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2009

30th July – 1st August 2009

Kuala Lumpur

PEPCAD IV DM
(Paclitaxel-eluting PTCA catheter in
coronary artery disease -
Diabetes Mellitus)

ROSLI Mohd Ali

On behalf of PEPCAD IV Investigators

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The aim of the study is to compare the efficacy of the Paclitaxel-eluting PTCA-balloon dilation (SeQuent® Please) followed by cobalt-chromium stent (Coroflex® Blue) deployment versus Paclitaxel-eluting stent (Taxus™ Liberté™) deployment in the treatment of de-novo-stenoses in native coronary arteries of well-controlled diabetics

Study Design

Reference diameter: ≥ 2.5 mm and ≤ 3.5 mm

Length of stenosis ≥ 10 mm ≤ 22 mm

Patients with diabetes mellitus for ≥ 5 years for procedural success and preservation of vessel patency,

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- Background is the recent discussion surrounding DES and associated late complications.
- Recent studies have suggested that the polymer coating and sustained release of the DES might be responsible for reported complications as e.g. subacute thrombosis
- Drug Eluting Balloons should offer a viable alternative to Drug Eluting Stents in the treatment of coronary artery disease as they provide the drug to the affected area efficiently and without use of a stent (and hence polymer)
- Two Clinical Trials carried out in Germany – PEPCAP I and II – showed excellent results for In-Stent restenosis and de-novo lesions in small vessels.

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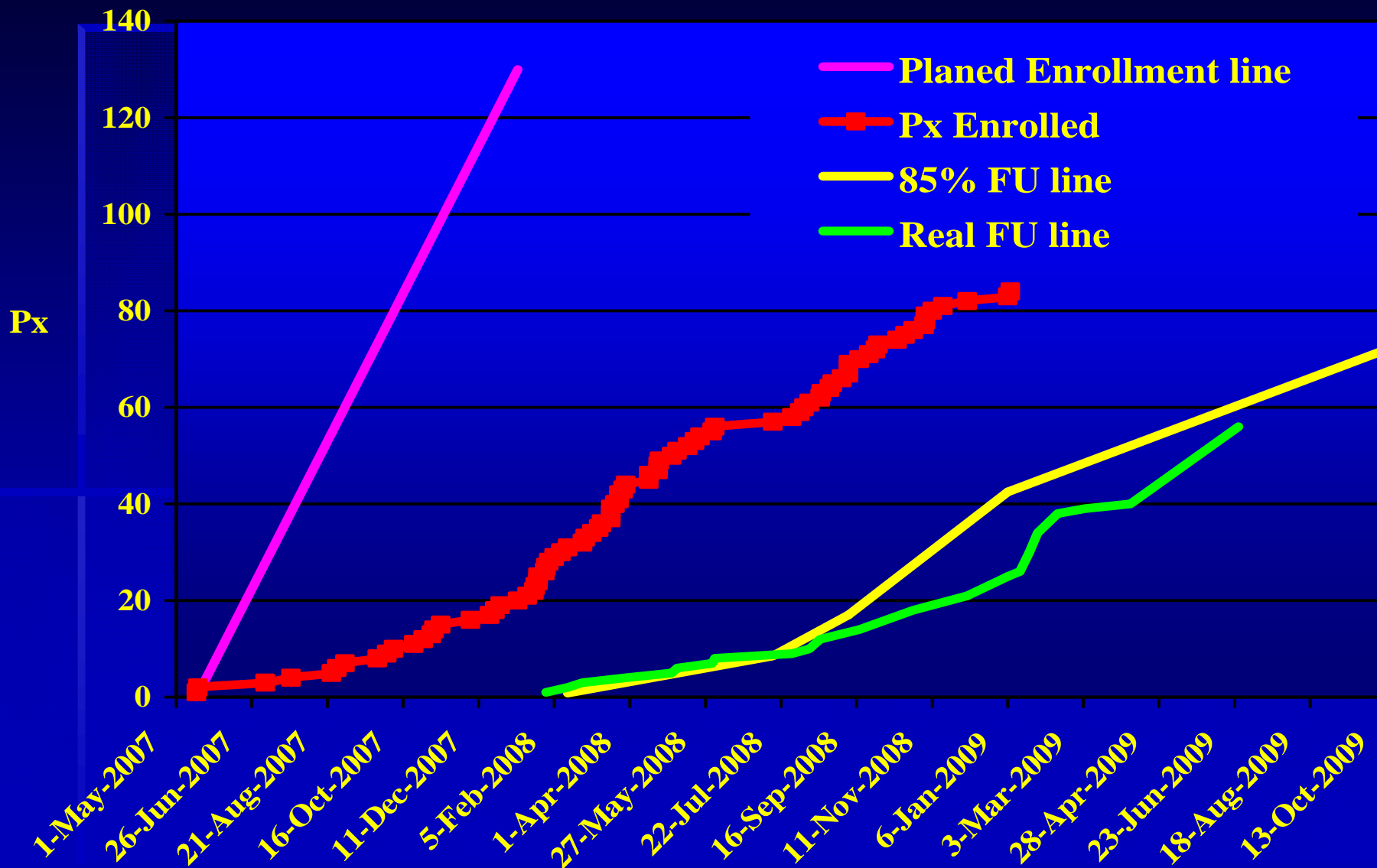
- To confirm the excellent results as well in the subset of diabetic patients (and due to high prevalence of these patients in South East Asia)
- The investigators look forward to the PEPCAP IV trials results to confirm that SeQuent® Please in combination with bare metal stents can offer an optimized treatment also to diabetic patients.
- Besides the expected lower MACE and restenosis rates the costly anti-platelet therapy can be reduced from 12 to 3 months.

