ESOC 2026

12th European Stroke Organisation Conference

Final Results of the DISTALS Randomized Trial of TIGERTRIEVER 13 - EVT for DMVO

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Objective and design

Distal Ischemic Stroke Treatment with Adjustable Low-profile Stentriever

- To evaluate the safety and effectiveness of the Tigertriever 13 Revascularization Device in restoring blood flow in the neurovasculature in patients presenting within 24 hours of onset with an ischemic stroke with disabling neurological deficits due to a primary distal vessel occlusion (DMVO).
- US and EU, multi-center, prospective, randomized, blinded (endpoint), controlled, IDE study
  - Randomization 1:1
    - Treatment: Medical Management + Tigertriever 13
    - Control: Medical Management
- Sample size - 118 randomized patients in up to 25 total centers

Inclusion criteria

DISTALS

1. Age 18-85 years old
2. Pre-stroke mRS ≤2
3. Disabling presenting deficits that localize to the territory of the distal vessel occlusion
4. **NIHSS 4-24, or NIHSS 2-24** for patients with aphasia and/or hemianopia
5. Perfusion lesion (Tmax >4.0 seconds) volume ≥10 cc on CTP or MR PWI within **non-/co-dominant M2 MCA, M3 MCA, ACA, or PCA**
6. Occluded distal vessel diameter ≥1.5 mm as measured on CTA or MRA
7. **Ischemic core** (rCBF<30% CTP or ADC <620 DWI) **≤50% of perfusion lesion volume**
8. Study treatment can be initiated **within 24 hours of last known well**
9. Signed informed consent by patient or legally authorized representative
10. **Subject is not eligible for intravenous thrombolysis**

