**Do Multiple Prior Interventions for In-Stent Restenosis Impact the Success of Gamma Brachytherapy?**

**Aim:**

To investigate the relationship between vessel size and late lumen loss after gamma vascular brachytherapy. These high-risk patients may require special considerations such as brachytherapy dose adjustments or other therapies such as drug-eluting stents.

**Methods:**

Patients with history of multiple episodes of prior in-stent restenosis are at higher risk for target lesion revascularization and subacute thrombosis even after gamma vascular brachytherapy. These high-risk patients may require special considerations such as brachytherapy dose adjustments or other therapies such as drug-eluting stents.

**Proximal edge**

<table>
<thead>
<tr>
<th>Arterial area, mm²</th>
<th>Post</th>
<th>Follow-up</th>
<th>( \Delta )</th>
<th>( p )</th>
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<tbody>
<tr>
<td>13.4±3.7</td>
<td>13.2±4.2</td>
<td>0.16</td>
<td>NS</td>
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<tr>
<td>7.6±3.5</td>
<td>7.6±4.0</td>
<td>0.01</td>
<td>NS</td>
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<tr>
<td>6.3±2.2</td>
<td>6.2±2.6</td>
<td>0.10</td>
<td>NS</td>
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**Distal edge**

<table>
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<th>Arterial area, mm²</th>
<th>Post</th>
<th>Follow-up</th>
<th>( \Delta )</th>
<th>( p )</th>
</tr>
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<tr>
<td>10.1±4.2</td>
<td>10.1±3.1</td>
<td>-0.03</td>
<td>NS</td>
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<tr>
<td>5.7±2.3</td>
<td>5.6±2.2</td>
<td>0.05</td>
<td>NS</td>
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<tr>
<td>4.3±2.6</td>
<td>4.3±2.2</td>
<td>0.01</td>
<td>NS</td>
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**Conclusions:**

The classical negative relationship between vessel size and late lumen loss seen in the US group, but not in the SES group. SES prevents neointimal growth and late lumen loss irrespective of the vessel size.

**The Absence of Edge Effect After Implantation of Sirolimus-Eluting Stents to Treat In-Stent Restenosis: A Three-Dimensional Intravascular Ultrasound Volumetric Analysis**

**Introduction:**

Vessel size is an established predictor of angiographic outcome after catheter-based intervention. Neointimal growth is a uniform vascular reaction to vessel injury. Small vessels tend to have relatively more neointimal hyperplasia than larger vessels.

**Background:**

Multiple prior episodes of in-stent restenosis (ISR) adversely affects the clinical success of brachytherapy for ISR. Pts in SCRIPPS III were divided into 3 groups according to the number of prior interventions to the target lesion: 1 prior PCI (n=211); 2 prior PCIs (n=176); and ≥3 prior PCIs (n=86). Procedural and 6 month clinical outcomes were examined.

**Results:**

There were no significant differences in baseline patient and lesion characteristics, procedural outcomes and in-hospital results between the 3 groups. There was no significant difference in the average seed length between the groups. There were no episodes of late stent thrombosis beyond 30 days.

**Conclusions:**

The absence of edge effect after implantation of Sirolimus-eluting Stents to Treat In-Stent Restenosis: A Three-Dimensional Intravascular Ultrasound Volumetric Analysis.

**Abigail A. Abdollah, Patrick Semynny, Andreia Abdollah, Fausto Feres, Mariella Centemoro, Luiz A. Mattos, Judith L. Jager, David Foley, Yosiaki Kobayashi, Pim de Feyter, Amanda Sousa, J. Eduardo Sousa, Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil**

**Background:**

"Edge effect" has become an important issue in assessing new technologies for inhibiting restenosis (i.e. brachytherapy). We sought to determine whether there is an "edge effect after implanting Sirolimus-eluting (SE) BX velocity stents to treat in-stent restenosis (ISR).**

**Methods:**

Forty patients with ISR in native coronary arteries were treated with one or two 18mm SE stents (mean stent length 23.3±7.1 mm). Serial volumetric intravascular ultrasound (IVUS) measurements were obtained at baseline and 4 months, including the 10mm long reference segments adjacent to the proximal and distal edges of the stent. Volumes were normalized for the lengths of the reference segments, and mean areas are reported (Table). Results: In the 22 pts that underwent 4-month angiographic and IVUS follow-up, there was no recurrence either within the stent or at the stent edges. At follow-up, IVUS in-stent intimal hyperplasia volume measured 6.3±5.6mm³, occupying only 5% of the stent volume. Serial IVUS analysis showed neither positive nor negative arterial remodeling, no increase in proximal or distal edge plaque, and no changes in edge lumen dimensions.
Sirolimus Coated Stent Versus Bare Stent: Angiographic and IVUS Analysis at Four-Month and One-Year Follow-Up


Background: Sirolimus (Rapamycin) coated stent has been shown to decrease intimal hyperplasia (IH) compared to bare stent.

