

# REVASCAT

## KEY FINDINGS

The REVASCAT study was conducted to determine the efficacy and safety of neurovascular thrombectomy with the Solitaire™ device in conjunction with medical therapy versus medical therapy alone, among eligible acute ischemic stroke patients treatable within 8 hours of symptom onset.



IV t-PA OR  
MEDICAL  
MANAGEMENT  
RANDOMIZED



LESS THAN  
5% LOSS TO  
FOLLOW UP



INDEPENDENT  
DATA REVIEW



An investigator-initiated, multicenter, prospective, randomized, sequential, open-label study with blinded-endpoint (PROBE) in acute ischemic stroke patients who had contraindications to IV t-PA or had received IV t-PA therapy within 4.5 hours without revascularization after 30 minutes of IV t-PA.



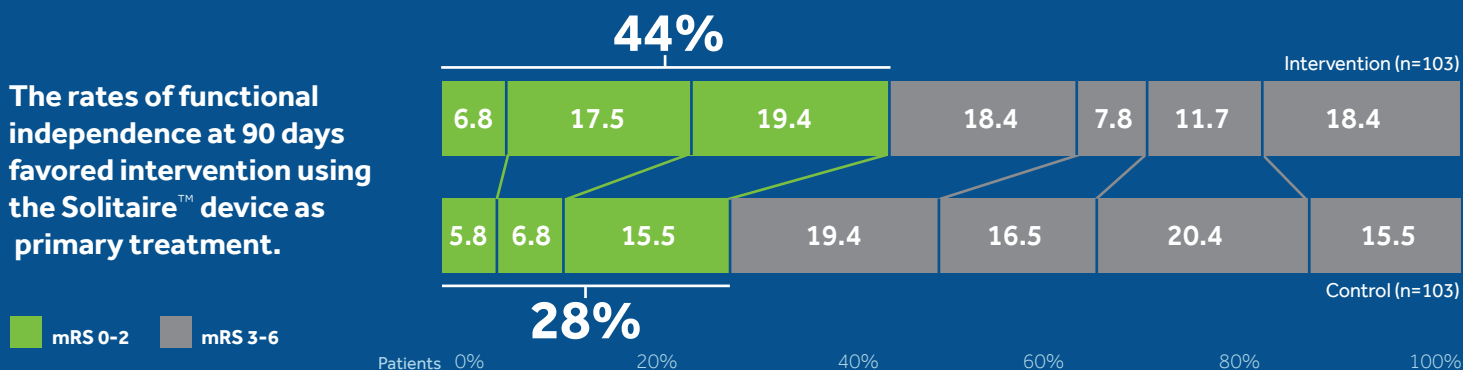
## NO SIGNIFICANT DIFFERENCE IN STUDY POPULATIONS:

CHARACTERISTIC	CONTROL	INTERVENTION*
Number of randomized subjects	103	103
Age (year) - mean (SD)	67.2 (9.5)	65.7 (11.3)
Male sex - no. (%)	54 (52.4%)	55 (53.4%)
NIHSS score - Median (IQR)	17 (12-19)	17 (14-20)
History of hypertension - no. (%)	72 (69.9%)	62 (60.2%)
History of diabetes - no. (%)	19 (18.4%)	22 (21.4%)
Time from stroke symptom onset to initiation of alteplase (min) - Median (IQR)	105 (86.0-137.5)	117.5 (90-150)
Site of vessel occlusion - no./total no. (%)		
▪ Intracranial Internal Carotid Artery (ICA) without involvement of M1	1/101 (1%)	0
▪ Terminus ICA with involvement of Middle Cerebral Artery (MCA) M1 segment	27/101 (26.7%)	26/102 (25.5%)
▪ Middle Cerebral Artery (MCA) M1 segment	65/101 (64.4%)	66/102 (64.7%)
▪ Middle Cerebral Artery (MCA) single M2 segment	8/101 (7.9%)	10/102 (9.8%)

## STUDY RESULTS:

OUTCOME	CONTROL	INTERVENTION*	UNADJUSTED EFFECT (95% CI)
Modified Rankin scale (mRS) score 0-2 at 90 days - no./total no. (%)	29/103 (28.2%)	45/103 (43.7%)	Odds Ratio (OR): 2.0 (1.1-3.5)
TICI classification 2b-3 per core laboratory - no./total no. (%)	N/A	67/102 (65.7%)	N/A
Death at 90 days - no./total no. (%)	16 (15.5%)	19 (18.4%)	Risk Ratio (RR): 1.2 (0.6-2.2)
Symptomatic Intracranial Hemorrhage (SITS-MOST) - no. (%)	2 (1.9%)	2 (1.9%)	Risk Ratio (RR): 1.0 (0.1-7.0)

The rates of functional independence at 90 days favored intervention using the Solitaire™ device as primary treatment.



## STUDY CONCLUSION:

In patients with anterior circulation stroke treatable within 8 hours of symptom onset, stent retriever thrombectomy reduces post-stroke disability and increases the rate of functional independence.

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\* Solitaire™ FR Revascularization Device and Solitaire™ 2 Revascularization Device used in Intervention group

SOURCE: Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. N. Engl. J. Med. Jun 11 2015;372(24):2296-2306.

CAUTION: Federal (USA) law restricts these devices to sale distribution and use by or on order of a physician. Indications, contraindications, warnings and instructions for use for Solitaire™ X Revascularization Device can be viewed at [www.medtronic.com/manuals](http://www.medtronic.com/manuals)

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