Impact of Diabetes on Long-term Outcomes of Drug Eluting Stents in Asian Patients

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Diabetes ; Different Disease Pattern
Anatomy of CAD in Diabetics

- Small vessel caliber (impaired remodeling or diffuse atherosclerosis)
- High incidence of multi-vessel disease
- High incidence of left main stem disease
- Complex lesion morphology; total occlusion
- Poor collateral development
- Increased coronary calcification

Diabetic patients tend to have a more aggressive form of CAD compared to non-diabetics
Diabetes

; Cardiovascular Morbidity and Mortality
Type 2 DM increases the risk of CVD

- Any cardiovascular event
- Stroke
- Intermittent claudication
- Cardiac failure
- Coronary heart disease
- Myocardial infarction
- Angina pectoris
- Sudden death
- Coronary mortality

Age-adjusted risk ratio

(1 = risk for individuals without diabetes)

*P < 0.1; †P < 0.05; ‡P < 0.01; §P < 0.001

Am Heart J 1990; 120:672–676.
Diabetes & Cardiovascular Mortality
OASIS Registry

$N=8,013$

Diabetes & CVD
RR 2.85 (2.30-3.53)

Diabetes & No CVD
RR 1.71 (1.25-2.33)

No Diabetes & CVD
RR 1.71 (1.41-2.06)

No Diabetes & No CVD
RR 1.00

Diabetes

; Revascularization Treatment (PCI or CABG)
Medical vs. PCI vs. CABG in stable multi-vessel CAD (n=611 pts)

MASS II RCT

**P=0.039 after 1 year

Soares, PR et al. Circulation 2006; 114:I420
Surgery, PCI, and medical treatment did not influence the risk of death for nondiabetic subjects.

For diabetic subjects, percutaneous or surgical revascularization was associated with a protective effect compared with medical treatment, significantly decreasing the risk of death after 1 year and up to 5 years.

Therefore, aggressive invasive revascularization should be considered in diabetic patients to improve long-term outcomes.
Diabetes

; PCI Treatment
Suggested Biological Influence of Diabetes on PCI outcomes

Enhanced Platelet Activation and Release of Growth Factors
Accelerated Proliferation and Migration of Smooth Muscle Cells
Impaired Fibrinolysis (elevated t-pa, PAI-1, D-dimer)
Increased Inflammation (CRP, fibrinogen)
Excessive Matrix Deposition
Delayed Wound Healing
Endothelial Dysfunction

(1) Increased intimal proliferation at the stented site
(2) Rapid progression of non-culprit lesions
Diabetes

; In the era of BMS
Neointimal Hyperplasia in Diabetic Patients

Late Loss
Elezi S et al. JACC 1998;32:1866

P<0.001

Intimal Hyperplasia (%)

Kornowski et al. Circulation 1997;95:1366

P<0.001

No Diabetes (n=2230)
Diabetes (n=525)

No Diabetes (n=178)
Diabetes (n=63)
Risk of Restenosis in BMS
Diabetic vs Nondiabetic Patients

- Carozza: 20% (No Diabetes), 55% (Diabetes), P=0.001
- Van Belle: 27% (No Diabetes), 25% (Diabetes), P=ns
- Lau: 17% (No Diabetes), 41% (Diabetes), P=0.02
- Elezi: 28% (No Diabetes), 37% (Diabetes), P=0.001
- Schofer: 24% (No Diabetes), 33% (Diabetes), P<0.001
- Overall: 26% (No Diabetes), 37% (Diabetes), OR=1.6 (1.4-1.9), P<0.001

N=230, 270, 84, 2255, 1439, 4808
MACE: Death, MI, TLR in BMS
Diabetes vs. non-diabetics

Event-free survival, %

Nondiabetics: 79%
Diabetics: 73%

P<0.001

Diabetes is independent predictor of restenosis and MACE in the era of BMS
Diabetes

; In the era of DES
CYPHER Trials Meta-Analysis in Diabetes

RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS, DIRECT, SVELTE

Abizaid et al. Angioplasty Summit 2005
TAXUS Trials Meta-Analysis in Diabetes

TAXUS II, IV, V, VI

- Non-Diabetic: Taxus 5.4%, Control 13.6%
  - P < 0.0001
- Diabetic (oral agents): Taxus 7.9%, Control 19.4%
  - P < 0.0001
- Diabetic (insulin): Taxus 5.8%, Control 16.9%
  - P = 0.0063

Stone GW et al. Angioplasty Summit 2005
However, Diabetic patients still have higher Restenosis rate compared to non-diabetics even in the era of DES.

