Supplementary Material

Polymer-free Sirolimus Versus Polymer-based Paclitaxel-eluting Stents: An Individual Patient Data Analysis of Randomized Trials

Salvatore Cassese,[a] Steffen Desch,[b] Adnan Kastrati,[a,] Robert A. Byrne,[a] Lamin King,[a] Tomohisa Tada,[a] Bernward Lauer,[c] Albert Schömig,[d] Holger Thiele,[b] and Jürgen PACHE[a]*

[a]*Deutsches Herzzentrum, Technische Universität, Munich, Germany*

[b]*Department of Internal Medicine/Cardiology, University of Leipzig-Heart Center, Leipzig, Germany*

[c]*Department of Cardiology, Zentralklinik Bad Berka, Bad Berka, Germany*

[d]*Medizinische Klinik, Klinikum rechts der Isar, Technische Universität, Munich, Germany*

Supplementary Material

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Table 1

Main Features of Trials and Patients Included in the Pooled Analysis

Study	ISAR-TEST[1,*]	LIPSIA Yukon[2]
Time of enrollment (year range)	2004-2005	2006-2008
Year of publication	2006	2011
Multicenter	Yes	Yes
Allocation ratio	1:1	1:1
Inclusion criteria	Stable or unstable angina or positive stress test; PCI indication; de novo native coronary lesions (>50% DS)	DM diagnosis; angina pectoris or positive stress test; PCI indication; de novo native coronary lesions (>50% DS to • 99% DS)
Primary endpoint	In-stent LLL (mm)	In-stent LLL (mm)
Patients included (n)	450	240
Male (%)	77	69
Age (mean, years)	67	67
Diabetes mellitus (%)	29	100
Stable CAD (%)	57	76
Pre PCI stenosis (%)	58	79
Pre PCI MLD (mm)	1.14	0.6
Lesion length (mm)	12.7	13.6
Lesion type B2/C	76	36
Angiographic FU (%)	81	79

CAD, coronary artery disease; DM, diabetes mellitus; DS, diameter stenosis; FU, follow-up; LLL, late lumen loss; MLD, minimum lumen diameter; PCI, percutaneous coronary intervention.

*ISAR-TEST trial: intracoronary stenting and angiographic restenosis-test equivalence between 2 drug-eluting stents trial.

Table 2

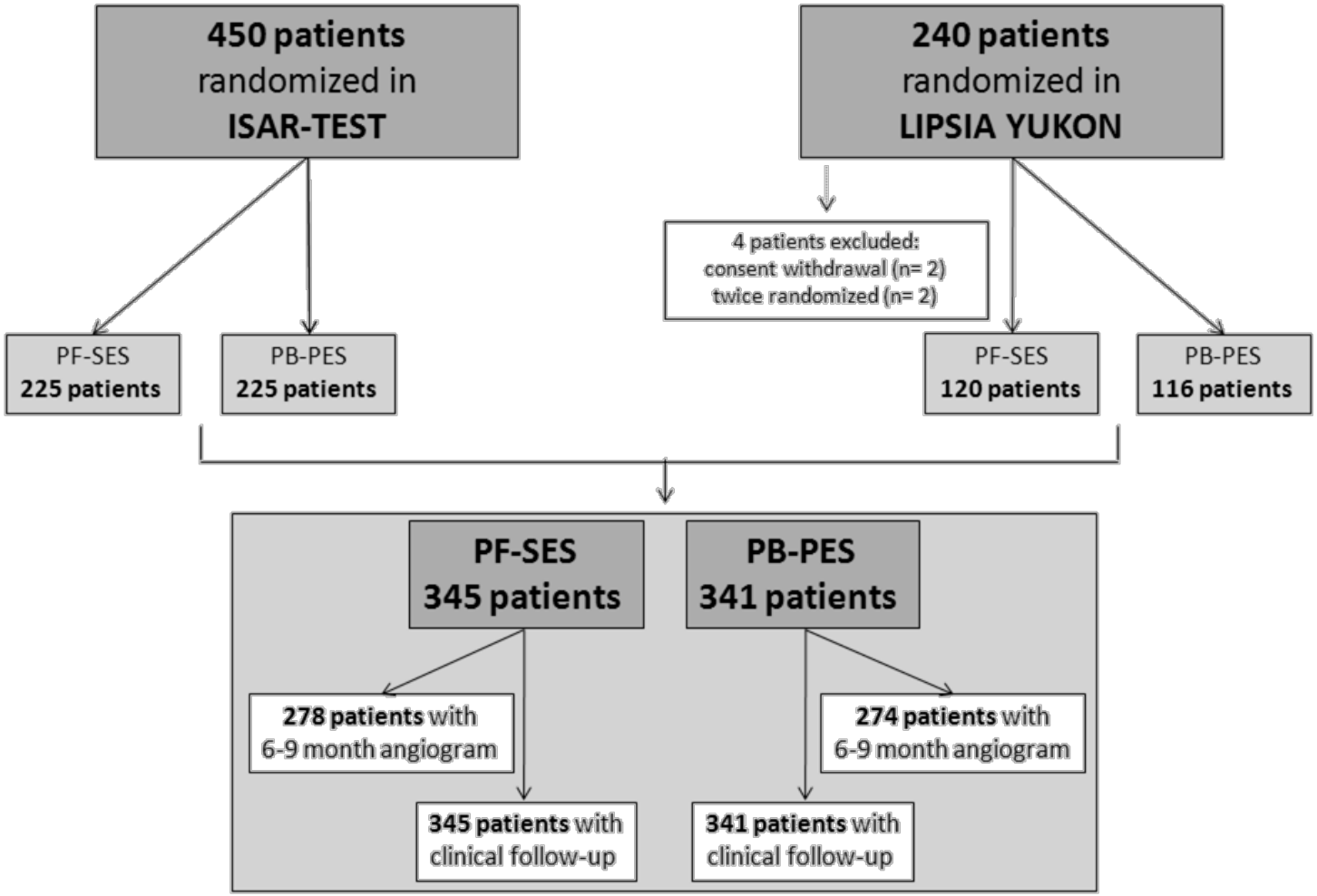
Definitions of Clinical Endpoints for Trials Included in the Pooled Analysis

