

Biodegradable Polymer Versus Durable Polymer Drug-Eluting Stents for Patients With Coronary Artery Disease:

**3-year Pooled Analysis of Individual Patient Data
from ISAR-TEST 3, ISAR-TEST 4, and LEADERS
Randomized Trials**

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I do not have any potential conflict of interest

Background

- **Biodegradable polymer DES** offer controlled drug-release without requirement for durable polymer coatings and may potentially improve long-term outcomes after stenting
- Detection of differences in the rates of rarely-occurring late adverse events require the **analysis of large patient numbers**

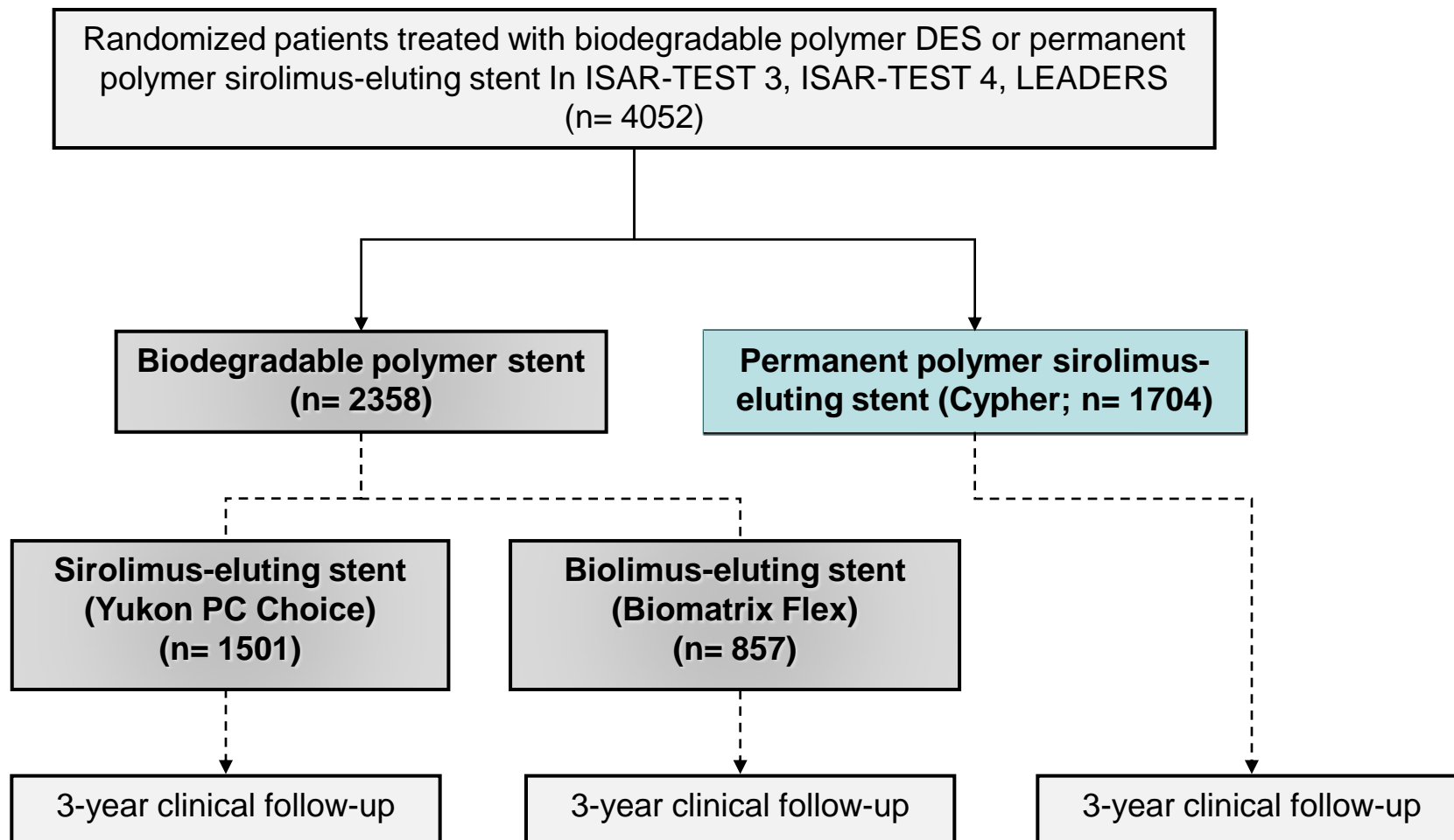
- We pooled the 3-year outcome data from the **3 largest randomized clinical trials** comparing biodegradable polymer with durable polymer sirolimus-eluting DES

