

# THERAPY TRIAL: STAIR 2015 Update

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FOR THE PENUMBRA THERAPY TRIAL INVESTIGATORS

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# Study Design

- Prospective, RCT, randomized 1:1
  - Combined IV rtPA + IA Penumbra System vs Monotherapy IV rtPA
- Key inclusion criteria
  - 18 - 85 years of age
  - Clot length  $\geq$  8mm on thin-slice NCCT
  - Anterior circulation (ICA, M1, M2)
  - NIHSS  $\geq$  8
- Enrollment halted on October 29, 2014 (MR CLEAN) and then closed (EXTEND IA and ESCAPE)
  - 108 patients enrolled of 692 planned

# Baseline Characteristics: Demographics

Variable	IA + IV	IV Alone	p-value
Age, mean (SD)	67.4 (11.4)	70.1 (10.3)	0.2257
Female	38.2% (21/55)	56.6% (30/53)	0.0823
Admission NIHSS, median [IQR]	17 [13,22]	18 [14,22]	0.4254
Glucose mg/dL, median [IQR]	110.5 [99.0,151.0]	116.0 [103.0,133.0]	0.9305
Systolic BP mmHg, mean (SD)	148.2 (22.3)	150.4 (19.1)	0.4664

# Baseline Characteristics: Medical History

Characteristics	IA + IV (N=55)	IV Alone (N=53)	p-value
Previous stroke	9.6%	7.5%	0.7415
Previous transient ischemic attack (TIA)	6.1%	3.8%	0.6692
Myocardial infarction	8.0%	1.9%	0.1964
Angina/CAD	29.1%	15.1%	0.1058
Hypertension	77.8%	78.8%	1.0
CHF (congestive heart failure)	13.2%	7.7%	0.5260
Dyslipidemia	43.4%	49.0%	0.6942
Diabetes	32.1%	37.3%	0.6810
Atrial fibrillation	30.9%	49.1%	0.0765
Peripheral artery disease	2.0%	3.8%	1.0
Extracranial cerebral artery disease	8.3%	11.5%	0.7429
Current or former smoker	59.6%	38.8%	0.0655

# Imaging Characteristics

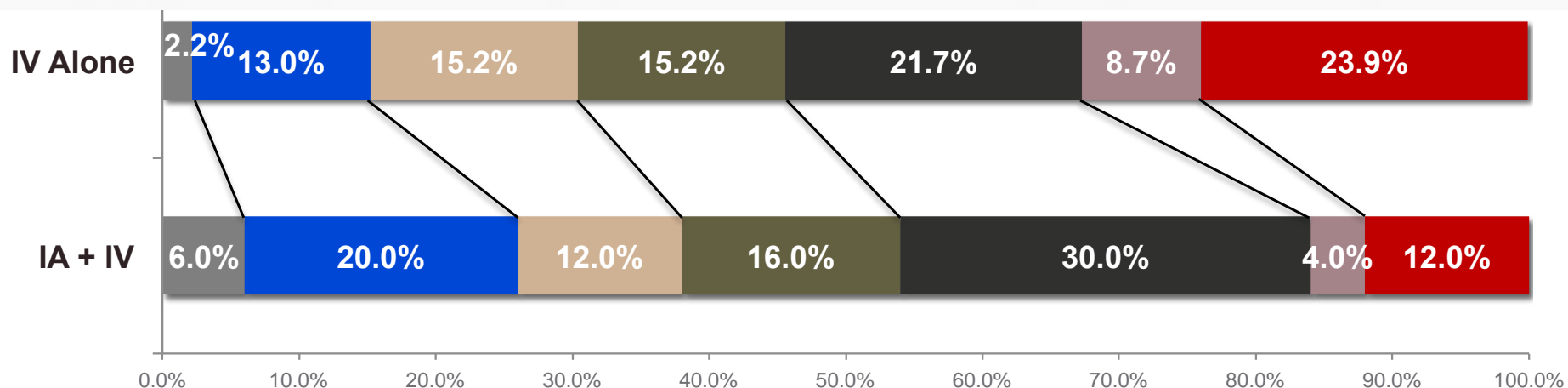
Characteristic <sup>a</sup>	IA + IV	IV Alone	p-value
Location of stroke: Left hemisphere	60.0% (33/55)	58.5% (31/53)	1.0
Site of primary occlusion			
Intracranial ICA	32.7% (18/55)	22.6% (12/53)	0.4365
MCA M1	56.4% (31/55)	67.9% (36/53)	
MCA M2	10.9% (6/55)	9.4% (5/53)	
ASPECTS, median (IQR)	7.5 [6.0,9.0]	8.0 [7.0,9.0]	0.4867
0 to 4	11.1% (6/54)	7.5% (4/53)	0.7140
5 to 7	38.9% (21/54)	35.8% (19/53)	
8 to 10	50.0% (27/54)	56.6% (30/53)	
Clot length, median (IQR)	12.9 [9.4,22.2]	14.1 [10.1,18.6]	0.8925

