

**Natural History FIRST Stroke Study Interim Results**



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**Background**

Limited information is available on the natural history of the mechanical thrombectomy-eligible stroke cohort. Therefore, FIRST aims to collect real-world data in an appropriate population.

**Methods**

The FIRST Trial is a prospective natural history study of a stroke cohort eligible for but untreated by endovascular therapy presenting with a large vessel occlusion and ineligible or unresponsive to IV rtPA. The primary endpoint is 90-day mRS 0-2.

**Results**

Sixty-two patients met analysis criteria. Mean age was 68; median NIHSS score was 18. Occlusions were in the ICA (31%), MCA (66%) and other (3%). The admission TIMI 0-1 rate was 100% and TICI 0-1 was 98%, in which 10% and 12.5% spontaneously recanalized. Good 90-day outcome was achieved in 21%; 42% died, 34% had SAEs and 52% were IV rtPA-refractory. Compared to PROACT II, the FIRST cohort has substantially different entry criteria, less recanalization and worse outcome.

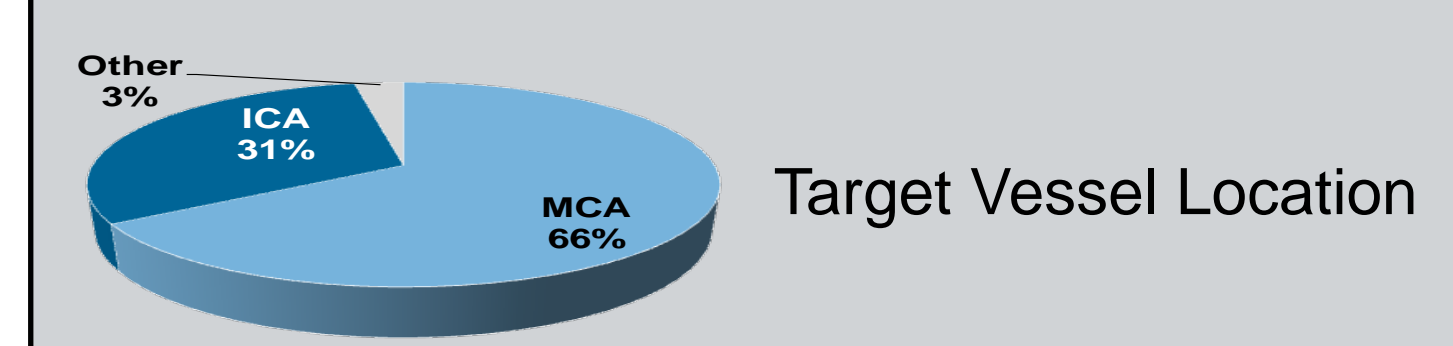
**Conclusion**

If untreated, 78% of patients with large vessel acute ischemic stroke will die or suffer long-term disabilities. Results suggest FIRST data could provide a benchmark for future thrombectomy trials.

