The randomized physiologic assessment of thrombus aspiration in patients with ST-segment elevation myocardial infarction trial

PATA-STEMI study

Dejan Orlic, MD on behalf of PATA STEMI investigators

Clinical center of Serbia

Belgrade, Serbia

Potential conflicts of interest

Speaker's name: Dejan Orlic

☑ **I do not have any potential conflict of interest**

Background and aim

- Routine thrombus aspiration is superior to conventional PPCI in terms of improved myocardial perfusion in patients with STEMI
- However, myocardial perfusion after thrombus aspiration has not been evaluated by a quantitative, invasive method, such as determining the index of microcirculatory resistance (IMR)
- Our aim was to assess impact of thrombus aspiration on myocardial perfusion assessed by IMR in patients presenting with first STEMI

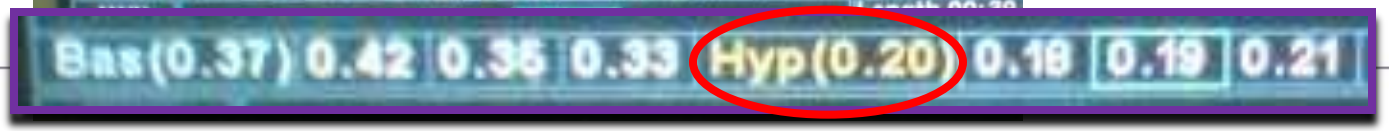
Method

Rmyo= ΔP/F= Pd-Pv/1/Tmn
F≈1/Tmn
Pv≈0 mmHg

IMR= Pd x Tmn

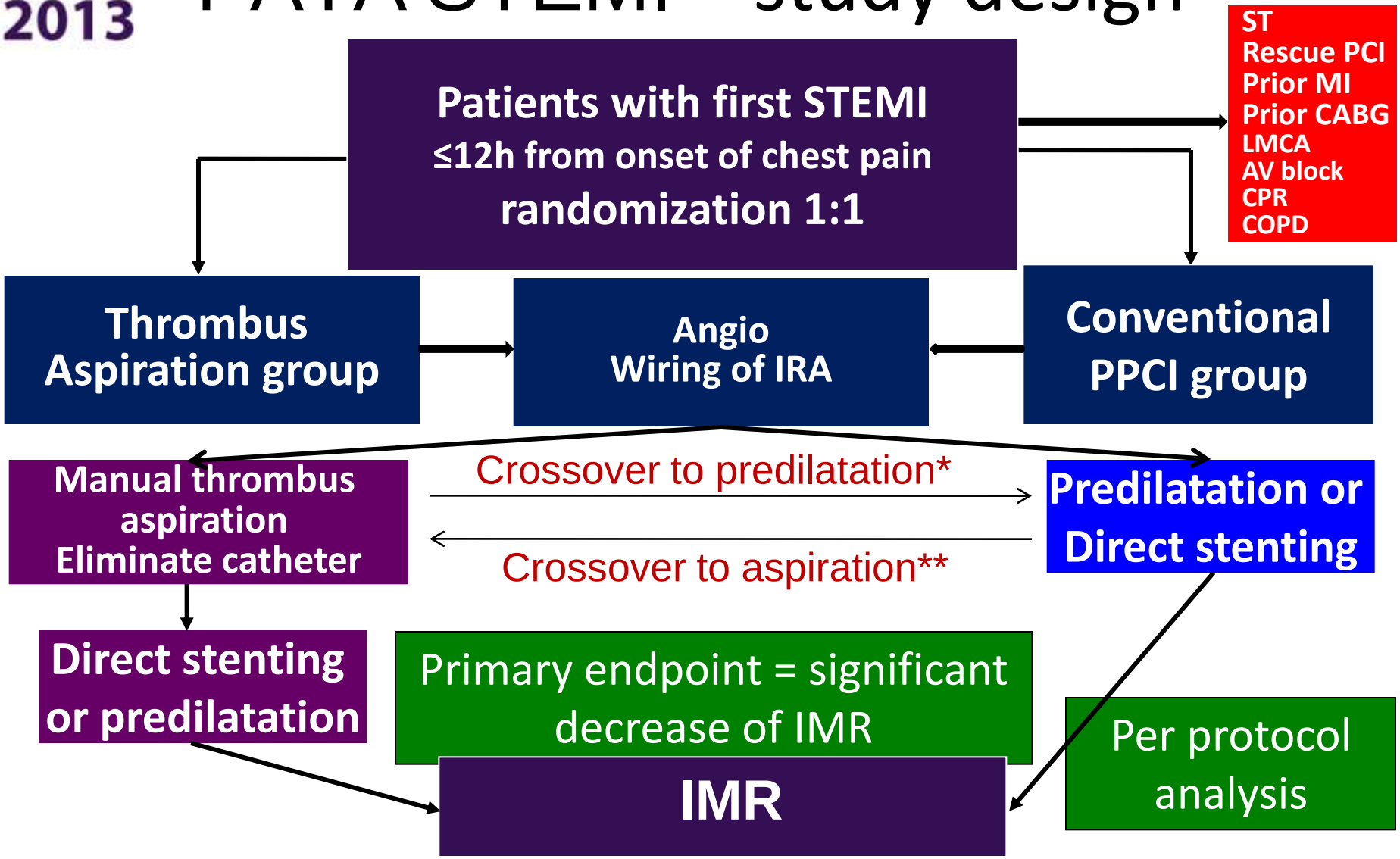
IMR= 63x0,20=12,6 U

CV Tmn res= 12,9 %
CV Tmn hyp= 7,9 %



Fearon WF, Circ 2003

PATA STEMI – study design



*Thrombus aspiration catheter did not cross the lesion site and did not aspirate thrombi.

