TCT-196

Preliminary results from the DIRECT-II Study: a prospective, randomized, active-control, multi-center, non-inferiority study comparing the safety and efficacy of the Svelte drug-eluting coronary stent IDS to the Medtronic Vascular (Santa Rosa, CA) Resolute Integrity™ DES

Stefan Verheyen1, Josef Bartunek2, Jacques Berland1, Didier Carril2, Victor M. Legrand3, Ton Slagboom4, Pieter R. Stella5, Robert J. Van Geuns5, Mathias Vrolix6

1Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, 2Antwerp, Belgium, 3Christchurch Hospital, Christchurch, New Zealand, 4Associate Center, Aalst, Belgium, Aalst, Belgium, 5Clinique saint hilare, rozen, France, 6Hôpital Rangueil, Toulouse, France, 7University hospital of Lille, IIEGE, Belgium, 8Uts-Ziee Vrouwe Gasthuis, Amsterdam, Netherlands, 9University Medical Center Utrecht, Utrecht, Netherlands, 10Zusamms NC, Rotterdam, Netherlands, 11Hospital Oost Limburg, Genk, Limburg

Background: The Svelte (New Providence, NJ) drug-eluting stent (DES) combines sirolimus with a novel, amino-acid based (PEA) bioabsorbable drug carrier. The stent is mounted on an Integrated Delivery System (IDS) consisting of a low compliant balloon with balloon control bands (BCBs) enveloping the balloon edges and affixed to a 0.014" wire, providing an ultra low profile, highly flexible drug-eluting coronary stent system specifically designed for direct stenting. The DIRECT I First-In-Man study (Webster, Ornston et al., n=30) reported 0% clinically-driven MACE at 12-months with 2.7% stent volume obstruction (via IVUS) and 98% strut coverage (via OCT) observed at 6-months. All imaging was reviewed and adjudicated by independent core lab and DSMB.

Methods: The DIRECT II study is a prospective, randomized, active-control, multi-center, non-inferiority study comparing the safety and efficacy of the Svelte drug-eluting coronary stent IDS to the Medtronic Vascular (Santa Rosa, CA) Resolute Integrity™ DES. 159 patients (2:1 randomization Svelte IDS : Resolute Integrity™) were treated with angiographic follow-up scheduled at 6-months to assess the primary endpoints of TVF and LLD. Patients with symptomatic ischemic heart disease due to a novo stenotic lesions in arteries with RVD 2.5mm – 3.5mm and lesion length < 20 mm were included. Stent evaluation post-procedure and at 6-month follow-up in 30 patients was also performed at sites with OCT capability. Additional clinical follow-up will take place through 5-years for all patients. Enrolment began January 2013 and will complete August 2013.

Results: Procedural and 30-day data on all patients, along with OCT image analysis, will be presented. Comparative data for time and cost savings, including overall procedural time, adjunctive product use, contrast use and radiation exposure, will be reported.

Conclusions: A review of the Svelte DES platform and available procedural and 30-day results from the study will be provided. These data provide insights into the potential procedural and clinical benefits, as well as time and cost savings, of this unique drug-eluting stent system.

---

TCT-197

The Svelte Drug-eluting Stent and Integrated Delivery System: 12 Month Results of the DIRECT I First-in-man Study

Mark W. Webster1, Andrew Aitken1, Scott Harding2, Dougal McClean3, John A. Ornston4, Timothy Watson1

1Auckland City Hospital, Auckland, New Zealand, 2Wellington Hospital, Wellington, New Zealand, 3Christchurch Hospital, Christchurch, New Zealand, 4Associate Professor, University of Auckland Medical School, Auckland, New Zealand

Background: The Svelte (New Providence, NJ) drug-eluting stent combines sirolimus with a novel, amino acid-based fully bioabsorbable drug carrier. The stent is mounted on an Integrated Delivery System (IDS) consisting of a low compliant balloon with balloon control bands enveloping the balloon edges and affixed to a 0.014" wire, providing a very low profile, flexible, drug-eluting coronary stent system specifically designed for direct stenting. The DIRECT I first-in-man study was designed to evaluate the feasibility of the Svelte drug-eluting stent IDS.

