Angioplasty Summit

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STEMI Now: Same Story, Different Tales
'Thrombus Aspiration before PCI: Selective Optional'
from the Experience of Korea Acute Myocardial Infarction Registry

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Kamir.or.kr

On-line Korea Acute Myocardial Infarction Registry: KAMIR

http://www.kamir.or.kr

Purpose of KAMIR Study

1. One-line registration for Korean AMI patients
2. Early detection for high risk patients
3. Risk factor documentation and analysis
4. New therapeutic strategy for AMI
5. Effective prevention strategy for AMI

KAMIR: Korea Acute Myocardial Infarction Registry

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Co-investigators: **55 primary PCI centers**

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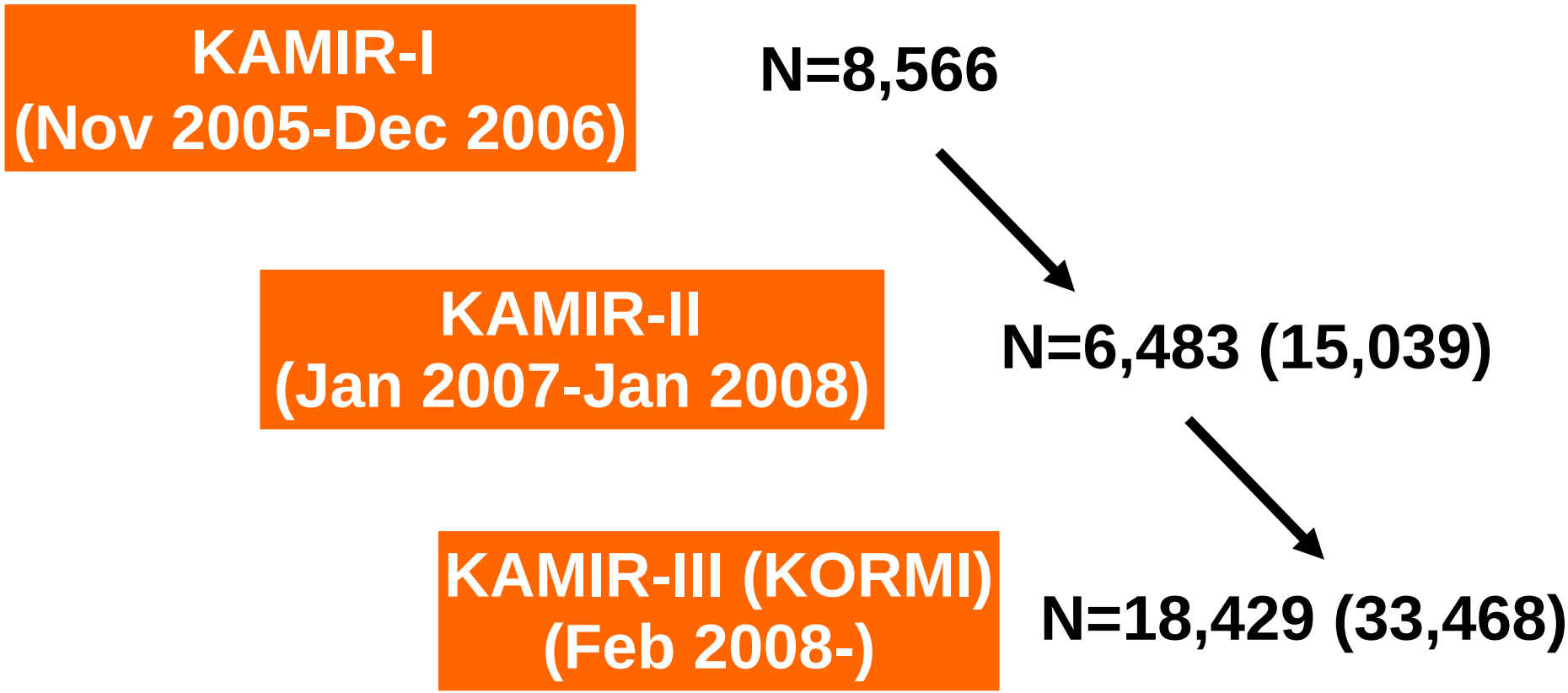
Three Phases of KAMIR Study



