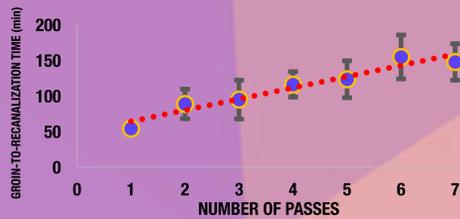


BREAKING BIASES : A single-center retrospective cohort study of stent retriever safety, 1-pass efficacy and functional outcome in acute stroke

Introduction: Many different stent retrievers are commercially available for use in endovascular mechanical thrombectomy (EVT). Interventional radiologists opt for their preferred device hoping it could lead to a complete recanalization after 1-pass as it reduces groin-to-recanalization time as depicted in figure 1. Other available devices are not selected for EVT treatment for a variety of bias reasons and perceived flaws. Our center uses primarily three different devices : Solitaire™ (Medtronic, USA), Trevo® ProVue™ (Stryker, USA) and Catch+ (Balt, France). Differences in performance and long-term outcome among these devices during EVT are based on meta-analyses. Unfortunately, these studies differ in design, patient selection, technique and operator experience^{1,2}. Moreover, the success rate of 1-pass recanalization success is not reported. This single-center cohort study retrospectively studied performance and functional outcome of these devices.

FIG 1. THROMBECTOMY TIME



Methods: All ischemic stroke cases managed in our department by EVT between 2014 and 2017 were analyzed retrospectively. Inclusion criteria were: all acute ischemic stroke with proven occlusions at the terminal portion of the internal carotid artery, M1 and M2 occlusion managed by EVT as per our institutional protocol using either a Solitaire, Trevo or Catch device. Exclusion criteria were: device use following direct thrombo-aspiration, intra-arterial thrombolysis or failed EVT using a different device (Merci®, Phenox CRC, MindFrame Capture™). Patient age, sex, i.v. thrombolysis, NIHSS, time-to-groin, baseline and 3-month mRS from the ASTRAL registry were recorded. The number of EVT passes, complications, and mTICI score and rescue stent use were compared

Results: Two-hundred-thirty patients were included. A total of 82 cases were treated with the Solitaire device, 119 with the Trevo and 29 with the Catch device. Table 1 shows patient characteristics according to occlusion type. No significant difference in age or sex, average baseline mRS, NIHSS and iv thrombolysis was observed.

TBL 1. PATIENT CHARACTERISTICS

	INTERNAL CAROTID ARTERY: TERMINAL SEGMENT				MIDDLE CEREBRAL ARTERY: M1 SEGMENT				MIDDLE CEREBRAL ARTERY: M2 SEGMENT			
	Solitaire (n=22)	Trevo (n=24)	Catch (n=5)	P Value	Solitaire (n=49)	Trevo (n=55)	Catch (n=3)	P Value	Solitaire (n=11)	Trevo (n=40)	Catch (n=21)	P Value
AGE (YEARS)	71.3 ± 12.8	69.2 ± 12.9	65.6 ± 13.1	0.5742	69.7 ± 16.1	71.5 ± 13.2	70.9 ± 14.9	0.5327	57.4 ± 15.9	73.6 ± 15.9	70.4 ± 15.1	0.0043
SEX MALE (%)	13 (0.59)	14 (0.58)	4 (0.80)	0.5978	27 (0.55)	25 (0.45)	2 (0.66)	0.2161	6 (0.55)	18 (0.45)	11 (0.52)	0.4117
BASELINE mRS	0.91 ± 1.1	0.54 ± 0.7	0.21 ± 0.5	0.186	2.88 ± 2.44	2.90 ± 2.04	1.5 ± 2.12	0.9638	0.18 ± 0.60	0.71 ± 0.86	0.62 ± 0.74	0.0616
NIHSS	19.4 ± 6.2	17.3 ± 5.6	15.8 ± 7.2	0.8022	15.4 ± 5.8	15.2 ± 6.3	16.6 ± 10.0	0.8671	15.7 ± 4.6	11.4 ± 5.6	10.8 ± 6.2	0.0237
i.v. rTPA (%)	14 (0.63)	17 (0.71)	4 (0.80)	0.4183	34 (0.69)	42 (0.76)	2 (0.66)	0.281	9 (0.81)	28 (0.70)	14 (0.67)	0.358
SYMPTOM-TO-GROIN (MIN)	179.7 ± 149.9	177.3 ± 170.0	137.6 ± 123.6	0.9917	160.7 ± 157.5	212.7 ± 219.3	180.7 ± 129.6	0.1726	123.1 ± 111.2	282.8 ± 295.4	154.0 ± 87.9	0.0867

Recanalization rates were similar between all three devices. The Solitaire device achieved a successful recanalization score of mTICI>2b of 86.6% in all occlusion locations. The Trevo device achieved mTICI >2b in 91.6% of cases regardless of occlusion site and the Catch device in 82.8% of cases, figure 2. No significant difference was observed in hemorrhage rate, rate of rescue stent use or 3-month mRS. A breakdown of performance at each occlusion is elaborated in table 2.

