

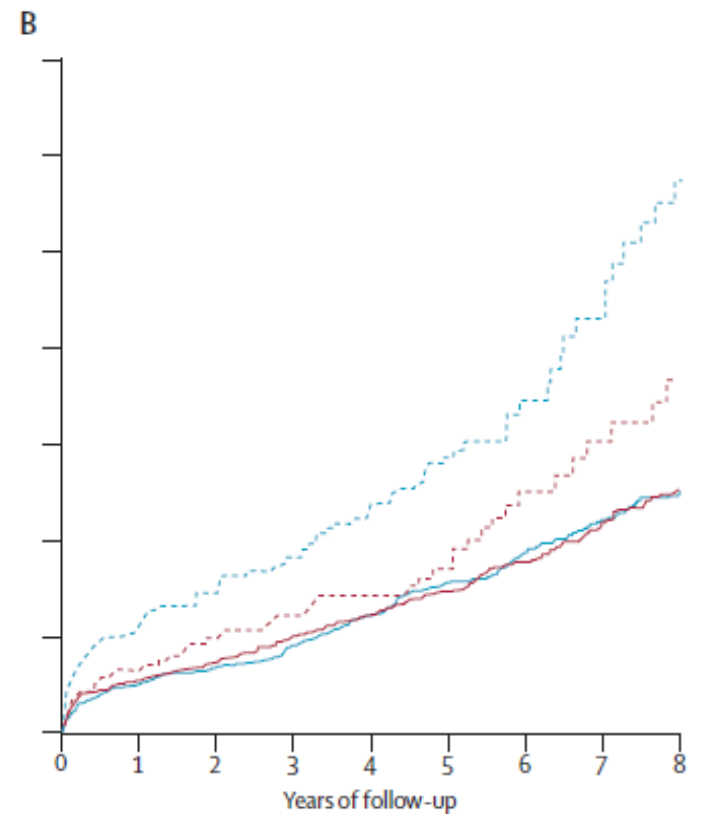
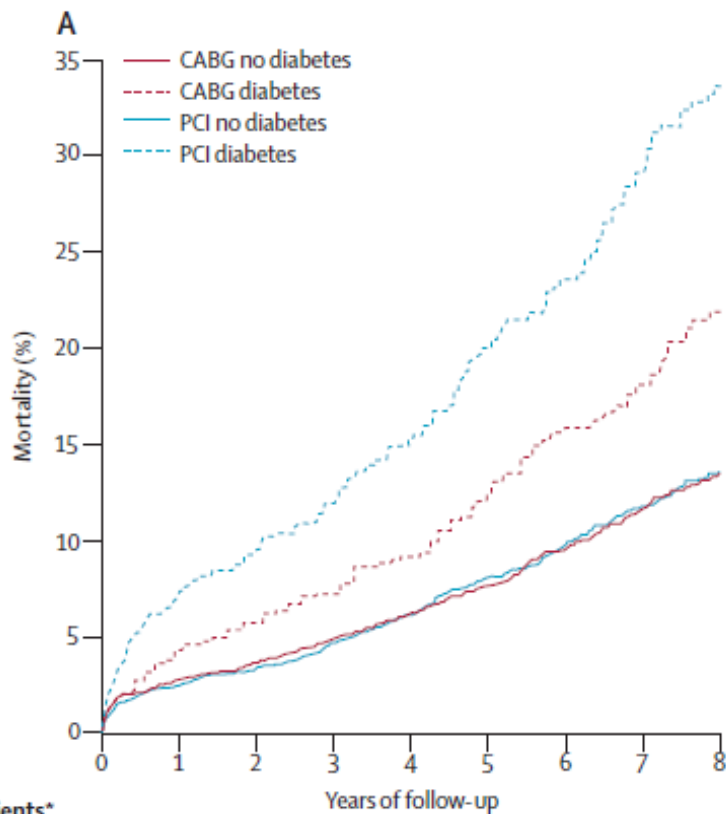
DEAR Registry : DiabEtics ARgentina Registry of Paclitaxel Eluted Balloon

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Why Diabetics?????????