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PEP IV Patients Enrolled vs Time (n=84) 14-July-2009

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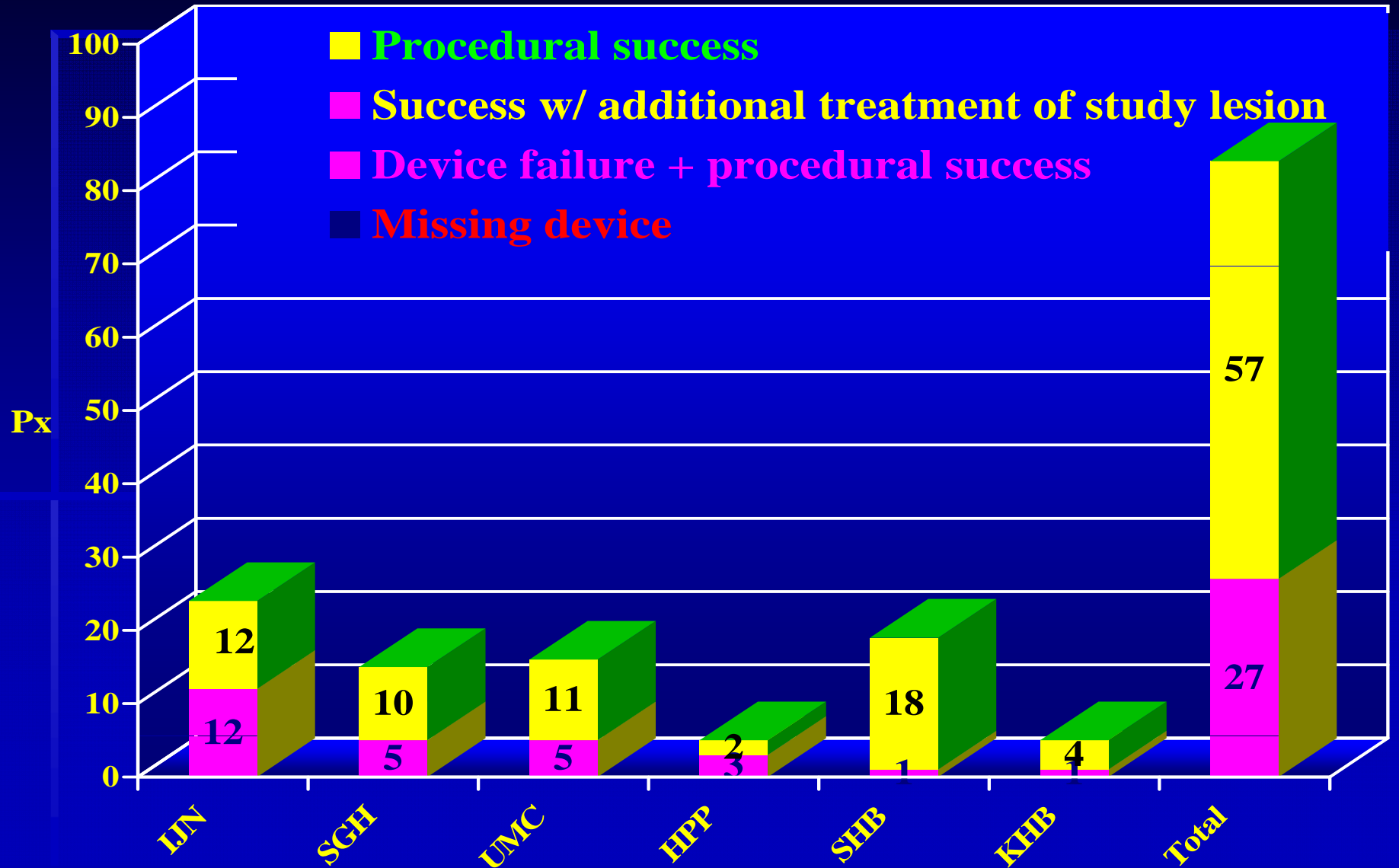
n= 46 SeQuent Please + Coroflex Blue vs. n= 38 Taxus



