Drug Eluting Stents

CRT-604

Efficacy and Safety of Drug Eluting Stents in the Real World: 8 Year Follow Up

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Introduction: Drug eluting stents have been used in daily practice since 2002, with clear advantage in reducing the risk of target vessel revascularization, with the impressive reduction of 50% to 70% in restenosis rate. However, the occurrence of late thrombosis could compromise results in the long term, especially if the risk of this event were sustained over the years. In this context, the registry of clinical practice gains special value.
Objective: Evaluation of efficacy and safety of drug-eluting stents in the real world.
Methods: We report the findings of all patients that underwent percutaneous coronary intervention with a drug eluting stent in the period from January 2002 to April 2007, and followed up for 8 years. Drug eluting stents were used in accordance with the clinical and interventional cardiologist decision and availability of the stent.
Results: A total of 611 patients were included, with clinical follow-up obtained for 96.2% up to 8 years. Total mortality was 8,7%. Non-fatal infarction occurred in 4.3 % of the cases. Target vessel revascularization was 12.4% and the target lesion revascularization 8%. The rate of stent thrombosis was 2.1%. There were no new episodes of stent thrombosis after the fifth year of follow-up. Comparative subanalysis showed no outcome differences between the stents Cypher, Taxus and Endeavor.
Conclusion: These findings indicate that drug eluting stents remain safe and effective at very long term follow-up. Patients in the "real world" may benefit from drug eluting stenting with excellent results in the long-term.

CRT-605*

Everolimus Eluting Bioresorbable Vascular Scaffolds for Treatment of Patients Presenting with ST-Segment Elevation Myocardial Infarction, BVS STEMI FIRST Study

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Aims: We evaluated the, feasibility and the acute performance of the bioresorbable vascular scaffolds (BVS) for treatment of patients presenting with ST-segment elevation myocardial infarction (STEMI).
Methods and Results: The present investigation is a prospective, single-arm, single-centre study, reporting data after BVS implantation in STEMI patients. Quantitative coronary angiography and optical coherence tomography (OCT) data were evaluated. Clinical outcomes are reported at 6 months follow-up. The intent-to-treat population comprises a total of 49 patients. The procedural success was 97.9%. Pre-procedure TIMI-flow was 0 in 50.0% of the patients; after BVS implantation a TIMI-flow III was achieved in 91.7% of patients and the post-procedure percentage diameter stenosis was 14.7 ± 8.2%. No patients had angiographically visible residual thrombus at the end of the procedure. OCT analysis performed in 31 patients, showing that the mean lumen area was 8.02±1.92 mm^2, minimum lumen area 5.95±1.61 mm^2, mean incomplete scaffold apposition area 0.118±0.162 mm^2, mean intraluminal defect area 0.013±0.017 mm^2, mean percentage malapposed struts per patient 2.80±3.90%. Scaffolds with >5% malapposed struts were 7. Six months follow-up will be available in Feb 2014.
Conclusion: a. : In the present series the BVS implantation in patients presenting with acute myocardial infarction appeared feasible, with high rate of final TIMI-flow III and good acute scaffold apposition on OCT. Medium term follow-up data will be presented at CRT.

Renal Denervation

CRT-606

Arterial Stiffness as an Early Marker of Renal Sympathetic Denervation Effectiveness

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Background: Renal sympathetic denervation (RSD) has been reported to reduce blood pressure in patients with resistant arterial hypertension, although it takes time before noticeable changes after the procedure occur. There are several reports on late changes in arterial stiffness after RSD. We have investigated early and late changes in arterial stiffness after denervation searching for the markers of RSD effectiveness.
Methods: We have evaluated 20 patients with resistant arterial hypertension (age 56.2±7.4 years, 11 male, 9 female, mean 24-hour ambulatory blood pressure (BP) - 160/96±19/16 mm Hg, using 6.1±1.1 antihypertensive drugs), who underwent bilateral RSD. Arterial stiffness parameters were measured before the procedure, during the first 48 hours after RSD and, subsequently, after 1, 3 and 6 months.
Results: During the first 48 hours after RSD, a significant reduction in peripheral BP from 182/107±28/19 to 163/95±17/11 mmHg (p=0.003), and mean arterial pressure (MAP) from 135±23 to 116±13 mmHg (p=0.0003) was observed. RSD significantly reduced carotid-femoral pulse wave velocity (PWV) during the first 48 hours from 11.2±2.9 to 9.7±2.1 m/s (p=0.0004) and carotid-radial PWV from 10.3±2.4 to 8.8±1.4 (p=0.008). Analysis of variance revealed the MAP independent improvement of PWV during 48 hours after RSD (r=-0.07, p=0.8). Furthermore, a substantial decrease in carotid-femoral PWV has been recorded at 1, 3 and 6 months, 9.5±2.3 (p<0.001), 9.41±2.78 (p=0.006) and 8.94±2.03 (p<0.001), respectively. In addition, reduction in carotid-radial PWV sustained at 1, 3 and 6 months, 9.24±1.33 (p=0.051), 8.99±1.65 (p=0.063) and 8.67±1.20 (p=0.007), respectively.
Conclusion: Changes in arterial stiffness occur early after RSD. During the first 48 hours after the procedure, a significant reduction of arterial stiffness parameters, which remained at 1, 3 and 6 months have been noted. RSD effects on PWV were independent from blood pressure changes.