**TIMI 0 or 1, or residual thrombus grade 4, or multipli thrombi persisted after predilatation.

Sample size calculation

Expected IMR in conventional PPCI* = **38±20 U**

Expected reduction by TA = **26%** (**28±20 U)**

Alfa error = 5%; Power 80%

Sample size to detect difference **128 patients**

***Fearon W et al., JACC, 2008**

PATA STEMI – patient flow

RANDOMIZATION 1:1

Coronary angiography

Coronary wire

Thrombus aspiration (N=66)		Conventional PCI (N=62)
Thrombus aspiration (N=60)	Crossover to predilatation (N=0) →	Predilatation (N=30)
	← Crossover to aspiration (N=10)	
Gentle predilatation (N=6)		
Stent implantation (N=68) Direct stenting (N=58) PTCA (N=4) TA alone (N=4)		Stent implantation (N=51) Direct stenting (N=21) PTCA (N=1)
IMR (N=76)		**IMR** (N=52)

Final angiogram N=128

ECG at 60 min N=128

Echo ≤24h N=127 and at 4 mo N=125

Baseline characteristics

	Thrombus aspiration (N=76)	Conventional (N=52)	P value
Clinical characteristics			
Age	59,0±11,0	59,9±11,2	0,88
Male	50 (64,9%)	38 (73,1%)	0,94
Body mass index	26,8±3,86	27,9±4,56	0,41
Diabetes	9 (11,8%)	5 (9,6%)	0,78
Hypertension	39 (51,3%)	28 (53,8%)	0,86
Hypercholesterolemia	17 (22,9%)	14 (27,4%)	0,67
Total ischemic time, min	190 (140-300)	175 (120-260)	0,12
System delay*, min	100 (65-165)	105 (65-145)	0,62
Killip class II	4 (5,2%)	3 (3,9%)	0,5
Angiographic characteristics			
LAD	31 (40,8%)	22 (42,3%)	0,9
TIMI flow grade			
0 or 1	60 (78,9%)	41 (78,8%)	1
2	9 (11,8%)	6 (11,5%)	1
3	7 (9,2%)	5 (9,6%)	1
Thrombus length	10.5±7.48	7.04±4.81	0,014

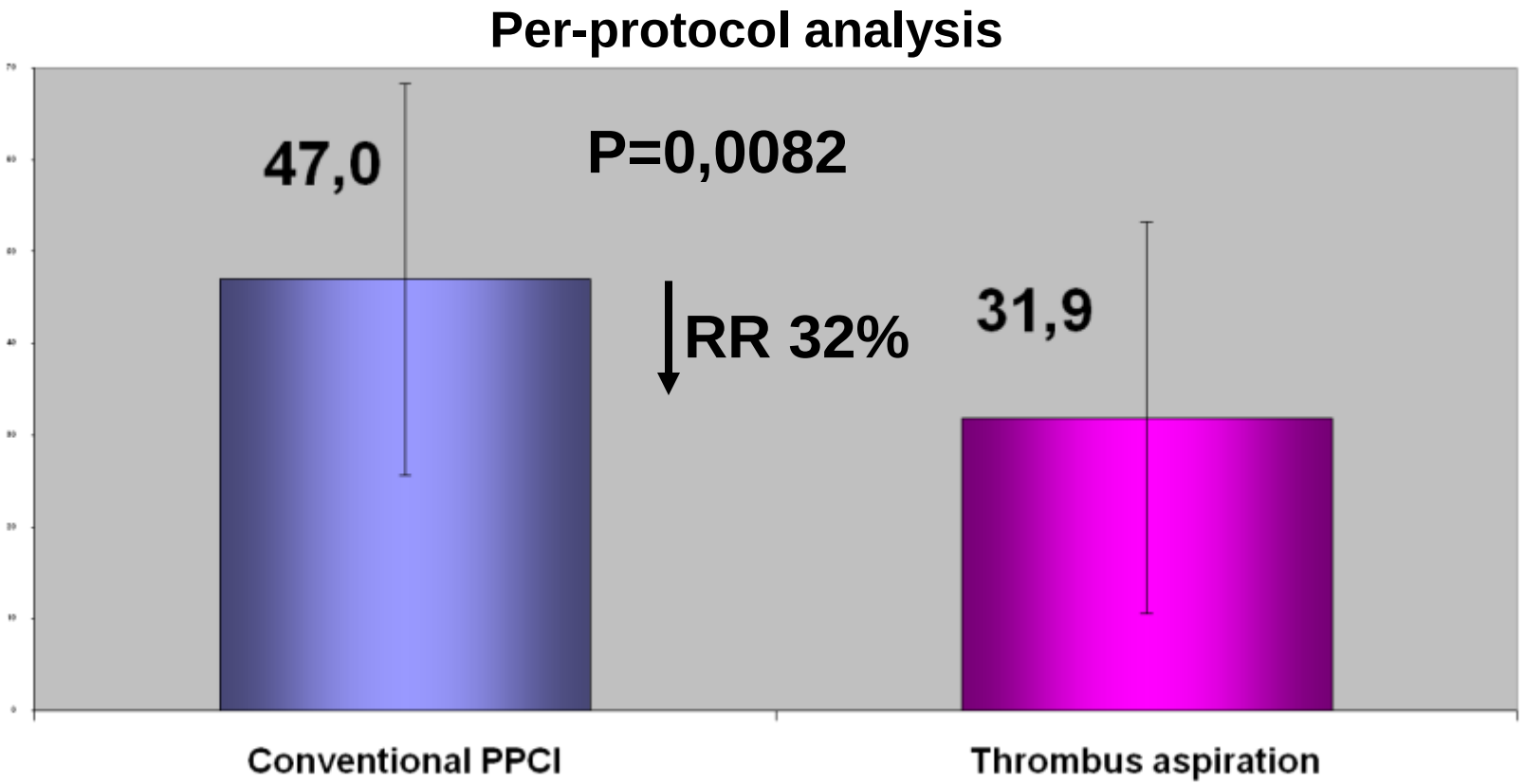
*time from the first medical contact to the first balloon inflation or aspiration.

