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The new generation BOBBY Balloon Guide Catheter for mechanical thrombectomies: Final results of the international prospective STRAIT study

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IINTRODUCTION

The use of a Balloon Guide catheter (BGC) in mechanical thrombectomy (MT) procedures is associated with better technical and clinical results, e.g., by reducing embolization to new territories (ENTs) and higher success rates.[1-3]

BOBBY™ BGC is a new generation of balloon guide catheters specifically designed by Microvention to address known challenges of these devices like limited inner lumen and unbalanced mechanical properties. Single centers experience published are positive. [5,6]

The 1st experience with this device has been evaluated in the present STRAIT trial, following GCP standard, and final results at 3 months are presented.

OBJECTIVES

This GCP standard study aim to assess safety, efficacy, and performance of the Bobby BGC when used in routine practice according to its indication with stent retriever and/or aspiration catheter.

MATERIALS & METHODS

STRAIT is a prospective, multicenter, single-arm European trial conducted in 9 high volume centers in Germany and Switzerland. The study received regulatory authorization according to each country's requirements.

Prospective data from patients enrolled were analyzed after being 100% monitored by independent CRO.

Key inclusion criteria included acute ischemic stroke (AIS) within the anterior cerebral circulation, occlusions ranging from M1 to proximal M2, treatment initiated within 8 hrs of symptom onset, NIH Stroke Scale (NIHSS) ≥ 5, Alberta Stroke Program Early CT Score (ASPECT) ≥ 6, and treatment within routine hospital protocols.

Angiographic and clinical characteristics, technical proficiency, and 90-day outcomes were evaluated and analyzed, supported by an independent core lab and the clinical event committee.

A full analysis set was performed, as well as a per-protocol (PP) analysis.

BASELINE CHARACTERISTICS

From April 2022 to September 2023, **171 patients** were enrolled.

Population

- Gender: 49.7% female
- Age: 71.6 ±10.6 (range 36-85)
- Main Medical history: 67% HTA, 36% A Fib, 33% Dyslipidemia, 20% Obesity, 19% Coronary disease, 18% Previous stroke, 18% Smoker
- mRS pre stroke:

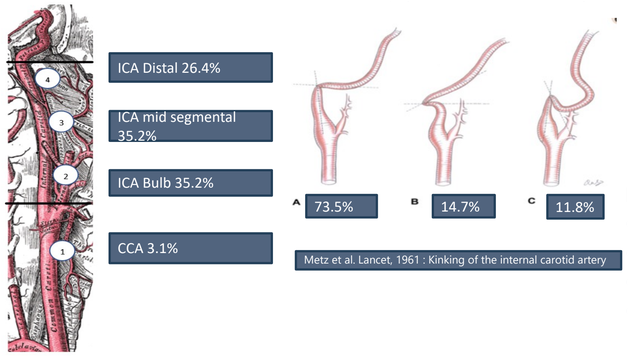
Stroke

- Mean NIHSS: 14.4 ± 5.1
- Mean ASPECT Score (Corelab assessed): 8.6 ± 1.5
- Main occlusion sites prior MT:
  50% M1 35% M2 13% ICA Terminus 6% ICA
- IVtPA administered: 64.3%
- Stroke onset to hospital admission: Mean: 2hrs21mn
  87%: <4.5hrs 10.4%: 4.5hrs-8hrs 3% ≥8hrs
- Stroke onset to start procedure: Mean: 3hrs29mn

RESULTS

Performance

- BOBBY placement and vessel tortuosity (Corelab assessed)



- Successful placement at skull base: 56%
- In 3 cases (2%) BOBBY could not be delivered or inflated

RESULTS

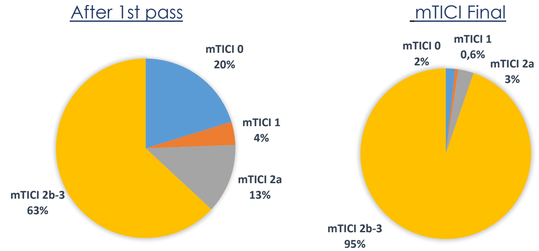
Procedural times

- Successful deployment of BOBBY

Mean time between BGC insertion and final positioning: 8.8mn
Mean time between BGC insertion and inflation: 21.9mn

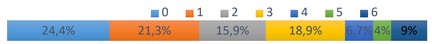
- Mean time from puncture to mTICI≥2b: 48.7mn

mTICI assessed by Corelab



Successful recanalization (mTICI 2b-3): 95%
Near complete reperfusion (mTICI 2c-3): 75.9%
Modified first pass effect (mFPE): 63%

mRS at 90 days



- Excellent functional outcome (mRS 0-1 or equal to pre-stroke): 53.7%
- Good functional outcome (mRS 0-2 or equal to pre-stroke): 65.2%

Imaging at 24hrs assessed by Corelab

- Type of exam: 81.3% CT & 18.7% MRI
- Embolization in new territory (ENT): 6.0%
- sICH: 0%
- Any hemorrhage: 32%

CONCLUSIONS

The STRAIT study results of the performance of the BOBBY™ BGC when used in routine practice show very high efficacy rates, good neurological and functional outcomes, low safety risks and favorable procedure times.

These results suggest that the device is a viable option for clinicians seeking to optimize success rates and patient outcomes in recanalization procedures.

The observed performance characteristics also support BCG's use in general to enhance the efficiency and safety of recanalization procedures, potentially benefiting comprehensive patients needing such interventions.

These results add independent assessed evidence to previous publication on BOBBY™ BGC and BGC.

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