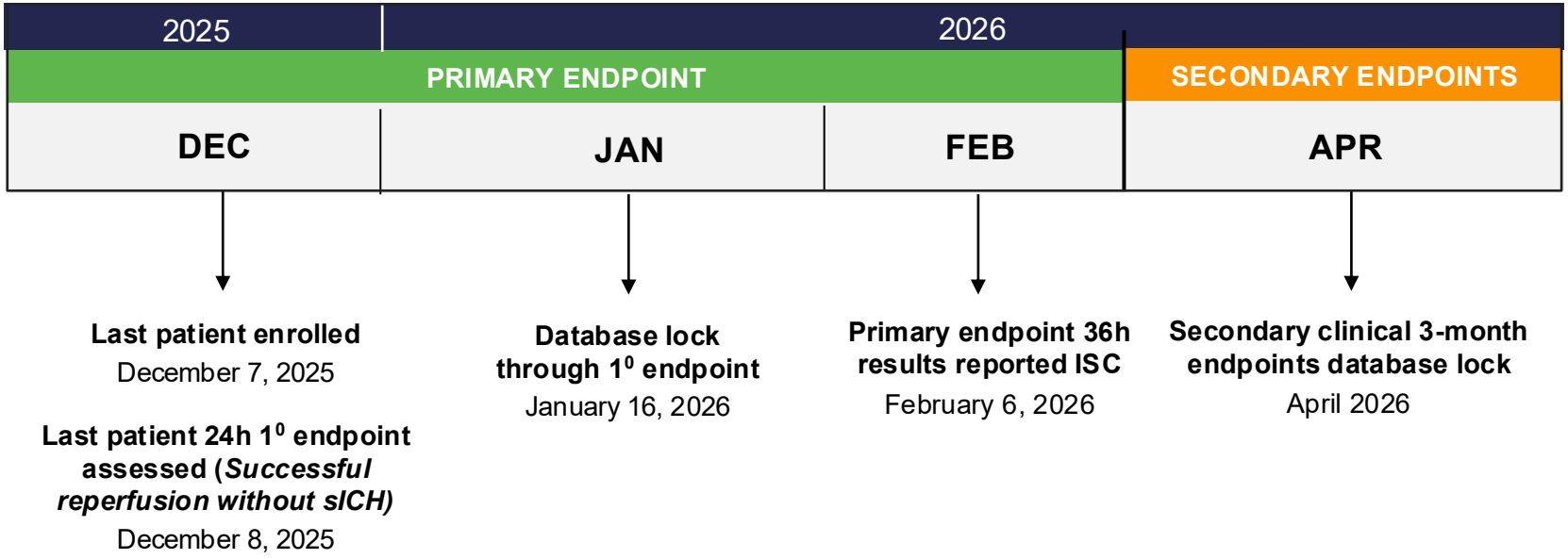
Major exclusion criteria

1. Acute brain hemorrhage on CT and/or MRI at admission.
2. Excessive tortuosity or stenosis that prevents placement of the microcatheter in the target vessel (on CTA or MRA prior to randomization).
3. Tandem occlusion in the cervical/intracranial ICA, M1 MCA, dominant M2 MCA, VA, BA on CTA or MRA.
4. Stroke in the last 3 months.
5. **Warfarin treatment with INR >1.7**
6. **Direct oral anticoagulant (DOAC) treatment within 48 hours**
7. Treatment with heparin within 48 hours with a PTT >2X normal.

Trial endpoints

ENDPOINT	MEASURE
Primary Effectiveness and Safety Composite	**Successful reperfusion* (CTP or MR PWI) without sICH**** *Successful reperfusion defined as >50% reduction in substantial hypoperfusion (Tmax >4 seconds) volume between baseline and 24 ±6 hours of randomization. **sICH defined as local or remote PH2 as detected on 24±6 hours post-procedure CT combined with a neurologic deterioration of ≥4 points NIHSS deterioration at 24 hours (±6 hours) of randomization or hemorrhage leading to death within 24 hours (SITS-MOST).
Secondary Effectiveness	• Successful reperfusion (eTICI ≥2b50) (treatment arm only) • Disability level @ 90 days (mRS shift-tetrachotomized: 0, 1, 2, 3-6) • NIHSS change from baseline to day 4/discharge • Health-related quality of life (EQ-5D) at 90 days • Cognitive function at 90 days (Montreal Cognitive Assessment, MoCA)
Secondary Safety	• All cause mortality @ 90 days • Any asymptomatic intracranial hemorrhage within 24 hours • Device/procedure related serious adverse events (SAEs) • Unanticipated adverse device effect (UADEs)

Trial status



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RESULTS

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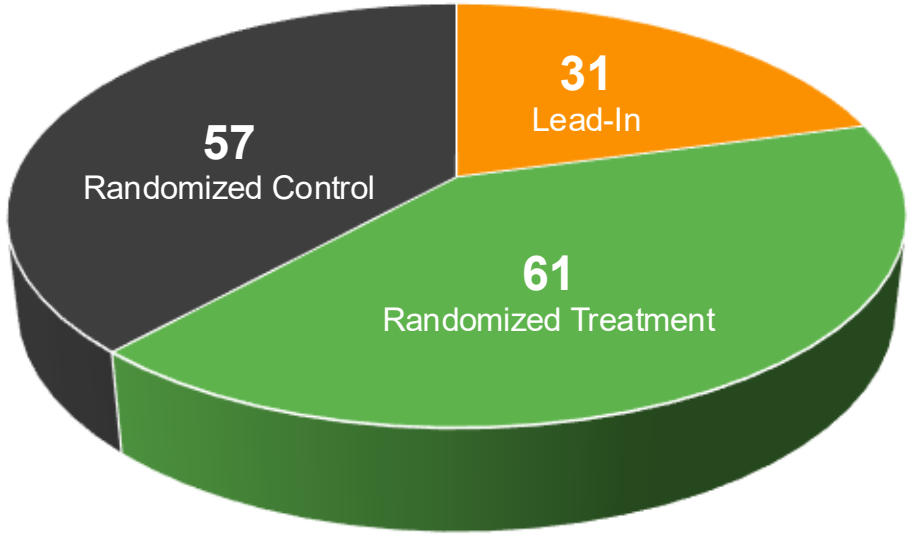
Enrollment flow

- **Screened** ~ 2400
- **Enrolled** 149
- **Lead in** 31
- **Randomized** 118
- **Treatment Arm** 61
- **Control Arm** 57
- **First patient enrolled** May 2022
- **Last patient enrolled** December 2025
- **Last 90 d FU** March 2026