CRT-607*

Renal Denervation with a Percutaneous Bipolar Radiofrequency Balloon Catheter in Patients with Resistant Hypertension: Efficacy and Safety Results From the REDUCE-HTN Trial

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Background: The Vessix Renal Denervation System (Boston Scientific, Natick, MA) consists of a radiofrequency generator and a balloon catheter mounted with a bipolar radiofrequency electrode array. The objective of the REDUCE-HTN Clinical Study is to evaluate the performance of the Vessix System in treating medication-resistant hypertension.

**Indicates iMPACT Trial Accepted for Oral Presentation*

Methods: The REDUCE-HTN trial is a prospective, multicenter, single-arm study. Patients were required to have office-based systolic blood pressure (BP) ≥160 mmHg despite compliance with ≥3 antihypertensive medications at maximally tolerated doses. The primary efficacy endpoints were the 6-month reductions in office-based systolic and diastolic BPs, and reductions in systolic and diastolic BP as measured by 24-hour ambulatory monitoring. Acute safety (ie, freedom from renal artery dissection or perforation requiring stenting or surgery, renal artery infarction or embolus, cerebrovascular accident, myocardial infarction, or sudden cardiac death at the time of the procedure) and long-term safety, including renal artery patency and renal function, were assessed.
Results: Mean baseline office BP was 182.4±18.4/100.1±14.0 mmHg among enrolled patients (N=146; age 58.5±10.5 years, 61% men, 27.4% with type 2 diabetes). No patients experienced any of the prespecified acute safety events. Among 139 patients with 6 month data, mean office BP was reduced to 157.7±23.8/89.4±15.7 mmHg; a reduction of 24.6±22.3/10.3±12.9 mmHg ($p<0.0001$). Mean baseline ambulatory BP was 153.0±15.1/87.5±13.2 mmHg (n=103); at 6 months it was reduced by 8.5±14.6/5.9±9.2 mmHg (n=67; $p<0.0001$). Renal artery patency by duplex ultrasound at 6 months was 99.1%. Mean estimated glomerular filtration rate (eGFR) changed -0.9±16.5 at 6 months, and 11% of patients (15/136) had a reduction in eGFR >25%. Six-month results for the full cohort of enrolled patients are expected to be available at the time of presentation.
Conclusions: Primary endpoint results from the REDUCE-HTN trial demonstrate that the Vessix System is an efficacious method for treating resistant hypertension. No acute safety endpoint events were observed and 6-month patency and renal function results are favorable.

CRT-608*

Pooled 3-Year Symplicity Htn-1 and Symplicity Htn-2 Results and Diabetes Subgroup Analysis

