iMPACT TRIALS

CRT-226

Two Year Safety And Clinical Performance Of The Drug Eluting Orsiro Stent In The Treatment Of Subjects With Single De Novo Coronary Artery Lesions-II (BIOFLOW-II)

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OBJECTIVES BIOFLOW-II is a randomized controlled study, comparing the clinical efficacy of the Orsiro Hybrid Drug Eluting Stent (Orsiro) with the Xience Prime™ Everolimus Eluting Stent (XiencePrime) at 2 years in the complete study population as well as in the diabetic and small vessel subgroups, which are known to have a higher risk for cardiac complications. Here we present the outcome through the clinical endpoints Target Lesion Failure (TLF) and Stent Thrombosis (ST).

METHODS A total of N=452 subjects (62.7 ± 10.4, 38-80 yrs) were enrolled in the Intention to Treat population in the BIOFLOW-II study, registered at clinicaltrials.gov (NCT01356888). All subjects were stratified for diabetes and then randomly assigned (2:1) to receive the Orsiro or the Xience Prime stent. The diabetic subgroup accounted for 28.3% N=128 (Orsiro N=84, Xience Prime N=44) of all subjects. The small vessel cohort included all subjects with a reference vessel diameter ≤2.75mm, accounting for 57.3% N=259 (Orsiro N=168, Xience Prime N=91) of all subjects. Clinical follow up visits are performed at 1, 6, 12 months and annually up to 5 years after the procedure. All angiographic images were analyzed by an independent Corelab. All clinical events were adjudicated by 3 independent clinical events committee.

FINDINGS All three study groups showed comparable populations in both randomization arms in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The TLF rate at 24 months was 8.4% for the Orsiro vs. 10.0% for the Xience Prime in the full cohort, 9.7% vs. 9.1% in the diabetic subgroup and 9.4% vs. 13.3% for subjects with small vessel lesions. There was no statistical significance between the two study arms in any of the three analyzed populations. No ST (definitive, probable or possible) occurred through 24 months in the Orsiro arm. One event alone, very late possible ST, occurred in the diabetic subgroup of the Xience Prime arm during the same time.

CONCLUSIONS In this RCT the clinical event rates of the Orsiro SES with a biodegradable polymer the clinical event rates were low and comparable to the Xience Prime™ until 24 months in all three analyzed populations.

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Diamondback 360° Coronary Orbital Atherectomy System for Treating *De Novo*, Severely Calcified Lesions: 2-Year Results of the Pivotal ORBIT II Trial

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PURPOSE Compared to non-calcified lesions, the presence of calcification at the target lesion leads not only to a higher incidence of major adverse cardiac events (MACE) during percutaneous coronary intervention but is also associated with a high frequency of inadequate stent expansion, stent fracture, restenosis or revascularization, and a higher treatment cost.

METHODS ORBIT II (49 U.S. sites, 443 subjects) is the first prospective trial to exclusively study severely calcified lesions, and included high-risk patients usually excluded from large trials such as those on dialysis or with a low left ventricular ejection fraction (>25%). Investigators utilized the Diamondback 360° Coronary Orbital Atherectomy System (OAS) to modify and prepare severely calcified lesions before stent placement. The OAS utilizes a centrifugal sanding action and is the first novel technology to receive FDA approval to treat severely calcified lesions. The ORBIT II trial 2-year follow-up assessed the following MACE components: 1) cardiac death, 2) myocardial infarction (MI), and 3) target vessel revascularization (TVR).

RESULTS The ORBIT II 2 year MACE rate and its components will be presented for the first time. We anticipate that the rates will be lower compared to the literature. Low rates of ORBIT II 1-year MACE (16.4%), cardiac death (3.0%), MI (9.7%), and TVR (5.9%) were previously reported.

CONCLUSION Modification of severely calcified plaque with the OAS improves outcomes in this difficult-to-treat patient population. Thus, using the OAS as a lesion preparation tool prior to stent implantation offers patients with severely calcified coronary lesions a new treatment option.

CRT-832

EVEREST II REALISM - A Continued Access Study To Evaluate The Safety And Effectiveness Of The MitraClip Device: Demographics And Procedural Outcomes

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BACKGROUND EVEREST II REALISM is a prospective, multi-center, continued access study to collect data on "real world" use of MitraClip in high risk (HR) and non-high risk (NHR) patients. Baseline demographics, clinical and acute procedural data are presented.

METHODS HR was defined as STS score ≥12% or pre-specified risk factors. As of December 2013, 628 HR and 271 NHR patients were enrolled.

RESULTS Mean ages of HR and NHR patients were 77 and 74 years respectively. Mean STS score in HR was 11±7%. Baseline characteristics in HR and NHR vary with respect to extent of co-morbidities and NYHA Class status. A majority of patients were in NHYA Class III/IV and had atrial fibrillation. A higher percentage of HR patients had CAD and prior CABG surgery. A majority of HR had functional mitral regurgitation (MR). In HR, 96% of patients received 1 or 2 MitraClip devices with a mean hospital stay of 3.2 days. MR ≤2+ was observed in 90% of patients at discharge. In NHR, 95% of patients received 1 or 2 MitraClip devices with a mean hospital stay of 2.8 days. MR ≤2+ was observed in 89% of patients at discharge. Mortality at 30 days was 4.2% in HR and 1.5% in NHR. There were no intra-procedural deaths in either group.

CONCLUSION Baseline data indicate that patients treated with MitraClip in REALISM are elderly and have significant co-morbidities. The procedural data demonstrate the feasibility, acute safety and acute effectiveness of MitraClip in a complex "real world" US population.

Baseline Characteristics

	High Risk Arm (n=628)	Non-High Risk Arm (n=271)
Age (mean ± SD)	77 ± 11 years	74 ± 11 years
Coronary Artery Disease	78%	49%
Atrial Fibrillation	71%	56%
Moderate to Severe Renal Disease	30%	9%
Prior CABG Surgery	54%	17%
NYHA Functional Class III/IV	85%	55%
Functional Mitral Regurgitation	70%	32%
LV Ejection Fraction (mean ± SD)	47 ± 14%	56 ± 11%
LVIDs (mean ± SD)	4.4 ± 1.1 cm	3.7 ± 0.9 cm