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Original research

Performance of the new generation BOBBY balloon guide catheter for endovascular treatment of acute ischemic stroke: results of the prospective, multicentric STRAIT study

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ABSTRACT

Background Balloon guide catheters (BGCs) are used during mechanical thrombectomy to arrest or reverse blood flow in order to improve revascularization results.

Objective STRAIT was an early post-market study of the new generation BOBBY BGC to evaluate performance and safety in the treatment of anterior circulation large vessel occlusion (LVO).

Methods This prospective, core lab-controlled multicenter study was conducted across nine sites in Germany and Switzerland. Key inclusion criteria were LVO at the distal internal carotid article through proximal M2, symptom onset to treatment initiation within 8 hours, National Institute of Health Stroke Scale (NIHSS) ≥5, and Alberta Stroke Program Early CT Score (ASPECTS) ≥6.

Results After having reached the primary endpoint in the planned interim analysis, enrollment was stopped early. Therefore, STRAIT enrolled 171 subjects from April 2022 to September 2023. Included patients were 49.7% female, median age was 73 years, and median NIHSS was 15. The primary endpoint of successful final reperfusion, as defined by Thrombolysis In Cerebral Infarction (TICI) 2b-3, was achieved in 94.7% of cases (n=161), and modified first pass effect (FPE) was 63.1%, with a median procedure time of 51 min. There were no device malfunction-related serious adverse events or adverse events. At final follow-up, 107/171 subjects (65.2%) had good neurological function (modified Rankin Scale ≤2) and an overall mortality of 8.5%.

Conclusion Mechanical thrombectomy using BOBBY BGC demonstrates high rates of FPE and overall success with a good safety profile, further supporting the additional benefit of the new generation BGCs in interventional stroke treatment.

Trial registration number NCT05361187.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The use of balloon guide catheters (BGCs) in mechanical thrombectomy (MT) is an accepted practice aiming to reduce embolization of clot fragments, to improve first pass effect and revascularization success, and to improve neurological outcomes in acute stroke treatment—notions recently challenged by the Protect-MT trial.

⇒ BOBBY BGC marks one of the new generation BGCs specifically designed to overcome former limitations of BGCs with now improved stability and trackability characteristics, as well as a sufficient inner lumen for large-bore distal aspiration catheters.

WHAT THIS STUDY ADDS

⇒ In the context of recent conflicting randomized data, the STRAIT results provide supportive real-world evidence for the use of a new-generation BGC during MT.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ Performance and safety profiles of the new-generation BOBBY BGC are upheld in the routine clinical setting and act as a counterbalance against the recently published negative results of older-generation BGC performance.

⇒ Results of this study may reassure clinicians to follow the still valid official recommendations in favor of the use of BGCs during MT.

INTRODUCTION

After several landmark randomized clinical trials have led the foundation for the adoption of mechanical thrombectomy (MT) as the standard of care for acute ischemic stroke,[1–4] focus has switched to the development or refinement of strategies for the improvement of technical success rates and the overall outcome for the treated patients. A number of in vitro and animal studies showed the potential benefit of creating flow arrest during clot retrieval, both in aspiration and stent retriever or combined approaches, especially by diminishing the distal embolization of micro- and macro-clot fragments.[5] Balloon guide catheters (BGCs) are ideally suited to providing this kind of stable flow arrest and, consequently, multiple clinical studies have demonstrated higher revascularization rates and better neurological outcomes from BGC-assisted MT.[6–17]

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BGCs have been found to not only reduce fragment migration and thromboembolization, but also decrease clot fragmentation during MT.[6–8 18] Further, based on their findings, Pedersen *et al* reported that one extra person per 12 treated would be expected to have good functional outcomes and one less person would die per 24 treated with BGC-assisted MT.[17]

Nevertheless, although experimental and clinical data seemed convincing, early generations of BGCs did not achieve a general adoption for routine clinical use because of several technical constraints, such as increased stiffness or floppiness, and a smaller inner diameter, restricting the use of large-bore aspiration catheters. Additionally, one of the two published randomized controlled trials (RCTs)[19] evaluating the benefit of BGC usage reported negative results with serious safety concerns forming a contrast to nearly all previously published data including the second RCT.[20]