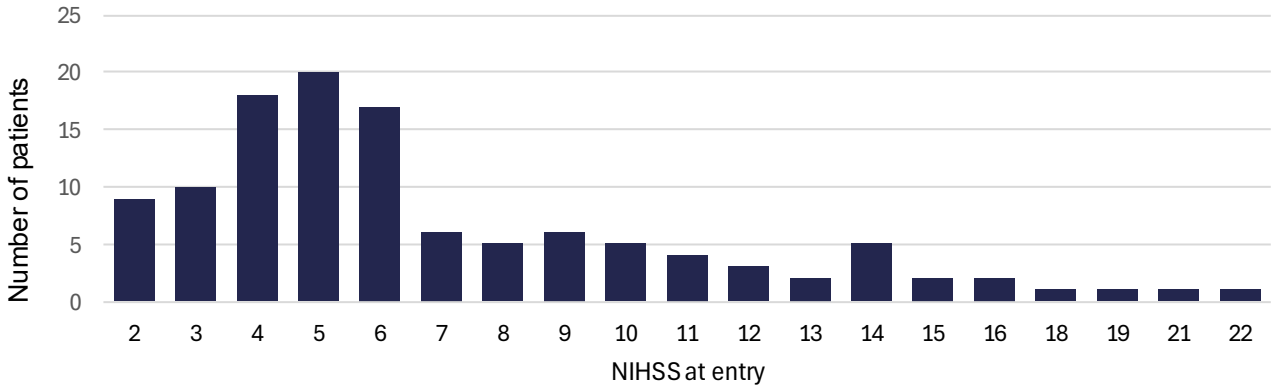


Trial demographics

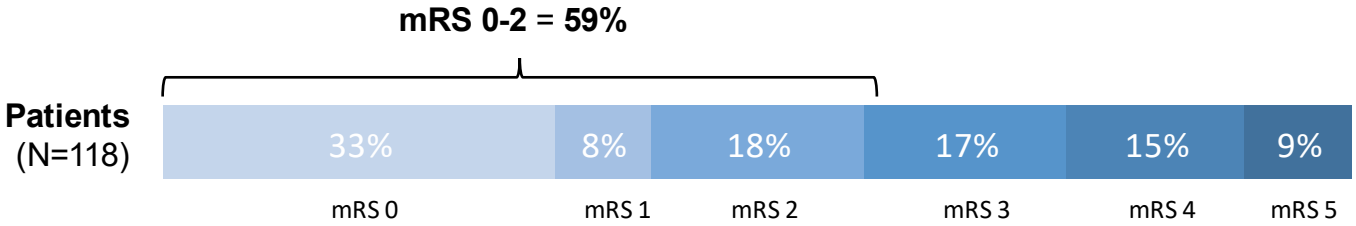
Demographics	Randomized: Treatment (n=61)	Randomized: Control (n=57)
Age, mean (SD)	70 (10.6)	68 (11.9)
Sex, male %	59%	63%
NIHSS		
Median (IQR)	6 (4-10)	6 (4-9)
Mean (SD)	7.1 (4.6)	6.8 (4)
Pre-stroke mRS, %		
0	77%	82.5%
1	8.2%	7%
2	13.1%	10.5%
3	1.6%	N/A