Procedural characteristics

	Thrombus aspiration (N=76)	Conventional (N=52)	P value
Procedural characteristics			
Fluoroscopy time	13.2±7.76	8.9±5.00	0,005
GP IIbIIIa inhibitor	24 (31,6%)	10 (19,2%)	0,15
Stent implantation	68 (89,5%)	51 (98,1%)	0,08
Stent length, mm	21,2±5,4	21,5±5,1	0,72
TIMI flow grade after wire			
0 or 1	39 (51,3%)	16 (30,8%)	0,029
2	17 (22,4%)	25 (48,1%)	0,004
3	20 (26,3%)	11 (21,1%)	0,54
TIMI after TA/predilatation			
0 or 1	1 (1,4%)	2 (6,7%)	0,20
2	8 (10,8%)	2 (6,7%)	0,72
3	65 (87,8%)	26 (86,6%)	1
TIMI final			
2	4 (5,3%)	2 (3,8%)	1
3	72 (94,7%)	50 (96,2%)	1
Periprocedural complications			
Distal embolizations*	11 (14,5%)	8 (15,4%)	0,9
Side branch occlusion	1 (1,3%)	4 (7,7%)	0,16

*3 pts with crossover had distal embolizations (10,5 vs 21,2, P=0,09).

Primary endpoint
index of microcirculatory resistance



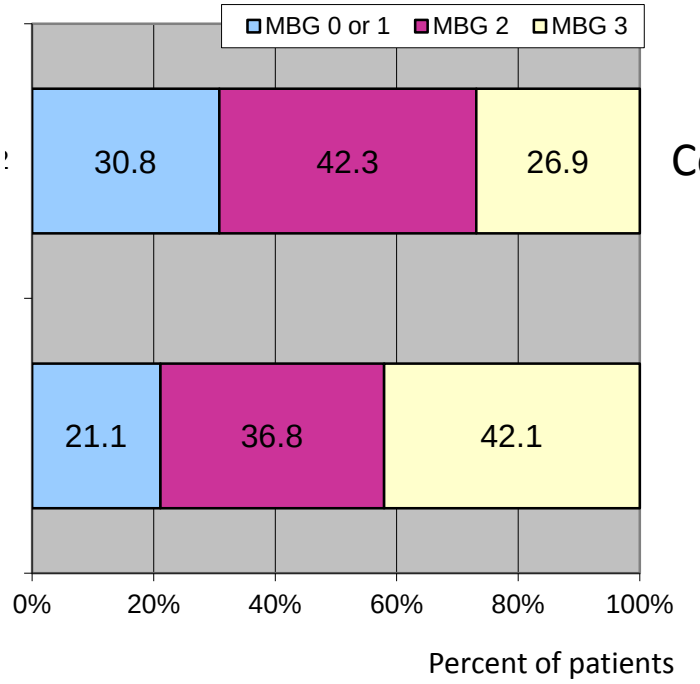
Adjacent non-IRA IMR 22,0±11,2 U vs. contralateral non-IRA IMR 25,8±17,9 U, p=0,3

CV Tmn rest 15,3±8,9%; CV Tmn hyp 15,1±8,1%

Intention-to-treat analysis: IMR 42,4±36,1 vs. 32,0±22,4 U, P=0,020

Angiographic and ECG signs of myocardial reperfusion

Myocardial blush grade

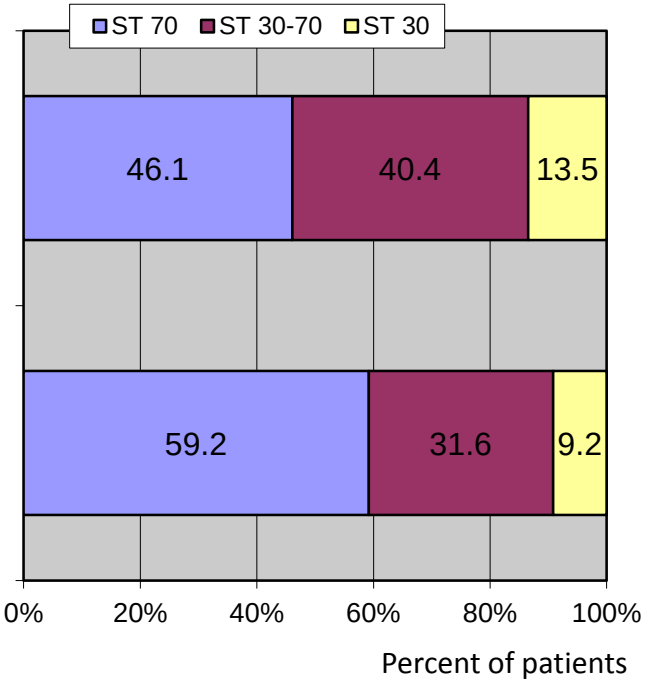


Conventional PCI

Thrombus aspiration

MBG 0 or 1: RR 0,68 (95% CI 0,38 to 1,24; p=0,21)