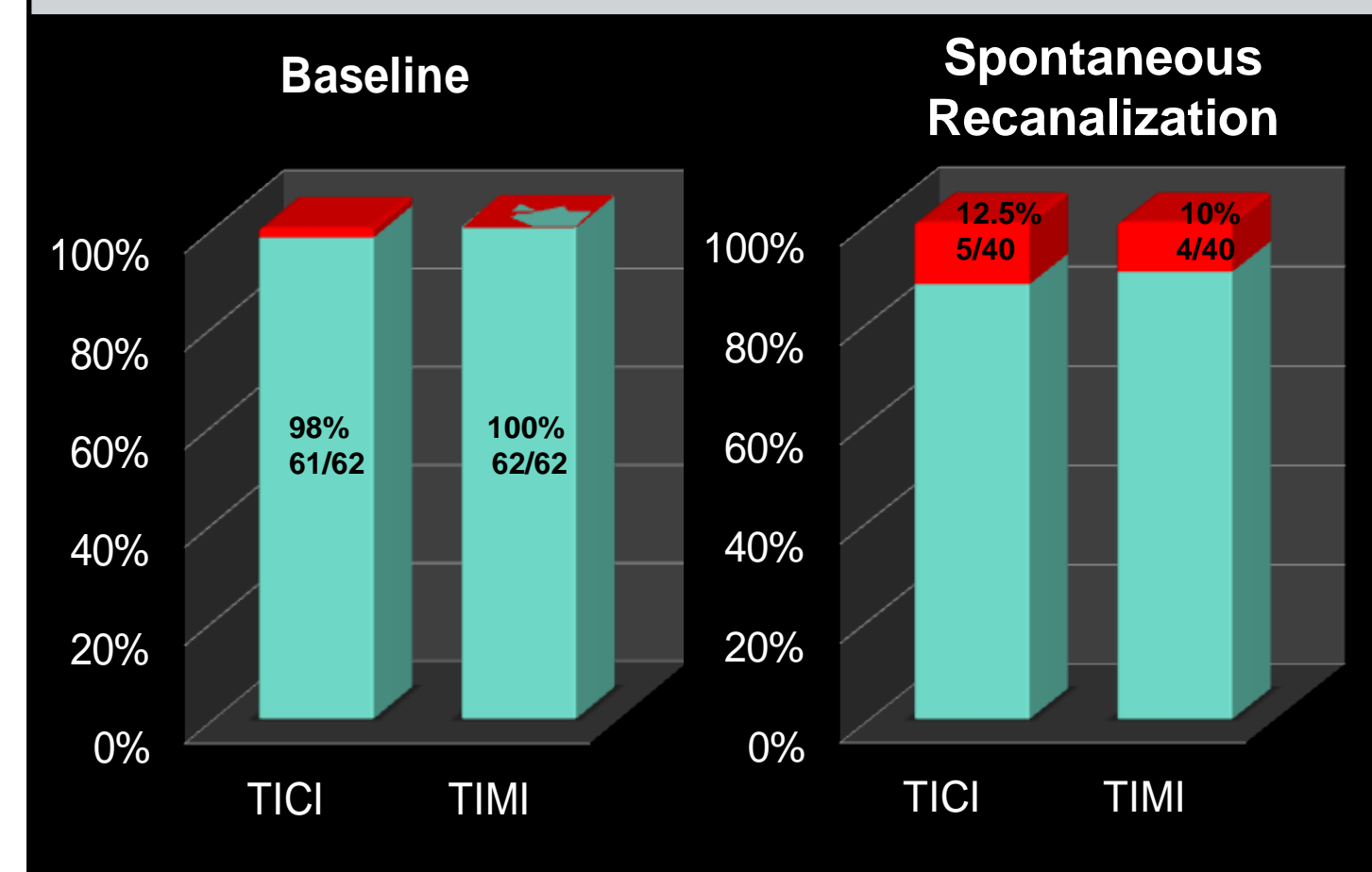
**Results**

Baseline Characteristics	
Patients (N)	62
Age (years) [mean/(SD)]	68.0 ± 15.6
Female	59.7% (37/62)
NIHSS [median/(IQR)]	18 (14-22)
TIMI 0 – 1	100% (62/62)
TICI 0 – 1	98.4% (61/62)
Refractory to IV rtPA*	52% (32/62)

\* No significant differences between IV tPA refractory vs. ineligible in baseline NIHSS, 90-day mRS, good neurological outcome, mortality, ICH, or revascularization rates



**Recanalization**



**Neurological Outcome**

Good Neurological Outcome	% (n/N)
Discharge/7-Day NIH 0-1 or 10 point improvement	14.5% (9/62)

Functional Outcome	
<b>Good Outcome at 90 Days</b>	<b>% (n/N)</b>
mRS 0-2	20.7% (12/58)

Safety	
<b>Event</b>	<b>Rate (n/N)</b>
All-Cause Mortality	41.9% (26/62)
All SAEs within 24 hrs of Stroke Onset	33.9% (21/62)*

Safety (continued)	
<b>Event</b>	<b>Rate (n/N)</b>
Symptomatic ICH	8.1% (5/62)
Asymptomatic ICH	9.7% (6/62)
Total ICH	17.7% (11/62)

**Summary of SAEs within 24 hrs of Stroke Onset**

Event	% (n/N)
Cerebral Edema	12.9% (8/62)
Respiratory Failure	9.7% (6/62)
Myocardial Infarction	3.2% (2/62)
Infection	3.2% (2/62)
Atrial Fibrillation	1.6% (1/62)
Herniation Syndrome	1.6% (1/62)
Congestive Heart Failure	1.6% (1/62)

**Participating Centers**

Center	Principal Investigator
Medical Center of Plano, Plano, TX, USA	Vallabh Janardhan, MD
Queen Mary Hospital, The University of Hong Kong, HK	Raymond Cheung, MD PhD
Medical City Dallas Hospital, Dallas-Fort Worth, TX, USA	Vallabh Janardhan, MD
Prince of Wales Hospital, The Chinese University of Hong Kong, HK	Thomas Leung, MD

**FIRST and PROACT II Study Entry Criteria**

	FIRST	PROACT II
Time from Onset (hrs)	≤ 8	≤ 6
Baseline NIHSS	≥ 10	4 - 30
Vessel Location	ICA + MCA	MCA
Enrollment	Consecutive	3 NIHSS Strata: 4-10; 11-20; 21-30

**MCA Baseline Characteristics FIRST and PROACT II Control**

	FIRST	PROACT II
Patients (N)	41	59
Age (years) [mean]	69.8 *	64
Female	56.1%	39%
NIHSS [median/IQR]	18.5 (9-34)	17 (4-28)

\* Significant vs FIRST with p < 0.05  
\*\* Significant vs FIRST with p < 0.01

**MCA Outcomes FIRST and PROACT II Control**

Outcomes	FIRST (N= 41)	PROACT II Control (N = 59)
Recanalization to TIMI 2/3	8.0%	18.0%
All ICH	19.5%	13.0%
sICH	7.3%	1.9%
Mortality	36.6%	27.1%
Follow Up NIHSS Score Improved by ≥ 50%	21.4% (7-day data)	44% (90-day data)
90-Day mRS 0-2	23.1%	25.4%