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Number of patients*

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|------------------|------|------|------|------|------|------|------|------|------|
| CABG no diabetes | 3263 | 3169 | 3089 | 2877 | 2677 | 2267 | 1592 | 1380 | 1274 |
| CABG diabetes | 615 | 587 | 575 | 532 | 498 | 421 | 257 | 225 | 200 |
| PCI no diabetes | 3298 | 3217 | 3148 | 2918 | 2725 | 2281 | 1608 | 1393 | 1288 |
| PCI diabetes | 618 | 574 | 555 | 508 | 475 | 373 | 218 | 179 | 160 |

| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|------------------|------|------|------|------|------|------|-----|-----|-----|
| CABG no diabetes | 2529 | 2457 | 2382 | 2179 | 1992 | 1598 | 940 | 747 | 655 |
| CABG diabetes | 435 | 420 | 410 | 371 | 344 | 278 | 120 | 91 | 73 |
| PCI no diabetes | 2556 | 2493 | 2432 | 2215 | 2031 | 1606 | 946 | 750 | 655 |
| PCI diabetes | 445 | 421 | 408 | 369 | 344 | 258 | 110 | 81 | 66 |

Mortality in patients assigned to CABG or PCI by diabetes

Lancet 2009; 373: 1190–97

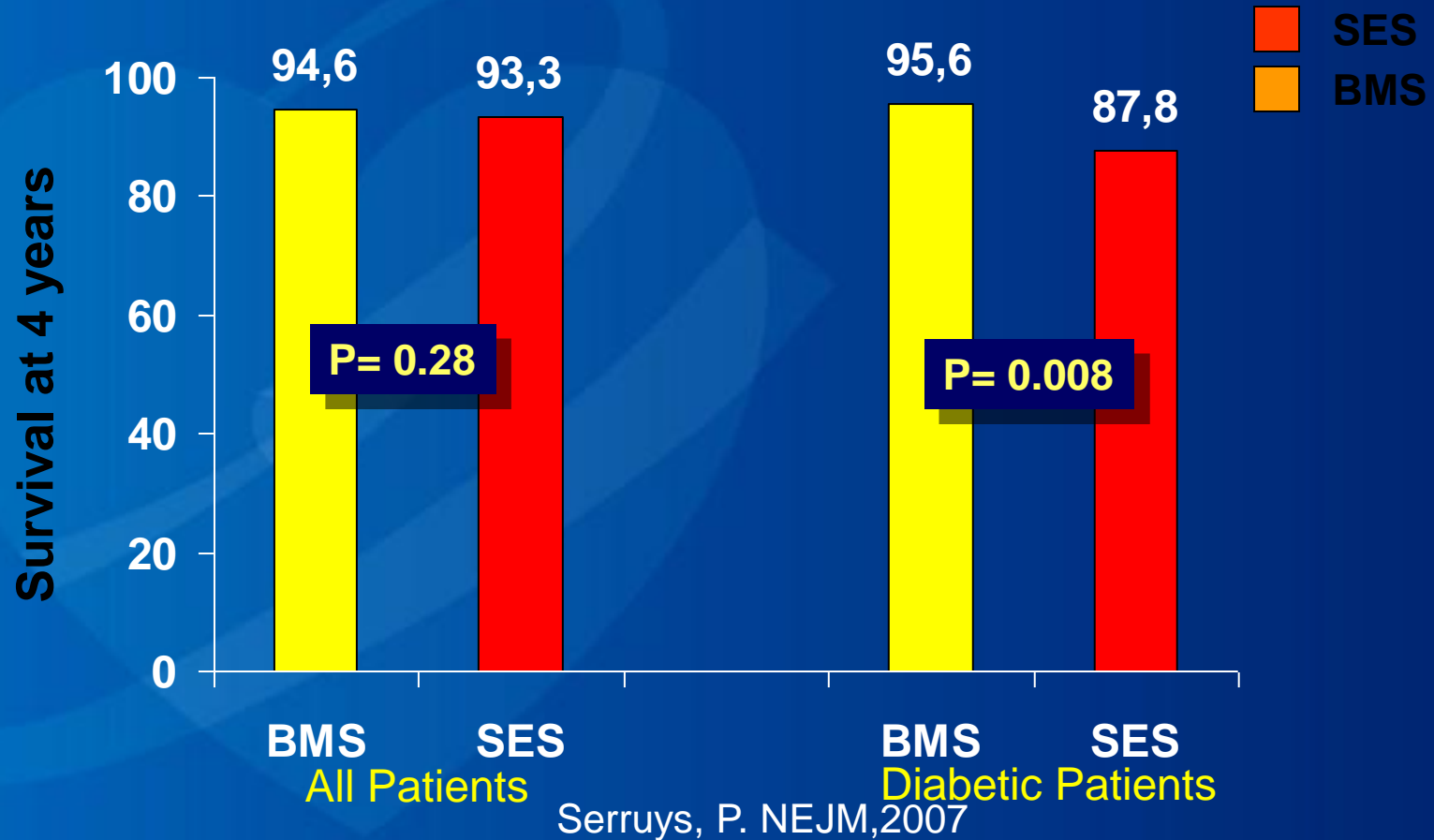
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Unresolved Issues in DES Era

