

**TCT-483**

**Angiographic and two-year clinical outcomes following percutaneous coronary intervention for in-stent restenosis of polymer-free sirolimus- and probucol-eluting stent compared with durable polymer zotarolimus-eluting stent**



Yukinori Harada,<sup>1</sup> Roisin Colleran,<sup>1</sup> Sebastian Kufner,<sup>2</sup> Daniele Giacoppo,<sup>1</sup> Tobias Rheude,<sup>2</sup> Jonathan Michel,<sup>3</sup> Jens Wiebe,<sup>1</sup> Salvatore Cassese,<sup>1</sup> Tareq Ibrahim,<sup>4</sup> Karl-Ludwig Laugwitz,<sup>4</sup> Adnan Kastrati,<sup>2</sup> Robert Byrne<sup>1</sup>

<sup>1</sup>Deutsches Herzzentrum München, Technische Universität München, Munich, Germany; <sup>2</sup>Deutsches Herzzentrum München, Munich, Germany; <sup>3</sup>Deutsches Herzzentrum München, Munich, Germany; <sup>4</sup>Medizinische Klinik, Klinikum rechts der Isar, Technische Universität München, Munich, Germany

**BACKGROUND** Outcomes following treatment of in-stent restenosis (ISR) of polymer-free drug-eluting stents remain unknown.

**METHODS** Patients originally included in ISAR-TEST 5 randomized trial who were subsequently treated for ISR in polymer-free sirolimus- and probucol-eluting stents (SPES) vs. durable polymer zotarolimus-eluting stents (ZES) were included in this study. Angiographic outcomes at 6 to 8 months and clinical outcomes at 2 years were analyzed. Survival analysis was performed using Kaplan-Meier method and hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated using Cox proportional hazards models.

**RESULTS** A total of 326 patients with ISR were included in this study: 220 with ISR of polymer-free sirolimus- and probucol-eluting stents and 106 with ISR of durable polymer zotarolimus-eluting stents. The proportion of patients undergoing repeat stenting was similar in both groups (SPES: 59.6% vs. ZES: 55.6%,  $p=0.45$ ) though the proportion of patients undergoing drug-coated balloon angioplasty was higher with SPES (SPES: 26.2% vs. ZES: 8.5%,  $p=0.006$ ). At angiographic follow-up, no difference was observed in terms of binary restenosis between the two groups (SPES: 31.7% vs. ZES: 27.0%,  $p=0.38$ ). At 2 years, the incidences of composite of all-cause death, myocardial infarction, or target lesion revascularization (SPES: 35.7% vs. ZES: 34.0%, HR=1.04, 95% CI, 0.70-1.55;  $p=0.83$ ) and target lesion revascularization (SPES: 29.8% vs. ZES: 31.5%; HR=0.91, 95% CI, 0.60-1.39;  $p=0.68$ ) were comparable in both groups.

**CONCLUSION** Outcomes after treatment of ISR was similar in patients with ISR in polymer-free SPES vs. durable polymer ZES.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**TCT-484**

**Difference in Restenosis Pattern and Related Clinical Presentation between Early, Late, and Very Late Restenosis after Sirolimus-Eluting Stent Implantation**



Shunsuke Kubo,<sup>1</sup> Akimune Kuwayama,<sup>2</sup> Takenobu Shimada,<sup>3</sup> katsuya miura,<sup>4</sup> Masanobu Ohya,<sup>5</sup> Hideo Amano,<sup>6</sup> Yusuke Hyodo,<sup>7</sup> Suguru Otsuru,<sup>8</sup> Seiji Habara,<sup>9</sup> Takeshi Tada,<sup>10</sup> Hiroyuki Tanaka,<sup>11</sup> Yasushi Fuku,<sup>12</sup> Tsuyoshi Goto,<sup>13</sup> Kazushige Kadota<sup>14</sup>

