M1304

Poor natural history of large vessel acute ischemic stroke underscores the need for mechanical thrombectomy: 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

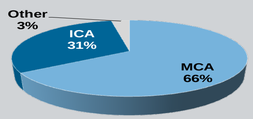
If untreated, 78% of patients with large vessel acute ischemic stroke will die or suffer long-term disabilities. Results suggest FIRST data could provide a benchmark for future thrombectomy trials.

Results

Baseline Characteristics

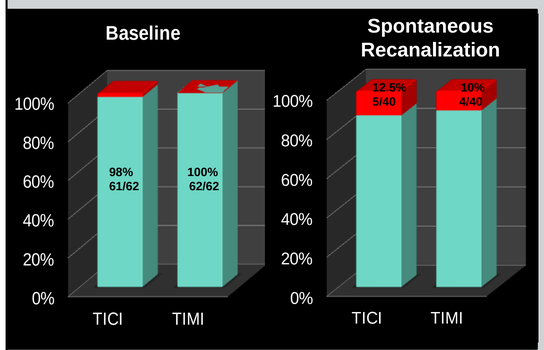
Patients (N)	62
Age (years) [mean/(SD)]	68.0 ± 15.6
Female	59.7% (37/62)
NIHSS [median/(IQR)]	18 (14-22)
TIMI 0 – 1	100% (62/62)
TICI 0 – 1	98.4% (61/62)
Refractory to IV rtPA*	52% (32/62)

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



Target Vessel Location

Recanalization



Neurological Outcome

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

Functional Outcome

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

Safety

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

* 21 events in 16 patients

Event	Rate (n/N)
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
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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%

Presenter Disclosure: Dr. V. Janardhan Penumbra, Inc.: None