Matched comparison (192: 192)

Radke PW et al. Am J Cardiol 2006;98:1218
Higher MACE in Diabetics after SES

6-month follow-up

DM  No DM

Q-MI: 3  1  \( P=0.02 \)
Death & Q MI: 6  3  \( P=0.01 \)
TLR-MACE: 6  3  \( P=0.01 \)

Kuchulakanti et al. Am J Cardiol 2005;96:1100
## Risk of Restenosis in DES

### Multivariate Predictors of In-Segment Restenosis after SES

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISR</td>
<td>4.16</td>
<td>1.63-11.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ostial lesion</td>
<td>4.84</td>
<td>1.81-12.07</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2.63</td>
<td>1.14-6.31</td>
<td>0.02</td>
</tr>
<tr>
<td>Stent length</td>
<td>1.42</td>
<td>1.21-1.68</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ref diameter</td>
<td>0.46</td>
<td>0.24-0.87</td>
<td>0.03</td>
</tr>
<tr>
<td>LAD</td>
<td>0.30</td>
<td>0.10-0.69</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

A Pooled Analysis of Data Comparing Sirolimus-Eluting Stents with Bare-Metal Stents

Christian Spaulding, M.D., Joost Daemen, M.D., Eric Boersma, Ph.D., Donald E. Cutlip, M.D., and Patrick W. Serruys, M.D., Ph.D.

Pooled analysis of 1748 patients in 4 RCTs comparing SES with BMS
(Pivotal SES Trials: RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS)

NEJM 2007;356:989-97
No difference in rates of death, MI, or stent thrombosis at 4 year
Significant difference in rates of deaths from both cardiovascular and noncardiovascular cause in **Diabetic Patients** at 4 year F/U.
Impact of diabetes mellitus on long-term outcomes in the drug-eluting stent era

Raisuke Iijima, MD, Gjin Ndrepepa, MD, Julinda Mehilli, MD, Christina Markwardt, MD, Olga Bruskina, MD, Jürgen Pache, MD, Maryam Ibrahim, MD, Albert Schömig, MD, and Adnan Kastrati, MD  Munich, Germany

Prospective database of 2557 patients in 2 centers: Diabetes (n=727) vs. Non-diabetes (n=1830)

Am Hear J 2007;154:688-93
Angiographic and clinical restenosis (TLR)

- **Angiographic Restenosis**
  - Diabetic patients: 15.2% (P = .32)
  - Nondiabetic patients: 13.5%

- **Clinical Restenosis**
  - Diabetic patients: 12.8% (P = .56)
  - Nondiabetic patients: 12.0%
Long-term clinical outcome

All-cause mortality

Death or MI

Diabetes is independent predictor of 3 year mortality
Incidence, Predictors, and Outcome of Thrombosis After Successful Implantation of Drug-Eluting Stents

*JAMA* 2005;293:2126-2130

**Diabetes** (HR 3.71, 95% CI, 1.74–7.89).

Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study

*Lancet* 2007;369: 667–78

**Diabetes** (HR 2.03, 95% CI, 1.07–3.83).

Diabetes is independent predictors of stent thrombosis
General Concerns
about Diabetic Influence
in Patients Undergoing PCI with DES

• Still higher restenosis rate and MACE in diabetics compare to non-diabetics
• Higher mortality after PCI with DES?
• Higher incidence of stent thrombosis?
Prognostic Influence of Diabetes Mellitus on Long-Term Clinical Outcomes and Stent Thrombosis Following Drug-Eluting Stent Implantation in Asian Patients

Overall 3160 patients:
Diabetes (n=865) vs. Non-diabetes (n=2295) during 3-year follow-up.
Outcomes of study

• Primary end-point
  ; Composite of death, nonfatal MI, or TVR

• Secondary end-points
  ; Death, MI, TLR, TVR, and stent thrombosis (ARC criteria)
Clinical characteristics is different