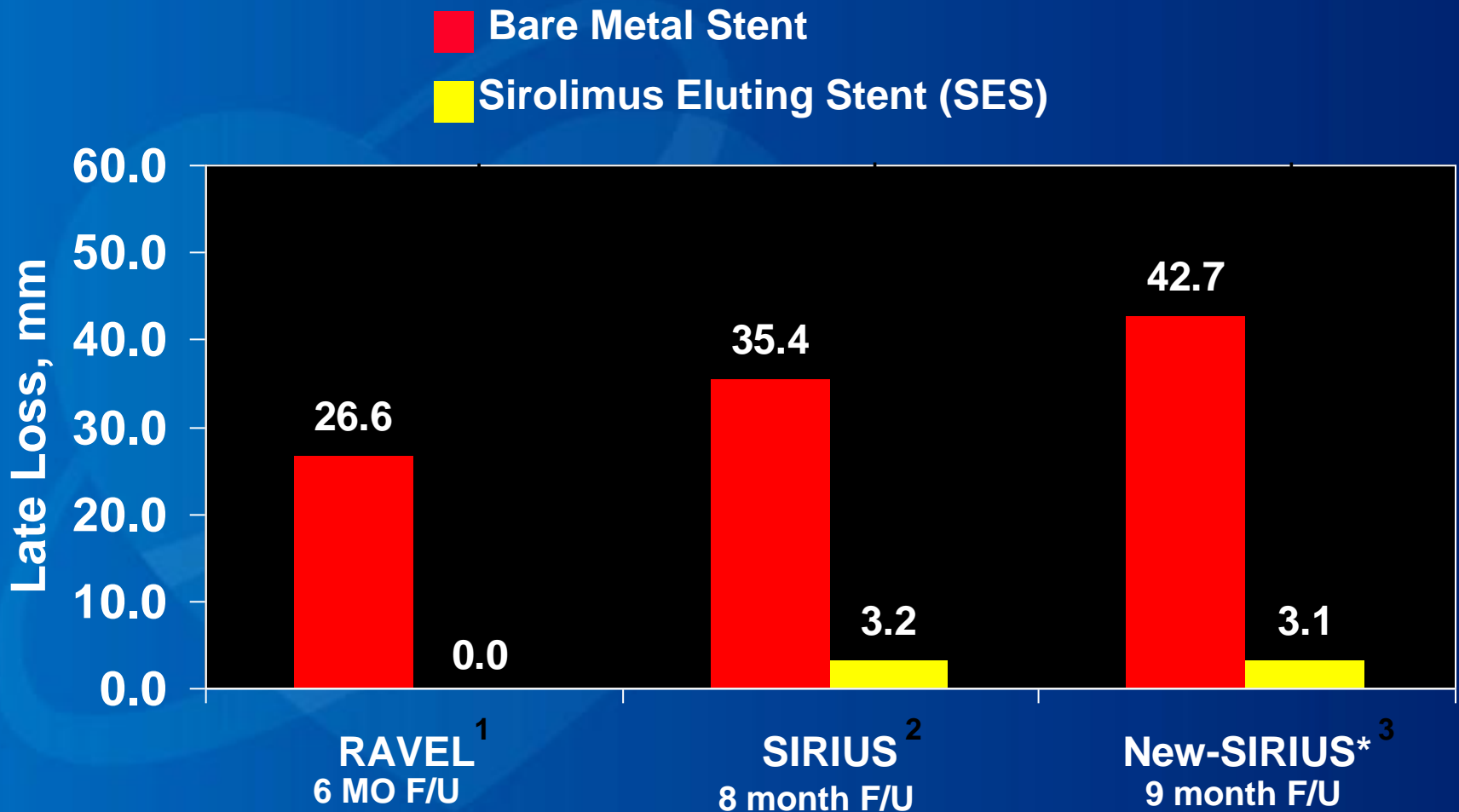
- **DIABETES**
- **IN-STENT RESTENOSIS**
- **BIFURCATIONS**
- **SMALL VESSELS**
- **ACUTE MYOCARDIAL INFARCTION**
- **LONG TERM DUAL ANTIPLATELET THERAPY**