PEP IV Patients Enrolled (n=84) 14-July-2009

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n= 46 SeQuent Please + Coroflex Blue vs. n= 38 Taxus

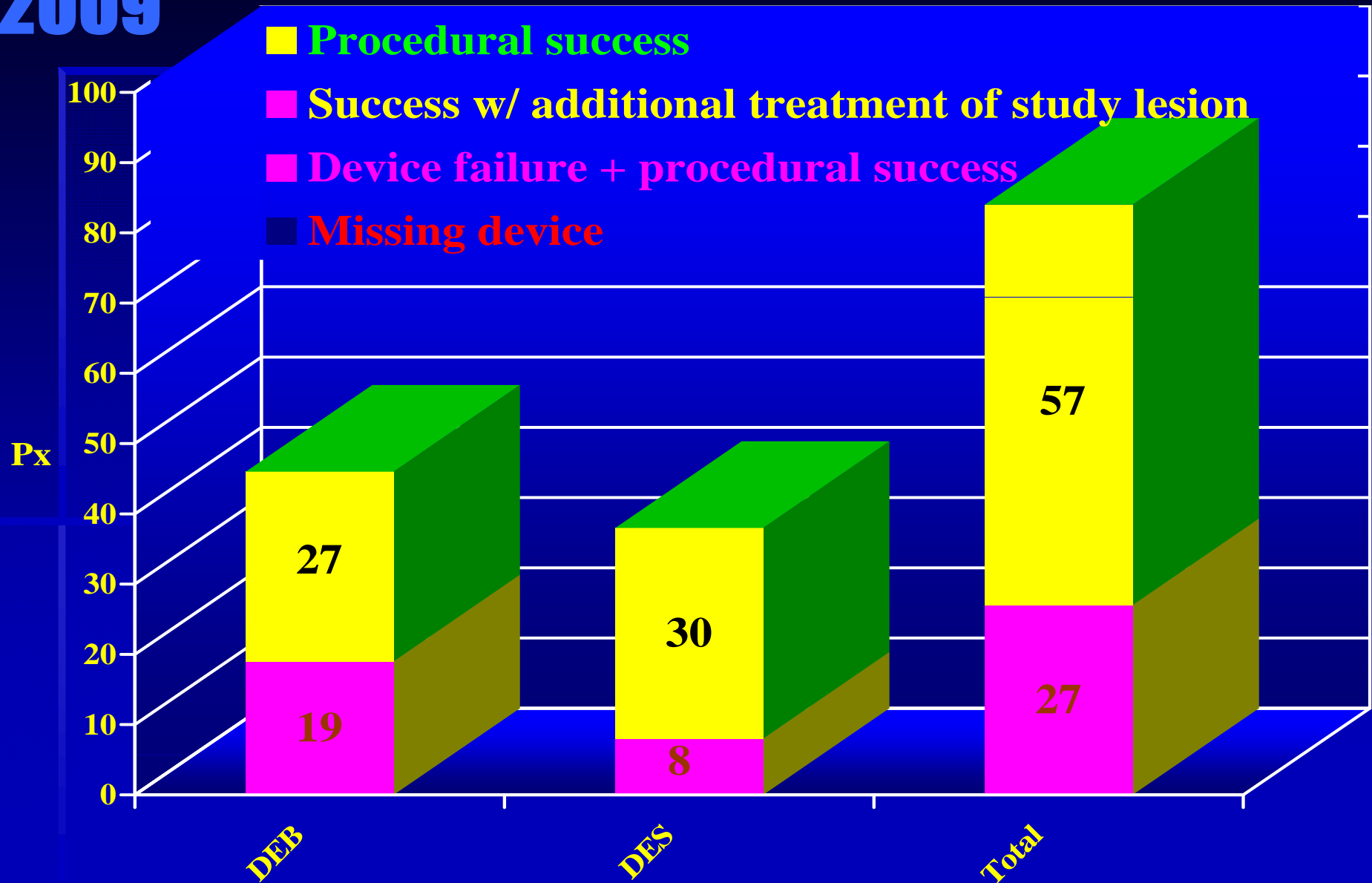


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PEP IV Patients Enrolled (n=84) 14-July-2009

