 22-27} Additional factors that have been associated with BGC include a decreased number of passes, shorter procedure times, and a reduced number of distal embolizations.^{5 28} In this Walrus cohort, the final recanalization rate was 94.4% and first-pass TICI 2b/3 occurred in 64.8%, demonstrating comparable metrics to the high-end of historical data, and further reinforcing the potential value of using a large bore BGC during stroke intervention.

According to more recent randomized clinical trials using contemporary thrombectomy devices and techniques in which independent core lab adjudication was performed, there was no difference in clinical outcomes when first-line modalities (contact aspiration and stent retriever) were compared.^{16 29} The ASTER trial reported per-protocol successful recanalization rates of 91.5% and 84.9%.¹⁶ Similarly, rates of 92% for aspiration and 89% for stent-retriever of successful recanalization were reported in the Aspiration thrombectomy vs stent retriever thrombectomy as first-line approach for large vessel occlusion (COMPASS) trial, with first-pass TICI 2b or better being achieved in 57% and 51% of cases for aspiration and stent-retriever, respectively.²⁹ Our analysis also depicted no difference in procedure recanalization rates when we compared the first-line approaches, although we did observe longer procedure times in the stent-retriever subgroup ($p=0.001$).

The inclusion of patients who were older, not functionally independent at baseline, and posterior circulation stroke cases represents a real-world experience but ultimately limit our comparison to prospective trials, with regard to functional outcomes. Patients ≥ 80 years old represented 29.4% of the follow-up and demonstrated lower rates of favorable functional outcome when compared with younger patients (23.0% vs 61.2%, $p<0.001$) and higher rates of mortality (47.3% vs 15.7%, $p<0.001$). Nonetheless, several studies have previously suggested the association between BGC use and improved functional outcomes.^{6 23-26 30 31} According to a meta-analysis by Brinjikji *et al*, favorable functional outcomes (OR 1.84, 95%CI 1.52 to 2.22) and lower mortality (OR 0.52, 95%CI 0.37 to 0.73) were more likely to be seen with the use of BGC.⁵ The exact mechanism accounting for this shift most likely represents an amalgamation of different factors, including increased rates of successful recanalization and first-pass effect, reduced number of passes, shorter procedure times, and decreased risk of distal embolization.

The WICKED study represents the first large clinical series reporting the use of a large bore 0.087 inch ID BGC in treating patients with acute ischemic stroke due to ELVO. The device demonstrated excellent trackability performance and an acceptable safety profile. Additionally, it confirms that the Walrus BGC successfully gives physicians the ability to use large ID aspiration catheters

without having to give up using a BGC. Further studies are needed to evaluate the implication of different techniques and concurrent devices used in the procedure and patient outcomes.

LIMITATIONS

Our study has significant limitations. Namely, the study's retrospective nature and absence of independent adjudication, both of which limit the interpretation of these data. We emphasize the necessity of prospective studies with independent core laboratory adjudicators and standardization of inclusion criteria. Additionally, the different types of intermediate catheter and stent-retrievers and small variations of utilized thrombectomy technique may contribute to data heterogeneity. Although the true loss of follow-up occurred in less than 10% of the cases, an additional 58 cases had not reached the 3 months follow-up at the time of analysis, due to the catheter's recent FDA approval, further limiting clinical outcome interpretation.

CONCLUSION

The WICKED study demonstrates that among patients with acute ischemic stroke undergoing thrombectomy, use of the Walrus large-bore BGC demonstrated excellent navigability and low rates of device-related adverse events, and allowed the accommodation of several brands of large bore aspiration catheters.

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Contributors All authors have substantially contributed to the conception and design of the study and/or data acquisition. All authors made critical revisions to the manuscript. GMC drafted the original manuscript.

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Patient consent for publication Not required.

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