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diabetes (n=865)</th>
<th>Non-diabetes (n=2295)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>62.7±9.1</td>
<td>59.7±10.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td>312 (36.1)</td>
<td>619 (27.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>533 (61.6)</td>
<td>1066 (46.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Lipid profiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>178.2±53.3</td>
<td>172.2±48.5</td>
<td>0.003</td>
</tr>
<tr>
<td>Triglyceride (mg/dl)</td>
<td>161.2±102.8</td>
<td>147.0±93.5</td>
<td>0.005</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dl)</td>
<td>41.9±17.3</td>
<td>43.2±15.1</td>
<td>0.10</td>
</tr>
<tr>
<td>Current smoking</td>
<td>201 (23.2)</td>
<td>719 (31.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Renal failure</td>
<td>50 (5.8)</td>
<td>30 (1.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>99 (11.4)</td>
<td>198 (8.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>Previous coronary angioplasty</td>
<td>161 (18.6)</td>
<td>383 (16.7)</td>
<td>0.20</td>
</tr>
<tr>
<td>Previous coronary artery bypass graft</td>
<td>31 (3.6)</td>
<td>53 (2.3)</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Clinical characteristics is different

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diabetes (n=865)</th>
<th>Non-diabetes (n=2295)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical indication</td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stable angina</td>
<td>450 (52.0)</td>
<td>1074 (46.8)</td>
<td></td>
</tr>
<tr>
<td>Unstable angina</td>
<td>334 (38.6)</td>
<td>865 (37.7)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>81 (9.4)</td>
<td>356 (15.5)</td>
<td></td>
</tr>
<tr>
<td>Multivessel disease</td>
<td>585 (67.6)</td>
<td>1280 (55.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)</td>
<td>57.9±9.3</td>
<td>58.6±8.7</td>
<td>0.04</td>
</tr>
<tr>
<td>Medications at discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td>10 (1.2)</td>
<td>21 (0.9)</td>
<td>0.54</td>
</tr>
<tr>
<td>Statin</td>
<td>498 (57.6)</td>
<td>1240 (54.0)</td>
<td>0.07</td>
</tr>
<tr>
<td>β-Blocker</td>
<td>631 (72.9)</td>
<td>1629 (71.0)</td>
<td>0.28</td>
</tr>
<tr>
<td>Calcium Channel Blocker</td>
<td>417 (48.2)</td>
<td>1129 (49.2)</td>
<td>0.62</td>
</tr>
<tr>
<td>ACE inhibitor</td>
<td>536 (62.0)</td>
<td>1271 (55.4)</td>
<td>0.001</td>
</tr>
</tbody>
</table>
### Lesion characteristics is different

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diabetes (n=865)</th>
<th>Non-diabetes (n=2295)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated lesions, No.</td>
<td>1301</td>
<td>3190</td>
<td></td>
</tr>
<tr>
<td>Left anterior descending artery</td>
<td>637 (49.0)</td>
<td>1579 (49.5)</td>
<td>0.74</td>
</tr>
<tr>
<td>Left main artery</td>
<td>83 (6.4)</td>
<td>224 (7.0)</td>
<td>0.44</td>
</tr>
<tr>
<td>Lesion Characteristics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACC/AHA type B2 or C lesion</td>
<td>1008 (77.5)</td>
<td>2330 (73.0)</td>
<td>0.002</td>
</tr>
<tr>
<td>Ostial</td>
<td>84 (6.5)</td>
<td>271 (8.5)</td>
<td>0.02</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>236 (18.1)</td>
<td>501 (15.7)</td>
<td>0.05</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>70 (5.4)</td>
<td>181 (5.7)</td>
<td>0.70</td>
</tr>
<tr>
<td>Restenotic lesion</td>
<td>68 (5.2)</td>
<td>183 (5.7)</td>
<td>0.50</td>
</tr>
</tbody>
</table>
### Procedure related characteristics is different