n= 46 SeQuent Please + Coroflex Blue vs. n= 38 Taxus



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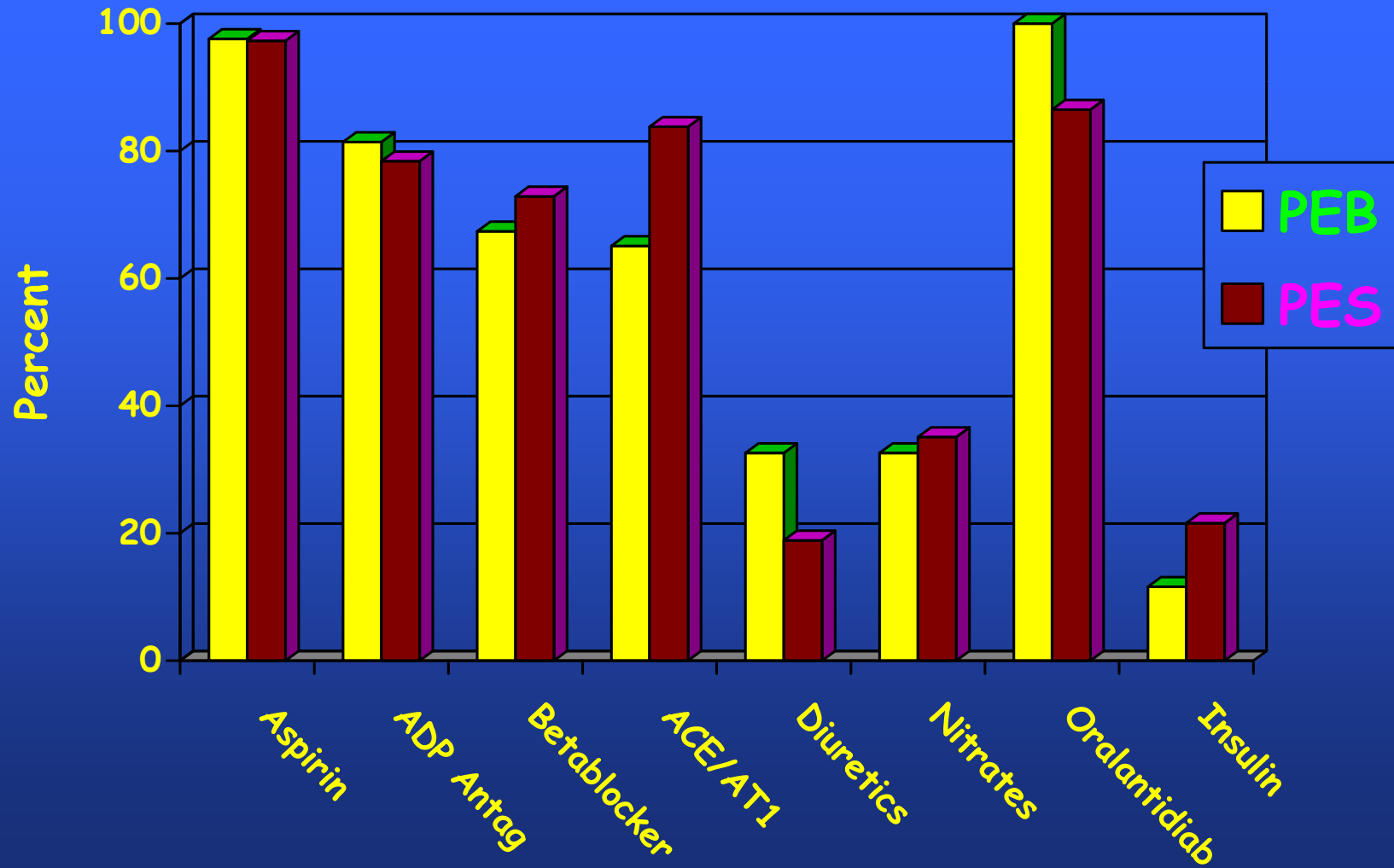
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Patients Baseline (ALL: N=84)