Severity at Time of Enrollment

NIHSS at entry



mRS at entry



Target occlusion

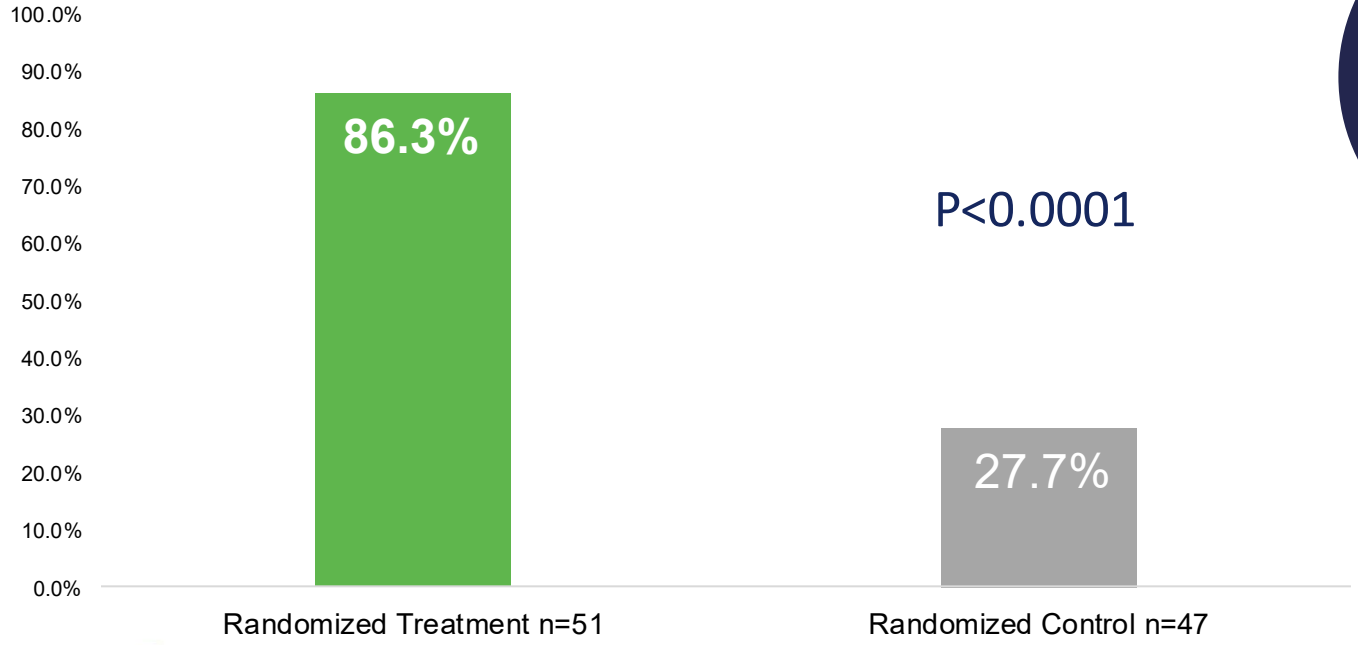
Target Vessel	Randomized: **Treatment (n=61)**	Randomized: **Control (n=57)**	Pvalue
M2 MCA	**37.7% (23)**	**43.9% (25)**	**0.73**
Co-dominant M2	21.3% (13)	19.3% (11)	1
Non-dominant M2	16.4% (10)	24.6% (14)	0.5
M3 MCA	**23.0% (14)**	**24.6% (14)**	**1**
ACA	**8.2% (5)**	**8.8% (5)**	**1**
A1	1.6% (1)	(0)	1
A2	4.9% (3)	7.0% (4)	0.7
A3	1.6% (1)	1.8% (1)	1
PCA	**31.2% (19)**	**22.8% (13)**	**0.54**
P1	11.5% (7)	10.5% (6)	1
P2	16.4% (10)	10.5% (6)	0.43
P3	3.3% (2)	1.8% (1)	1

Workflow and procedural data

	Randomized: **Treatment (n=61)**	Randomized: **Control (n=57)**
LKW to Randomization (min)		
Median (IQR)	548 (270-815)	420 (208-904)
Mean (SD)	591 (362)	549 (392)
Vessel Diameter (mm)		
Mean (SD)	1.8 (0.3)	1.8 (0.3)
Range	1.5-3	1.5-3.1
Anesthesia Type, % N=60		
General Anesthesia	71.7%	n/a
Local	13.3%	n/a
Sedation/Monitored Anesthesia Care(MAC)	15%	n/a