ISAR-TEST 3	Mehilli et al. EHJ 2008
ISAR-TEST 4	Byrne et al. EHJ 2009
LEADERS	Windecker et al. Lancet 2008

Analysis Methods

- **Primary endpoint** was:
 - the composite of cardiac death, myocardial infarction and target lesion revascularization at 3-years
- **Secondary endpoints** were:
 - stent thrombosis
 - cardiac death/myocardial infarction
 - target lesion revascularization
- Meta-analysis was performed on individual patient data and using random effects methods

Study Flow

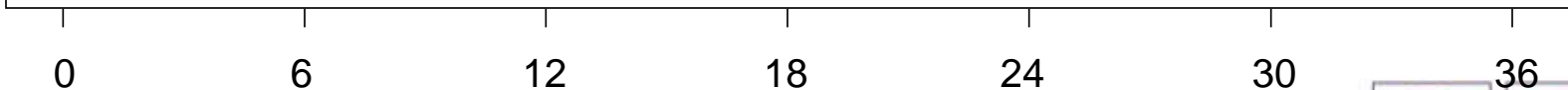
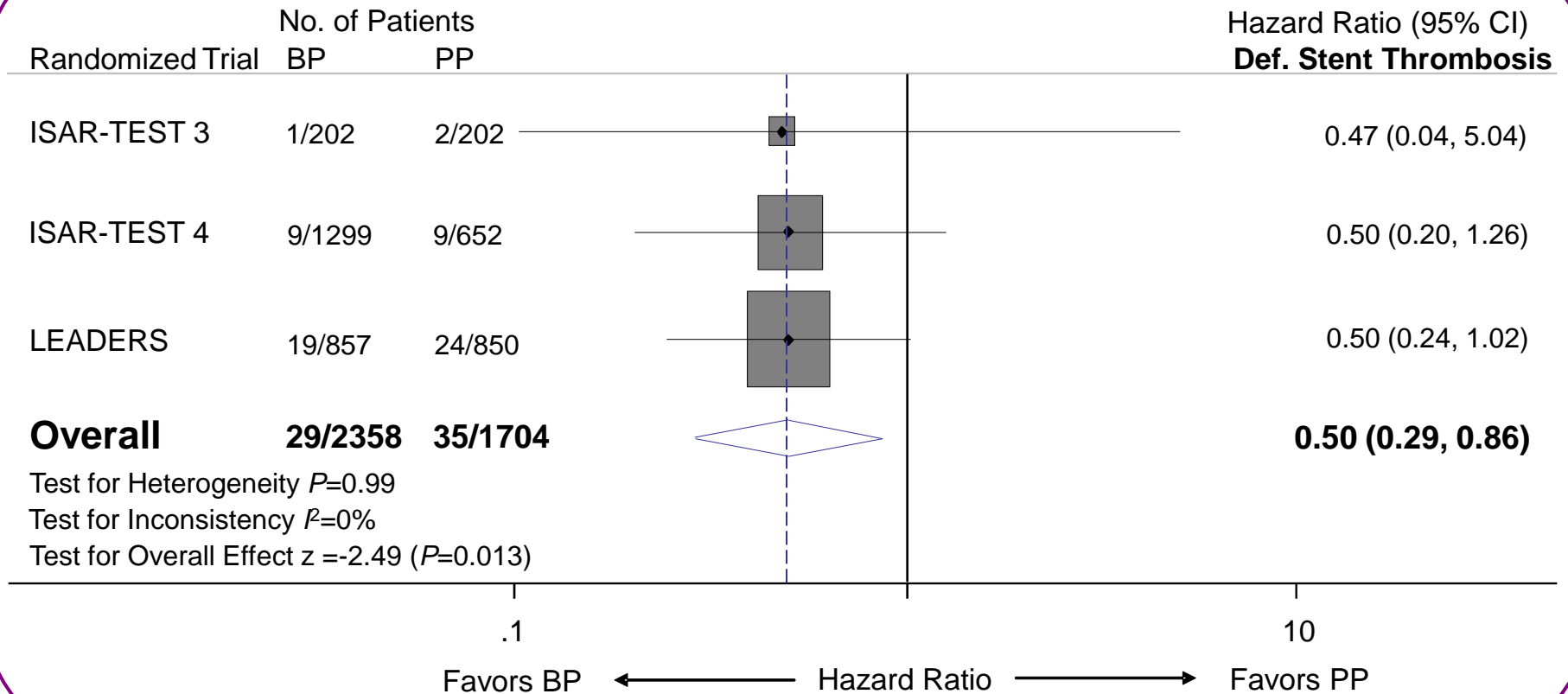