Objective: To assess the difference of IH between 4 and 12 months of sirolimus-coated compared to uncoated (bare) Bx-velocity coronary stent in patients with CAD.

Methods: Forty-five patients underwent elective, single vessel stenting in our institution. Sirolimus-coated stents were implanted in 30 patients (15 fast [15 days] release formula and 15 slow [28 days] release formula). Angiographic and volumetric IVUS analyses were performed by two experience analysts, after the procedure, at 4 and 12 month follow-up.

Results: All stents were successfully deployed after balloon pre-dilatation and pts were discharged without complications. Baseline characteristics were similar between groups and 23% of the pts had diabetes. Reference vessel diameter was 2.96 ± 0.3 mm (FR), 2.98 ± 0.4 (SR) and 2.9 ± 0.4 mm (noncoated stent group). pNS.

FR 4mm FR12mm SR 4mm SR12mm Bare 4mm Bare12mm
Late loss (mm) 0.11±0.11 2.20±0.3 0.05±0.03 0.80±0.37 0.91±0.4

Angiographic (mmHg) (mm) 2.04±0.38 2.54±0.32 0.25±0.39 0.13±0.30 0.12±0.15 4.32±3.25

FR vs SR: p = N.S; FR vs Bare: p < 0.0001; SR vs Bare: p < 0.0001; 4 mm vs 12 mm p = N.S

Conclusion: Despite the use of sirolimus-coated stents significantly less than non-coated stents, regarding the formulation used (FR versus SR) and the time of follow-up (4 versus 12 months).

1174-17

Effect of Restenosis With a Paclitaxel Eluting Stent: Factors Associated With Inhibition in the Elutes Clinical Study


Background: In-stent restenosis remains a clinical problem and the efficacy of drug-coated stents is proven. Paclitaxel inhibits mitobule formation rendering cells cytostatic and has been shown to inhibit restenosis in animal models.

Methods: To evaluate the safety and efficacy of the paclitaxel-eluting V-Flex™ coronary stent (without polymer coating), a multicenter, randomized, triple-blinded, dose-ranging clinical trial with 4 progressive dose treatment groups and one control group (uncoated stent) was conducted. In-hospital and 6 month clinical and angiographic data were collected. Patients with severe calcification, left main lesion and multiple lesions in the target vessel were excluded. Study endpoints were percent diameter stenosis at late loss at 6 months measured by QCA, and MACE at 1 and 6 months. The study had independent core lab QCA analysis, clinical events adjudication, and data monitoring.

Results: 190 pts received stents (31% CAD, 37% RCA, 21% LCX, 5% RAM). Patients were 81% male. Mean age was 62 years. Patients had 56% one- and 27% two-vessel disease. 11% unstable angina, 34% prior MI, 2% prior CABG. Lesions were 27% B1, 63% B2, and 9% B3. There was 1 death, no 0 Wave MI's, no emergent CABG, one re-PTCA (0.5%) and 5 (2.6%) non-Q MI. MACE rate at 30 days was 1.1%, Procedural CCA on 183 patients and follow-up CCA on 110 patients revealed a reference vessel diameter of 2.36 ± 0.14 mm, a minimum lumen diameter of 0.55 ± 0.27mm presistent, 2.88 ± 0.39 mm post stent, and 2.16 ± 0.78 mm at 6 months. Overall residual stenosis at follow-up was 27.1 ± 24.5% and late loss was 0.49 ± 0.68 mm including the control group and the four progressive dose groups. Follow-up will be completed in November 2001 after which unblinding and analysis of clinical, angiographic and procedural factors associated with restenosis inhibition will be completed.

Conclusions: Even without unblinding, a paclitaxel coated coronary stent with no polymer appears to be associated with reasonable short-term safety and seems compatible with mid-term restenosis inhibition. Unblinding will permit further description of factors associated with efficacy at the time of the presentation.