<table>
<thead>
<tr>
<th>Variable</th>
<th>Diabetes (n=865)</th>
<th>Non-diabetes (n=2295)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated lesions, No.</td>
<td>1301</td>
<td>3190</td>
<td></td>
</tr>
<tr>
<td>Direct stenting</td>
<td>174 (13.4)</td>
<td>553 (17.3)</td>
<td>0.001</td>
</tr>
<tr>
<td>IVUS guidance</td>
<td>798 (61.3)</td>
<td>2099 (65.8)</td>
<td>0.01</td>
</tr>
<tr>
<td>DES type</td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>Sirolimus-eluting stent</td>
<td>976 (75.0)</td>
<td>2478 (77.7)</td>
<td></td>
</tr>
<tr>
<td>Paclitaxel-eluting stent</td>
<td>325 (25.0)</td>
<td>712 (22.3)</td>
<td></td>
</tr>
<tr>
<td>Number of stents per patient</td>
<td>2.1±1.2</td>
<td>1.8±1.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total stent length per patient (mm)</td>
<td>53.5±33.3</td>
<td>46.0±29.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Average stent diameter per patient (mm)</td>
<td>3.1±0.3</td>
<td>3.2±0.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Use of Glycoprotein IIb/IIIa inhibitors</td>
<td>24 (2.8)</td>
<td>69 (3.0)</td>
<td>0.73</td>
</tr>
</tbody>
</table>
# Adjusted HRs of Clinical Outcomes
## Diabetic vs. Non-diabetics

<table>
<thead>
<tr>
<th>Outcome</th>
<th>HR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1.35</td>
<td>0.89-2.05</td>
<td>0.16</td>
</tr>
<tr>
<td>MI</td>
<td>1.08</td>
<td>0.78-1.50</td>
<td>0.63</td>
</tr>
<tr>
<td>TLR</td>
<td>1.06</td>
<td>0.78-1.43</td>
<td>0.71</td>
</tr>
<tr>
<td>TVR</td>
<td>1.37</td>
<td>1.04-1.81</td>
<td>0.03</td>
</tr>
<tr>
<td>Death/MI</td>
<td>1.18</td>
<td>0.92-1.53</td>
<td>0.20</td>
</tr>
<tr>
<td>Death/MI/TVR</td>
<td>1.24</td>
<td>1.02-1.51</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Stent thrombosis

| Definite                 | 0.62| 0.20-1.84  | 0.41|
| Definite/probable        | 0.87| 0.37-2.06  | 0.77|
| Any                      | 1.14| 0.69-1.99  | 0.64|
Composite of Death, MI, or TVR

Log-Rank $P<0.001$

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Diabetes (n=865)</th>
<th>Non-diabetes (n=2295)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>865</td>
<td>2295</td>
</tr>
<tr>
<td>Non-diabetes</td>
<td>2295</td>
<td>2295</td>
</tr>
</tbody>
</table>

Follow-up (days)

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>365</th>
<th>730</th>
<th>457</th>
<th>195</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>730</td>
<td>457</td>
<td>195</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-diabetes</td>
<td>2057</td>
<td>1339</td>
<td>581</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Stent Thrombosis

Event rates (%)

No. at Risk

Diabetes 865
Non-diabetes 2295

Follow-up (days)

0 365 730 1095

0 1 2 3 4

Log-Rank $P=0.25$

Diabetes (n=865)
Non-diabetes (n=2295)
Non-diabetes vs. Insulin-treated diabetes

<table>
<thead>
<tr>
<th>Event</th>
<th>Adjusted HR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2.77 (1.55-4.95)</td>
<td>0.001</td>
</tr>
<tr>
<td>MI</td>
<td>1.01 (0.54-1.89)</td>
<td>0.97</td>
</tr>
<tr>
<td>TLR</td>
<td>1.36 (0.77-2.39)</td>
<td>0.29</td>
</tr>
<tr>
<td>TVR</td>
<td>1.72 (1.02-2.88)</td>
<td>0.04</td>
</tr>
<tr>
<td>Death or MI</td>
<td>1.66 (1.09-2.53)</td>
<td>0.02</td>
</tr>
<tr>
<td>Death, MI, or TVR</td>
<td>1.65 (1.17-2.32)</td>
<td>0.004</td>
</tr>
<tr>
<td>ST (definite or probable)</td>
<td>0.99 (0.20-4.92)</td>
<td>0.99</td>
</tr>
<tr>
<td>ST (any ARC criteria)</td>
<td>1.75 (0.77-3.96)</td>
<td>0.20</td>
</tr>
</tbody>
</table>
Non-diabetes vs. Non-insulin-treated diabetes

