

Benefit of M2 Thrombectomy in ARISE II (Analysis of Revascularization in Ischemic Stroke with EmboTrap)

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INTRODUCTION

Patients with proximal (M1) and more distal occlusions (M2) of the middle cerebral artery (MCA) from the ARISE II study were assessed in order to characterize the outcomes of revascularization with the EmboTrap device, which has a 5 mm diameter, in small vessels.

METHODS

Data from the ARISE II Study concerning MCA occlusions were separated into 2 groups: M1 and M2 occlusions. From the ARISE II Study, inclusion criteria were NIHSS score ≥ 8 and ≤ 25, ASPECT ≥ 6. Comparison of the 2 groups was performed in order to evaluate M2 revascularization with the EmboTrap device.

RESULTS

227 subjects were treated with EmboTrap in the ARISE II study. M1 occlusion was present in 126 patients and M2 occlusions in 57 patients. M2 occlusions included the proximal, medial, distal segment and were distal in 35.1% cases (Figure 1). Baseline characteristics were similar in the two groups except for mean age (66.9 in M1 vs. 71.3 years in M2, p=0.033, Table 1). Angiographic outcomes were similar for both target locations, including revascularization with first pass (Table 2). Clinical outcomes at 90 days were also similar with comparable rates of functional independence (Table 4). Safety was similar between the two groups and symptomatic intracranial hemorrhage was observed in 4.8% of patients in M1 and 3.5% in M2 (p=1.000, Table 3).