Trial Characteristics

Trials	ISAR-TEST 3	ISAR-TEST 4	LEADERS
Patients	605	2603	1707
Mean age	66.1 yrs	66.8 yrs	64.6 yrs
Diabetes	27%	29%	24%
Exclusion	LMS/Bypass/Rest enosis	LMS/Bypass/Rest enosis	None
Lesion/patients	1.2	1.3	1.5
Follow-Up	3 years	3 years	3 years

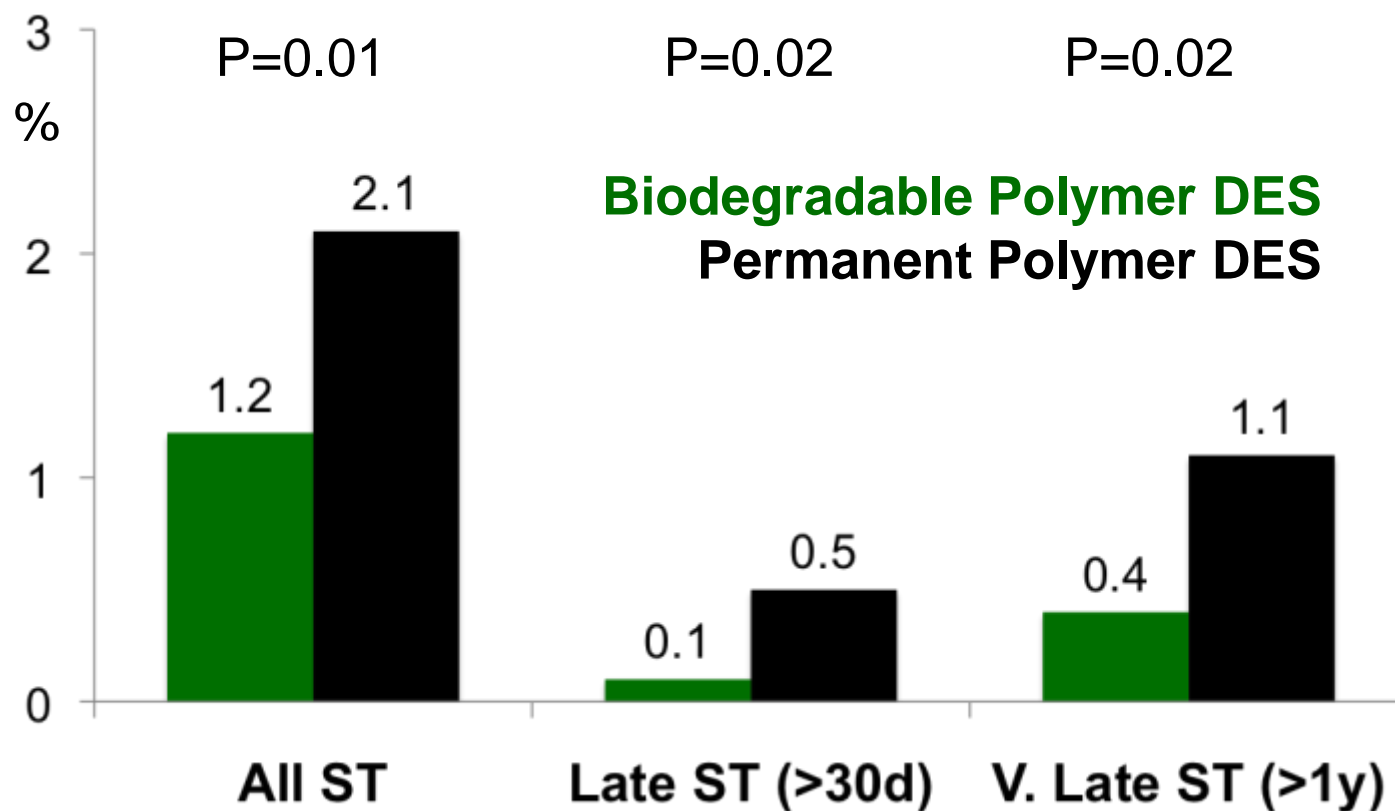
Results

Definite Stent Thrombosis