<table>
<thead>
<tr>
<th>Event</th>
<th>Adjusted HR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.86 (0.52-1.45)</td>
<td>0.58</td>
</tr>
<tr>
<td>MI</td>
<td>1.05 (0.74-1.49)</td>
<td>0.79</td>
</tr>
<tr>
<td>TLR</td>
<td>0.94 (0.67-1.32)</td>
<td>0.72</td>
</tr>
<tr>
<td>TVR</td>
<td>1.23 (0.91-1.67)</td>
<td>0.18</td>
</tr>
<tr>
<td>Death or MI</td>
<td>0.99 (0.74-1.31)</td>
<td>0.92</td>
</tr>
<tr>
<td>Death, MI, or TVR</td>
<td>1.08 (0.87-1.35)</td>
<td>0.47</td>
</tr>
<tr>
<td>ST (definite or probable)</td>
<td>0.62 (0.21-1.88)</td>
<td>0.40</td>
</tr>
<tr>
<td>ST (any ARC criteria)</td>
<td>0.74 (0.36-1.52)</td>
<td>0.41</td>
</tr>
</tbody>
</table>
Summary: Diabetic Impact in Asian Patients

- The overall mortality rate was similar in diabetic and non-diabetic patients.
- Diabetic patients have a higher incidence of TVR, without a significantly increased rate of TLR.
- There was no significant association between increased risk of stent thrombosis, whether insulin-dependent or not.
- Insulin-treated diabetes was independently associated with increased risk of death/MI/or TVR.
Any Differences of Mortality and Stent Thrombosis after DES Implantation in Asian vs. Western Patients?
All-cause mortality of Asian Registry is similar to Western RCT Results, but lower than Western Registry data.

Park et al. JACC: Cardiovascular Interventions 2008
Death or MI

All-Death or MI of Asian Registry is similar to Western RCT Results, but lower than Western Registry data.

Park et al. *JACC: Cardiovascular Interventions* 2008
Incidence of ST of Asian Registry is similar to western RCT Results, but lower than Western Registry data.
Incidence of ST (Definite+Probable)

Incidence of ST of Asian Registry is similar to western RCT Results

Park et al. JACC: Cardiovascular Interventions 2008
Independent risk factors of ST

- Acute coronary syndrome
- Diabetes
  \textit{Bern / Rotterdam}

- Lower ejection fraction
- Renal failure
- Stent length
  \textit{AMC Registry}

Patient’s factors may be more involved in development of ST in the DES era. Diabetics is independent predictor in western study.
Stent Thrombosis

Log-Rank $P=0.25$

Event rates (%)

No. at Risk

<table>
<thead>
<tr>
<th>Condition</th>
<th>Data Points</th>
<th>Follow-up (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>865</td>
<td>842, 561, 247</td>
</tr>
<tr>
<td>Non-diabetes</td>
<td>2295</td>
<td>2248, 1521, 674</td>
</tr>
</tbody>
</table>

AMC Data
Impact of DM on Restenosis after DES Implantation

1126 Cypher lesions and 308 Taxus lesions

- DM: 28/383 (7.3%)
- Non-DM: 87/1051 (8.3%)

P = NS

TH Y et al. Am J Cardiol 2005;96:1389
Impact of Diabetes

All-Cause Mortality

Death at 4 yr F/U

Patients with Diabetes

Death at 2 yr F/U

Patients with Diabetes

Death at 3 yr F/U

Patients with Diabetes

All-Cause Mortality

<table>
<thead>
<tr>
<th>RCTs</th>
<th>J-Cypher</th>
<th>AMC Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>(RAVEL, SIRIUS, E-SIRIUS, C-SIRUS)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Overall Survival (%)

0 360 720 1080 1440

Days

P=0.004

BMS (95.6%)

SES (87.8%)

P=0.63

BMS (92.7%)

SES (92.3%)

P=0.03

DES (94.3%)

BMS (91.5%)
Summary

• Incidence of ST and all-cause mortality of Asian registry was similar to those of western RCT, but lower than results of western registry.
• Important predictors of ST was mainly due to patient’s clinical factors.
• Impact of diabetes on the long-term outcomes in Asia was very modest, compared to the features from Western data.
Diabetes
;
CYPHERER vs. TAXUS
ISAR-DIABETES Trial