Background

- **TAPAS (Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study) , and EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) demonstrated that TA improved clinical outcomes as well as reperfusion status.**
- **American College of Cardiology / American Heart Association (ACC/AHA) guidelines for the management of patients with STEMI recommended thrombus aspiration (TA) as Class ⅡⅡa, Level of Evidence B.**

Background

- **A number of meta-analyses or randomized controlled trials (RCTs) have shown that TA did not improve clinical outcomes but improved only reperfusion surrogate endpoints.**
- **The role of thrombus aspiration (TA) as an adjunct to primary percutaneous coronary intervention (PPCI) remains a matter of controversy.**

Objective

- **The aim of this study is to investigate not only clinical impacts of TA, but also which settings were effective for reducing clinical events as subgroup analyses.**

Subjects and Methods

- **2,105 patients enrolled in the nationwide prospective Korea Acute Myocardial Infarction Registry (KAMIR) between Dec 2007 and Oct 2009.**
- **A cohort of 745 (35.4 %) patients who underwent TA during PPCI was compared with 1,360 (64.6 %) patients who underwent conventional PCI without TA.**

Subjects and Methods

- **Clinical outcomes at 12-month of overall enrolled patients and subgroups according to key variables were assessed using Cox regression models adjusted by propensity score.**
- **In this registry, manual thrombus aspiration devices such as Thrombuster® (Kaneka, Japan) were used and decision of whether to use depended on operators.**

Endpoint

- **Major adverse cardiac events (MACE)**
  - **Cardiac death**
  - **Non-fatal MI**
  - **Repeat revascularization.**
    - **Target lesion revascularization (TLR)**
    - **Target vessel revascularization (TVR).**

Statistical analysis

- All analyses were performed using SPSS software version 17.0 (SPSS Inc. Chicago, USA).
- The crude survival curves were made using the Kaplan-Meier method, and log-rank tests were applied to evaluate differences between the treatment groups.
- A propensity score was created to adjust confounding factors using a logistic regression model. Pretreatment variables which occurred before TA were included.
- Adjusted survival curves were calculated with the use of the Cox regression models adjusted by propensity score and important risk covariates which showed $p < 0.2$ in univariate analysis for end-points and other variables that have been reported to be associated with prognosis of patients with acute MI.

Baseline Characteristics

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Age (years)	62.6 ±12.9	61.0 ± 12.9	0.005
Male gender, n (%)	998 (73.4%)	585 (78.7%)	0.007
Body mass index (kg/m^2)	24.0 ± 3.2	24.2 ± 3.1	0.138
Risk factors			
Hypertention, n (%)	609 (45.6%)	344 (47.1%)	0.549
Diabetes Mellitus, n (%)	329 (24.7%)	172 (23.5%)	0.555
Hyperlipidemia, n (%)	155 (12.3%)	93 (13.2%)	0.571
Coronary artery disease, n (%)	148 (11.0%)	72 (9.8%)	0.413
Smoker, n (%)	828 (61.9%)	476 (65.5%)	0.115
Family history of heart disease, n (%)	102 (8.2%)	96 (14.0%)	<0.001

Baseline Characteristics

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Previous angina symptom before onset, n (%)	549 (40.8%)	220 (29.9%)	<0.001
Resuscitation prior to arrival, n (%)	25 (1.8%)	12 (1.6%)	0.863
Death on arrival, n (%)	0 (0%)	4 (0.5%)	0.016
Systolic blood pressure < 100, n (%)	143 (10.8%)	99 (13.9%)	0.044
Heart rate > 100, n (%)	108 (8.2%)	67 (9.4%)	0.362
Killip class > 1, n (%)	318 (24.3%)	268 (38.6%)	<0.001
Thrombolysis prior to PCI, n (%)	111 (8.2%)	39 (5.2%)	0.013
Left ventricular ejection fraction	52.4 ±13.6	50.9 ±19.8	0.043
Left ventricular ejection fraction < 35 %, n (%)	91 (7.2%)	42 (6.3%)	0.509
eGFR (mL/min/1.73m^2)	61.6 ± 30.5	58.8 ± 20.4	0.028
eGFR < 60, n (%)	708 (52.3%)	402 (54.5%)	0.336