TBL 2. RECANALIZATION PERFORMANCE, COMPLICATION RATE, 3-month mRS

	INTERNAL CAROTID ARTERY: TERMINAL SEGMENT				MIDDLE CEREBRAL ARTERY: M1 SEGMENT				MIDDLE CEREBRAL ARTERY: M2 SEGMENT			
	Solitaire (n=22)	Trevo (n=24)	Catch (n=5)	P Value	Solitaire (n=49)	Trevo (n=55)	Catch (n=3)	P Value	Solitaire (n=11)	Trevo (n=40)	Catch (n=21)	P Value
mTICI 3	12 (0.55)	14 (0.58)	5 (1)	0.5152	32 (0.65)	33 (0.60)	1 (0.33)	0.3617	9 (0.81)	21 (0.53)	6 (0.29)	0.0775
mTICI 2B	6 (0.27)	6 (0.25)	0	0.5626	12 (0.25)	20 (0.36)	2 (0.66)	0.3617	0	15 (0.38)	10 (0.48)	0.0126
mTICI 2A	0	2 (0.18)	0	0.2667	1 (0.02)	2 (0.04)	0	0	2 (0.18)	3 (0.08)	1 (0.05)	0.2919
mTICI < 2	4 (0.18)	2 (0.18)	0	0.291	4 (0.08)	0	0	0.0461	0	1 (0.03)	4 (0.19)	0.7843
HEMORRHAGE	1 (0.05)	1 (0.04)	0	0.7333	3 (0.06)	0	0	0.1012	1 (0.09)	2 (0.05)	5 (0.24)	0.5256
RESCUE DEVICE	6 (0.27)	7 (0.29)	0	0.574	6 (0.12)	9 (0.16)	0	0.3617	1 (0.09)	6 (0.15)	1 (0.05)	0.5257
3-MONTH mRS	4.25 ± 1.8 (sd)	3.06 ± 2.5	1.75 ± 0.96	0.0729	2.88 ± 2.44	2.90 ± 2.04	1.5 ± 2.12	0.9638	1.71 ± 0.95 (sd)	2.72 ± 2.14	3.36 ± 2.34	0.1359

FIG 2. Recanalization performance



1-pass recanalization success rate in obtaining either mTICI 2b or 3 was identical for all device types even after subgroup analysis at each occlusion site, figure 3. Rate of 1-pass success is higher for the Catch device for occlusions at the internal carotid artery and for the Solitaire device in occlusions of the M2 portion of the middle cerebral artery, but remains statistically insignificant due to they infrequent use at these sites. Average number of passes not statistically different between devices. Totally procedure time (groin-to-recanalization) was similar for each device. Table 3 includes all elaborated data.

TBL 3. 1-pass success rate, number of passes, thrombectomy time

	INTERNAL CAROTID ARTERY: TERMINAL SEGMENT				MIDDLE CEREBRAL ARTERY: M1 SEGMENT				MIDDLE CEREBRAL ARTERY: M2 SEGMENT			
	Solitaire (n=22)	Trevo (n=24)	Catch (n=5)	P Value	Solitaire (n=49)	Trevo (n=55)	Catch (n=3)	P Value	Solitaire (n=11)	Trevo (n=40)	Catch (n=21)	P Value
1-pass mTICI 3	7 (0.32)	7 (0.29)	4 (0.80)	0.549	18 (0.37)	22 (0.40)	1 (0.33)	0.4448	8 (0.73)	15 (0.38)	4 (0.19)	0.0409
1-pass mTICI 2b-3	8 (0.37)	11 (0.46)	4 (0.80)	0.2778	27 (0.55)	32 (0.58)	1 (0.33)	0.4528	8 (0.73)	23 (0.58)	9 (0.43)	0.2897
Number of passes	2.54 ± 1.7	2 ± 1.4	1.4 ± 0.9	0.1773	1.7 ± 1.0	2.1 ± 1.6	2 ± 1	0.1349	1.1 ± 0.3	1.8 ± 1.2	2.0 ± 1.5	0.0626
Procedure time (mins)	77 ± 51.8	70 ± 43.8	40 ± 21.8	0.1344	69.1 ± 74.2	75.2 ± 73.0	28 ± 5.6	0.6738	74.1 ± 63.4	69.3 ± 37.8	74.7 ± 25.6	0.9618

FIG 3. (left) Kaplan-Meier to show recanalization percent as a function of number passes

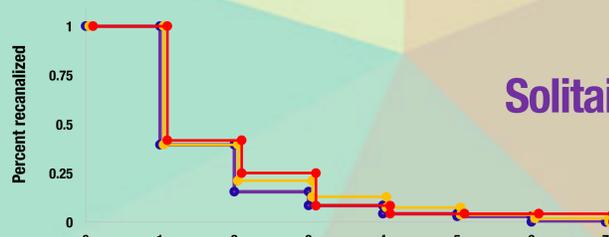


FIG 4. (right) Time to recanalization by device as a function of number of passes



Conclusion: All three EVT devices, the Solitaire, Trevo and Catch stent retrievers, achieve a high rate of 1-pass recanalization success and as result, low total procedure time to obtaining optimal recanalization in acute ischemic stroke. Despite the claims of device superiority between these three particular devices, no statistical significant difference in recanalization performance, rate of 1-pass success or decrease in groin-to-recanalization time could be obtained with the data analyzed in this retrospective study. Moreover, use of any of these three devices leads to similar long-term functional independence and they have a relatively good safety profile. No significant differences in functional outcomes or complication rate could be demonstrated. There are limitations to this study. First, due to recent changes to stroke management such as broadening of inclusion criteria for EVT treatment as well as technical refinement and optimization of EVT devices commercial available, only a retrospective and un-blinded study could be designed. Second, an analysis of confounding factors such as operator skill and time of procedure were not performed. Finally, long-term follow-up data is incomplete and may overestimate long-term functional outcome.