	PEB (46)	PES (38)	P
Age(Years)	62.0 ± 8.4	58.4 ± 10.2	0.2
Male	71%	81%	0.2
BMI (Kg/m ²)	26.8 ± 4.4	26.1 ± 3.5	0.5
Serum Cholesterol (mmol/l)	4.2 ± 1.0	4.2 ± 1.1	0.9
Serum LDL (mg/dl)	2.2 ± 1.0	2.4 ± 1.1	0.4
Diabetes Treatment			
Oral	88%	82%	0.7
Insulin	12%	18%	0.7
Current/Ex-Smokers	50%	51%	0.9
Hypertension	93%	79%	0.2
Serum Crea (mmol/l)	114.9 ± 150.3	88.4 ± 17.7	0.4

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Medication before procedure



Treated Vessel

Vessel	PEB	PES	P
LAD	41.50%	53.10%	0.52
LCX	22.00%	21.90%	
RCA	36.50%	25.00%	

Procedure Analysis

	PEB	PES	BMS*
Predilatation [%]	36.6	94.6	N/A
length [mm]	21.9±5.0	19.4±3.9	17.4±4.2
diameter [mm]	2.9±0.3	2.9±0.4	2.9±0.3
pressure [mm]	9.9±3.6	14.5±3.6	14.2±4.1
duration [sec]	45±12	28±8	23.3±9.4
Additional POBA	N/A	29.7%	31.7%
Additional BMS	2.4%	0%	N/A
Additional PES	0%	2.7%	N/A

