Multivessel coronary disease diagnosed at the time of primary PCI for STEMI: complete revascularization versus conservative strategy. PRAGUE 13 trial

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On behalf of the PRAGUE-13 Investigators

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Potential conflicts of interest

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☑ I do not have any potential conflict of interest

PRAGUE-13 trial

Primary PCI of the infarct artery is a method of choice in STEMI treatment.

Aim: To find the optimal management of STEMI patients who have at least one significant (≥70%) stenosis of non-culprit coronary artery.

PRAGUE-13 trial

Type of study: Open, prospective, randomized, multicenter, two-branch trial.

Inclusion criteria:

· Patient with acute myocardial infarction with ST segment elevation (STEMI)

· Successful primary PCI of infarct-related stenosis (TIMI flow grades II-III)

· At least one stenosis (≥70%) of "non-infarct" coronary artery (arteries) found by coronary angiography, diameter of artery ≥ 2,5mm

· Enrolment ≥48 hours following onset of symptoms

Exclusion criteria:

· Stenosis of the left main of left coronary artery ≥ 50%

· Hemodynamically significant valvular disease

· Patients in cardiogenic shock during STEMI

· Hemodynamic instability

· Angina pectoris > grade 2 CCS lasting 1 month prior to STEMI

Interventional cardiologists had to agree, that both treatment options are acceptable.

Randomization – 2 groups

1. Complete revascularization of all significant stenoses of "non-infarct" coronary arteries (staged PCI performed between 3rd-40th day after primary PCI)

2. Conservative management -standard guideline-based medical therapy

Baseline characteristics

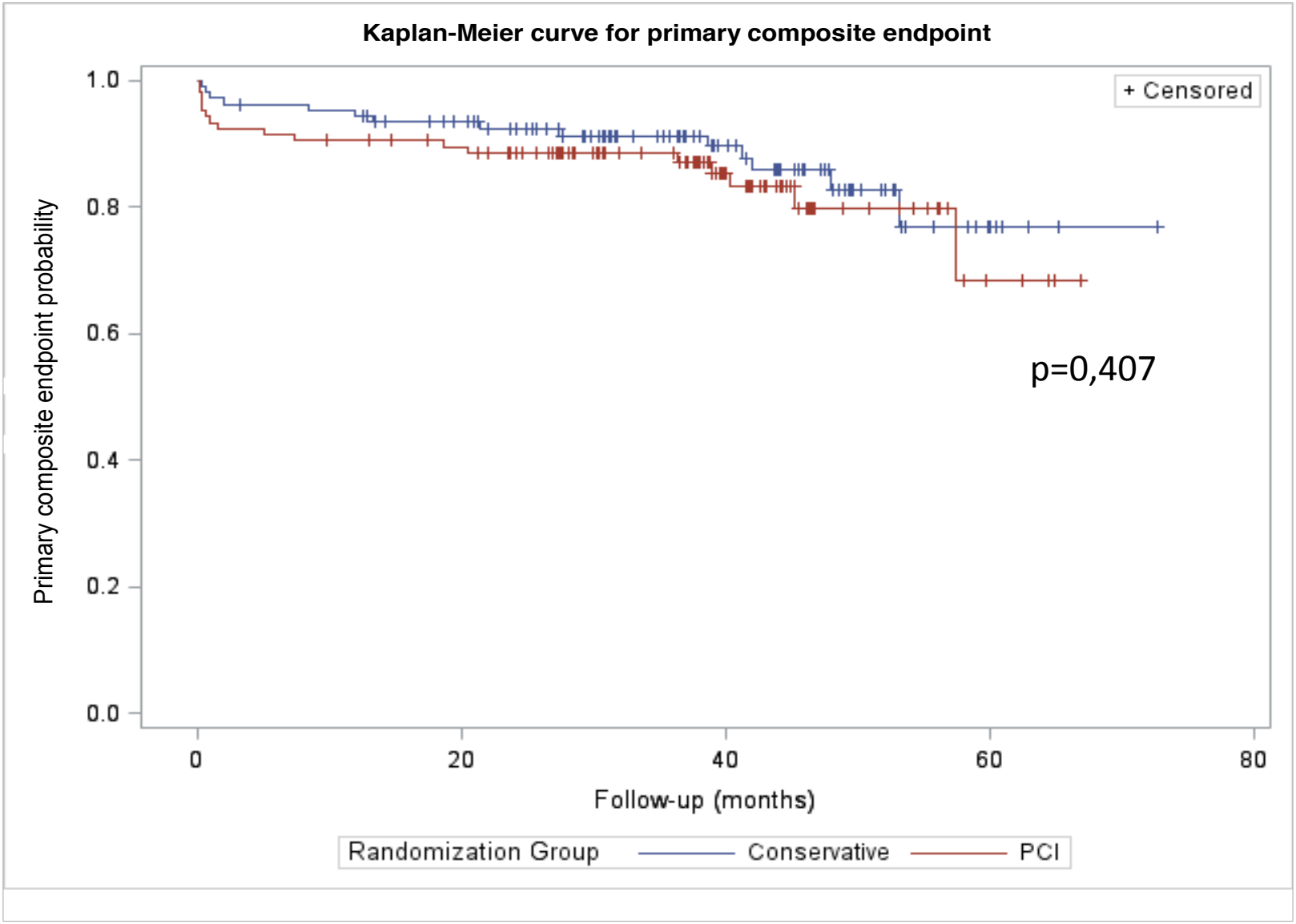
214 patients (106 staged MV-PCI, 108 conservative after pPCI) enrolled in six centers from 2009 till 2013
Follow-up 38 months (median)