Positive primary endpoint

Efficacy and Safety Composite – Successful reperfusion at 24 hours without sICH

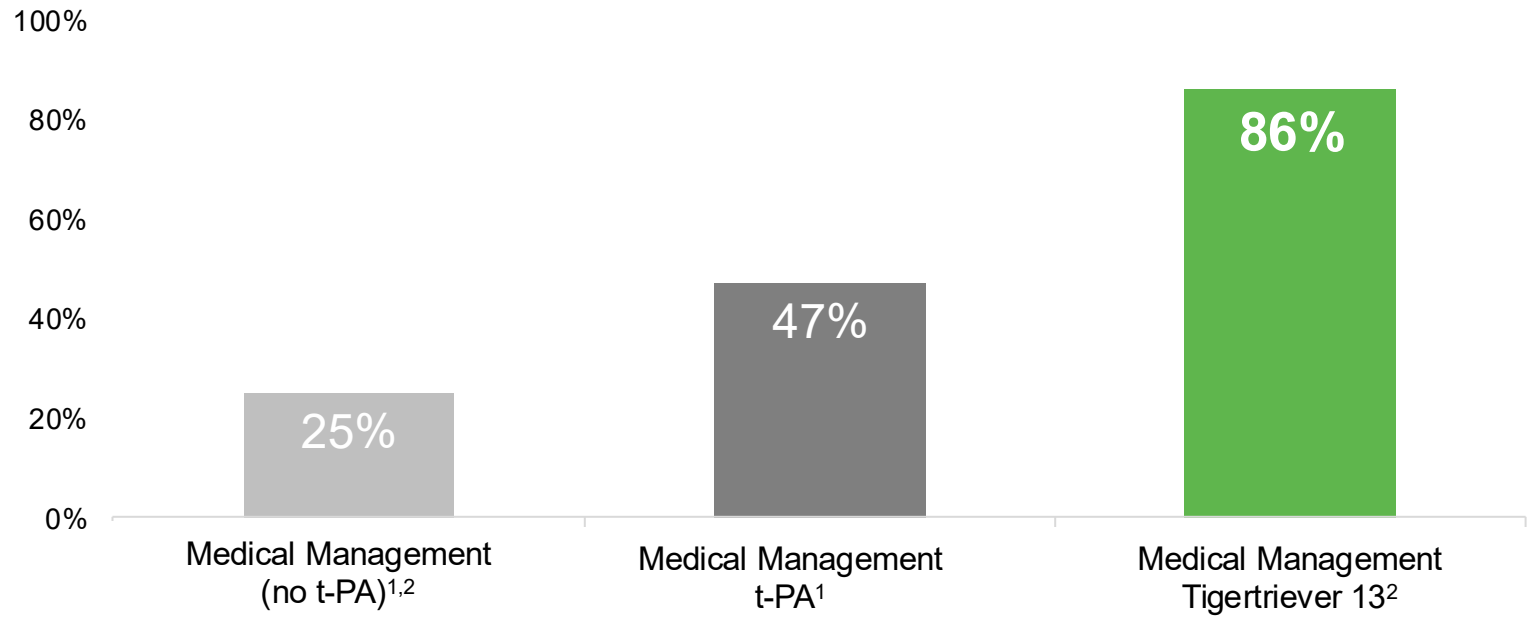


0 sICH with Tigertriever 13

Data is not evaluable for 20 patients (10 Treatment; 10 Control), perfusion either not done or imaging with poor quality; results robust with multiple imputation and worst-case sensitivity analyses.