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Meta-Analysis of Survival at 4 Year Follow-Up of BMS vs. DES



In-Stent Binary Restenosis:



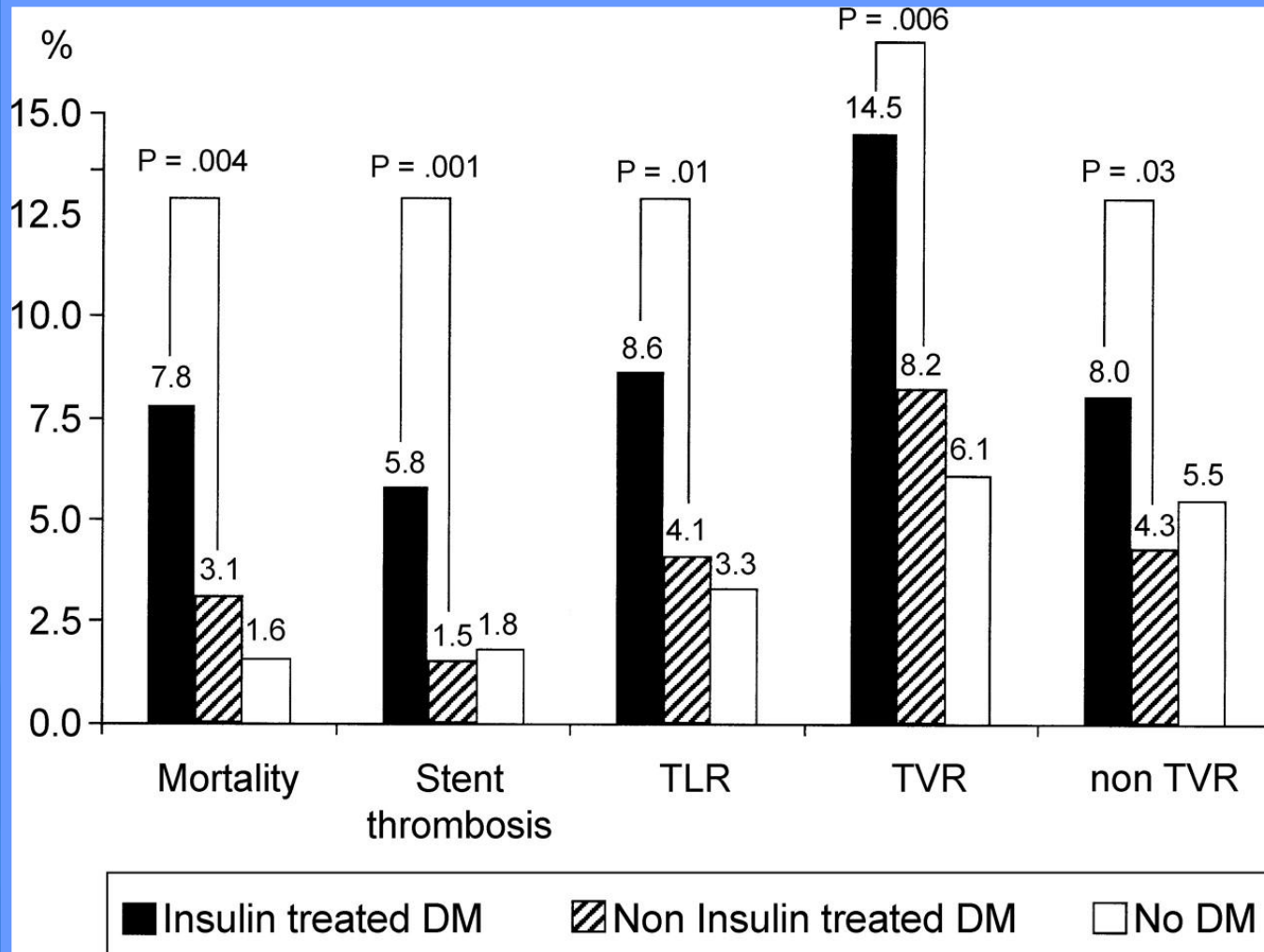
¹ MC Morice, et al., *N Engl J Med* 2002;346:1773-80.

² Moses J., et al., *N Engl J Med* 2003; 349:1315-23.

³ <http://www.tctmd.com> (accessed on 2/17/2005).

Event Rate in Diabetics With or Without Insulin Therapy after SES Stent

Deployment



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Event Rate in Diabetics With or Without Insulin Therapy after SES or BMS Stent Deployment

Results of Diabetes Trial

At 2 years of follow up, patients treated with SES had significant lower incidence of TVR compared to BMS: 7.7% vs 35% $p=0.001$ (EHJ, 2007)

However, serial IVUS analyses in diabetic patients in whom LASMA was observed in 14.7% of the cases after SES compared with 0% after BMS implantation ($P=0.001$).