Recently, a new generation of BGCs has become available, designed to overcome the former technical restrictions, claiming improved stability, navigability, and compatibility with large-bore aspiration catheters. However, only a few prospective studies of this emerging era of BGCs have been published to date, with promising results.[21–23]

The BOBBY Balloon Guide Catheter represents one of these new-generation BGCs. The purpose of the **S**afety and Performance of the BOBBY Balloon Guide Catheter for Endovascular **T**reatment of **A**cute **I**schemic **S**troke (STRAIT) study was to evaluate this device as an adjunct during MT for the endovascular treatment of anterior circulation acute ischemic stroke. In this article, the performance and safety outcomes of the STRAIT study are presented with the aim of adding new prospective data for these novel catheters.

METHODS

Study design and population

STRAIT was a prospective, single-arm, multicenter, observational clinical study conducted across nine sites in Germany and Switzerland. All procedures were in accordance with national and local ethical and institutional guidelines and routine clinical practice at each site. The planned enrollment was 270 subjects with large vessel occlusion (LVO) at the distal internal carotid artery (ICA) through proximal M2, confirmed by CT angiography, MR angiography, or digital subtraction angiography (DSA).

Main baseline criteria for inclusion included subjects age ≥18 and ≤85 years, eligibility for MT using the BOBBY BGC, symptom onset to groin puncture within 8 hours, National Institutes of Health Stroke Scale (NIHSS) ≥5, and core-infarct volume of Alberta Stroke Program Early CT Score (ASPECTS) ≥6. Excluded were cases of planned stenting for vessel stenosis, posterior circulation stroke, and acute intracranial bleed/mass effect. Treatment strategies and choice of MT devices to be used (other than the BOBBY BGC) were determined by the standards of care for each site and at the discretion of the interventionalist.

Study endpoints

The primary objective of this study was to evaluate effectiveness using the BOBBY BGC as an adjunctive device during MT for acute anterior ischemic stroke. Successful reperfusion, defined as modified Thrombolysis In Cerebral Infarction score (mTICI) ≥2b by core lab evaluation, was the measure for this outcome. Based on a review of the relevant literature, the study hypothesis was that this rate would be >77%.

Secondary prespecified objectives were to evaluate the grade and speed of successful BOBBY BGC placement in optimal position, safety of the procedure (device malfunctions and adverse events (AEs)), and procedural characteristics.

Study device

The BOBBY BGC (MicroVention, Aliso Viejo, CA) is an 8 French sheath-compliant guide catheter, with an 8.4 French outer diameter and 0.086 inch inner diameter, providing 95 cm working length; on maximum inflation, the balloon is 10 mm in diameter and length. The device design is based on a combination of the SOFIA aspiration catheter (Microvention) and the Scepter/Scepter Mini balloon microcatheters (Microvention).

Procedure

For all subjects, the treatment plan was MT with adjunctive use of the BOBBY BGCs. MT device selection and strategies were at the discretion of the interventionalists. Intravenous (IV) thrombolytic therapy was administered as appropriate, per the standard of care at a given site. DSA was the imaging standard for all procedures.

The BOBBY BGC was prepared ex vivo by purging the luminal air via injection of 50% iodinated contrast (Visipaque, iodixanol 320 mg/mL) through the balloon lumen while keeping the balloon tip of the catheter immersed in a saline bowl, with the balloon constrained using gentle manual pressure to prevent ex vivo balloon inflation (an analogous technique is described elsewhere for preparation of the Scepter and Scepter Mini balloon microcatheters (Microvention). Contrast injection was stopped when no more air bubbles could be purged from the balloon lumen and gentle pressure could be felt by the operator constraining the balloon. The estimated balloon preparation time is 20–45 s.