Late Lumen Loss

In-stent
p<0.002
In-lesion
P<0.001

Re-stenosis

Kastrati et al., NEJM 2005;353:663-70
There was a trend towards a reduction in TLR ($p=0.13$)

*Kastrati et al., NEJM 2005;353:663-70*
CYPHER vs. TAXUS in Diabetic Patients:

Data from the Strategic Transcatheter Evaluation of New Therapies (STENT) Group Registry
## DES Only Patients with Completed 9 Month Follow-Up

### Patient Level Analysis

PES or SES *Patients* with 9 mo F/U  

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Diabetic Patients</td>
<td>1680</td>
<td>30.2%</td>
</tr>
<tr>
<td>Sirolimus Eluting Stent Only</td>
<td>875</td>
<td>52.1%</td>
</tr>
<tr>
<td>Paclitaxel Eluting Stent Only</td>
<td>805</td>
<td>47.9%</td>
</tr>
<tr>
<td>Non-Insulin Treated Diabetics</td>
<td>1182</td>
<td></td>
</tr>
<tr>
<td>Sirolimus Eluting Stent Only</td>
<td>612</td>
<td>51.8%</td>
</tr>
<tr>
<td>Paclitaxel Eluting Stent Only</td>
<td>570</td>
<td>48.2%</td>
</tr>
<tr>
<td>Insulin-Treated Diabetics</td>
<td>498</td>
<td></td>
</tr>
<tr>
<td>Sirolimus Eluting Stent Only</td>
<td>263</td>
<td>52.8%</td>
</tr>
<tr>
<td>Paclitaxel Eluting Stent Only</td>
<td>235</td>
<td>47.2%</td>
</tr>
</tbody>
</table>
9 Month Clinical Outcomes: Non-Insulin Treated Diabetics (unadjusted)

P=NS for all

- Death: SES 2.5, PES 1.9
- MI: SES 1.3, PES 1.2
- TVR: SES 3.1, PES 4.4
- MACE: SES 5.6, PES 7.2
- SAT: SES 0.5, PES 1.1
9 Month Clinical Outcomes: Insulin Treated Diabetics (unadjusted)

- Death: SES 5.7%, PES 2.1%
- MI: SES 1.9%, PES 1.3%
- TVR: SES 4.2%, PES 3.4%
- MACE: SES 10.7%, PES 6.0%
- SAT: SES 0.4%, PES 0.4%

P = 0.08
P = NS for all
Adjusted Hazard Ratios for Time to Event
Comparing PES- and SES-Only Non-Insulin Treated Patients

Note: Reference group for HR is SES group

HR=1.2  95% CI (0.6-2.3), p=0.55

HR=1.2  95% CI (0.8-2.0), p=0.40
Adjusted Hazard Ratios for Time to Event Comparing PES- and SES-Only Insulin Treated Patients

HR=0.78, 95% CI (0.29-2.11), p=0.63

HR=0.48, 95% CI (0.23-1.01), p=0.05

Note: Reference group for HR is SES group
Conclusions: STENT Registry

• PES and SES procedures show similar and very favorable late clinical outcomes in diabetic patients, similar to that reported in prior studies for non-diabetics.

• The insulin-treated diabetic group shows a trend favoring PES over SES for late MACE, but needs to be confirmed by further studies.
Summary (1)
PCI in Diabetics

- Aggressive revascularization strategy improves the survival in diabetic patients compared to medical treatment.
- Diabetic patients treated with DES bring a reduced risk of TLR, TVR, TVF and MACE compared with BMS.
- Diabetics still have higher TVR and Death/MI/TVR especially, insulin treated diabetics have a clear trend of poor clinical outcomes (Death, TVR and Death/MI/TVR) compared to non-diabetics even in the era of DES.
According to the ISAR-DIABETES and DECLARE-DIABETES Trial, SES appears to be more effective than PES in preventing restenosis in on-label lesions. However, in real practice, two stent had similar outcomes.

Adjunctive pharmacologic therapy (Cilostazol, GP IIb/IIIa, Thiazolidinediones, ACEI, strict glycemic control) is likely to further improve PCI outcomes.

Efficacy concerns of DES compare to surgery should be evaluated in the future.