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EMERGENT Study

Efficacy and Safety of a Novel Thrombectomy Device in Patients With Acute Ischemic Stroke.

A randomized, prospective, controlled, multicenter, single-blind, non-inferiority trial.

Study Purpose

To compare the safety and efficacy of the **Thrombite™ Clot Retriever Device** with the **Solitaire FR**.

Primary endpoint

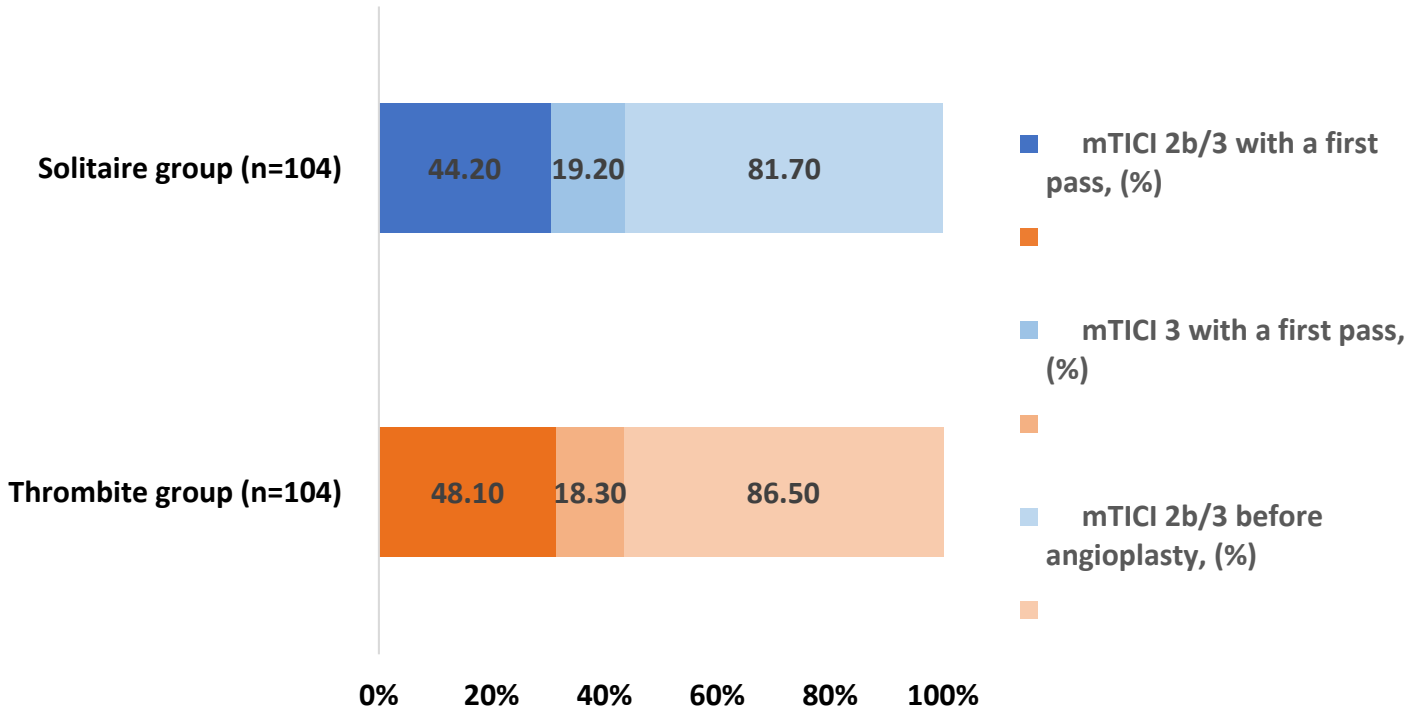
Successful reperfusion defined as achieving modified thrombolysis in cerebral infarction (mTICI) of 2b/3.

Study Results Demonstrated:

More patients in the Thrombite group achieved successful reperfusion (92.3 vs. 84.6%, 95% CI of difference value 0.9–16.7%, p < 0.0001).