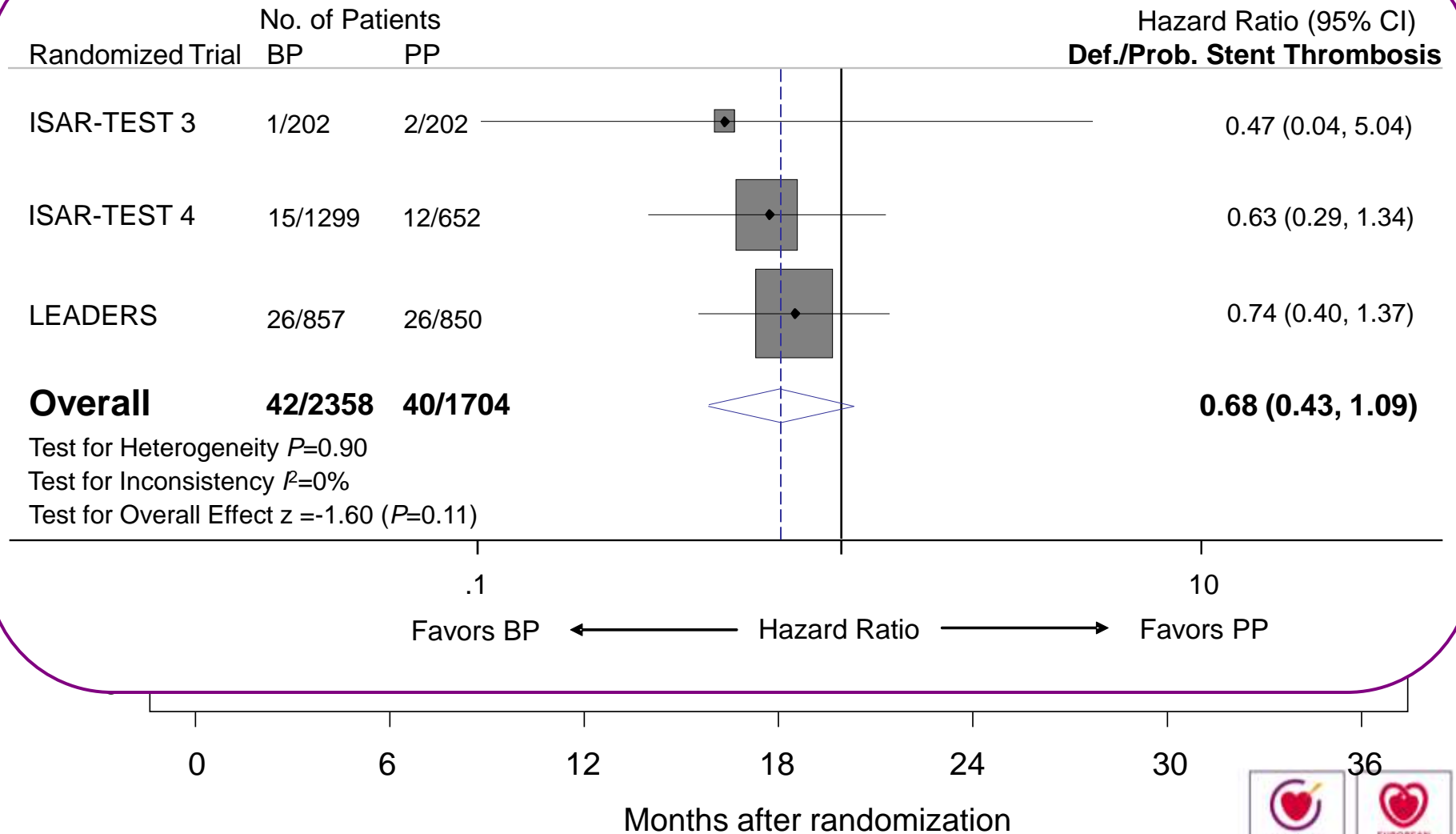


Months after randomization

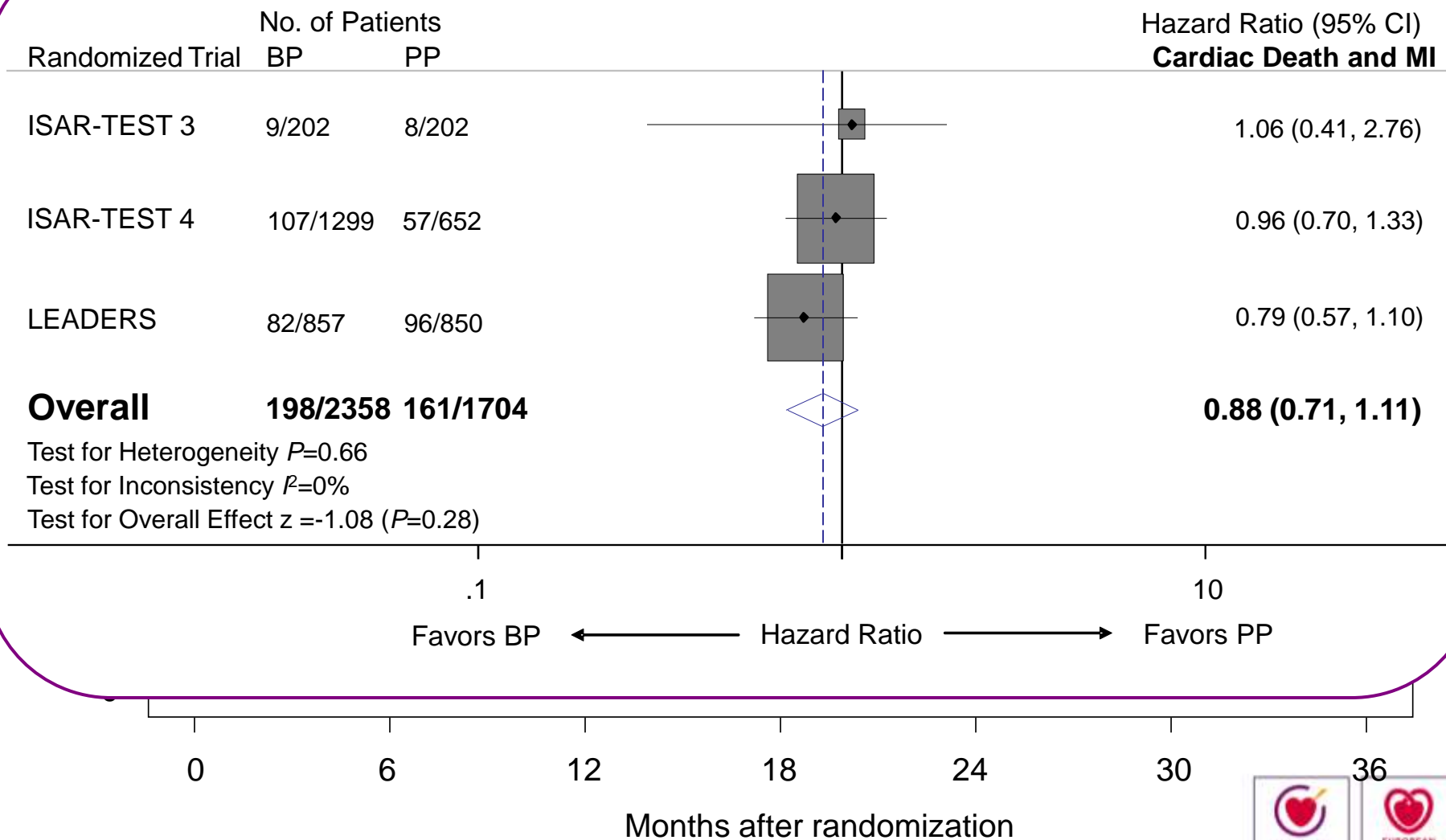
Definite Stent Thrombosis Landmark Analysis



