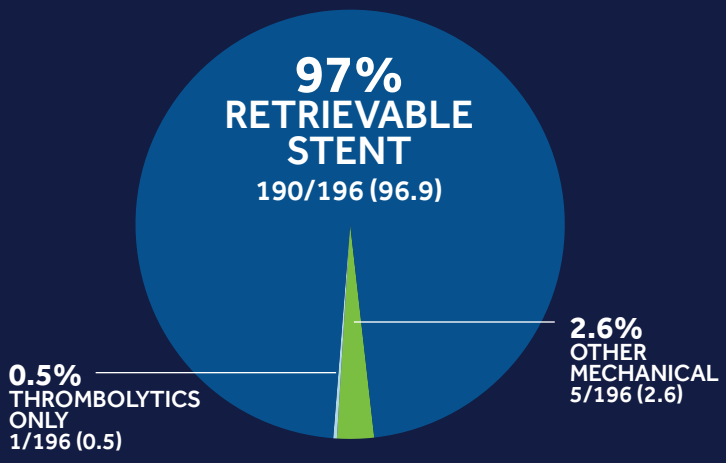
MR CLEAN
KEY FINDINGS

STUDY PURPOSE: In patients with acute ischemic stroke caused by proximal intracranial arterial occlusion, intra-arterial treatment (IAT) is highly effective for emergent revascularization. 500 patients with a proximal arterial occlusion in the anterior cerebral circulation demonstrated on vessel imaging, treated with IAT within 6 hours were randomized to IAT plus usual care (IV t-PA or medical management) or usual care alone.

PREDOMINANTLY STENT RETRIEVERS INCLUDING THE SOLITAIRE™ DEVICE USED FOR INTERVENTIONAL THERAPY.



n = 196
(of the 233 assigned to intervention, only 196 underwent intervention therapy)*

A randomized trial of intra-arterial treatment for acute stroke

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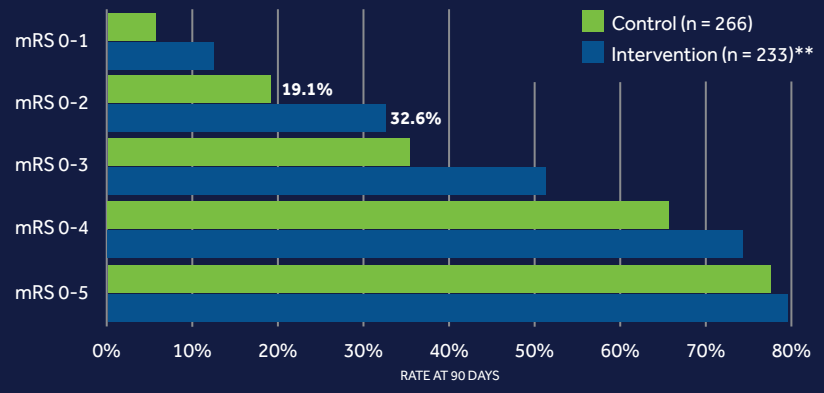
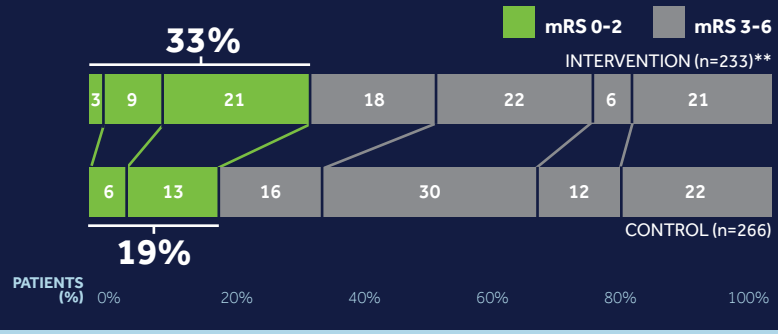
NO SIGNIFICANT DIFFERENCE IN BASELINE CHARACTERISTICS BETWEEN STUDY ARMS:

CHARACTERISTIC		INTERVENTION** (n=233)	CONTROL (n=266)
Age in years - median (Interquartile range, IQR)		65.8 (54.5 to 76.0)	65.7 (55.5 to 76.4)
Male sex - n (%)		135 (57.9%)	157 (58.8%)
NIHSS score - median (IQR; range)		17 (14 to 21; 3 to 30)	18 (14 to 22; 4 to 38)
Treatment with IV alteplase - n (%)		203 (87.1%)	242 (90.6%)
Time from onset to start of IV alteplase - minutes median (IQR)		85 (67 to 110)	87 (65 to 116)
INTRACRANIAL ARTERIAL OCCLUSION LOCATION	ICA - n (%)	1 (0.4%)	3/266 (1.1%)
	ICA - T - n (%)	59 (25.3%)	75/266 (28.2%)
	M1 segment - n (%)	154 (66.1%)	165/266 (62.0%)
	M2 segment - n (%)	18 (7.7%)	21/266 (7.9%)
	A1/2 segment - n (%)	1 (0.4%)	2/266 (0.8%)
Time from onset to randomization - minutes median (IQR)		204 (152 to 251)	196 (149 to 266)
Time from onset to groin puncture - minutes median (IQR)		260 (210 to 313)	NA

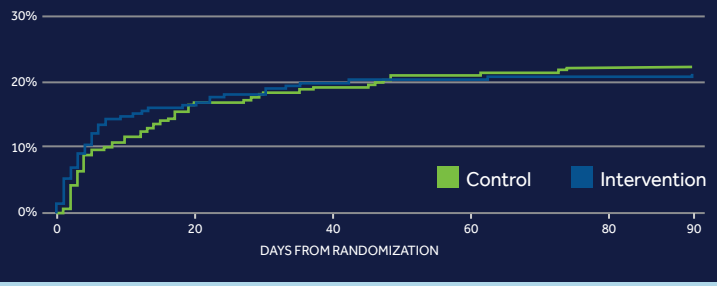
SIGNIFICANT IMPROVEMENT IN FUNCTIONAL OUTCOMES AT 90 DAYS OBSERVED WITH THE ADDITION OF INTERVENTIONAL THERAPY.

OUTCOME	ADJUSTED EFFECT (aOR, 95%CI)
mRS 0-1	2.1 (1.1 to 4.0)
mRS 0-2	2.2 (1.4 to 3.4)
mRS 0-3	1.9 (1.4 to 3.0)
mRS 0-4	1.5 (1.0 to 2.4)
mRS 0-5	1.1 (0.7 to 1.7)





NO SIGNIFICANT DIFFERENCE IN MORTALITY OUT TO 90 DAYS.



STUDY CONCLUSION:

The MR CLEAN study observed that the addition of stent thrombectomy for acute ischemic stroke care is safe and effective when administered within 6 hours of symptom onset.

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* Solitaire™ FR Revascularization Device used in Intervention group ** Merci Retriever® used in Intervention group

SOURCE: Berkhemer OA, Fransen PS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. N. Engl. J. Med. Jan 1 2015;372(1):11-20.

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