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Medication in hospital			
Platelet GP Ⅱb/Ⅲa inhibitor, n (%)	322 (24.4%)	199 (27.1%)	0.186
Low molecular weight heparin, n (%)	241 (19.7%)	122 (21.0%)	0.530
Medication at discharge			
Asprin, n (%)	1296 (98.9%)	717 (98.5%)	0.538
Clopidogrel, n (%)	1301 (98.9%)	714(98.5%)	0.537
Cilostazol, n (%)	346 (27.3%)	177 (24.7%)	0.203
Ca channel blocker, n (%)	82 (6.5%)	42 (5.9%)	0.630
Beta blocker, n (%)	1102 (84.7%)	616 (85.6%)	0.649
ACE-I or ARB, n (%)	1148 (87.5%)	638 (87.8%)	0.889
Nitrate, n (%)	657 (51.4%)	297 (41.4%)	<0.001
Nicorandil, n (%)	280 (22.2%)	110 (15.4%)	<0.001
Diuretics, n (%)	221 (17.5%)	140 (19.6%)	0.249
Spironolactone, , n (%)	106 (8.4%)	84 (11.8%)	0.017
Statin, n (%)	984 (75.6%)	559 (77.3%)	0.384
Fibrate, n (%)	5 (0.4%)	6 (0.8%)	0.221

Coronary Angiographic Characteristics

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Left main complex, n (%)	37 (2.7%)	12 (1.6%)	0.130
Multivessel, n (%)	676 (50.1%)	355 (48.2%)	0.436
Infarct-related artery			
Left main trunk, n (%)	17 (1.3%)	9 (1.2%)	1.000
Left anterior descending, n (%)	733 (54.4%)	340 (46.1%)	<0.001
Left circumflex, n (%)	155 (11.5%)	75 (10.2%)	0.381
Right coronary artery, n (%)	442 (32.8%)	313 (42.5%)	< 0.001
Type B2/C lesion, n (%)	945 (79.0%)	470 (70.0%)	<0.001
Preprocedural TIMI flow grade 0, n (%)	692 (54.7%)	450 (63.3%)	<0.001
Postprocedural TIMI flow grade 3, n (%)	1197 (94.3%)	629 (90.5%)	0.002
Supportive treatment, n (%)	192 (14.2%)	109 (14.9%)	0.696