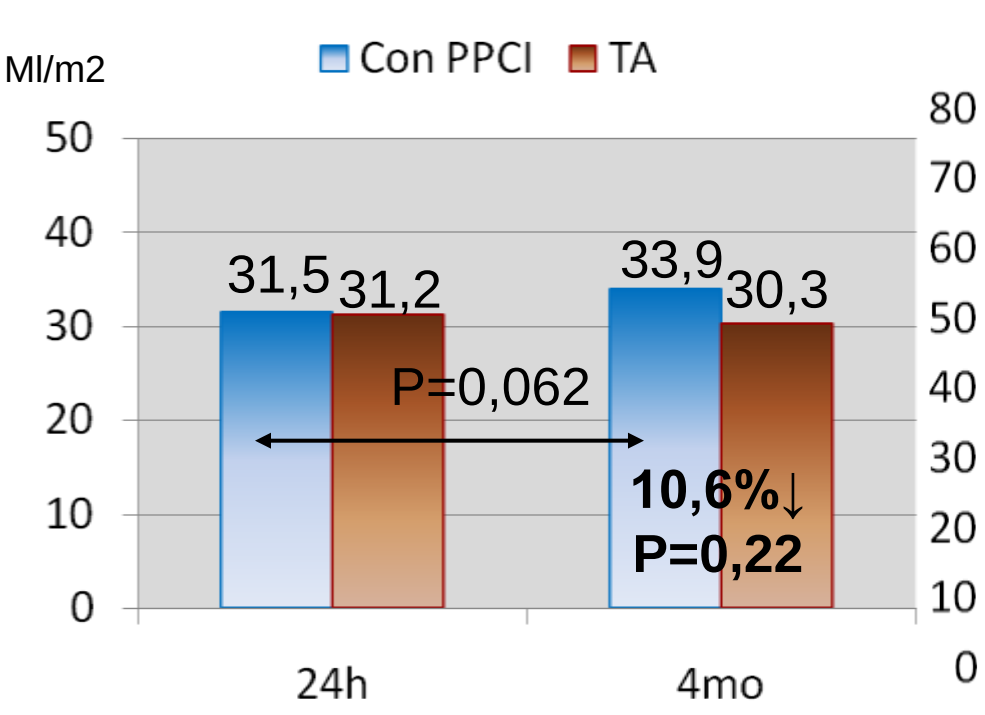
Resolution of ST-segment elevation



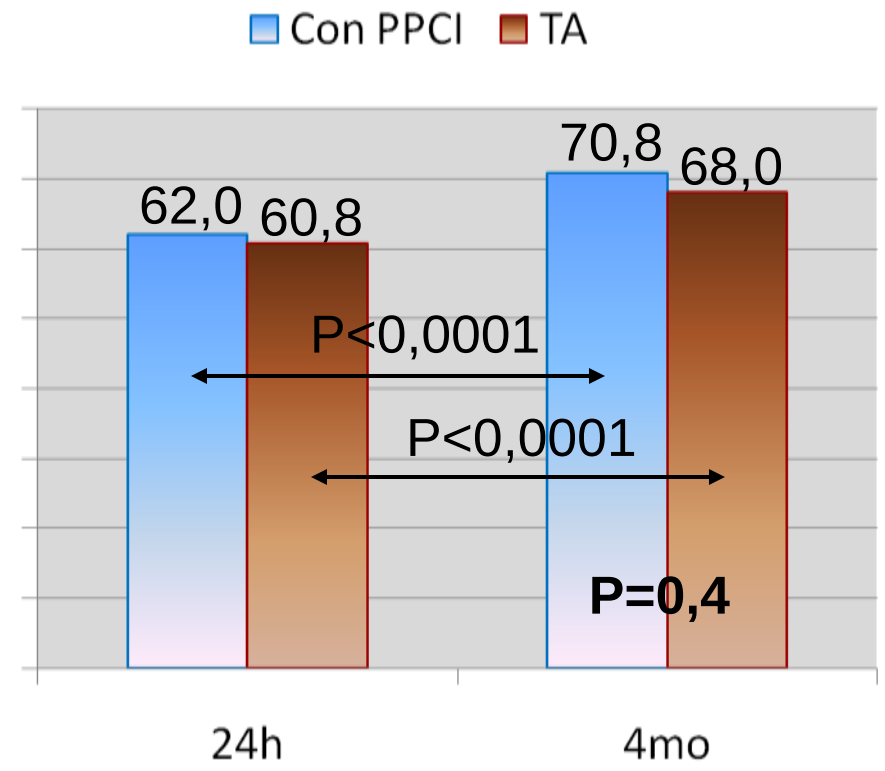
ST >70%: RR 1,28 (95% CI 0,91 to 1,82; p=0,16)

Histopathological examination confirmed successful thrombus aspiration in 90,8% of patients.

