PRAGUE-18 Study: Randomized comparison of ticagrelor versus prasugrel in STEMI.

Outcomes during the first month.

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Declaration of Interest

- Others (occasional speakers honoraria)

Study aims

1. „Head-to-head“ comparison of prasugrel vs. ticagrelor in STEMI treated by p-PCI
2. Safety of (economically motivated) post-discharge switch from prasu/tica to clopidogrel.

Entry criteria

Inclusion:

- STEMI (or non-STEMI with ongoing ischemia)
- Emergent CAG / pPCI
- Signed informed consent.

Exclusion criteria:

- History of stroke
- Serious bleeding during previous 6 months
- Indication for OAC
- Prerandomization clopidogrel ≥300 mg
- Body weight <60 kg in a patient >75 years
- Moderate-to-severe liver disease
- Concomitant treatment with potent CYP3A4 inhibitors
- Known hypersensitivity to prasugrel or ticagrelor.

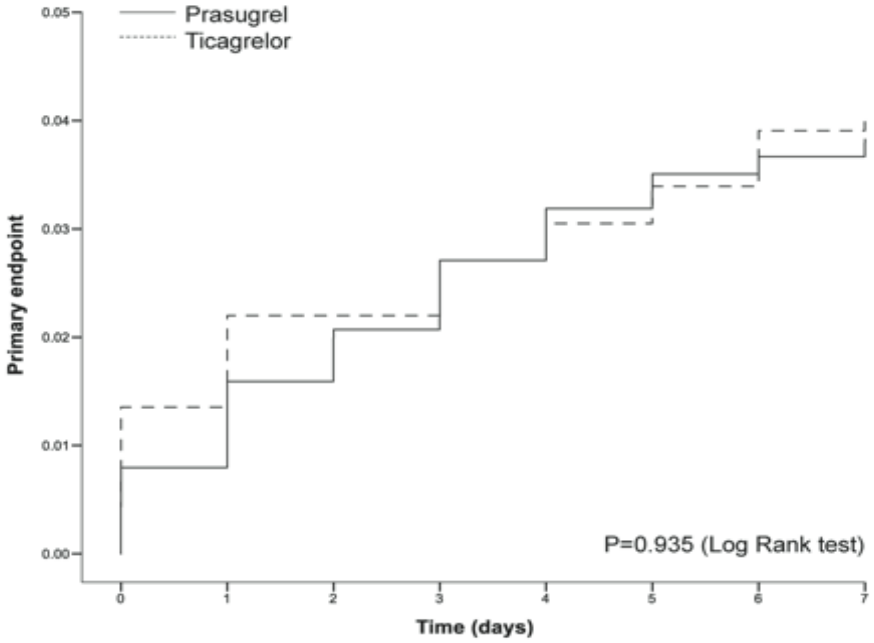
Methods

- Randomization immediately after arrival to PCI center: (A) prasugrel 60 mg orally followed by 10 mg / day (5mg / day if > 75 years or < 60 kg) for 1 year or (B) ticagrelor 180 mg orally followed by 90 mg b.i.d. for 1 year.
- Purely academic study, no industrial support
- Patients had to cover the costs of ticagrelor or prasugrel after hospital discharge as per local health care regulations.
- Thus, some patients decided to switch after discharge to clopidogrel (fully covered by local health care).
- The planned number of patients in the study was 2500 (total). Interrupted preliminarily for futility.

Baseline and procedural characteristics

	Prasugrel (n=634)	Ticagrelor (n=596)	P value
Females	22.9%	26.3%	0.157
Mean age	61.8 (42.7; 78.7)	61.8 (44.6; 79.8)	0.755
Killip III-IV class on admission	5.4%	4.8%	0.696
Known diabetes mellitus	20.0%	20.8%	0.736
Prior MI	7.4%	9.2%	0.249
Known chronic kidney disease	1.3%	1.3%	0.901
History of old serious bleeding (>6 mo)	0.8%	0.2%	0.219
GP IIb/IIIa inhibitors during PCI	19.4%	20.5%	0.639
Radial access	66.7%	66.1%	0.820
DES used	65.9%	64.4%	0.553

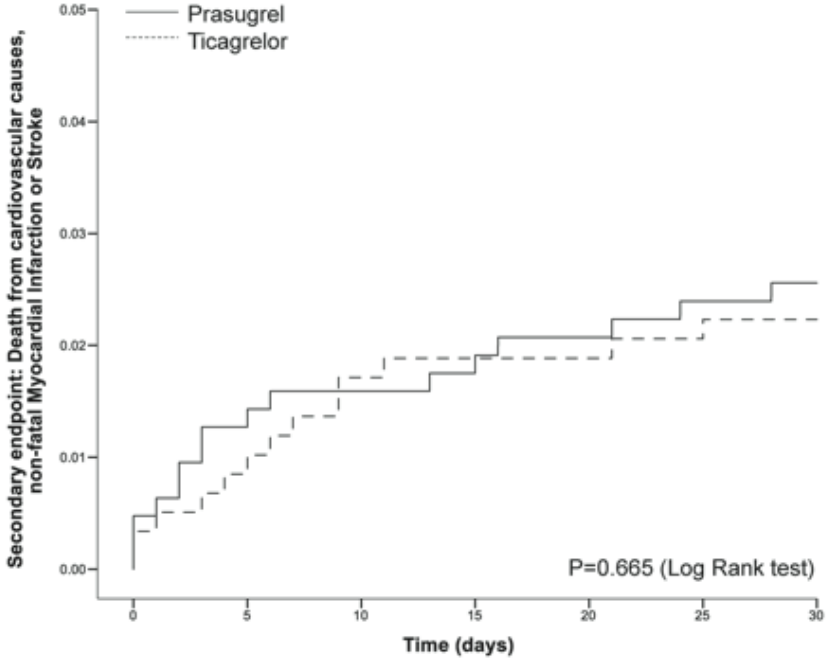
Primary end-point (7 days)



No at risk

Time (day)	1	2	3	4	5	6	7
Prasugrel (N=634)	629	624	621	617	614	612	611
Ticarelor (N=596)	588	583	583	580	578	576	573

Key secondary end point (30 days)



No at risk

Time (day)	5	10	15	20	25	30
Prasugrel (N=634)	626	623	622	619	617	616
Ticarelor (N=596)	591	585	583	583	582	580

Conclusions

The study did not show any difference between ticagrelor and prasugrel in the early phase of acute myocardial infarction treated by primary PCI.