*PEB-group

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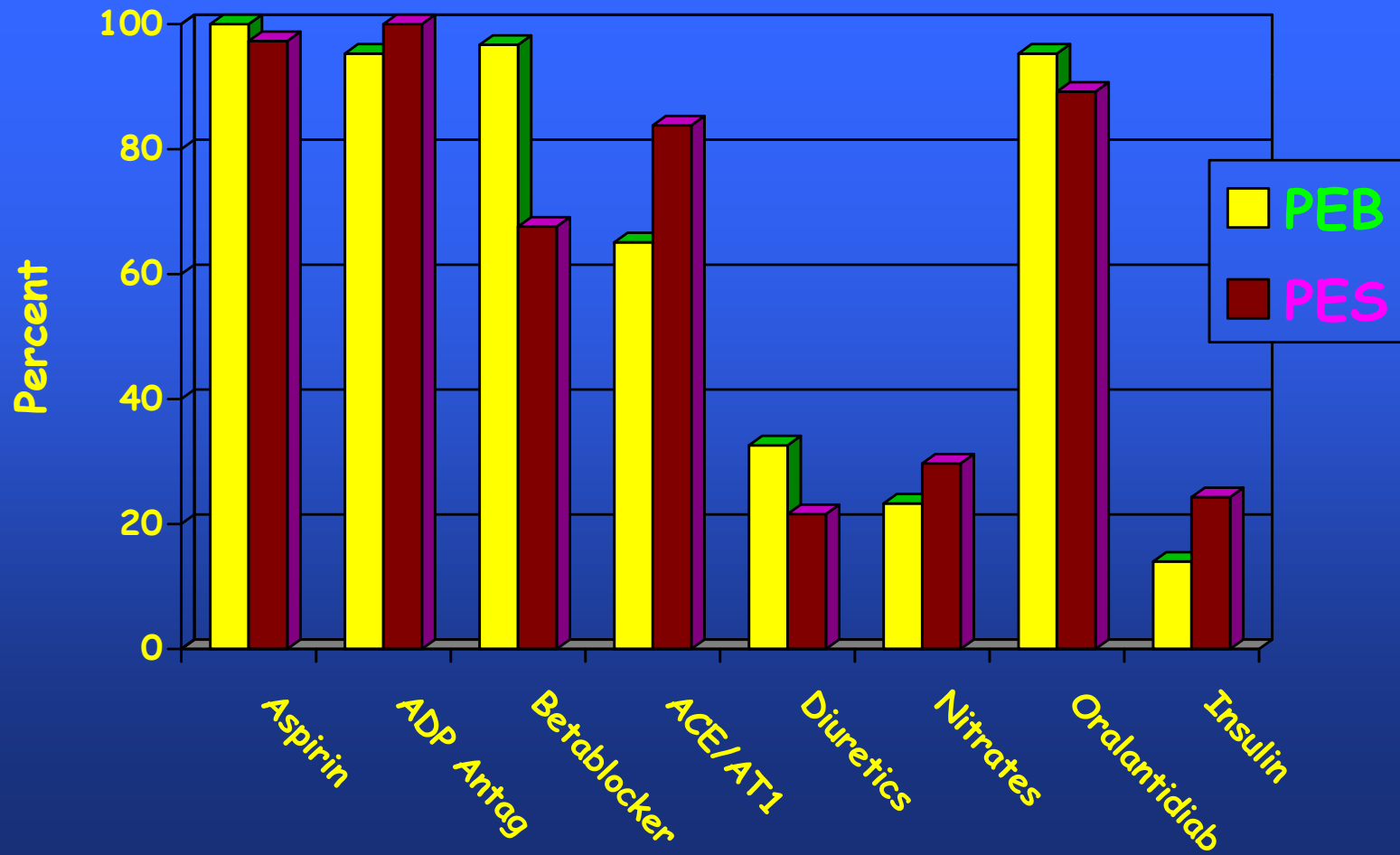
Baseline Angiography (ALL: N=84)

	PEB	PES	p
1-vessel disease [%]	34.2	60.6	0.06
2-vessel disease [%]	39.0	27.3	
3-vessel disease [%]	26.8	12.1	
Stenosis length [mm]	13.6 ± 5.1	12.9 ± 4.6	0.6
Typ A	2.9%	6.7%	0.6
Typ B1	48.6%	43.3%	
Typ B2	48.6%	46.7%	
Typ C	0%	3.3%	
MLD pre PCI [mm]	0.69 ± 0.27	0.87 ± 0.33	0.03
Stenosis pre PCI [%]	74 ± 9	69 ± 10	0.03
MLD post PCI [mm]	2.48 ± 0.33	2.64 ± 0.33	0.05
Stenosis post PCI [%]	12 ± 7	6 ± 6	0.0005