Data collection and analysis

For all subjects, informed consent was obtained according to the local or regional ethics committee approval obtained for each participating site in compliance with the regulations. The data were collected in accordance with the International Conference on Harmonization Guideline for Good Clinical Practice. Blinded review of all diagnostic imaging was performed by an independent core lab, and safety outcomes based on AEs that occurred were adjudicated by the Clinical Event Committee (CEC).

Statistics, as descriptive analyses, are presented only for subjects with complete data; missing data are not included in the denominator. Qualitative parameters are described by frequency distribution with ranges and bilateral 95% CI. For quantitative parameters, median and IQRs or averages with SD are presented. Data summaries for the full analysis set (FAS) and per protocol analysis set (PP) are provided in the tables. The FAS population is based on the intention-to-treat approach and includes all patients on whom the BOBBY BGC was used. The PP population includes all patients of the FAS population meeting inclusion and exclusion criteria, on whom the BOBBY was used according to the IFU (Instructions For Use) and with the modified Rankin Scale (mRS) at 90 days documented.

RESULTS

Study populations for analysis

Planned enrollment was 270 subjects and interim analysis of the primary endpoint was preset following the first 116 cases. However, on determination of a 94.87% successful reperfusion rate at interim, enrollment was stopped for early success.

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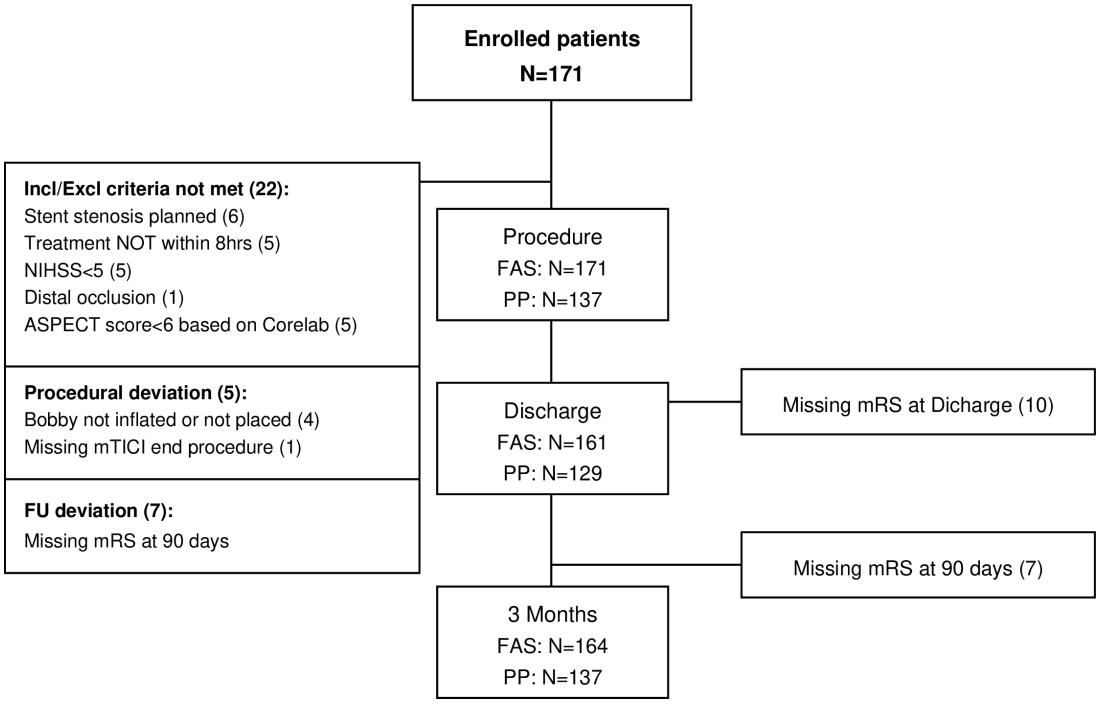


Figure 1 Flow diagram. ASPECT, Alberta Stroke Program Early CT; FAS, full analysis set; mRS, modified Rankin Scale; mTICI, modified Thrombolysis In Cerebral Infarction; NIHSS, National Instututes of Health Stroke Scale; PP, per protocol set.