Jimenez-Quevedo et al DIABETES trial, JACC, 2006

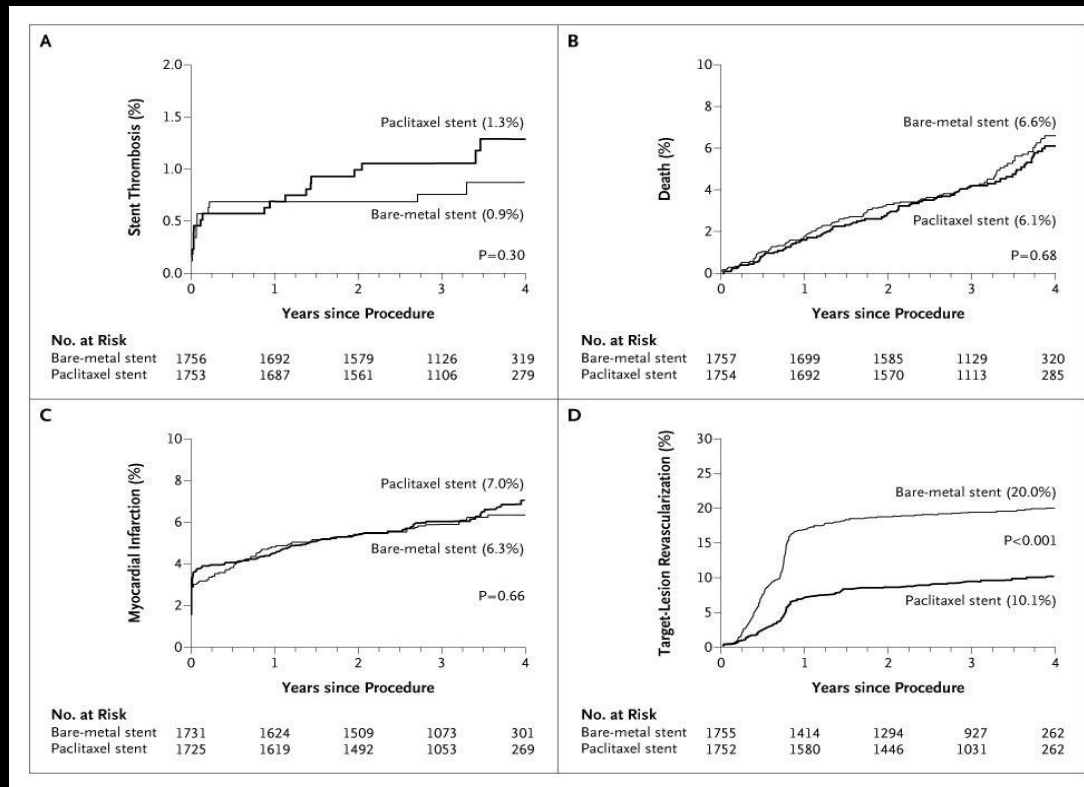
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Why Paclitaxel???????

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DES Myths and Realities

Kaplan-Meier Curves Representing the Estimated 4-Year Cumulative Incidence Rates of Stent Thrombosis, Death, Myocardial Infarction, and Target-Lesion Revascularization for the Pooled Randomized Trials of Paclitaxel-Eluting Stents and Bare-Metal Stents



Stone G et al. N Engl J Med 2007;356:998-1008



The NEW ENGLAND
JOURNAL of MEDICINE

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Background

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Treatment of Coronary In-Stent Restenosis with a Paclitaxel-Coated Balloon Catheter

Bruno Scheller, M.D., Christoph Hehrlein, M.D., Wolfgang Bocksch, M.D.,
Wolfgang Rutsch, M.D., Dariush Haghi, M.D., Ulrich Dietz, M.D.,
Michael Böhm, M.D., and Ulrich Speck, Ph.D.

N Engl J Med 2006;355:2113-24.

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End Points

Primary: Incidence of TVR, TLR and MACCE and TVF at 6 months, one and three years of follow- up.

Secondary: Incidence of Stent thrombosis. Late luminal loss and IVUS findings at 9 Months follow-up

Inclusion Criteria

Age : 18-85 year

Diabetes patient

Patient with positive stress test

Patient with unstable or Non-STEMI

Candidate for PCI with stent-implantation.

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Exclusion Criteria

Unable to give written informed consent

Left main stenosis $\geq 50\%$

Intolerance for aspirin or clopidogrel

Life expectancy ≤ 12 months

Malignancy disease

Pregnancy

DEAR Registry

FREEDOM Definition of Diabetics

1- Diabetes type I

2- Diabetes type II

3-Two samples of Hiperglycemia, 126mg (FC).