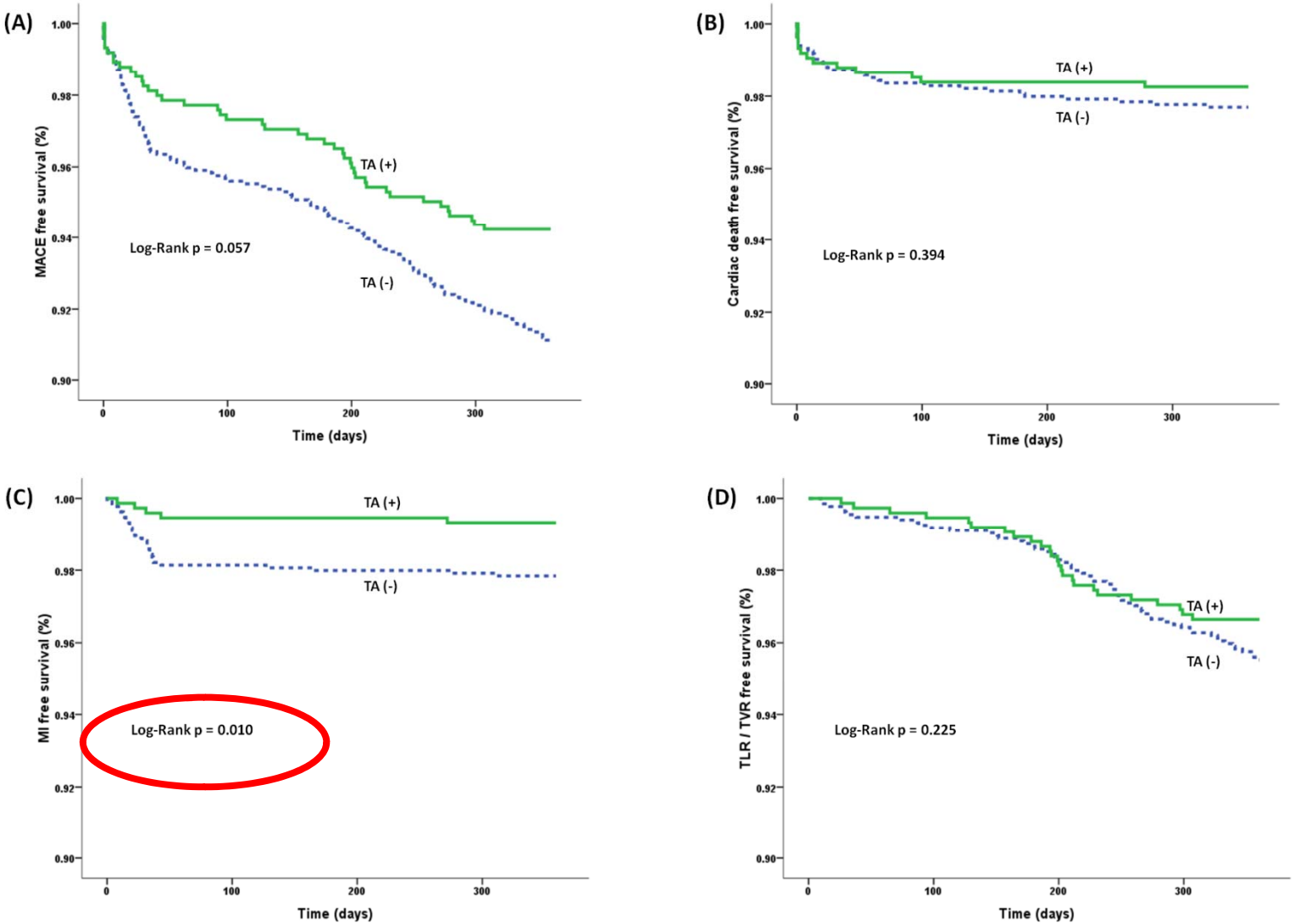
Procedural Characteristics

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Symptom to balloon time, median (IQR), hours	5.7 (3.2-12.6)	4.7 (2.7-12.08)	0.100
Symptom to balloon time < 4 hours, n (%)	509 (39.4%)	311 (45.3%)	0.013
Door to balloon time, median (IQR), minutes	71.0 (45.0-172.8)	55.0 (35.0-95.0)	<0.001
Door to balloon time < 90 minutes, n (%)	814 (62.1%)	480 (69.4%)	0.001
Use of IVUS, n (%)	263 (57.7%)	193 (27.0%)	<0.001
Administration of GP IIb/IIIa inhibitor, n (%)	402 (29.7%)	237 (32.2%)	0.253
Drug-eluting stent implantation, n (%)	1073 (85.0%)	605 (88.7%)	0.027
Stent length ≧ 25 mm, n (%)	474 (37.3%)	260 (38.1%)	0.732
Stent diameter ≦ 2.5 mm, n (%)	89 (7.0%)	42 (6.1%)	0.508
Success of primary PCI, n (%)	1293 (96.9%)	697 (97.2%)	0.688
Intraprocedural complications, n (%)	225 (16.6%)	110 (14.9%)	0.319
Supportive treatment, n (%)	192 (14.2%)	109 (14.9%)	0.696