Primary Endpoint

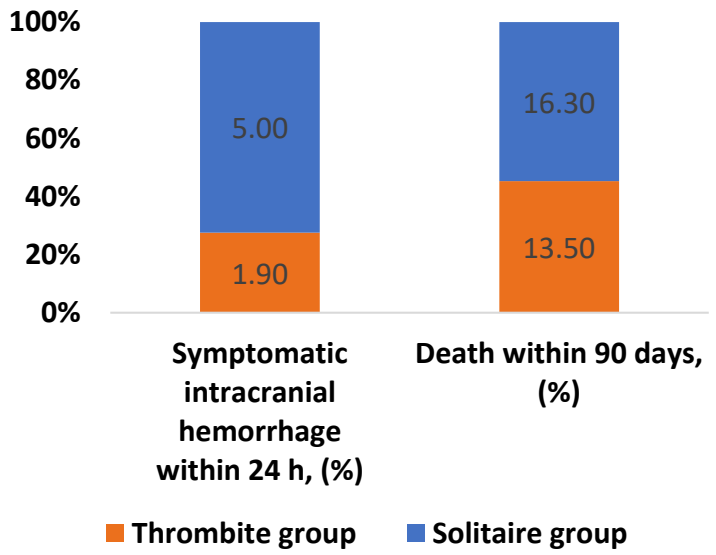
Thrombite	Solitaire FR
92.3%	**84.6%**
SUCCESSFUL REPERFUSION	SUCCESSFUL REPERFUSION

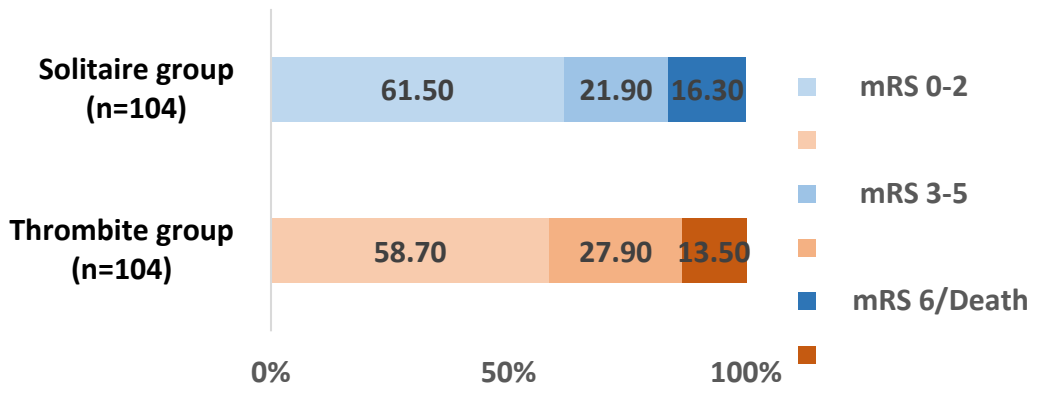


First-pass effect was achieved in 39/208 patients, with no significant differences noted between the Thrombite group and the Solitaire group (18.3 vs. 19.2%, respectively).

Before angioplasty, 90 patients (86.5%) in the Thrombite group and 85 (81.7%) in the Solitaire group reached successful reperfusion (p = 0.343).

There were no significant differences on sICH within 24 ± 6 h between the two groups. All-cause mortality within 90 days was 13.5% in the Thrombite group and 16.3% in the Solitaire group (p = 0.559).





No significant differences between groups on the NIHSS at either 24 h or 7 days and the mRS of 0–2 at 90 days.

No significant difference in Patient Population

Characteristic	Thrombite group (n = 104)	Solitaire group (n = 104)
Age—years, median (IQR)	63.98 (53.96–71.39)	66.50 (55.82–72.76)
Male sex, no. (%)	62 (59.6%)	61 (58.7%)
Prestroke mRS 1, no. (%)	10 (9.6%)	14 (13.5%)
NIHSS—median (IQR)	15 (12–19)	16 (13–19)
Intracranial arterial occlusion, no. (%)		
• ICA	21 (20.2%)	31 (29.8%)
• MCA M1 segment	71 (68.3%)	62 (59.6%)
• MCA M2 segment	11 (10.6%)	10 (9.6%)
• ACA A1 segment	0 (0%)	0 (0.0%)
• ACA A2 segment	1 (1.0%)	1 (1.0%)

Study Conclusion

In this randomized clinical trial, the Thrombite was non-inferior to the Solitaire FR in the treatment of large vessel occlusion stroke within 6 h of symptom onset.

INDICATIONS FOR USE:

The Thrombite Clot Retriever Device is intended to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke symptom onset.
Indications: acute ischemic stroke caused by large artery occlusions.

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