The 171 subjects enrolled by that time were followed through the 90-day visit (median 93 days). All cases in which a BOBBY BGC was inserted into the groin defined the 171 subject FAS. In 34/171 cases (19.9%), deviations from the protocol occurred, yielding the PP analysis set of 137 subjects. Inclusion/exclusion criteria deviations were the most common (17/34), followed by no mRS at 90 days (7/34), ASPECT score exclusion on core lab evaluation (5/34), study device inserted but not inflated (4/34), and missing mTICI post-procedure (1/34) (see figure 1). While the FAS did not differ substantially in the main baseline and outcome parameters, the following results are based on the FAS. Complementary results for the PP analysis set are provided as online supplemental material.

Study population characteristics

Included patients were 49.7% female, median age 73 years, median NIHSS 15, median ASPECTS 9, and LVO locations were mainly in M1 (49.7%) or M2 segments (34.5%) per core lab (see table 1 for further details). Vascular tortuosity was evaluated by the core lab according to the grading system by Metz *et al*[24] and determined to be grade A for the majority of subjects (125/170=73.5%) and grade B (25/170=14.7%) or C (20/170=11.8%) for the remaining subjects. For the 170 subjects with occlusions, most presented with only one on admission (157/170=92.4%). Tandem lesions were detected in 11 subjects (6.4%): five stenoses and six occlusions.

For 86.6% of subjects (142/171), stroke onset was within 4.5 hours of admission. The majority of subjects received IV thrombolytics (110/171=64.3%) and all but three were treated within the recommended window. Nearly all subjects met the inclusion criterion for symptom onset to procedure in less than 8 hours (165/171=96.5%). Visit completion rate was 100% for the pre-procedural, procedural, and 24 hour post-procedural time points and 93.0% (159/171) at 90 days. Premature exit from the study occurred for 18 subjects: 14 died and four were lost to follow-up evaluation.

Primary endpoint and related reperfusion parameters

The primary endpoint of successful reperfusion was achieved in 161/170 cases (94.7%) per core lab reading, with nine unsuccessful cases and one image not evaluable. Rates of near complete reperfusion (mTICI ≥2c at procedure end) and modified first pass effect (FPE) (mTICI ≥2b after first pass) were 75.9% and 63.1%, respectively (n=129 and 106). For most subjects, treatment was initiated within 4.5 hours of symptom onset (79.5%) and median time was 2.8 hours. Median time points for key procedural milestones were 40 min from groin puncture to first

Table 1 Main baseline characteristics for the full analysis set; a comparison with the per protocol set is provided in the online supplements

Baseline characteristics	n=171
Age (mean)	73
Gender (male)	86 (50.3%)
Right-sided stroke	95 (55.6%)
IV thrombolytics	110 (64.3%)
NIHSS	15
ASPECTS	9
Occlusion location	
ICA	11 (6.4%)
ICA terminus	22 (12.8%)
M1	85 (49.7%)
M2	59 (34.5%)
A2	1 (0.6%)
Other*	7 (4.1%)

*Other includes A3, A4, P2, PCOM, CCA, M3, M3+
ASPECTS, Alberta Stroke Program Early CT Score; CCA, common carotid artery; ICA, internal carotid artery; IV, intravenous; NIHSS, National Institutes of Health, Stroke Scale; PCOM, posterior communicating artery.

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Table 2 Main and secondary clinical and safety endpoints