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Background: Treatment resistant hypertension (rHTN) is defined as uncontrolled blood pressure despite use of ≥3 antihypertensive drugs including a diuretic. The sympathetic nervous system plays an important role in the pathogenesis of hypertension. The Symplicity™ renal denervation system uses a percutaneous approach to deliver low-power radiofrequency energy to interrupt the efferent sympathetic and afferent renal nerves. Up to 3 year follow-up of pooled patient level data are available to evaluate renal denervation (RDN) efficacy and safety, including patients with type II diabetes mellitus (DM).
Methods: The Symplicity HTN-1 and Symplicity HTN-2 prospective, multicenter trials enrolled rHTN subjects with a systolic BP (SBP) ≥160 mm Hg; (≥150 mm Hg for DM subjects). Subjects remained on their antihypertensive drugs for 6 months after which changes were allowed as clinically indicated. A subset of subjects in Symplicity HTN-1were consented to 3 years; all subjects randomized to immediate RDN on Symplicity HTN-2 were followed to 3 years post-RDN. Change from baseline BP was measured at each follow-up and all safety events were evaluated.
Results: Baseline characteristics of 128 subjects followed through 3 years include mean age, 58 years; 34% DM, 38% female, and body mass index of 32 kg/m^2. Mean baseline SBP was 175.7 ± 14.1 mm Hg and was reduced by 24.6 ± 22.7 mm Hg at 6 months ($p<0.01$). This BP reduction was sustained at 3 years with a mean drop of 32.2 ± 19.7 mm Hg ($p<0.01$). DM and non-DM subjects had similar baseline SBP and experienced a similar and significant reduction in SBP at 3 years (-30.0 mm Hg vs -33.3 mm Hg, respectively, $p<0.001$ compared with baseline, $p=0.37$ between DM and non-DM subjects). Procedure-related adverse events included 2 dissections (1 before radiofrequency energy was delivered), and 1 access site hematoma. Serious adverse events included 6 deaths, 4 renal failure cases (all resolved), and 1 stenosis requiring stenting.
Conclusions: The data indicates that treatment of rHTN with the Symplicity catheter provides safe and sustained reductions in SBP through 3 years. The reduction in SBP was similar in both DM and non DM subjects.

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CRT-610

Bipolar Multi-Electrode Balloon Catheter Radiofrequency Renal Denervation with the Vessix System: Preclinical Safety Evaluation

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Background: A bipolar multi-electrode balloon catheter radiofrequency (RF) renal denervation system offers advantages of short procedure time and low power to minimize risk of non-target tissue thermal injury. We report a preclinical safety study of a 7 French (F) system in a domestic swine model.
Methods: The 7F device was used to treat the renal arteries of 20 pigs, with overlapping treatments in the proximal 12 mm to mimic clinical balloon overlap. Each histopathology cohort (30 & 90 day follow-up) had 4 RF-treated and 3 sham-treated (no RF energy delivered) pigs and response of artery and surrounding nerves to bilateral treatment was examined (28 arteries). Scanning electron microscopy was used to examine the renal artery flow surface for endothelialization, with unilateral whole artery treatment with proximal overlap: RF on one side and sham on the other (3 pigs/cohort; 12 arteries). Treatment duration was 30 seconds. Animals received 2 to 3 treatments per artery depending on artery length. Histology on all 40 kidneys and assessment for non-target injury was undertaken in all 20 pigs.
Results: Renal artery injury was transmural and segmental, with variable percentages of the circumference (<10% to >90%, typically 30-50%) demonstrating overlying nerve injury and associated segmental neointimal hyperplasia. No increase in thermal injury was observed in overlapped vs single-treatment segments. At 30 days, "islands" of necrotic media remained, but at 90 days healing was essentially complete with mature replacement fibrosis. Inflammatory activity was mild at 30 days and minimal by 90 days. Maximum lumen stenosis (all sections, both time points) was 17.7%, hemodynamically trivial, and typically <10%. Endothelialization was focally incomplete at 30 days, but completely confluent at 90 days. Sham-treated arteries showed only mild focal mechanical injury, which was also seen with thermal treatment. Kidney histology demonstrated no injury, and there was no injury to renal veins, ureters, adrenal glands, psoas muscles, peritoneum or intestines.
Conclusion: Safety of the Boston Scientific Vessix renal denervation system in 7F configuration was demonstrated for both single and overlap treatment.

Technology

CRT-611

Poor Outcome in Patients Requiring Intra-Aortic Balloon Pump Reinsertion in Cardiogenic Shock

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Background: Intra-aortic balloon pumping (IABP) is the most frequently utilized form of temporary mechanical support in cardiogenic shock. Withdrawal of IABP support occasionally precipitates hemodynamic compromise or collapse such that IABP reinsertion is considered or performed. The outcome of patients undergoing IABP reinsertion has not been formally studied.
Methods: Using the MedStar Washington Hospital Center Cardiac Care Unit (CCU) database, we identified a population of patients presenting with cardiogenic shock who required IABP reinsertion after failed wean. As a control we identified a matched population of patients who had received only a single IABP for cardiogenic shock. The primary outcome investigated was in-hospital mortality. Secondary outcomes included the utilization of other temporary or permanent methods of cardiac support, transplant, and discharge to hospice and a composite thereof.