No significant differences between baseline characteristics of both groups

Low risk patients

Ejection fraction at discharge (%)	48,7±8,9
Killip class	1,1 ±0,3
Symptom onset to primary PCI time (min)	229±64
LAD as infarct artery (%)	35
Non-culprit artery stenosis ≥95% (%)	6,1
Non-culprit stenosis (%)	80±10,1

Primary composite endpoint



Primary composite endpoint

	PCI (n=106)	Conservative (n=108)	Hazard ratio (95% CI)	p-value
All-cause mortality / nonfatal MI / stroke	17 (16,0%)	15 (13,9%)	1.35 (0.66 - 2.74)	0.407
All-cause mortality	6 (5,7%)	7 (6,5%)	0.91 (0.30 - 2.70)	0.859
Nonfatal MI	11 (10,4%)	8 (7,4%)	1.71 (0.66 - 4.41)	0.269
Stroke	0	3 (2,8%)		

4 (3,8%) periprocedural infarctions in PCI group with good prognosis.

Secondary endpoints

	Hazard ratio (95% CI)	p-value
Hospitalization for unstable angina	0.52 (0.19 - 1.40)	0.193
Crossover to another treatment group	0.25 (0.09 - 0.68)	0.006
Revascularization of non-infarct artery	0.51 (0.24 - 1.11)	0.089
Cardiovascular mortality	1.34 (0.30 - 6.01)	0.699
All-cause mortality + nonfatal myocardial infarction + hospitalization for unstable angina	1.03 (0.58 - 1.84)	0.921
All-cause mortality + nonfatal myocardial infarction + revascularization	0.86 (0.53 - 1.40)	0.538
Hospitalization for heart failure	0.68 (0.11 - 4.07)	0.672
Cardiovascular mortality + nonfatal myocardial infarction + revascularization	0.92 (0.56 - 1.53)	0.754

No non-infarct lesion progressed to myocardial infarction during follow-up. Progression of studied non-infarct lesions was very rare.

Why is PRAGUE-13 different?

- AP > 1 month before pPCI – exclusion criterium in PRAGUE-13
- More selected pts in PRAGUE-13
- Few DES in PRAGUE-13
- PRAMI (100%), CvLPRIT (60%) non-culprit lesions treated during primary PCI – periprocedural MI cannot be diagnosed

Conclusion

This trial found no difference (not even a trend) favouring staged multivessel PCI over culprit-only primary PCI in STEMI.

Larger trials are needed to clarify the revascularization strategy in STEMI patients with multivessel disease.