Imaging endpoints (core lab adjudicated)	n=171
Primary endpoint: successful reperfusion	161 (94.7%)
mTICI ≥2b	161 (94.7%)
mTICI 2b	32 (18.8%)
mTICI 2c	43 (25.3%)
mTICI 3	86 (50.6%)
Missing data	1
Near complete reperfusion	129 (75.9%)
Successful modified First Pass Effect(mFPE) ≥ 2b	106 (63.1%)
mTICI 2b	23 (13.7%)
mTICI 2c	30 (17.9%)
mTICI 3	53 (31.5%)
Missing data	3
Secondary endpoints: device	
Optimal placement of BOBBY BGC	96 (56.1%)
Missing data	12
Device malfunctions	12 (7.0%)
Perioperative device-related complications, AEs and SAEs	0 (0.0%)
24 hours postoperative device-related complications, AEs and SAEs	1 (0.6%)
90-day device-related complications, AEs and SAEs	5 (2.9%)
Secondary endpoints: clinical (CEC adjudicated)	
Functional outcomes at 90 days	
Good functional outcome at 90 days	107 (65.2%)
Excellent functional outcome at 90 days	88 (53.7%)
Missing data	7
NIHSS scores (median)	
Preoperative	15
24 hours postoperative	4
Discharge	2
90-day	0
mRS at 90 days	n=164
mRS ≤2	101 (61.6%)
mRS 6	14 (8.5%)

AEs, adverse events; BGC, balloon guide catheter; CEC, Clinical Event Committee; mFPE, modified First Pass Effect; mRS, modified Rankin Scale; mTICI, modified Thrombolysis In Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; SAEs, serious adverse events.

Table 3 Key procedural time characteristics (median, IQR)

Procedural milestone times	n=171
Onset to groin time (hours)	
<4.5	136 (79.5%)
4.5 to 8	29 (17.0%)
>8	6 (3.5%)
Procedure times (mins)	
Groin to BOBBY placement	6.00 (3.0 to 12.0)
Groin to BOBBY inflation	19.00 (13.0 to 28.0)
Groin to first recanalization	40.0 (28.0 to 60.0)
Procedure duration	51.0 (34.0 to 74.0)
Onset to first recanalization (hours)	3.53 (2.8 to 4.83)

Groin to first recanalization refers to the time between groin puncture and first successful recanalization mTICI ≥2b. Procedure duration refers to the time between groin puncture and the end of the procedure.
mTICI, modified Thrombolysis In Cerebral Infarction.

successful recanalization, 51 min for overall procedure duration, and 3.53 hours from symptom onset to successful reperfusion (see tables 2 and 3 for details).

Secondary performance endpoints

The median time from insertion to BGC catheter placement was 6 min. The median time was similar for the subjects with successful reperfusion after the first pass. In 98.8% of cases (169/171), the BOBBY BGC could be successfully placed in the target vessel common carotid artery to ICA. An optimal placement at the skull base level or above was possible in 56.1% of cases (96/171). Reasons for placements below that level were vessel tortuosity (44.0%=33/75) and other reasons such as vessel diameter, vasospasm, and tandem occlusion (14.7%=11/75).

Three different treatment strategies were applied by the investigators, defined as: 'stent retriever alone (SA)', 'direct aspiration (DA)', or 'combined approach', representing the combination of stent retriever and distal aspiration. For 70.2% of subjects (n=120), only one single strategy was used throughout the whole intervention. Distributions of strategies for these 120 patients were for combined approach 72.0% (n=85), DA only 15.3% (n=18), and SA only 1.7% (n=15). The remaining subjects required second line treatment in 23.4% (n=40), third line treatment in 4.7% (n=8), or fourth line treatment approach in 1.8% (n=3). A presentation of the first treatment approach used in the full population, including the cases requiring a rescue treatment, is provided in the online supplements, as well as details on the devices used.

Safety endpoints

An overview of the overall safety analysis with all reported serious adverse events (SAEs) or AEs is provided in the online supplements. Seventy-eight subjects (45.6%) experienced at least one AE or SAE. Most subjects had no sequelae following the events (68=63.6%) but 17 (15.9%) had events ongoing, seven (6.5%) had sequelae, and 14 (13.8%) died.

There were 12 study device malfunctions (12/171 subjects=7%) but none resulted in an AE or SAE or complication. Malfunction cases, as adjudicated by the CEC, occurred as follows: inflation difficulty/failure=6, difficulty in device delivery due to vessel anatomy=3, device damage before use=2, and failure to insert DAC into device.