References:

1. 1174-18

Are Sirolimus-Eluting Stents Inducing Vascular Remodeling? A Subgroup Analysis of 3D-Intervascular Ultrasound in the RAVEL Trial


Background: Abolition of in-stent neointimal hyperplasia after Sirolimus-eluting stent (SES) implantation has been demonstrated in a pilot study (FTS First In Men) and confirmed in the double-blind, randomized, controlled RAVEL trial. However, the influence of SES on plaque burden behind the struts and on the vessel wall (expansion or retraction of the external elastic membrane area; EEM) has not been documented. Aim: To compare vessel remodeling at 6-month follow-up (FL) after SES and uncoated stent (US) implantation in a subset of patients randomized in the RAVEL trial at 6 of 19 participating centers. Methods: Patients with single de novo lesions were randomized to receive either an 18 mm SES Bx-VELLOTM (sirolimus) or an US Bx-VELOCITYTM stent. Sirolimus (Rapamycin) pulpcoated Lilly 0.5 mm stent was performed at 6-month FU to be analyzed by an independent core lab (Cardialysis, Rotterdam, NL). Total vessel volume (TVV), stent volume (SV), and lumen volume (LV) were measured. Total plaque volume (TPV), plaque volume behind the stent (PVB) and necrotical intima/hypertension (NIH) were calculated as "TVV-LV", "TVV-SV", "SV-LV", respectively. Data were compared using an unpaired t-test.

Results:

![Table showing results](image_url)

Conclusion: PBS and TVV had similar volumes at FU suggesting that no significant plaque shrinking or positive/negative remodeling occurred as result of sirolimus elution. In other words, SES is effective in preventing NIH without influencing the vessel wall structure when compared with US.

1174-19

SCORE Six-Month Angiographic Results: Improved Restenosis in Patients Receiving the QUADDS-QP2 Drug-Eluting Stent Compared With the Control, Bare Stents


Background: The QUADDS-QP2 stent is a 316L stainless steel stent that delivers 4000 ug QP2 (an antiproliferative taxane derivative) from high capacity polymer sleeves. The SCORE trial was stopped early due to higher thrombosis with the QP2 Stent after randomizing 267 of 400 pts with de novo lesions to a bare metal control stent or the QP2 Stent (available sizes: 3.0 or 3.5mm; 13 or 17 mm long). Methods: We report the quantitative angiographic (QCA) results of the first 260 pts enrolled, with follow-up available in 77% (N=202). Restenosis rates (RS) include thrombotic cases (0.4% QP2 vs 0.2% Quest). Results: The stent was deployed successfully in all cases. Lesion characteristics were similar at baseline with ACC/AHA class B1 in 30.9% QP2 vs 33.6% bare stent, pNS (see table). Follow-up restenosis was reduced by 57%. Conclusion: Despite the safety concerns of high dose QP2 delivered via a high capacity polymer on the QUEST stent, striking reductions in RS are observed within the targeted stent zone, which remains overestimated due to the inclusion of thrombosis cases. Complete adjudicated 6 month data will be presented.

<table>
<thead>
<tr>
<th>QUADDS-QP2</th>
<th>QUEST</th>
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<tbody>
<tr>
<td>Reference, mm</td>
<td>2.92±0.43</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>11.67±4.62</td>
</tr>
<tr>
<td>Final MLD, mm</td>
<td>2.26±0.46</td>
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<tr>
<td>Follow-up Stent MLD, mm</td>
<td>2.31±0.7</td>
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<td>Stent Late Loss, mm</td>
<td>0.35±0.7</td>
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<td>Restenosis Stent %</td>
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1174-20

Treatment of In-Stent Restenosis Using Paclitaxel Eluting Stents: Results From the Leuven Pilot Trial

van de Schepper, Wim De Schepper, Yannning Huang, Joseph Dene, Lan Wang, Xiaoshun Liu, Walter Decriem, University Hospitals Leuven, Leuven, Belgium.

Coronary stents are still hampered by an increased neointimal hyperplasia caused by vessel injury due to stent implantation and due to a foreign body response induced by the stent itself. Paclitaxel, extracted from the Pacific Yew Tree, Taxus brevifolia, possess potent immunomodulatory effects, inhibiting cellular activities such as mitosis, migration, endotheylation and secretion. Pre-clinical investigation with the Cook Paclitaxel-coated coronary stent showed a slow in-vivo release of the drug, Fourteen days after stent implantation in a pig coronary artery, 65% of the drug was locally released. This resulted in a significant decrease of late loss,