<sup>a</sup> As adjudicated by the core laboratory; imaging ASPECTS not available for 1 subject

# Efficacy Outcomes: Intent to Treat

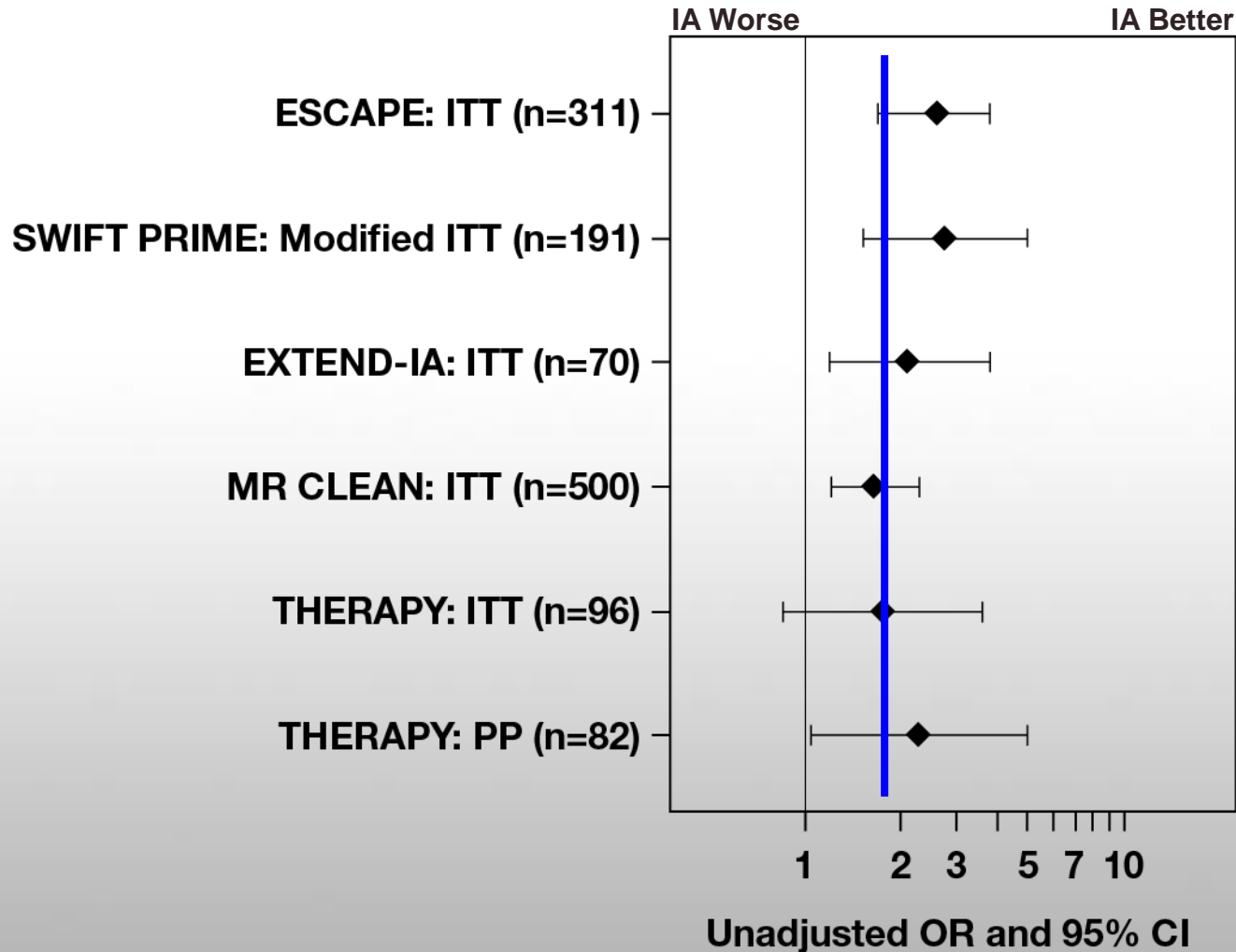
Outcome	IA + IV	IV Alone	p-value
Primary Endpoint:			
mRS 0-2 at 90 days	<b>38%</b> (19/50)	<b>30%</b> (14/46)	0.44

## Pre-Specified Secondary Endpoint: Ordinal mRS



OR 1.76 [95% CI: 0.86 to 3.59] p-value = 0.1216

# Endovascular Trials: Ordinal mRS



# Conclusions

- With limited sample size, THERAPY did not meet its primary endpoint
  - Demonstrated robust results with primary/secondary endpoints (not shown)
  - Demonstrated direction of effect towards benefit consistent with recent trials
  - Suggests that an alternate method of thrombectomy using aspiration may also benefit select patients