

Comparison of Manual

Aspiration with Rheolytic

Interpretation of the Interpretation of the

Myocardial Infarction: the

SMART Primary PCI Trial

ClinicalTrials.gov Identifier: NCT 01281033











Potential conflicts of interest

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□ I do not have any potential conflict of interest

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Sponsor: Investigators











Background

 Manual aspiration thrombectomy (MAT) is ineffective in 40% of patients with acute myocardial infarction (AMI) while rheolytic thrombectomy (RT) seems to be more effective in restoring a normal flow and has a more predictable effect also in unfavourable settings (tortuosity, calcification, giant thrombus).

 No data exist regarding the comparison between MAT and RT using the optical coherence tomography (OCT) to assess residual thrombus burden after thrombectomy.

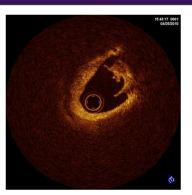




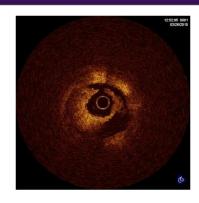








Aim



- The SMART trial compared by OCT the efficacy of RT and MAT in thrombus removal before infarct artery stenting in patients with AMI.
- The study was powered to demonstrate a decrease of the number quadrants containing thrombus from an an expected 55±20% in the manual aspiration group to 40±20% in the RT group (statistical power 91%, based on a maximum sample size of 80 patients randomized in a 1:1 allocation ratio, experimental type I error of 0.05 using a 2-sided hypothesis test).
- OCT core lab CRF, New York, NY











Methods

- Eighty AMI patients (≤ 6 hours from symptom onset)
 were randomly allocated (1:1) to RT or MAT.
- Primary end point: residual thrombus burden defined as number of coronary quadrants containing thrombus by OCT.
- Key secondary end points: post-thrombectomy TIMI thrombus grade, TIMI flow grade, TIMI blush grade,
 ST-segment elevation resolution.











Baseline Characteristics

	RT (n = 40)	MAT (n = 40)	P value
Age, years	65±11	64±12	0.698
Male gender	32 (80)	30 (75)	0.592
Smoker	20 (50)	15 (38)	0.260
Hypertension	24 (60)	22 (55)	0.651
Diabetes mellitus	3 (8)	8 (20)	0.105
Anterior infarct location	21 (52)	18 (45)	0.502
Cardiogenic shock	3 (8)	1 (3)	0.305
LV EF, %	43±8	44±11	0.647
Pre-PCI TIMI flow grade 0 - 1	32 (80)	33 (83)	0.775
Number of diseases vessels	1.7±0.7	1.6±0.7	0.529
RVD, mm	3.3±0.5	3.3±0.5	0.891
Pre-PCI thrombus grade	4.27±1.01	4.20±1.04	0.745











Procedural Characteristics and Angiographic and EKG Results

	RT (n =40)	MAT (n = 40)	P value
Lesion crossing failure	0	3 (8)	0.241
Post-Thrombectomy TIMI grade flow	2.8±0.4	2.5±0.7	0.004
Post-Thrombectomy TIMI grade 3 flow	35 (87)	23 (57)	0.003
Post-Thrombectomy TIMI thrombus	1.6±0.9	2.4±1.2	0.001
grade			
Direct stenting	33 (83)	30 (75)	0.412
Final TIMI flow grade 3	38 (95)	32 (80)	0.043
Final TIMI blush Grade 3	29 (72)	20 (50)	0.039
Early ST-segment resolution	37 (92)	31 (77)	0.060











OCT Results:



All but 1 patient had residual thrombus after MAT or RT.

	RT (n = 38)	MAT (n = 38)	P value
Number of coronary quadrants	53 [31-83]	65 [33-111]	0.083
containing thrombus			
Pts with coronary quadrants containing	14 (37)	23 (60)	0.039
thrombus > the median value			
Quadrants with white thrombus, n	8 [0-29]	8 [0-48]	0.783
Quadrants with red thrombus, n	0 [0-21]	0 [0-17]	0.934
Quadrants with mixed thrombus, n	18 [0-59]	21 [0-59]	0.801
Maximal thrombus area, mm ²	1.7 [0.7-2.6]	2.0 [1.1-3.5]	0.092











Conclusions

- > MAT or RT allow only incomplete removal of thrombus.
- ► RT as compared to MAT is more effective in thrombus removal and is associated with a better myocardial reperfusion.