Flow Chart

April 2009 a September 2010
Sanatorio Otamendi
Sanatorio Las Lomas
IMA Adrogué

1027 PCI patients

18 % Diabetic
184 patients

55 was included
In the DEAR Registry

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Baseline Characteristics

| | |
|--------------------------------|--------------------------|
| Age | 64.87 ± 9.8 years |
| Acute Coronary syndrome | 72 % |
| Stable angina | 28 % |
| Male | 81 % |
| Diabetics | 100 % |
| Hypertension | 80 % |
| Smokers | 12 % |
| Ex-smokers | 48 % |
| Hypercholesterolemia | 80 % |
| Obesity (BMI) ≥ 30 | 16 % |
| AMI previous | 36 % |
| PCI previous | 60 % |
| CABG previous | 4 % |

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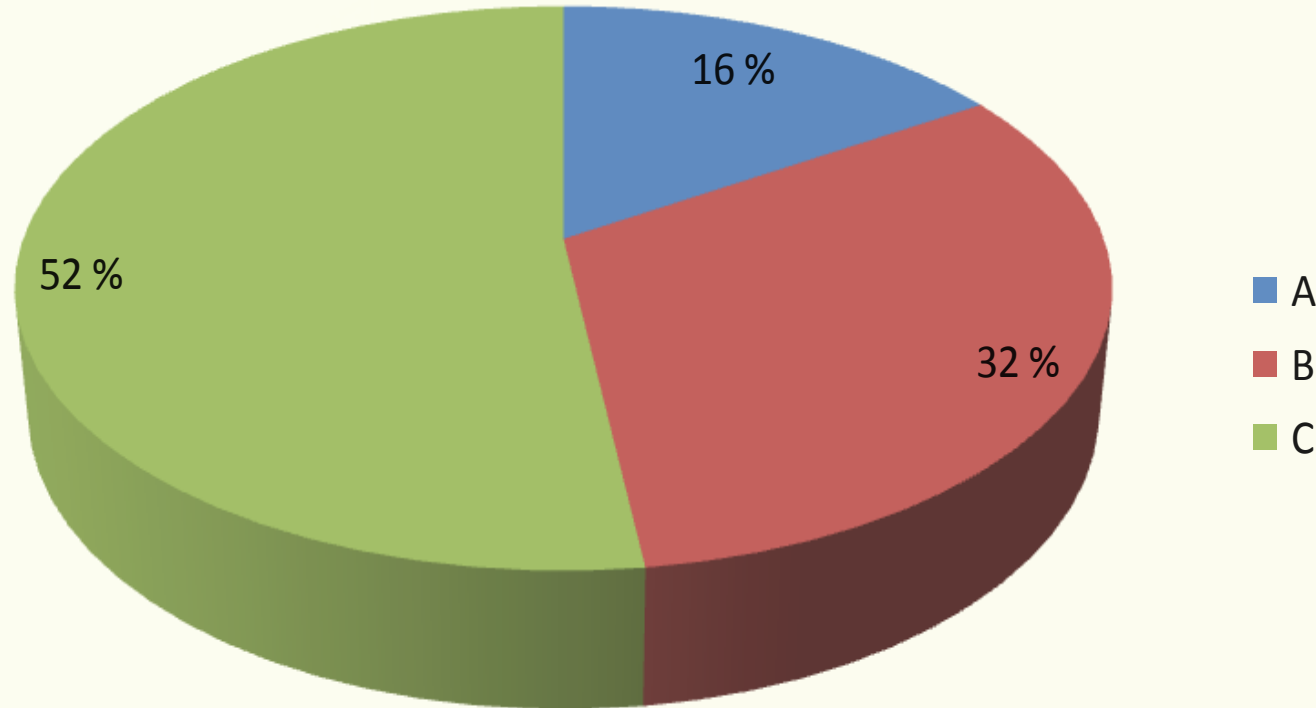
Angiographic Characteristics

| | |
|--------------------------------|--------------------------|
| Patients Number | 55 |
| Lesions Number | 65 |
| Multiple Vessel Disease | 88 % |
| LDA | 60 % |
| RCA | 21,5 % |
| LCX | 18,5 % |
| Novo Lesion | 60 % |
| Restenosis Lesion | 40 % |
| Dior Diameter | 2.41 ± 0.17 mm |
| Dior Length | 24,4 ± 4,2 mm |
| Stent Diameter | 3,0 ± 0.52 mm |
| Stent Length | 19,3 ± 4,2 mm |
| Balloon DIOR only | 15 % |
| Numbers of Balloon DIOR | 1,23 per patients |