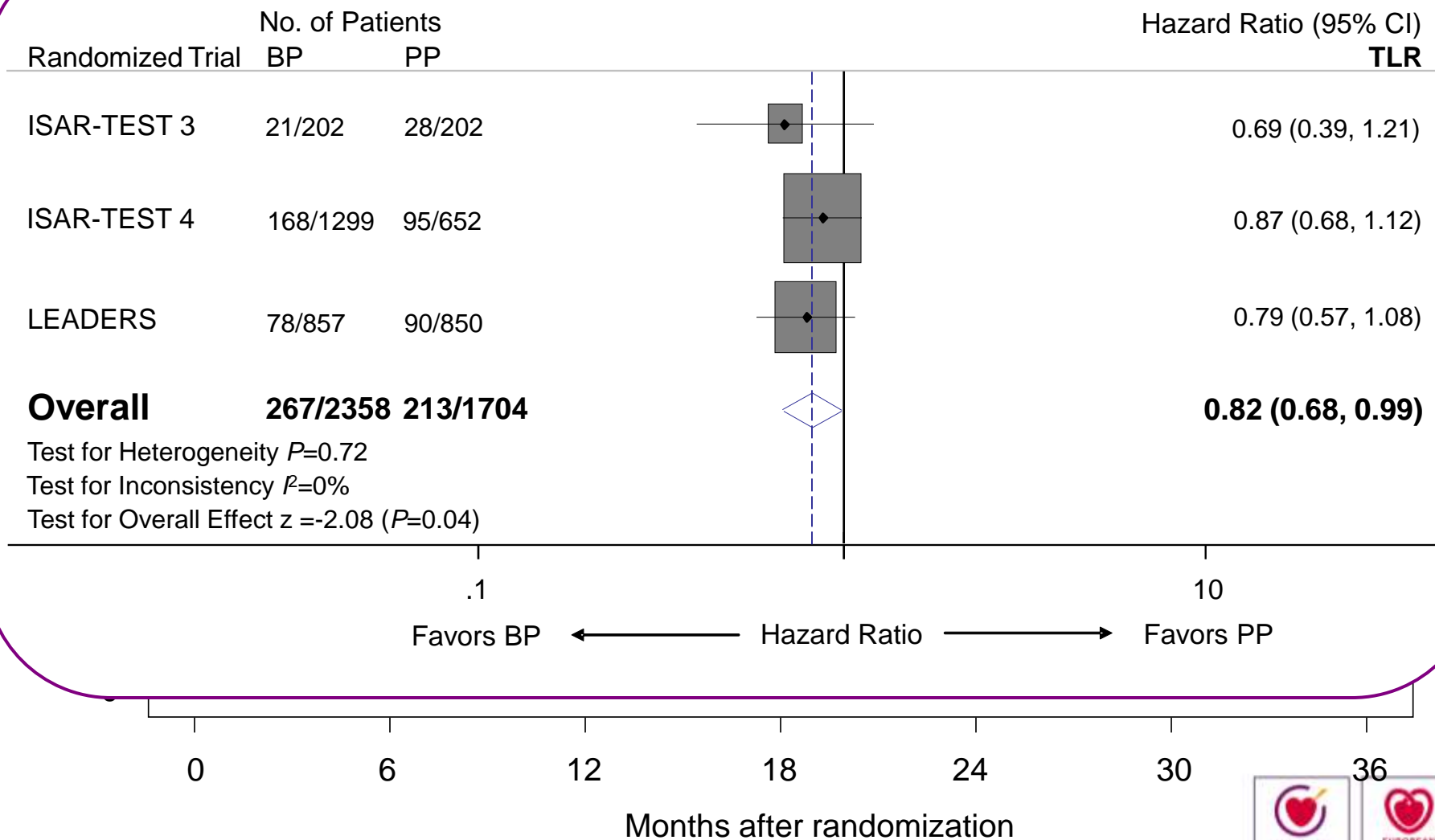
Definite/Probable Stent Thrombosis



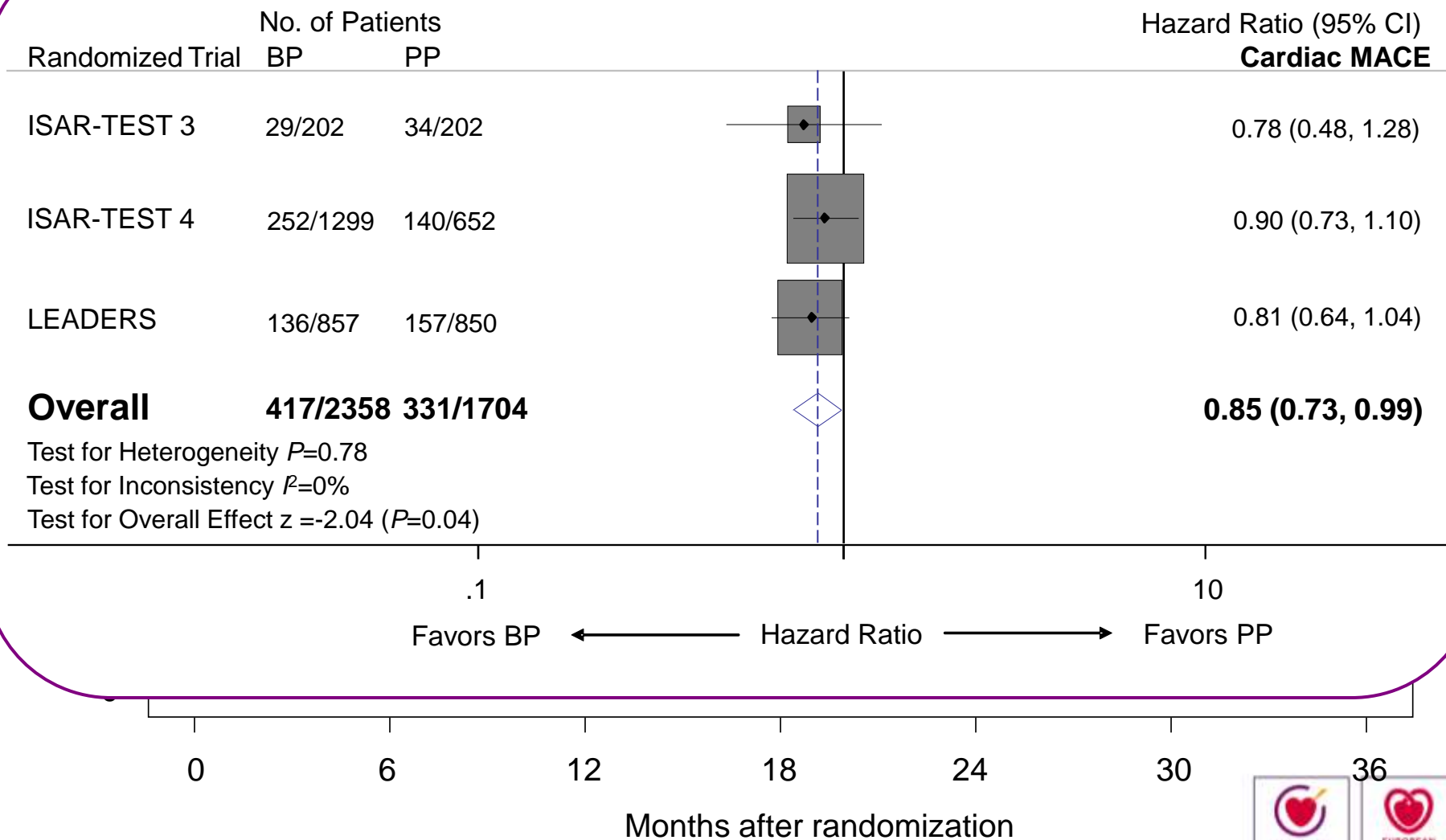
Cardiac Death/Myocardial Infarction



Target Lesion Revascularization



Primary Composite Endpoint



Conclusions

- At 3 years **biodegradable polymer DES** demonstrated **improved overall clinical outcomes** compared to first generation permanent polymer Cypher SES
- Biodegradable polymer DES were associated with a **50% reduction in definite stent thrombosis**

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Thank you for your attention