MECHANICAL THROMBECTOMY WITH NIMBUS FOR CHALLENGING OCCLUSIONS: FINAL RESULTS OF THE SPERO STUDY

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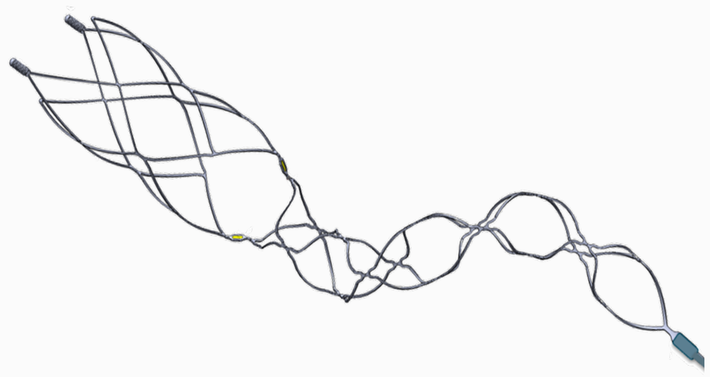
BACKGROUND



The NIMBUS device was developed for challenging occlusions, specifically those due to tough clots which can yield suboptimal mechanical thrombectomy outcomes. The study aimed to evaluate NIMBUS in patients where the first one or two passes with another MT device did not achieve substantial reperfusion ≥ mTICI 2b.

METHODS

SPERO is a prospective, multicenter, single arm, post-market observational study. From October 2019-February 2022, the SPERO Study (NCT03898960, Cerenovus) enrolled 54 subjects at 11 European centres. NIMBUS was used following one or two failed attempts with standard MT devices. Imaging and procedure angiography were assessed by an independent core lab, 90-mRS assessments were by an independent evaluator and clot analysis was conducted by a central clot lab.

RESULTS

Demographics and Baseline Characteristics

Age	71.9±14.09
Sex, F	50% (27/54)
Pre-stroke mRS 0-2	98.1% (53/54)
Baseline NIHSS	13.9±6.89
Baseline ASPECT#	
0-5	17.3% (9/52)
6-7	40.4% (21/52)
8-10	42.3% (22/52)
Use of IV-tPA	24.1% (13/54)
Witnessed stroke	50.0% (27/54)
Wake-up stroke	29.6% (16/54)
Unwitnessed non-wakeup stroke	20.4% (11/54)
Occlusion Location#	
Anterior	100% (54/54)
ICA & Carotid T	13.0% (7/54)
MCA, M1	63.0% (34/54)
MCA, M2	24.1% (13/54)

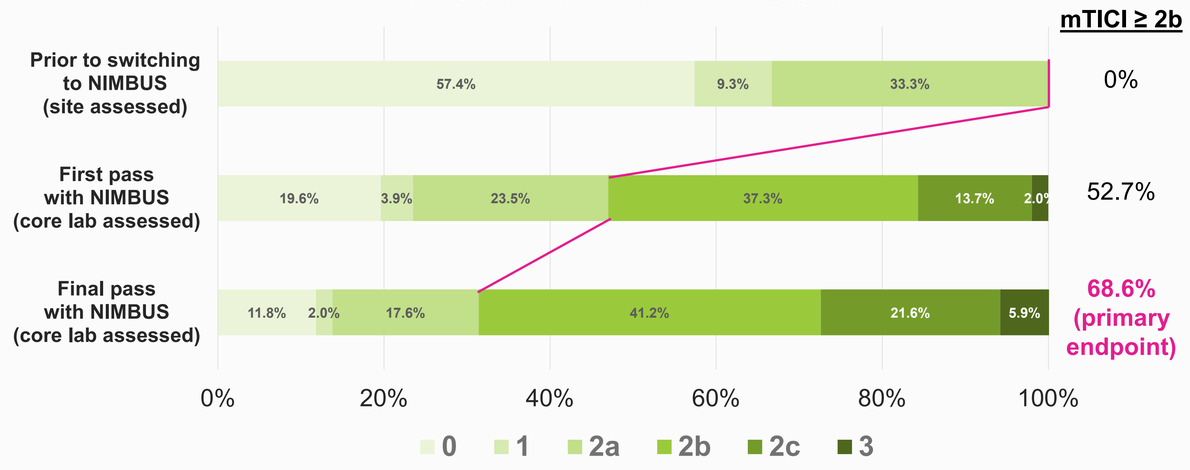
#core lab assessed

Procedural and Angiographic Outcomes

Total number of passes	4.6±1.72
Number of NIMBUS passes	2.2±1.13
Switched to NIMBUS at pass 2	24.1% (13/54)
Switched to NIMBUS at pass 3	75.9% (41/54)
Successful revascularization (mTICI≥2b) with NIMBUS#	68.6% (35/51)
Final mTICI ≥2b#	79.2% (42/53)
Final mTICI ≥2c#	37.7% (20/53)

#core lab assessed

mTICI scores with NIMBUS



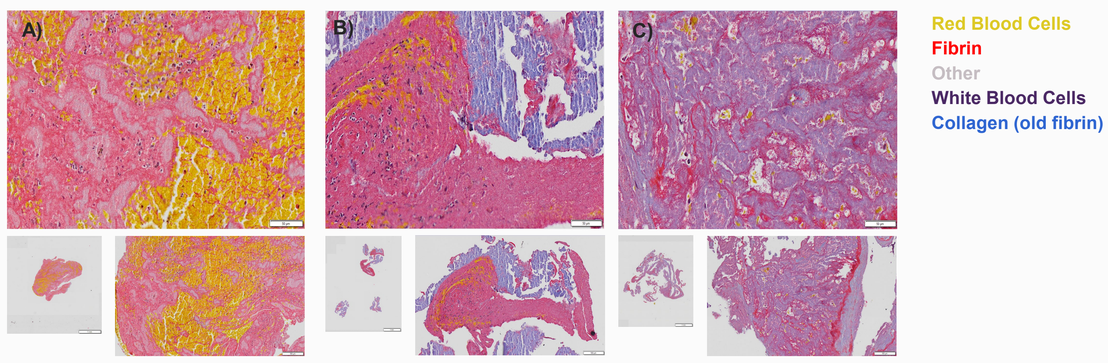
Clinical and Safety Outcomes

mRS 0-2 at 90 days*	38.9% (21/54)
All-cause mortality at 90 days	18.5% (10/54)
Embolization to new territory#	0.0% (0/54)
sICH at 24-h	3.7% (2/54)
Device-related adverse events	1.9% (1/54)
Procedure-related adverse events	11.1% (6/54)

*independent assessment; #core lab assessed

Clot Retrieval

The rate of clot retrieval in first NIMBUS pass was 51.9% vs 27.8% in first procedural pass with standard MT device



Illustrative Martius Scarlet Blue Staining of clots retrieved by NIMBUS.[1] A) Median RBC Composition, B) Median Fibrin Composition, C) Lowest RBC Composition

CONCLUSION

In a real-world setting, NIMBUS achieved substantial reperfusion in nearly 70% of cases where the first one or two passes with another MT therapy were not successful. NIMBUS dislodged and retrieved nearly twice as many clots on its first attempt vs. the first pass of standard MT devices.

[1]van den Berg, R. et al., NIMBUS Geometric Clot Extractor for Tough Clots: Clot Composition in the SPERO Study. Oral presentation at ESMINT; 2022, Nice, France

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