Methods: 30 patients with a de novo lesion in a native coronary artery, with a reference vessel diameter between 2.5 mm and 3.5 mm and lesion length < 23 mm, were assessed. Patients with successful, uncomplicated treatment of one additional lesion in a non-target vessel were also included. All patients completed 6-month QCA and IVUS (+ OCT in a subset) and are followed clinically for 5-years. The study primary endpoints were target vessel failure and angiographic late loss at 6-months.

Results: At 6 months, no patient had suffered a clinically-driven MACE, there was 2% stent volume obstruction (via IVUS) and stent strut coverage was 98% (via OCT). There were no adverse clinical results between 6 and 12 months, indicatiting evidence of late catch-up. Full independent core lab and DSMB adjudicated baseline and 6-month QCA, IVUS and OCT data, and clinical outcomes to 12-months will be reported.

Conclusions: The Svelte sirolimus-eluting coronary stent IDS, utilizing an anti-inflammatory, naturally-occurring amino acid-based drug carrier, demonstrated excellent clinical outcomes, low neointimal proliferation, and uniform vessel healing at 6-months. The clinical benefit was sustained in all patients through 12-months. DIRECT II, a prospective, randomized, active-control, multi-center, non-inferiority study is currently underway.

---

TCT-198

Six Years Consecutive Complete Follow-up Result of Sirolimus Eluting Stent (SES) Implanted Lesion

Yohei Inoue1, Yoshisato Shibata2

1Miyazaki Medical Association Hospital, Miyazaki City, Miyazaki Prefecture, 2Miyazaki medical association hospital, Miyazaki, Japan

Background: In many reports, SES is more effective in decreasing late lumen loss and restenosis rate than BMS. However, long-term follow-up results of SES remain uncertain. We sometimes experience late restenosis cases in SES implanted lesion.

Methods: We tried angiographic follow-up every year of the patients SES implanted. We could follow 60 lesions completely and evaluated MLD of those lesions in each year. We ruled out revascularised lesions. We sometimes experience late restenosis cases in SES implanted lesion.

Results: We implanted SES in 3972 lesions in the heart center from April 2004 to August 2012. We studied consecutive 58 lesions we could follow up every year. We estimated the changes of MLD of these 58 lesions. During 1 to 2-year follow-up, there is not remarkable change in MLD (1-year: 2.62±0.55, 2-year: 2.49±0.56). But at 3-year follow-up, MLD got smaller remarkably (3-year:2.29±0.65). After that there is not remarkable change (4-year: 2.30±0.70, 5-year:2.26±0.74, 6-year:2.21±0.58).

4.7% of 3-year follow-up patients, 5.5% of 4-year follow-up patients and 7.5% of 5-year follow-up patients are ruled out by revascularization.

Conclusions: MLD of SES implanted lesions get smaller. The extent of lumen loss was large after 3 years of PCI. We have to follow up SES implanted patients carefully and continuously because of late stent thrombosis and late restenosis. But this result suggest that late restenosis becomes less common in 4 years or later after SES implanted.
safety. Clinical events remained low through 24 months suggesting long term performance.

Conclusions: In this real life cohort, the treatment of highly complex lesions with the Osiris Stent was associated with excellent long-term results. Further randomized trials are warranted to confirm these findings.