Reperfusion success

BMT vs. Tigertriever 13



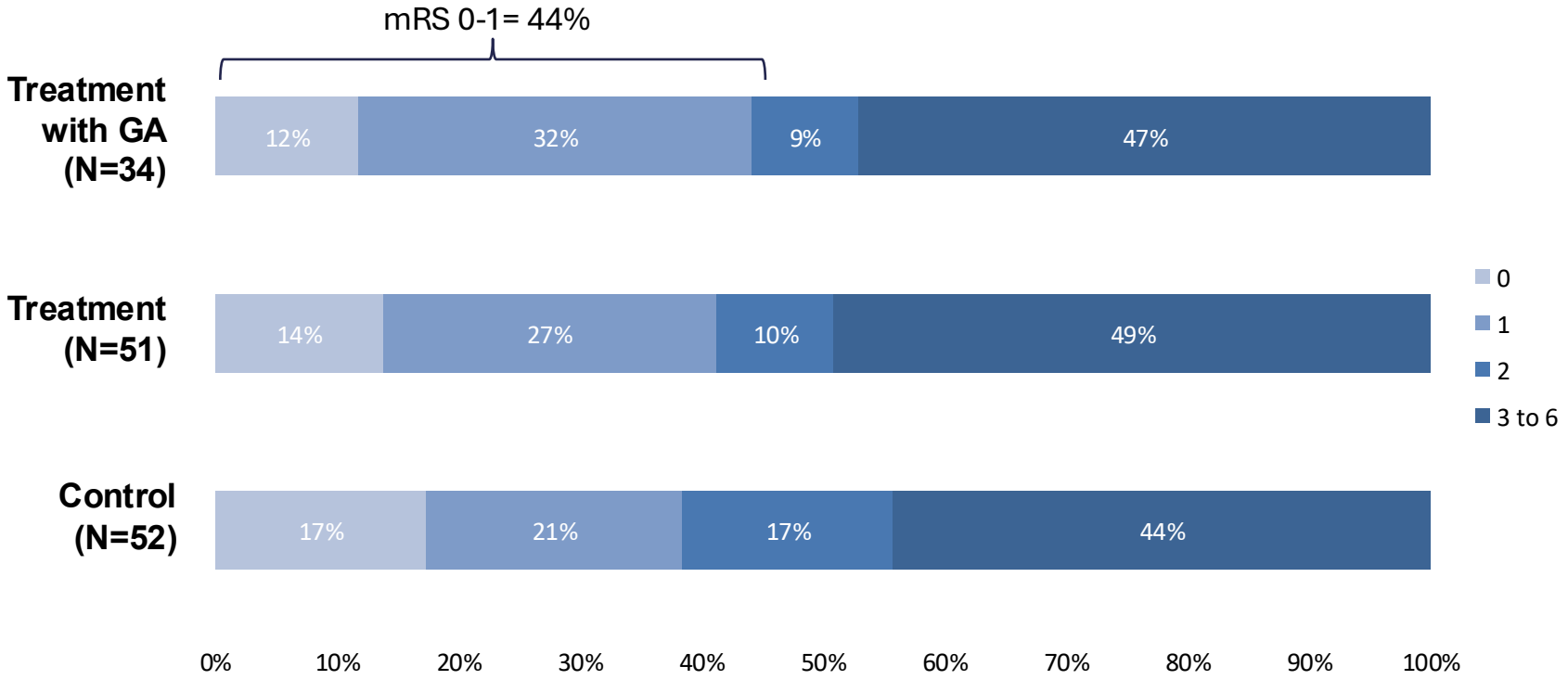
[1] Ospel et, al, STROKE 2020
[2] DISTALS

Safety outcomes: Early and Late

	Control (N=57)	Treated w T13 (N=54[1])	P Value
Early Mortality at 24h	0 (0%)	0 (0%)	1.00
sICH	0 (0%)	0 (0%)	1.00
Asymptomatic ICH within 24h	3.5% (2/57)	20% (11/54)	0.01
Mortality at 90 d	7.0% (4/57)	7.4% (4/54)	0.91

[1] Treatment arm: 7 were not treated with T13 (No occlusion(2), anatomy (3) , commercial device (1), extravasation after Microwire/MC (1)