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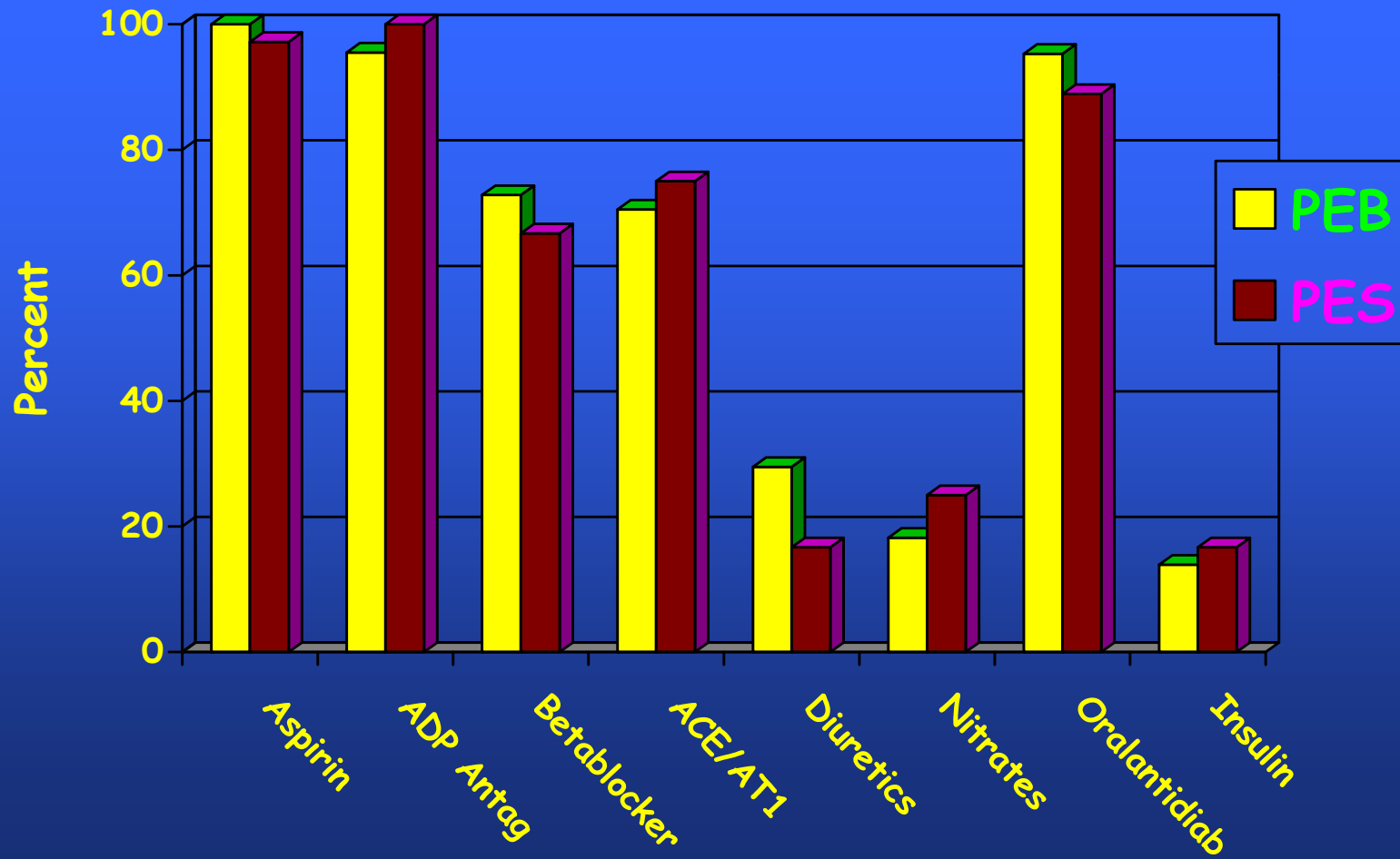
Medication at discharge



30 days MACE

- Two MACEs in the PES group
 - One Target Vessel MI followed by CABG 6 hours after study procedure
 - One Target Lesion MI due to subacute stent thrombosis three days after study procedure

Medication at 30 days FU



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Angiographic Follow-up

Currently being performed according to time schedule

Last patient out – early October 2009

Primary endpoint data analysis – end of the year

Q:

Is DEB + BMS implantation as efficacious as DES

In the treatment of de-novo lesions in diabetic patients

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Thank You