Echocardiographic analysis



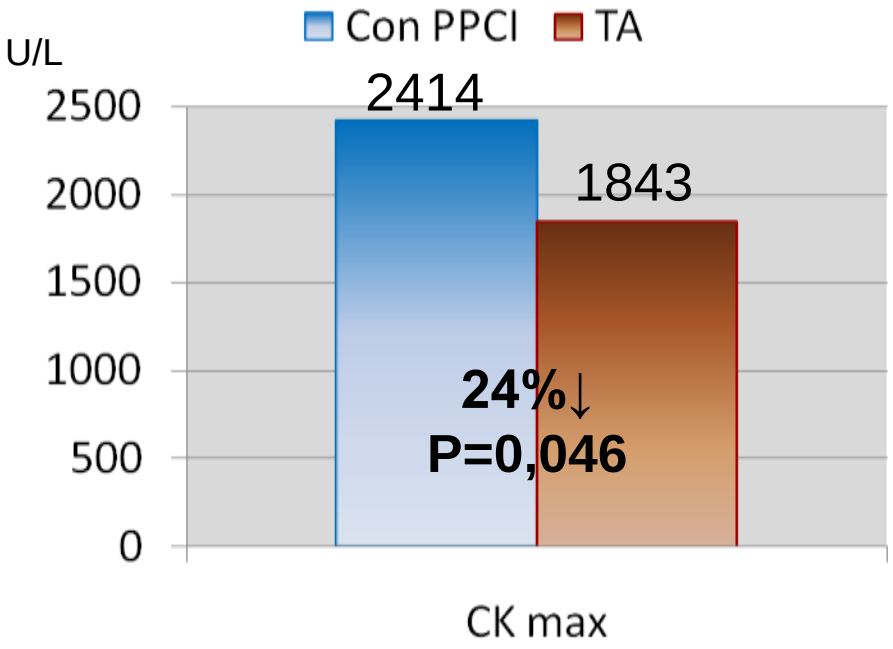
LV ESV/BSA

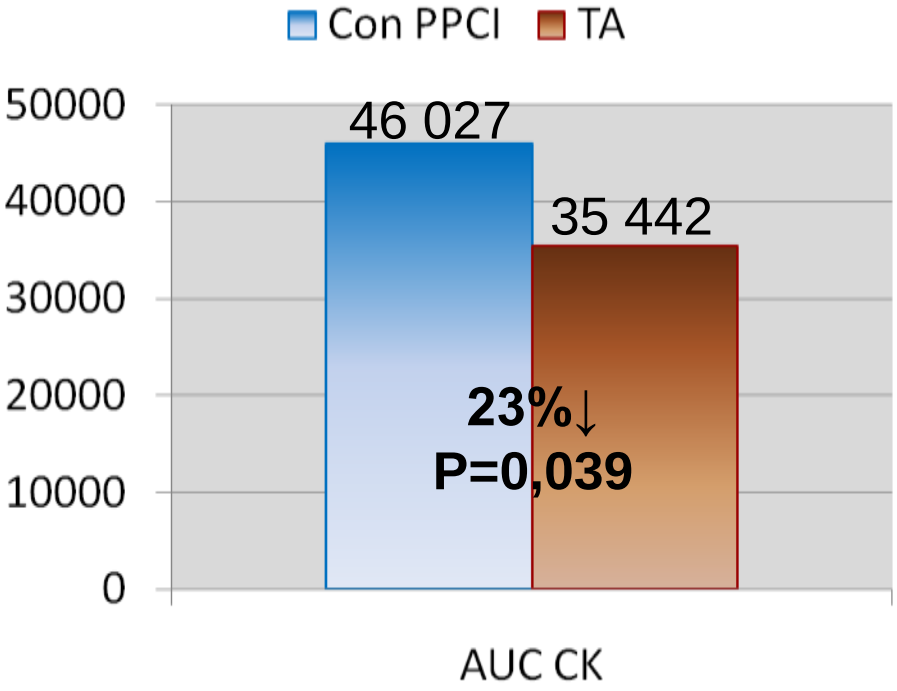


LV EDV/BSA

LV ESV (ml); LV EDV (ml); BSA (m^2)