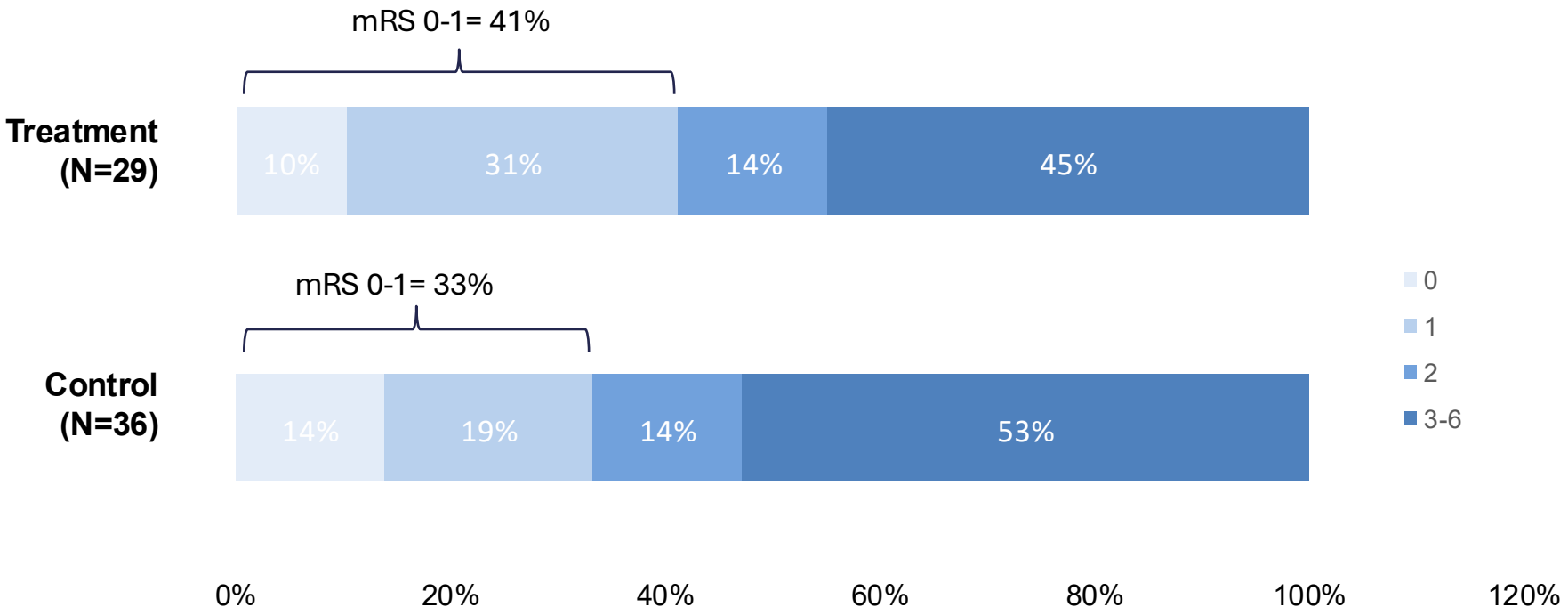
Level of Disability (4-Level mRS) at 90 days



*Not powered for clinical endpoints

90d mRS

Patients Admitted with **moderate** to **severe disability**, mRS 2-5



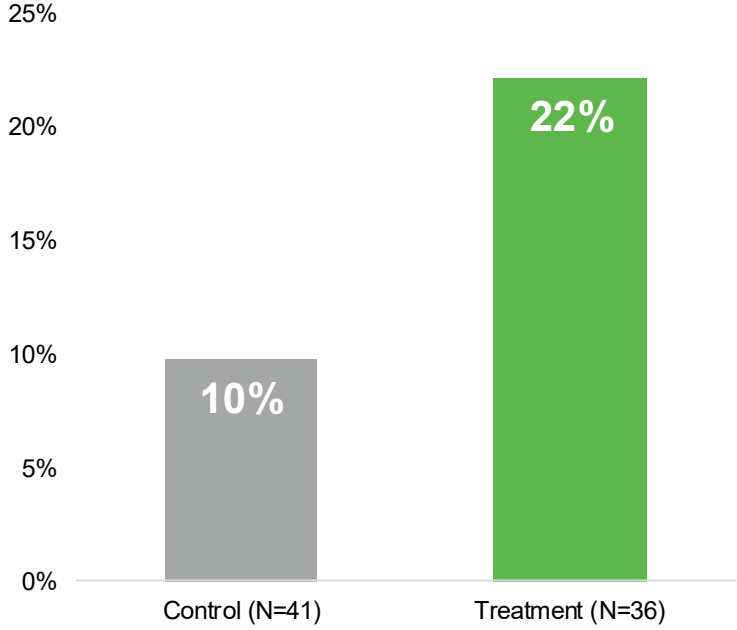
*Not powered for clinical endpoints

Health-related QoL at 90 Days

Median quality-of-life scores (IQR)

	Control	Treatment
Mobility	1.0 (1.0,2.0)	1.5 (1.0,3.0)
Self-care	1.0 (1.0,2.0)	1.0 (1.0,3.0)
Everyday activities	2.0 (1.0,3.0)	1.5 (1.0,2.3)
Pain or physical discomfort	2.0 (1.0,3.0)	2.0 (1.0,2.0)
Fear or depression	1.0 (1.0,2.0)	1.0 (1.0,2.0)

EQ-5D: No deficiency (perfect health)



*Not powered for clinical endpoints

THANK YOU DISTALS INVESTIGATORS

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Thank you

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