Possible or probable device-related events (two AEs and three SAEs) occurred for five subjects (2.9%), as adjudicated by the CEC, but none resulted from device malfunction. These events were two vasospasms, one thromboembolic event, and one internal carotid dissection during the procedure, all without sequelae, and one ischemic stroke at 24 hours with patient death 6 days post-procedure.

No symptomatic intracranial hemorrhage (sICH), defined as parenchymal hematoma type 2 (PH2) (Corelab) associated with a worsening NIHSS of 4 points or more compared with baseline NIHSS, was reported by investigators.

Verified by core lab assessment, embolization in new territory (ENT) was observed in eight cases (4.7%) during the procedure.

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Clinical endpoints

At 90 days post-procedure, 107 subjects (65.2%) achieved a good neurological function (mRS ≤2 or equal to the pre-stroke mRS). Good functional outcome, defined as only mRS ≤2 at 90 days, was 61.6% (101/164). In addition, 88 subjects (53.7%) exhibited an excellent neurological function outcome (mRS ≤1 or equal to the pre-stroke mRS). Overall mortality was 8.5% (14/164).

No death was related to the study device. The CEC adjudicated relationships were to study disease (n=7), concomitant disease (n=3), concomitant treatment (n=2), and general condition or unknown (n=2).

DISCUSSION

The presented STRAIT study is the first prospective observational evaluation of one of the new-generation BGCs, demonstrating a high successful revascularization and favorable clinical outcome rate. The main results nearly perfectly confirm the few previously published results from retrospective evaluations of these kinds of devices—for example, nearly identical rates of successful recanalizations and FPEs could be shown as have been reported in the Wicked study[21] or in a BOBBY matched-pair analysis,[22] although the STRAIT data are prospective and core-lab controlled. Prior studies of the BOBBY BGC have shown this device to be a safe and effective option for adjunctive use during MT for ischemic stroke.[7 23] In a prospective multicenter setting, STRAIT further supports these favorable profiles.

Characteristics of the STRAIT population were in keeping with recently published registry studies[12 25] and meta-analyses[17] in terms of key inclusion and exclusion criteria, baseline mRS, stroke onset to treatment time, and NIHSS. Similarly, our population was consistent with the published MT experience using the new generation of BGCs stroke.[22 23 26]

In designing the STRAIT study, the overall success rate for reperfusion was projected to be 77%. This rate was based on recent literature rates minus a conservative 10% core lab reduction from registries (85–91%) studies,[12 25] meta-analyses (78.9–87.6%),[13 17] and a survey of BGC studies (74.4–98.0%) in stroke.[11 22 23 27 28] Our results exceeded these expectations, demonstrating successful reperfusion in 94.6% of cases (final mTICI ≥2b).

There is an ongoing debate about the pros and cons of using BGCs in general, especially as in cases with small diameter, vasospasm, or tandem occlusions, large guiding systems including BGCs often are occlusive anyway, questioning the need for inflating a balloon in these cases. In this context, one recently published paper analyzing the MR Clean data could not find a benefit of BGC use in tandem occlusions,[29] although another comparative study reported better clinical and angiographical outcomes with BGC use.[30] We added a supplemental separate analysis of our 11 included (only in the FAS set) tandem occlusion cases and could not find any relevant outcome differences except longer overall procedure times due to the additional stenting. Additionally, there are concerns about provoking new ischemic areas by blocking the collateral flow, although the majority of the existing literature tends to report a reduced risk of ischemic events.

Previous generations of BGCs had, as already mentioned, several technical constraints including hindered trackability and stability besides their low inner lumen profile, potentially complicating and prolonging the procedures. In the STRAIT study, the majority of procedures were completed in less than 1 hour, and the median puncture to reperfusion time was 40 min, which is moderately longer than reported in the Wicked study[21] with 30.8 min, but with a much higher proportion of pure aspiration approaches (40.8% vs 15.3%). In Protect-MT,[19] the comparable time was reported as 53 min in the BGC group versus 44 min in the conventional guider group. Our median (51 min) and mean (61.59 min) overall procedure times were less than reported in meta-analyses (70.5–88.5 min),[13 17] and other relevant studies (46.7–54.3 min).[22 27] So overall, the time metrics can be considered as largely in line with pre-existing data, further supporting the notion that the new-generation BGCs have likely overcome technical difficulties of previous generations. Additionally, the substantial proportion of optimal BGC tip positioning at the skull base—probably a near-essential requirement for genuine flow reversal rather than simple flow arrest—further underscores the improved mechanical performance with its clinical implications.