TCT-200
Multi Center, Prospective, Randomized, Single Blind, Consecutive Enrollment Evaluation a Novolimus-Eluting Coronary Stent System with Bioabsorbable Polymer Compared to a Zotarolimus-Eluting Coronary Stent System: Long Term (24- Month) Clinical Follow Up from the EXCELLENIA BD Study

Stefan Verheyen1, Alexandre Abizaid2, Roberto Botelho3, Ricardo A. Costa4, laiz F. Tanajura5, Katsuhisa Waseda5, Manejeh Yaqub5, Lynn Morrison6, Sara Toyloy9, Peter J. Fitzgerald10, Joachim Schofer11
1Antwerp Cardiovascular Center, ZNA Middelheim, Antwerp, Belgium, Antwerp, Belgium, 2Triangulo Heart Institute, Uberlandia, Brazil, 3Instituto Dante Pazzanese de Cardiologia, Sao Paulo - Sao Paulo, 4Okayama Boom Periodo, Okayama, Japan, 5Dante Pazzanese Institute, Sao Paulo, Sao Paulo, 6Aichi Medical University, Nagakute, Aichi, 7Elixir Medical, Sunnyvale, CA, 8elixir medical corporation, Sunnyvale, CA, 9Stfonius University Medical Center, Stanford, California, 10Medicare center Prof Mathey, Prof Schofer, Humburg University Cardiovascular Center, Hamburg, Germany

Background: Long term safety and efficacy of the Elixir DESSyne® BD Novolimus Eluting Coronary Stent System (NECSS), a Co-Cr stent with a bioabsorbable polymer compared to the control Endeavor Zotarolimus Eluting Coronary Stent System is not known.

Methods: 149 patients were randomized 3:1, either to the Elixir DES Syne® BD Novolimus Eluting CSS loaded with 5mcg per mm of stent length of Novolimus, a sirolimus metabolite, eluted via a bioabsorbable polylactide-based polymer, or to the Endeavor Zotarolimus-eluting CSS (ZIECS) loaded with 10mcg per mm of stent length of a drug-eluting polymer via a durable polyethylene chloride polymer. All patients were analyzed for the primary endpoint of in-stent late lumen loss (LLL), assessed by qualitative coronary angiography (QCA) at 6 months. Moreover, all patients underwent evaluation for the secondary endpoints including the Device-orientated Compositie Endpoint (DoCE) defined as cardiac death, MI or not attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization; clinically-indicated Target Vessel Revascularization (TVR), and stent thrombosis at 1, 6, 9, and 12 months and annually through 5 years. Lesions were also evaluated for angiographic endpoints at 6 months including: in-segment LLL, percent diameter stenosis, minimal lumen diameter post-procedure, and angiographic binary restenosis (ABR) ≥50%. A subset of patients underwent intravascular ultrasound (IVUS) evaluation including percent (%) neointimal obstruction at 6 months.

Results: The study met the primary endpoint demonstrating both non-inferiority and superiority of the Elixir DESSyne® BD Novolimus Eluting CSS compared to the control (0.12±0.15 vs 0.67±0.47, p<0.01), additionally, in-stent ABR was significantly lower for DESSyne® BD 0% vs 7% (p<0.05). Overall results demonstrated for both devices (DoCE 2.7% vs. 3.2%, p=1.00). Sustained low clinical event rates were observed at 12 months and 24 months (DoCE 2.7% vs 3.2% p=1.0).

Conclusions: The DESSyne® BD NECSS demonstrated sequential non-inferiority and superiority over a durable polymer Endeavor ZECCS for in-stent late lumen loss at 6 months. Clinical events remained low through 24 months suggesting long term safety.

TCT-201
The mid-term outcome of small-vessel stenting with the second-generation drug-eluting stents.

Masakazu Tsutsui1, Toshiyu Marumatsu2, Reiko Tsukahara2, Yoshiaki Ito1, Hiroshi Ishimori1, Keisuke Hirano1, Masatsugu Nakano1, Motoharu Araki1, Masahiko Ouchi1, Satoru Sava1, Yutaka Matsuyama1, Shinsuke Nanto1, Kokura Memorial Hospital, Kitakyushu, Japan, 2Toho University Ohashi Medical Center, Tokyo, Japan, 1Saiseikai Yokohama-City Eastern Hospital, Yokohama, Japan, 2Seirei Hamamatsu General Hospital, Hamamatsu, Japan, 3Shova University Northern Hospital, Yokohama, Japan, 4Seirei University Shinshu University Hospital, Izunokuni, Japan, 5The University of Tokyo, Tokyo, Japan, 6Osaka University, Suita, Hyogo