Infarct size





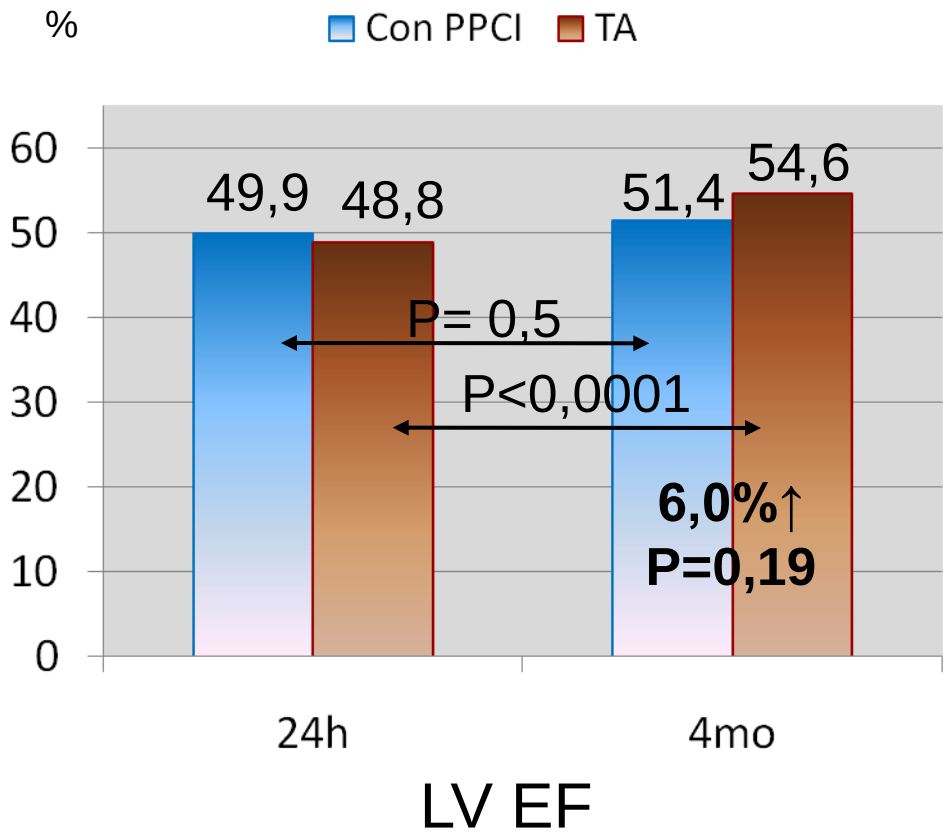
Median CK max

Con PPCI: IQR 114 – 7310 U/L
TA: IQR 72 – 5765 U/L

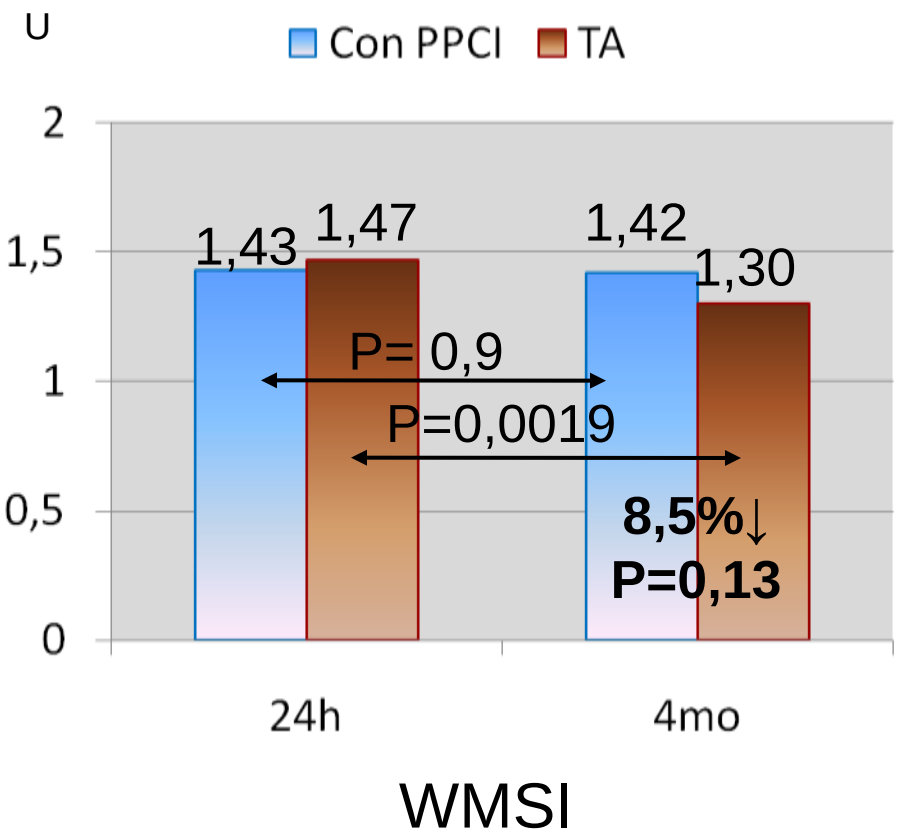
Median AUC CK

Con PPCI: IQR 5760 – 159135 U/L
TA: IQR 1395 – 108222 U/L

Echocardiographic analysis



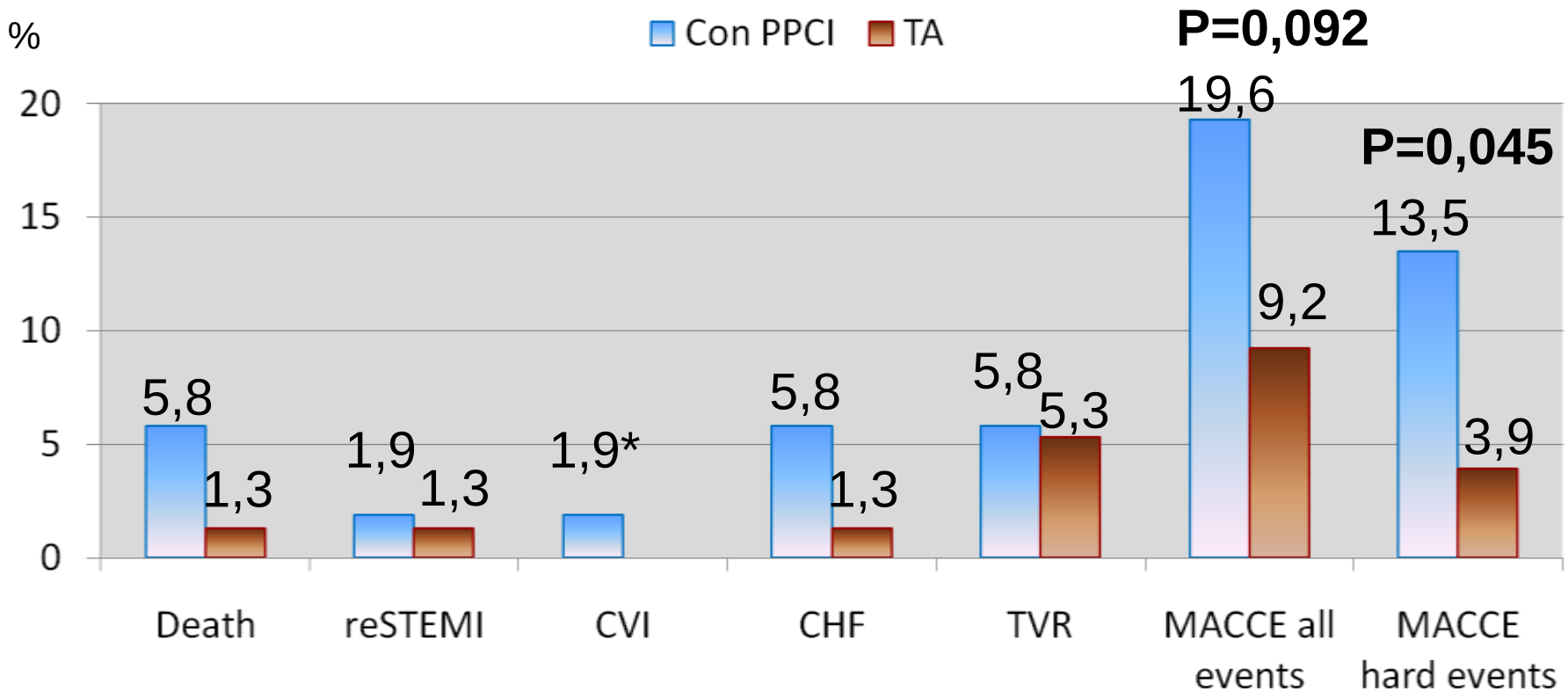
LV EF



WMSI

LV EF (%); LV WMSI = wall motion score index

Clinical FU at 9 months



MACCE rate at 9 months

MACCE (death, reMI, stroke, CHF or TVR): Con PPCI 3 deaths (2 sudden deaths=stent thrombosis possible and 1 stroke). 1 reSTEMI (stent thrombosis definite, TVR), 3 CHF and 3 TVR.
TA 1 death (sudden death), 1 reSTEMI, 1 CHF and 4 TVR (2 TLR).

*1 patient had CVI and death; CHF=congestive heart failure

Regression model on log-transformed IMR

Parameter	Estimate*	95% Lower Limit	95% Upper Limit	p-value
Aspiration vs. Con. PPCI	0,7515	0,610	0,926	0,0076
DBP	1,012	1,002	1,022	0,0166
CK max (per 1000 units)	1,0888	1,013	1,170	0,0213
Age	1,0169	1,008	1,026	0,0005

Thrombus aspiration is independent predictor of lower IMR
(36,11 U; 95%CI 30,74-42,41 vs. 27,14 U; 95%CI 23,79-30,95, P=0.0076).

*Per increase of 1 unit of the covariate, the IMR increases with the estimate as a FACTOR

Conclusion

- Manual thrombus aspiration reduces microcirculatory resistance indicating improved myocardial perfusion compared to conventional PPCI in patients with STEMI.

- At mid term clinical follow up, the rate of hard adverse cardiac events is lower in thrombus aspiration group compared to conventional PPCI group.

- Further studies powered for clinical outcomes are needed to confirm significance of our findings.