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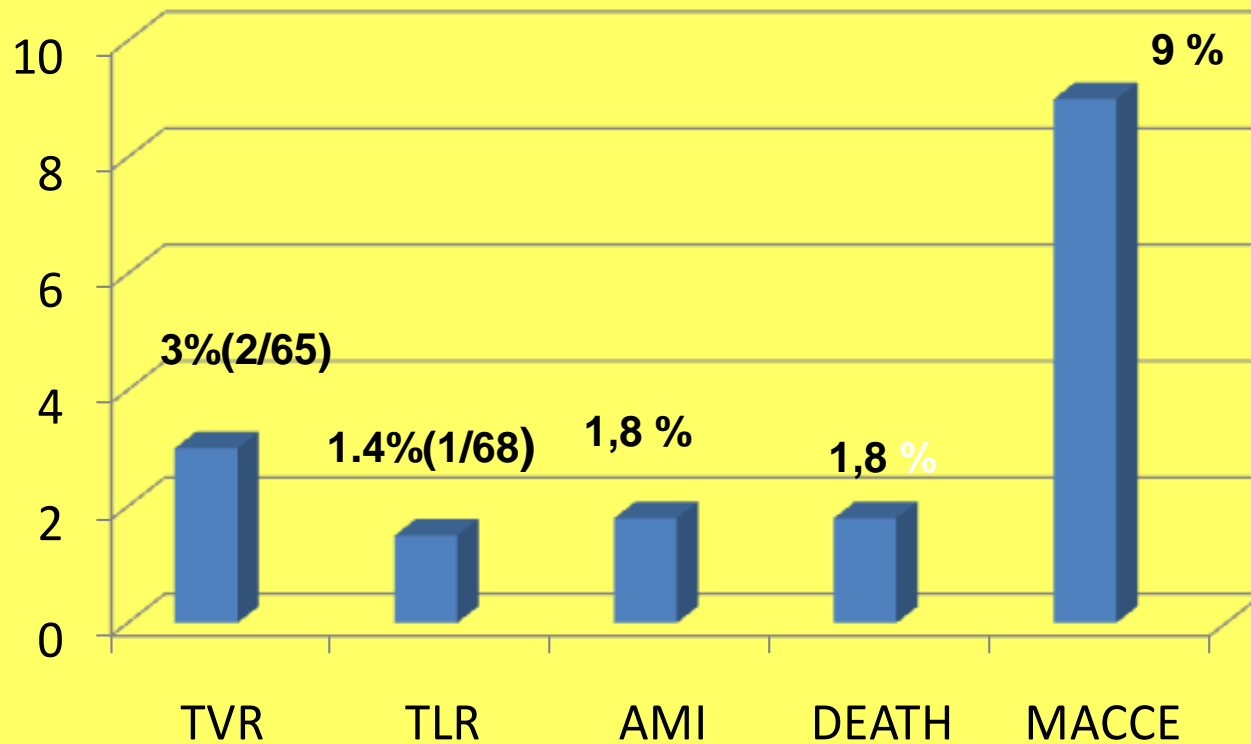
Angiographic Characteristics

Tipo de Placa Según AHA



Results

Follow at 154 ± 102 days



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DEAR Registry



GOALS

- *1- Sample size of 100 patients*
- *2- Angio/ IVUS FU in 50 patients.*
- *3- Incidence of MACCE and TVF at one year.*
- *4- Death, Cardiac Death, MI and Stroke at one year*
- *5- Any definition of Stent thrombosis at one year*

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