

SWIFT PRIME

KEY FINDINGS

STUDY PURPOSE: To compare the functional outcomes in Acute Ischemic Stroke subjects treated with either IV t-PA alone or IV t-PA in combination with the Solitaire™ revascularization device.



IV t-PA
RANDOMIZED



LESS THAN
5% LOSS TO
FOLLOW UP



INDEPENDENT
DATA REVIEW



A global multicenter, two-arm, prospective, randomized, open, blinded end-point trial.



NO SIGNIFICANT DIFFERENCE IN STUDY POPULATIONS:

CHARACTERISTIC

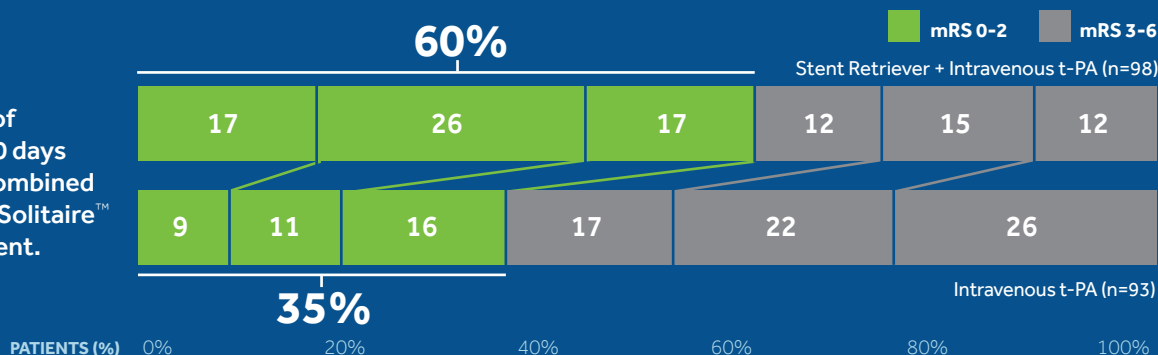
	INTRAVENOUS t-PA ALONE (n=98)	STENT RETRIEVER + INTRAVENOUS t-PA* (n=98)
Number of randomized subjects	98	98
Age (year) - Mean (SD)	66.3 (11.3)	65.0 (12.5)
Male sex - no./total no. (%)	45/96 (47%)	54/98 (55%)
NIHSS score - Median (Interquartile range, IQR)	17 (13-19)	17 (13-20)
History of hypertension - no./total no. (%)	56/97 (58%)	66/98 (67%)
History of diabetes mellitus - no./total no. (%)	15/97 (15%)	12/98 (12%)
Time from stroke symptom onset to initiation of intravenous t-PA (min) - Median (Interquartile range, IQR)	117.0 (80-155)	110.5 (85-156)
Site of vessel occlusion - no./no.total (%)		
▪ Internal Carotid Artery (ICA)	15/94 (16%)	17/93 (18%)
▪ First segment of Middle Cerebral Artery (M1)	72/94 (77%)	62/93 (67%)
▪ Second segment of Middle Cerebral Artery (M2)	6/94 (6%)	13/93 (14%)

STUDY RESULTS:

OUTCOME

	INTRAVENOUS t-PA ALONE (n=98)	STENT RETRIEVER + INTRAVENOUS t-PA (n=98)	RISK RATIO (95% CI)
Functional independence at 90 days - no./total no. (%)	33/93 (35%)	59/98 (60%)	1.70 (1.23-2.33)
Substantial reperfusion immediately after thrombectomy - no./total no. (%)	N/A	73/83 (88%)	N/A
Successful reperfusion at 27 hr. - no./total no. (%)	21/52 (40%)	53/64 (83%)	2.05 (1.45-2.91)
Death at 90 days - no./total no. (%)	12/97 (12%)	9/98 (9%)	0.74 (0.33-1.68)
Symptomatic intracranial hemorrhage at 27hr - no./total no. (%)	3/97 (3%)	0 (0%)	0.00 (N/A)

Statistically significant improvement in the rate of functional outcomes at 90 days with intervention using combined intravenous t-PA and the Solitaire™ as primary treatment.



STUDY CONCLUSION:

In patients receiving intravenous t-PA for acute ischemic stroke with confirmed large-vessel occlusions of the anterior circulation, treatment with the Solitaire™ stent thrombectomy device within 6 hours after symptom onset improved functional outcomes at 90 days.

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

SOURCE: Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N. Engl. J. Med. Jun 11 2015;372(24):2285-2295.

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

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