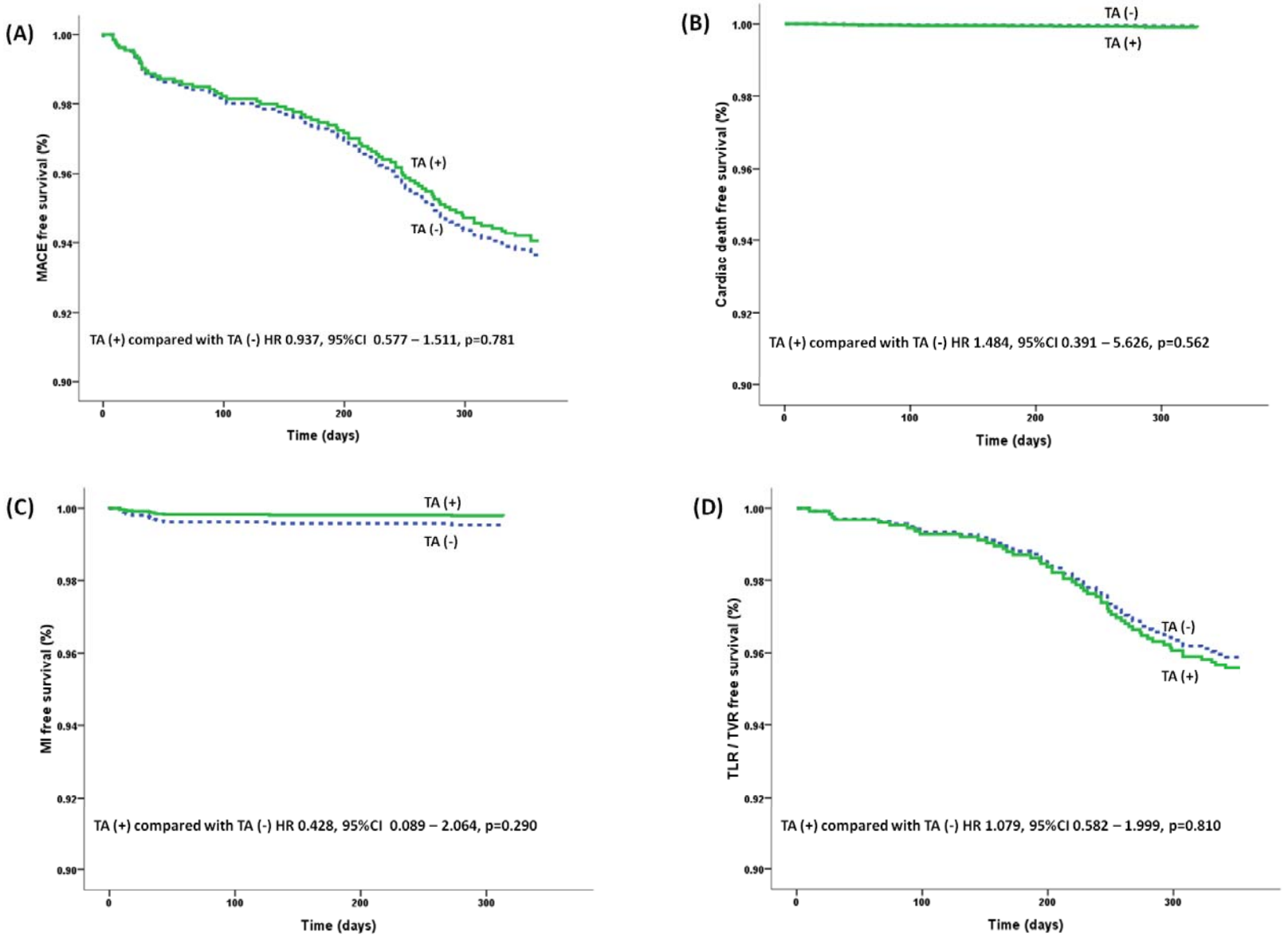
Clinical Outcomes at 12-Month

	TA (-) (n = 1,360)	TA (+) (n = 745)	*P* value
Total Major adverse cardiac events, n (%)	134 (10.0%)	56 (7.5%)	0.068
Cardiac death, n (%)	31 (2.3%)	13 (1.7%)	0.430
Non-fatal myocardial infarction, n (%)	29 (2.2%)	5 (0.7%)	0.010
Repeat revascularization, n (%)	60 (4.5%)	25 (3.4%)	0.248
Stent thrombosis (definite / probable), n (%)	25 (2.1%)	19 (3.4%)	0.141