Study	ISAR-TEST[1,*]	LIPSIA Yukon[2]
Death	All cause death.	All cause death.
Cardiac death	Any death after exclusion of other noncardiac cause.	Any death unless an unequivocal noncardiac cause could be established. Any death due to an unknown cause.
Target lesion revascularization	Restenosis in the presence of symptoms or objective signs of ischemia during the follow-up.	Any clinically indicated repeat PCI of the target lesion (equal to treated segment from 5 mm proximal to the stent and to 5 mm distal to the stent) or CABG of the
Myocardial infarction	New Q waves on the ECG and/or elevation of CK or CK-MB to • 3 times the ULN in • 2 blood samples.	CK-MB band elevation >3 times the ULN, • 48 hours after index PCI (periprocedural). Any increase in the CK-MB levels above the ULN, >48 hours after index PCI

CABG, coronary artery bypass graft; CK-MB, creatine kinase-myocardial band; ECG, electrocardiogram; PCI, percutaneous coronary intervention; ULN, upper level of normality.

*ISAR-TEST trial: intracoronary stenting and angiographic restenosis-test equivalence between 2 drug-eluting stents trial.

Figure. Flowchart of patients included in the original trials and in the pooled analysis. ISAR-TEST trial, intracoronary stenting and angiographic restenosis-test equivalence between 2 drug-eluting stents trial; PB-PES, polymer-based paclitaxel-eluting stents; PF-SES, polymer-free sirolimus-eluting stents.



DETAILED DESCRIPTION OF QUANTITATIVE CORONARY ANGIOGRAPHY ANALYSIS FOR TRIALS POOLED

ISAR-TEST

Baseline, postprocedural, and follow-up angiograms were analyzed at the quantitative angiographic core laboratory of DeutschesHerzzentrum, Munich, Germany, by personnel unaware of stent type. Angiographic image acquisition of the target lesion was done after intracoronary administration of nitroglycerin, and the same single worst-view projection was measured at all time points. Qualitative morphological lesion characteristics were graded by standard criteria (American Heart Association/American College of Cardiology classification modified by Ellis[3]). The off-line quantitative coronary angiographic analysis was performed with an automated edge-detection system (QCA-CMS V 6.0, Medis, Medical Imaging Systems, Leiden, The Netherlands). The contrast-filled, nontapered catheter tip was used for calibration. The reference diameter was measured by interpolation. Minimal lumen diameter (MLD) was measured within the stent and within the 5-mm proximal and distal edges of the stent. Quantitative analysis was performed in the in-stent area (in-stent analysis) and in the in-segment area including the stented segment, as well as both 5-mm margins proximal and distal to the stent (in-segment analysis). Percentage of diameter stenosis was calculated as [1-(minimal lumen diameter/reference vessel diameter)/100]. Restenosis (angiographic or binary) was defined as diameter stenosis • 50% in the in-segment area (including the stent area and 5-mm segments proximal and distal to the stent edges).

LIPSIA-Yukon

Baseline, postprocedural, and follow-up angiograms were analyzed in the core laboratory at the University of Leipzig Heart Center, Leipzig, Germany, by an experienced single observer blinded to the stent type. Angiograms were analyzed with a semi-automated edge-detection system (QAngio

XA Clinical Edition 7.1, Medis Medical Imaging Systems, Leiden, The Netherlands). Parameters assessed were: reference vessel diameter, lesion length, MLD, percent diameter stenosis, late lumen loss (the difference between MLD immediately after the procedure and the MLD at follow-up), in-segment binary restenosis rate (restenosis defined as • 50% diameter stenosis), and pattern of restenosis. Baseline grading of lesion complexity was performed according to standard criteria (American Heart Association/American College of Cardiology classification modified by Ellis[3]). Catheter tip calibration was used in all patients. Quantitative analysis was performed in the in-stent area (in-stent analysis) and in the in-segment area including the stented segment, as well as both 5-mm margins proximal and distal to the stent (in-segment analysis).

REFERENCES

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