Background: Pioglitazone is widely used for glycemic control in patients with type-2 diabetes mellitus (DM), and is associated with a lower risk of cardiovascular events according to a meta-analysis of randomized trials. To evaluate the effect of pioglitazone on ischemic cardiac events in Japanese patients with DM and coronary artery disease, after drug-eluting stents (DES) implantation, the 12-month data from the Japan-Drug Eluting Stents Evaluation; a Randomized Trial (J-DESsERT) was analyzed.

Methods: In this prospective, multicenter trial, 3,533 patients were randomized 1:1 to undergo coronary stenting with Sirolimus-eluting stents or Paclitaxel-eluting stents. Lesion lengths were ≤46 mm with vessel diameters from ≥2.5 mm to ≤3.75 mm. Randomization was stratified based on the presence or absence of DM. Definitions for allocation into the DM group at the time of this trial were: 1. Previous DM diagnosis; 2. Currently on diabetic medication (oral hypoglycemic drugs or insulin injections); 3. HbA1c (Japan diabetes society [JDS]) ≥6.5% within 30 days before the procedure. Patients who met one or more of the above criteria were allocated to the DM group. A total of 1,705 patients (48%) with DM were analyzed from the J-DESsERT trial.

Results: Target vessel revascularization (TVR) is defined as any ischemia-driven repeat percutaneous coronary intervention (PCI), target vessel bypass surgery, all death, myocardial infarction (Q wave and non-Q wave), and cerebrovascular accident (stroke, transient ischemic attack). Including TVR, major adverse cardiac events (MACCE) occurred in only 22 of 357 patients (6.33%) receiving pioglitazone at 12 months. Conversely, substantially more MACCE events occurred in the group not receiving the pioglitazone, 152 of 1,348 patients (11.06%, p<0.01). Pioglitazone is associated with a significantly lower MACCE rate at both 8 and 12 months, in Japanese patients with DM, post-DES implantation.

TCT-203
Mid-term Follow-Up Results of Drug-eluting Stent Implantations Following Rotational Atherectomy for Heavily Calcified Lesions: Impact of the Second-generation Drug-eluting Stent

Yasuhi Fuku1, Kaoru Kato2, Keiji Habara3, Hiroaki Tanaka4, Tsuyoshi Goto4, Kazuki Mizuno5, 1Kurashiki Central Hospital, Kurashiki, Japan, 2Kurashiki Central Hospital, Okayama, Japan

Background: The purpose of this study was to evaluate the impact of second-generation DES (2nd DES) as compared with first-generation DES (1st DES) in patients treated with DES implantation following rotatational atherectomy (RA) for heavily calcified lesions.

Methods: From December 2003 to August 2012, 616 lesions in 492 patients were treated with first-generation DES (Sirolimus-eluting stent [SES] or Paclitaxel-eluting stent [PDES]) or 2nd DES (Everolimus-eluting stent [EES] or Biolimus-eluting stent [BES]) implantations following RA exclusively and successfully. Of these lesions, 389 lesions in 312 (63.4%) patients who had undergone 8-month angiographic follow-up were analyzed.

Results: No deaths occurred in either group. In the 1st DES group, 48% of lesions were calcified >4 mm. In the 2nd DES group, 29.4% of lesions were calcified >4 mm. No MACCE was observed in either group. Target lesion failure was 10.8% in the 1st DES group and 5.9% in the 2nd DES group. The 2nd DES group showed a significantly lower rate of target lesion failure (p=0.04).

Conclusions: The 2nd generation DES implantation is superior to the 1st generation DES implantation with regard to target lesion failure in patients treated with DES implantation following RA for heavily calcified lesions.