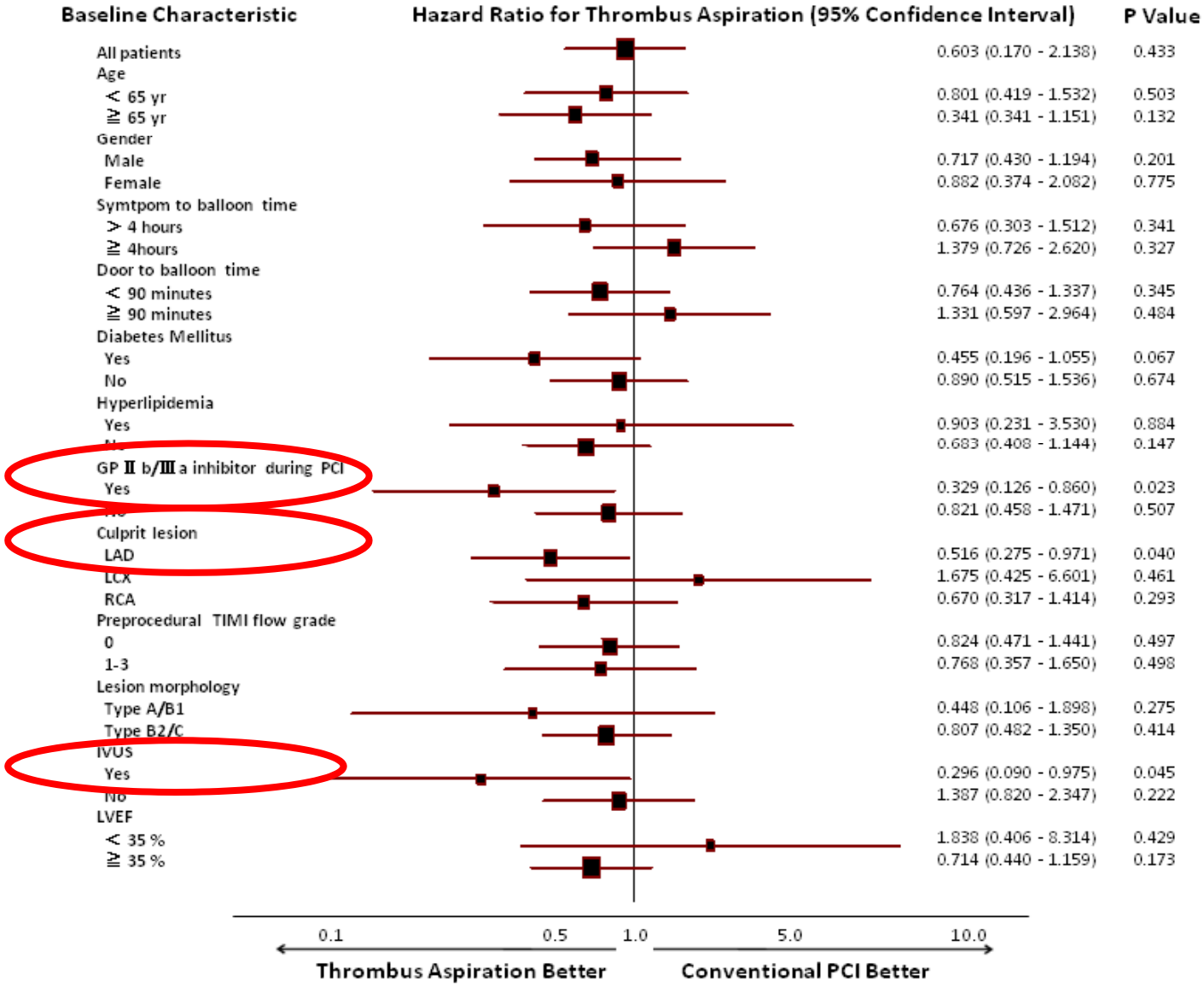
Unadjusted Survival Curve



Adjusted Survival Curve



Subgroup Analysis



Limitations

- This study was based on observational registry data. We used Cox regression models adjusted by propensity score to correct confounding factors, however, the result may be influenced by the nonrandomized assignment and some confounding factors. Randomized evaluation will be needed for more accurate evaluation. However, we deem this study worthy owing to its large number of patients and appropriate method of statistical analysis.
- In spite of presence of TIMI flow grade in this registry, there was no information about other markers of myocardial perfusion such as corrected TIMI frame count, myocardial blush grade, and ST-segment resolution that were linked to prognosis more precisely.
- Thrombus score and presence or absence of thrombus were not recorded, so we could not identify whether use of TA was affected by angiographical or IVUS findings or not.
- Adverse events about TA and cumulative data of stent thrombosis were not available.

Conclusions

- **Although TA did not improve clinical outcomes in overall STEMI patients who underwent primary PCI, the use of TA for LAD occlusion will improve 12-month MACE. Furthermore, combined use of IVUS and periprocedural use of GP IIb/IIIa inhibitors with TA have synergetic effect.**

Will be presented at 2011 Euro PCR, May 17-20, 2011