Study investigators

Cath Lab Staff

Dejan Orlic

Goran Stankovic

Branko Belelsin

Milan Dobric

Milorad Zivkovic

Miodrag Ostojic

Coronary physiology

Dejan Orlic

Miodrag Ostojic

Branko Beleslin

Milan Dobric

ECG analysis

Vladan Vukcevic

Milorad Zivkovic

Dejan Orlic

Angiographic analysis

Sinisa Stojkovic

Vladan Vukcevic

Milan Nedeljkovic

Dejan Orlic

Echo analysis

Milorad Tesic

Danijela Zamaklar

Histopathologic analysis

Milica Borovic

SPECT

Dragana Sobic-Saranovic

Data monitoring and analysis

Goran Stankovic

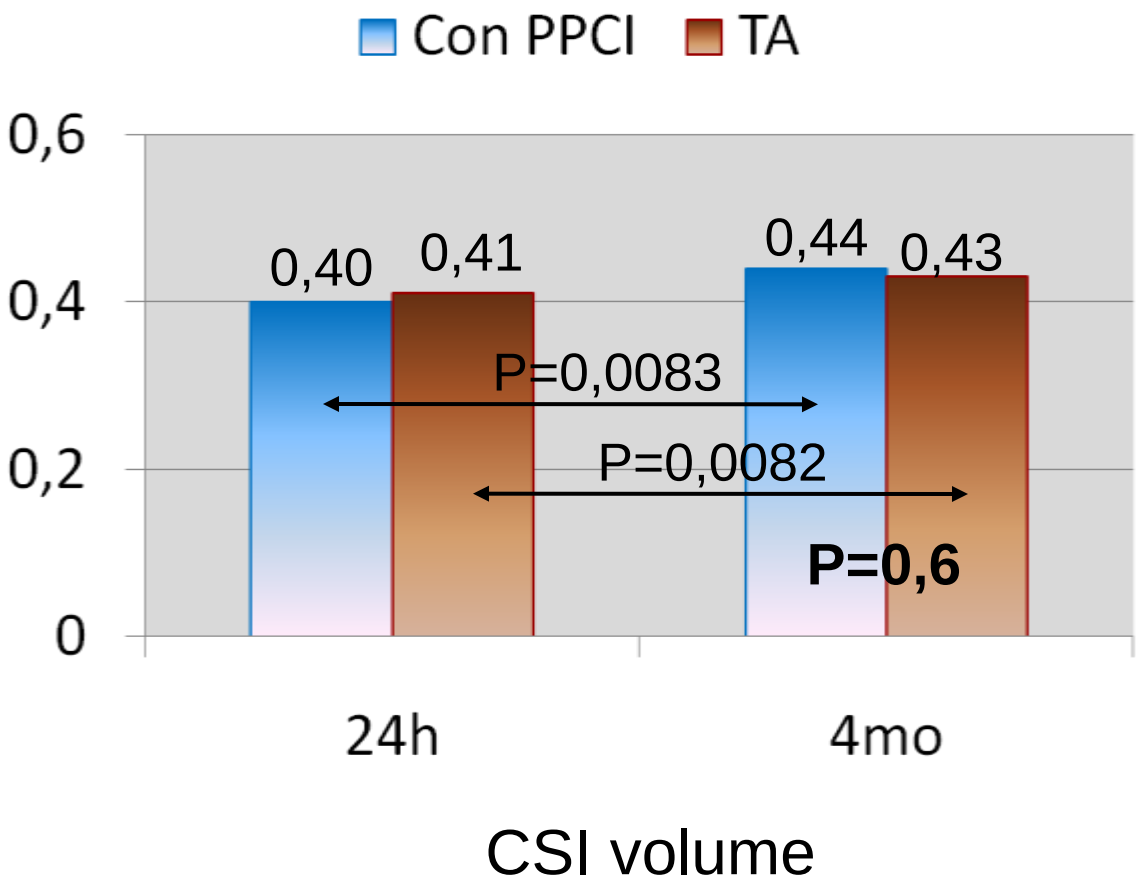
Dejan Milasinovic

Dejan Orlic

Cardiology clinic, Institute for histology, Institute for nuclear medicine
Clinical center of Serbia, School of medicine, University of Belgrade

