Delayed Coronary In-stent Restenosis and Disease Progression in Patients with Single Vessel Coronary Artery Disease

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Background: The impact of delayed clinical in-stent restenosis on the late re-interventions (RI) rate is currently unknown. To address this issue, we analyzed the long-term clinical outcome in patients undergoing stent implantation for single de novo lesions who were event-free after one year of follow-up, with an especial emphasis on the rate of delayed restenosis and disease progression.

Methods: Retrospective analysis in patients who underwent single-vessel stenting from January 2004 to December 2006 (N = 1385). In order to control for confounders, we excluded patients with multivessel disease and patients who had RI during their first year of follow-up (N = 1108). From November 2012 to March 2013, we contacted all patients included in the study (n = 277) and collected the following events: cardiac death, RI, target lesion RI (TLR) and RI to other coronary segments due to disease progression. Very late TLR was defined as TLR events occurring after 3 years of follow-up, while isolated TLR was defined as TLR events occurring without RI due to concomitant disease progression.

Results: Mean age was 60.3 ± 10.1 years, 20.6% were females, 16.2% diabetics and 72% had an acute coronary syndrome. 21.5% received a drug-eluting stent and 78.5% a bare-metal stent (50.2% to the left anterior descending, 26% to the circumflex and 23.8% to the right coronary artery). Follow-up was available in 97.9% (92% with 7 years, mean follow-up 6.3 ± 3.2 years). During follow-up, 89.2% of patients had at least one non-invasive exercise test during follow-up (mean test performed per patient 3.2 ± 1.8). 19.8% of those patients had a positive ischemic test at follow-up. 37.9% (n = 105) of patients underwent diagnostic coronary angiography, while 16% (n = 44) required RI (Table). Cardiac death occurred in 2.8% of patients.

Conclusions: 1) Disease progression in patients with single vessel obstructive coronary artery disease is an infrequent phenomenon but constitutes the dominant cause for late RI. 2) Delayed clinical restenosis is rare. It's very late manifestation, typically due to in-stent neointimal hyperplasia, appears to have a very low clinical impact at least until the seventh year of follow-up.

<table>
<thead>
<tr>
<th>Disease progression</th>
<th>N</th>
<th>% Total</th>
<th>% RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR</td>
<td>16</td>
<td>5.8</td>
<td>36.3</td>
</tr>
<tr>
<td>Very late TLR</td>
<td>7</td>
<td>2.5</td>
<td>15.9</td>
</tr>
<tr>
<td>Isolated TLR</td>
<td>7</td>
<td>2.5</td>
<td>15.9</td>
</tr>
<tr>
<td>Very late, isolated TLR</td>
<td>3</td>
<td>1.1</td>
<td>6.8</td>
</tr>
</tbody>
</table>

TCT-482

“Resistant” In-Stent Restenosis in the Drug-Eluting Stent Era: An Angiographic Description and Outcomes

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Background: In the drug-eluting stent era, in-stent restenosis (ISR) followed by ISR recurrence, represents a rare yet challenging clinical problem. The definition and angiographic patterns of this phenomenon have not yet been reported.

Methods: We defined “resistant” DES ISR (R-ISR) as the second occurrence of ISR after initial successful treatment with DES. We identified 213 lesions in 201 patients treated with DES who presented with R-ISR between 2003 and 2011 at our institution. We reviewed all angiograms to assess any patterns borne from either the first and second ISR episode as described by the Mehran classification.

Results: Patients with “resistant” ISR were more frequently male (72%) with a mean age of 63 years. They presented with a very high frequency of diabetes (56%), overweight (70%), and chronic kidney disease (35%). Most lesions were bifurcation (55%) with moderate to severe calcification (58%). R-ISR presented after 34 months from the first procedure, with a focal pattern (≤ 10 mm in length) in 78%, and diffuse pattern (> 10 mm in length) in 22% of the patients. The rates of all-cause mortality, MI, or target vessel failure (TVF) at 1-year were 4%, 3%, and 18%, respectively. Patients with paclitaxel-eluting stent (PES) R-ISR showed a higher rate of ischemic events compared with other type of stents at 1-year follow-up (Table 1).