Baseline Characteristics

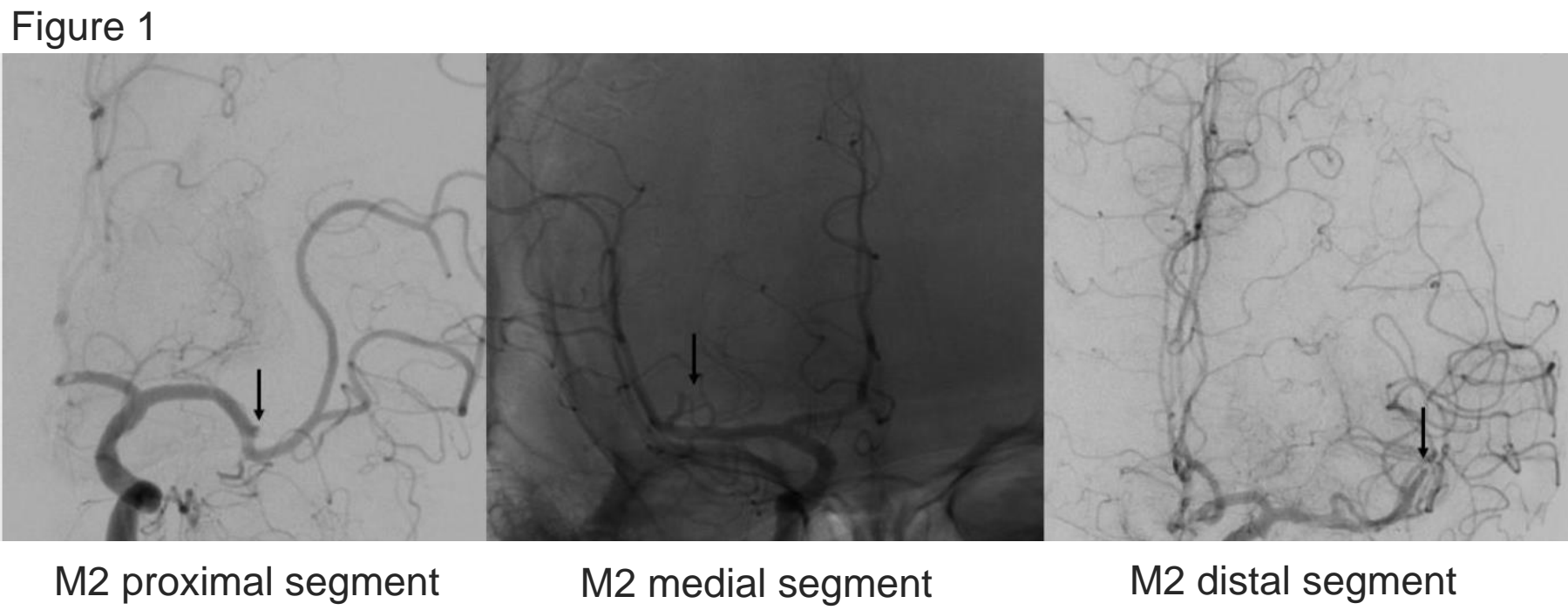


Table 1	MCA M1 (N=126)	MCA M2 (N=57)	p Value
Age at enrollment, years, mean (SD)	66.9 (13.1)	71.3 (12.0)	0.033
Male sex, n (%)	57 (45.2)	30 (52.6)	0.354
NIHSS at presentation, mean (SD)	15.90 (4.41)	14.37 (4.31)	0.030
Baseline APSECT, mean (SD)	9.31 (1.45)	9.37 (1.00)	0.728
Pre-stroke mRS, n (%)			0.898
0	96 (76.2)	43 (75.4)	
1	29 (23.0)	14 (24.6)	
2	1 (0.8)	0	
Occlusion side, left, n (%)	57 (45.2)	30 (52.6)	0.354
Medical history, n (%)			
Hypertension	85 (67.5)	42 (73.7)	0.398
Diabetes mellitus	25 (19.8)	12 (21.1)	0.850
Atrial fibrillation	47 (37.3)	25 (43.9)	0.400
Hyperlipidemia	50 (39.7)	30 (52.6)	0.102
Smoking	36 (28.6)	12 (21.1)	0.284
Previous MI/CAD	30 (23.8)	9 (15.8)	0.220
Neurological history, n (%)			
Previous stroke	21 (16.7)	12 (21.1)	0.475
Intravenous tPA failure	85 (67.5)	38 (66.7)	0.916

Core Laboratory Adjudicated Angiographic Outcomes

Table 2	MCA M1 (N=126)	MCA M2 (N=57)	p Value
Fist Pass mTICI ≥ 2b	65 (51.6%)	28 (49.1%)	0.758
First Pass mTICI ≥ 2c*	48 (38.1%)	22 (38.6%)	0.949
Fist Pass mTICI 3	33 (26.2%)	18 (31.6%)	0.452
Last of Up to 3 Passes mTICI ≥ 2b**	100 (79.4%)	45 (78.9%)	0.949
Last of Up to 3 Passes mTICI ≥ 2c	78 (61.9%)	37 (64.9%)	0.697
Last of Up to 3 Passes mTICI 3	49 (38.9%)	29 (50.9%)	0.129
Final Pass mTICI ≥ 2b	116 (92.1%)	52 (91.2%)	1.000
Final Pass mTICI ≥ 2c	94 (74.6%)	42 (73.7%)	0.895
Final Pass mTICI 3	59 (46.8%)	32 (56.1%)	0.243

* First pass effect; **definition of ARISE II Primary Endpoint

Clinical Outcomes

Table 4	MCA M1 (N=122)	MCA M2 (N=57)	p Value
90 day mRS, n (%)			0.936
0	37 (30.3)	16 (28.1)	
1	30 (24.6)	17 (29.8)	
2	18 (14.8)	7 (12.3)	
3	9 (7.4)	4 (7.0)	
4	15 (12.3)	5 (8.8)	
5	5 (4.1)	2 (3.5)	
6	8 (6.6)	6 (10.5)	
0-2	85 (69.7)	40 (70.2)	0.946
0-1	67 (54.9)	33 (57.9)	0.709

90 day modified Rankin Scale (mRS) scores were available for all 57 subjects with M2 occlusions and 122 of the 126 subjects with M1 occlusions

Clinical Events Committee Adjudicated Safety Events

Table 3	MCA M1 (N=126)	MCA M2 (N=57)	p Value
Symptomatic intracranial hemorrhage within 24 hours	6 (4.8%)	2 (3.5%)	1.000
All cause mortality at 90 days	8 (6.6%)	6 (10.5%)	0.379
Procedure-related mortality (at 7 days post procedure)	0	0	
Procedure-related serious adverse events	4 (3.2%)	5 (8.8%)	0.140
Serious adverse device events	0	0	

CONCLUSION

In this study, we analyzed patients with M2 occlusions treated with EmboTrap in the ARISE II trial. **Similar efficacy and safety was found for M2 compared to M1 occlusions treated with the device.** Use of the same device for proximal and more distal occlusions can have economic and technical advantages.