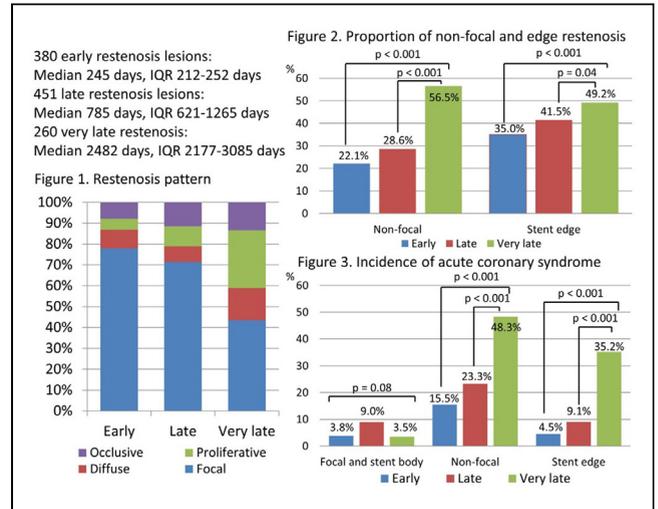
<sup>1</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>2</sup>Kurashiki central hospital; <sup>3</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>4</sup>Kurashiki central hospital, kurashiki, Japan; <sup>5</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>6</sup>Kurashiki central hospital; <sup>7</sup>Kurashiki central hospital; <sup>8</sup>Kurashiki City, Japan; <sup>9</sup>Kurashiki central hospital, Okayama, Japan; <sup>10</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>11</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>12</sup>Kurashiki Central Hospital, Kurashiki, Japan; <sup>13</sup>Kurashiki, Okayama, Japan; <sup>14</sup>Kurashiki Central Hospital, Kurashiki, Japan

**BACKGROUND** Target lesion revascularization due to very late restenosis is observed beyond 5 years after sirolimus-eluting stent (SES) implantation. Focal restenosis pattern is reported to be the most common morphology after SES implantation. However, the restenosis patterns and related clinical presentation in the very late phase remain unknown.

**METHODS** From 2002 to 2007, SES was implanted in 4097 lesions (2101 patients). Among them, this study included 380 restenosis lesions at early-term coronary angiography (CAG) (<1 year, 3564 lesions), 451 restenosis lesions at late-term CAG (1 to 5 years, 2935 lesions), and 260 very late restenosis lesions at very late-term CAG (>5 years, 659 lesions). Restenosis patterns were classified according to the Mehran's classification. Clinical presentation was divided

into acute coronary syndrome (ACS) and non ACS at the timing of CAG.

**RESULTS** The distribution of restenosis patterns is shown in Figure 1. Diffuse and proliferative patterns substantially increased from late to very late restenosis. The proportions of non-focal pattern and stent-edge pattern were significantly higher in very late restenosis lesions than in early and late restenosis lesions (Figure 2). In each non-focal and stent-edge restenosis lesion, the incidence of ACS was significantly higher in very late restenosis compared to early and late restenosis. However, that in focal and stent-body restenosis lesion was observed similarly between the 3 groups (Figure 3).



**CONCLUSION** Non-focal and stent edge restenosis patterns were more specific morphology and the main cause of ACS in the very late phase after SES implantation. Our findings suggest that diffuse stenotic change at the stent edge was the most common morphology of in-stent neoatherosclerosis of SES.

**CATEGORIES CORONARY:** Stents: Drug-Eluting

**TCT-485**

**A study of safety and efficacy of biodegradable polymer coated Everolimus-eluting coronary stent system [Everoflex] at intermediate follow-up in real world scenario**



Rajasekhara Durgaprasad,<sup>1</sup> Velam Vanajakshamma,<sup>1</sup> Vamsidhar Akkulagari,<sup>1</sup> Latheef Kasala,<sup>1</sup> Sreedhar Naik Kanavat,<sup>1</sup> Pathakota Sudhakar Reddy<sup>1</sup>

<sup>1</sup>Sri Venkateswara Institute of Medical Sciences, Tirupati, Andhra Pradesh, India

**BACKGROUND** Everoflex is a biodegradable everolimus-eluting Cobalt-Chromium coronary stent system with thin struts (60µ) developed by Sahajanand Medical Technologies Pvt Ltd (Surat, Gujarat, India). The aim of the study is to evaluate and collect the safety and performance data for an all-comers patient population treated with Everoflex coronary stents within daily clinical practice.

**METHODS** It is a single-center, non-randomized, prospective registry of 335 consecutive patients who underwent percutaneous coronary intervention with Everoflex stents between 1st January, 2015 and 10th January, 2016. Twelve cases lost follow-up and 323 cases were included. The primary end-point of this study was incidence of cardiac death, myocardial infarction and target lesion revascularization. Secondary endpoint was composite of device oriented end-points as well as patient oriented outcomes comprising overall mortality, any myocardial infarction and repeat revascularization. This study was approved by the institutional ethics committee of our institute.

**RESULTS** The mean age of the study group was 56.6±10.6 years, 242 (75.2%) were male, 107 (33.1%) were diabetic and 135 (41.8%) were hypertensive. Majority (61.3%) had single vessel disease. Left anterior descending artery (66.9%) was the most common revascularized