Conclusions: Patients with “resistant” DES ISR comprise a very high-risk population with suboptimal outcomes that are characterized by a high rate of ischemic adverse events. R-ISR after PES appears to result in worse outcomes compared with other DES.
**TCT-483**

Predictors of Early Stent Thrombosis After Implantation of Drug-Eluting Stents in Daily Clinical Practice – A Subanalysis of the Large, Prospective DESIRE (Drug-Eluting Stent In the REAL World) Registry

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**Background:** Previous studies have suggested that early ST (<30 days) may have a different physiopathology as compared to late events occurring after this period. Our objective was to investigate the predictors of ST in a large cohort of patients enrolled in the prospective, single center DESIRE Registry.

**Methods:** A total of 4,790 pts (7,530 lesions) undergoing elective for emergency PCI solely with DES (n=8,058) as a default strategy were enrolled between May/02-Mar/13. Clinical follow-up (FU) was performed at 1, 6 and 12 months and yearly up to 10 years (97.3%). ST was defined according to the propositions of the Academic Research Consortium.

**Results:** The overall incidence of ST was 2.4% (n=111), given that 95% of patients were ST-free up to 10 years FU (Kaplan-Meier estimate). Compared to those without ST, pts with ST had a trend towards more diabetes (36 vs. 30.5%, p=0.18) and target lesion in saphenous vein grafts (SVG) (7.4 vs. 5.6, p=0.10), and significantly more current smoking (41.2 vs. 30.1%, p=0.02), clinical presentation of recent MI (29.9 vs. 15.2%, p=0.001), moderate/severe lesion calcification (36.1 vs. 26.8%, p=0.001), poor left ventricle ejection fraction (<30%) (18.2 vs. 2%, p=0.02), multiple DES implanted (56.6 vs. 46.1%, p=0.03), and residual stenosis as assessed by QCA (5.0 vs. 3.7%, p<0.001). In the multivariate model, independent predictors of ST were recent MI (<72 hours) (HR 2.66, 95% CI 1.52-4.66, p=0.004), recent MI (3-30 days) (HR 1.89, 95% CI 1.08-3.29, p=0.03), clinical presentation of recent MI (29.9 vs. 15.2%, p=0.001), and residual MI (2.4% vs. 1.5%, p=0.05).

**Conclusion:** Compared to 1st generation DES, those treated with 2nd generation DES had more diabetes (p=0.001), multivessel disease (p<0.001), and multiple DES implanted (p<0.001), but angiographic success was similar in both groups (>99%). The occurrence curve for ST (ARC) up to 2 years FU with landmark analysis at 1 year is shown in the Figure.

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**TCT-484**

Impact of Second Generation Drug-Eluting Stents on the Occurrence of Late and Very Late Stent Thrombosis – A Subanalysis of the Large, Prospective DESIRE (Drug-Eluting Stent In the REAL World) Registry

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**Background:** In the second generation drug-eluting stent (DES) era, it had reported that clinical outcome of paclitaxel-eluting stent (PES) deployment was better than sirolimus-eluting stent. But clinical outcome of PCI with second generations DES was not established. Our aim was to investigate the clinical outcomes of hemo dialysis (HD) patients after PCI with DES.

**Methods:** In 6298 consecutive cases which underwent PCI with DES between April 2007 and June 2012, 182 consecutive patients (247 lesions) on HD patients were treated with PES (P group: 93 patients, 117 lesions), everolimus-eluting stent (E group: 54 patients, 78 lesions) or biolimus-eluting stent (B group: 35 patients, 52 lesions) implantation and were follow up to 8 months. The primary endpoints were angiographic outcomes and MACE (death, myocardial infarction, CABG, target lesion revascularization: TLR).

**Results:** Clinical follow up was obtained on all patients. Angiographic follow up was obtained in 201 lesions (81.4%). No significant difference was detected in the baseline demographic, angiographic, and lesion characteristics. In eight month follow-up, the mean values of late lumen loss (P group: 0.5 ± 0.6%, B: 0.6 ± 0.2%, E: 0.7 ± 0.6%, p=0.016), TLR (P group: 9.3%, E: 15.4%, B: 28.9%; p<0.01) and MACE (P group: 12.7%, E: 19.2%, B: 28.9%; p=0.04) in P group was the lowest in these groups. In multivariate analysis, predictors of TLR were diabetes mellitus (OR: 2.7, 95%CI: 1.1-7.0, p=0.025), BES deployment (OR: 3.4, 95%CI: 1.5-7.5, p=0.0027) and product of serum calcium and phosphorus (>38) (OR: 3.6, 95%CI: 1.6-8.9, p=0.016).

**Conclusion:** In PCI with DES for HD patients, second generation DES hasn’t improved clinical outcomes. PES deployment is still usefulness today.