It is still a matter of debate whether the use of BGCs is better suited with, for example, stent retriever-only approaches. Selection of first line strategy using a combined approach with DA plus stent retriever has shown improved results over a single device in some meta-analyses,[17] but others have not demonstrated this difference.[31 32] While a combined approach was the most common strategy for STRAIT, outcomes for either or both devices were similar (94.3–95.5%). However, STRAIT was neither designed nor powered to compare these approaches.

Recently, the Protect-MT study[19] raised serious safety concerns for the use of BGCs with high rates of symptomatic hemorrhages (sICH 15%) and overall mortality (24%), although the proFate study[20] showed opposite results. Differences in device generation, operator experience, and procedural protocols may partly explain the divergent findings observed in these recent randomized trials. In the STRAIT study, key safety variables like sICH (0%) and overall mortality (8.5%) were low, providing additional supportive data for a BGC in routine clinical use, and again building another counterbalance against the raised concerns. The direct safety of the specific BOBBY BGC assisted MT was further demonstrated by the absence of device or procedural death and by a low rate of device-related AEs (2.9%), all without clinical sequela. Kim *et al*,[22] in their recent retrospective match-pair analysis of 110 subjects, compared MT with and without the use of BGC and found comparable rates of complications (1.8%). Overall, the safety results are consistent with the recently updated meta-analysis by Pedersen *et al*[17] and the STRAIT study rates for overall mortality, ENT, and complications during and post-procedure are in keeping with the published literature.[12 13 17 22 23 25 28]

Outcome rates for good function (61.6%) and good neurological function matched or exceeded the good outcome rates found in other BGC studies (good outcome 40.7–52.0%),[22 28] meta-analyses, and registries (good outcome 55.7–61.0%),[12 13 17] supporting previous findings that BGC use during MT may contribute to improved outcomes after MT. Taken together, these findings should be interpreted as hypothesis-generating and complementary to randomized data.

Limitations

Observational studies in routine clinical settings share many of the same limitations. While the study design was prospective, STRAIT did not include a control group or treatment randomization. The timing of the consent process was post-procedural, yielding non-consecutive case enrollment, and may contribute to selection bias. The standard of care at each site governed the use of devices beyond the BOBBY BGC, introducing variability across sites. Early termination of the study—despite being for early success—reduced the size of the analysis population. This

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may have influenced the detection of outliers across all endpoints. Additionally, the number of protocol deviations was notable and may reduce the generalizability of the cohort analyses.

CONCLUSION

The STRAIT study provides, for the first time, prospective data in the evaluation of one of the new-generation BGCs, which might have overcome previous limitations of BGCs. The reported rates of technical success, good functional outcomes, low rates of device-related and overall safety events, and procedure times further strengthen previous positive evidence for the use of BGCs, especially for the new generation devices. Nevertheless, while these findings add supportive evidence for the use of new-generation BGCs, further well-designed RCTs would be desirable to clarify their role and potential benefit in MT more definitively.

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Contributors TBB is PI of the study and guarantees the content of the manuscript. The manuscript was written and approved by TBB and MBM. All other authors were investigators of the study and approved the final version of the manuscript.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants. All procedures were in accordance with national and local ethical and institutional guidelines and routine clinical practice at each site. The leading Ethics Committee of the TUM Klinikum Rechts der Isar of the Technical University of Munich approved the study (ID: 455/21-S), and the patients or their representatives provided written informed consent in accordance with local regulations. Participants gave informed consent to participate in the study before taking part.

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