Back-up slides

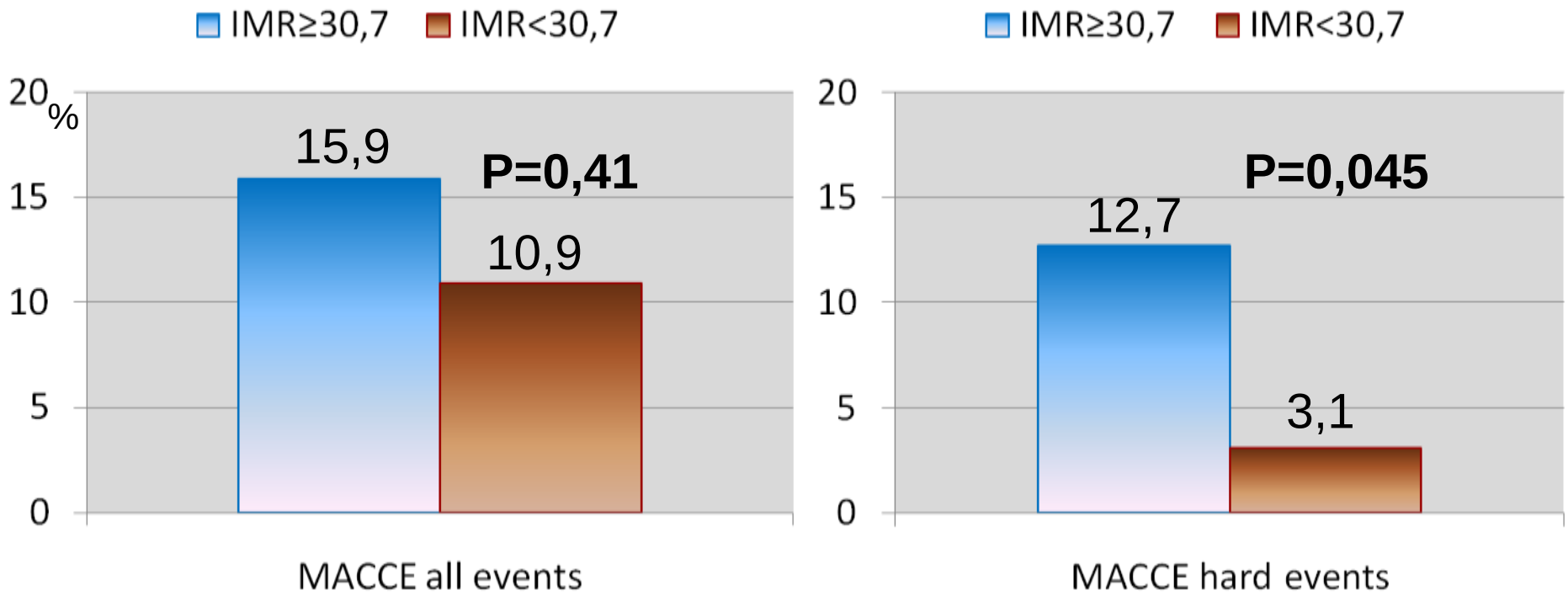
Echocardiographic analysis



CSI = cardiac sphericity index

IMR and MACCE rate

Median IMR 30,7 U



MACCE rate at 9 months

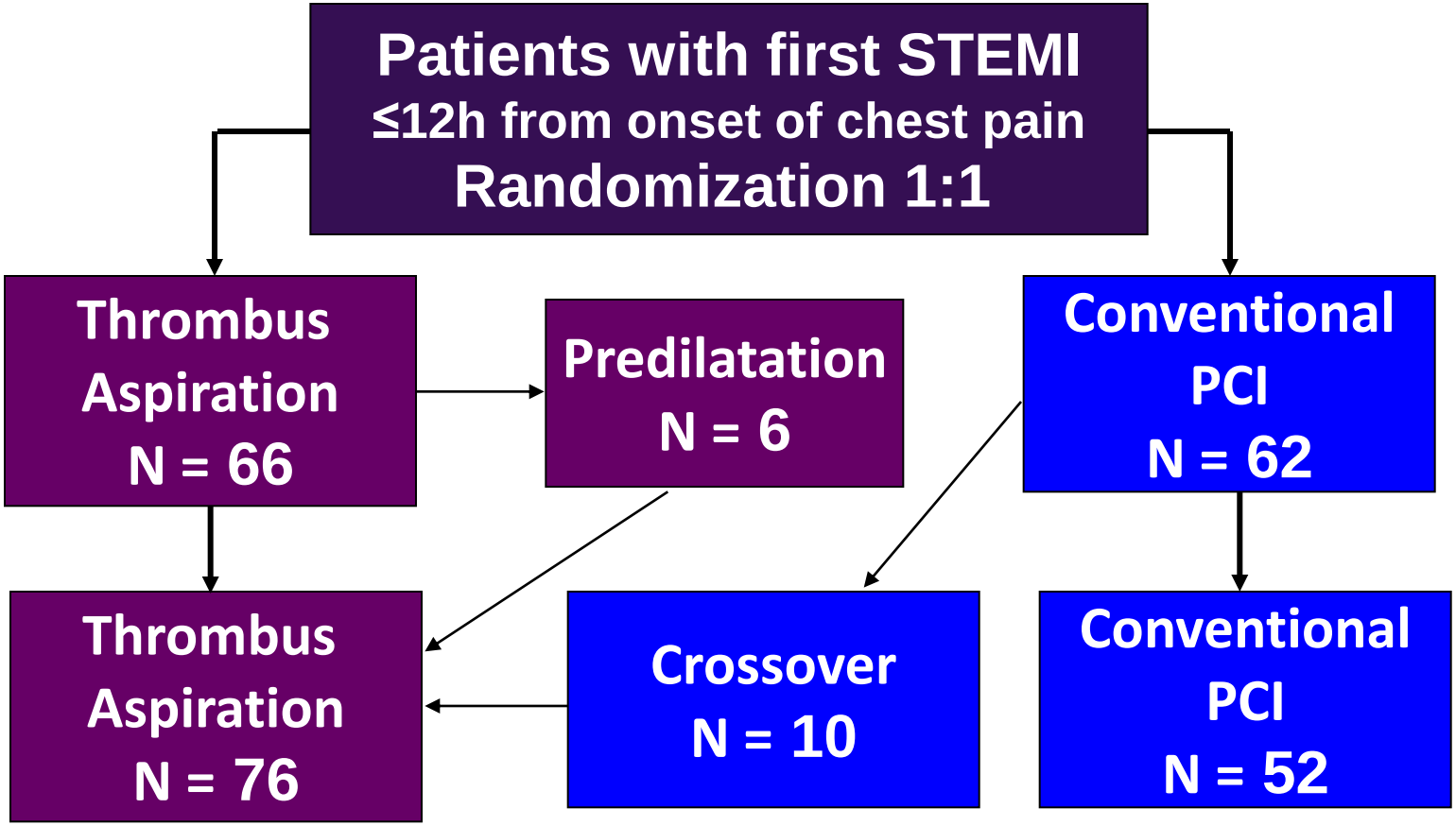
INCLUSION CRITERIA

- Consecutive patients aged > 18 years
- First STEMI (≥ 2 mm of ST-segment elevation in ≥ 2 contiguous leads)
- Total ischemic time <12h
- Hemodynamic stability

EXCLUSION CRITERIA

- Rescue PCI
- Stent thrombosis
- Prior CABG
- CPC resuscitation
- Advanced AV block
- Severe COPD
- Distal LMCA stenosis (non-IRA)

PATA STEMI



Crossover to aspiration: TIMI 0 or 1 after balloon inflation or thrombus >2 vessel diameter

Primary Endpoint = significantly decreased index of microcirculatory resistance

Background

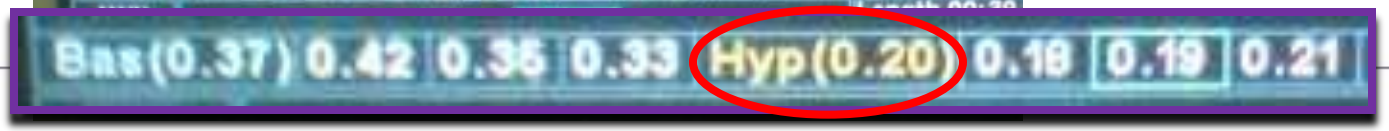
Rmyo= ΔP/F= Pd-Pv/1/Tmn
F≈1/Tmn
Pv≈0 mmHg
IMR= Pd x Tmn
Tmean= 3 boluses of saline at room t injected into coronary artery during max hyperemia.

Specific, reproducible measure of coronary microcirculatory status less subject to hemodynamic variation (changes in heart rate, blood pressure, and cardiac contractility).

IMR= 63x0,20=12,6 U

CV Tmn bas= 12,9 %

CV Tmn hyp= 7,9 %



End points

Primary endpoint

- significant decrease of IMR

Secondary endpoints

- blush grade
- ST-segment resolution
- infarct size by enzyme release
- LV remodeling indices by echo
- MACCE rate at 9 months

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