Boston Scientific
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InTouch Cardiology Newsletter

Issue 1

InTouch
Advanced Collaborative Services

Congresses and Events

See the key highlights of Boston Scientific at EuroPCR2016:

» Boston Scientific announces long-term data from the EVOLVE Trial of the SYNERGY™ Stent as well as EVOLVE II 2-Year data for the Diabetes substudy

» SYNTAX II 30-Day Results: FFR/iFFR and IVUS-guided percutaneous coronary revascularisation with new-generation DES in patients with De Novo three vessel disease

» Boston Scientific announces new data from the RESPOND study of the LOTUS™ Valve

» New data from the EWOLUTION registry confirms safety of the Boston Scientific WATCHMAN™ Left Atrial Appendage Closure device

Educational Corner

You were not able to attend EuroPCR? Here you can see the webcasts of the Boston Scientific Symposiums

» Expanding treatment options in LAA closure patients –Watchman

» The SYNERGY stent: expanding treatment options in complex PCI

» The Lotus™ Valve: simplifying treatment strategies and optimising outcomes in the real world

Learning with Clinical Cases

» A case study with FFR Comet™ Pressure guidewire (Clinica Montevergine, Mercogliano, Italy and Federico II University, Naples, Italy)

» A Tale of 4 Bifurcations (Royal Victoria Hospital, Belfast, UK)

Click here to visit the website.

Congresses and Events

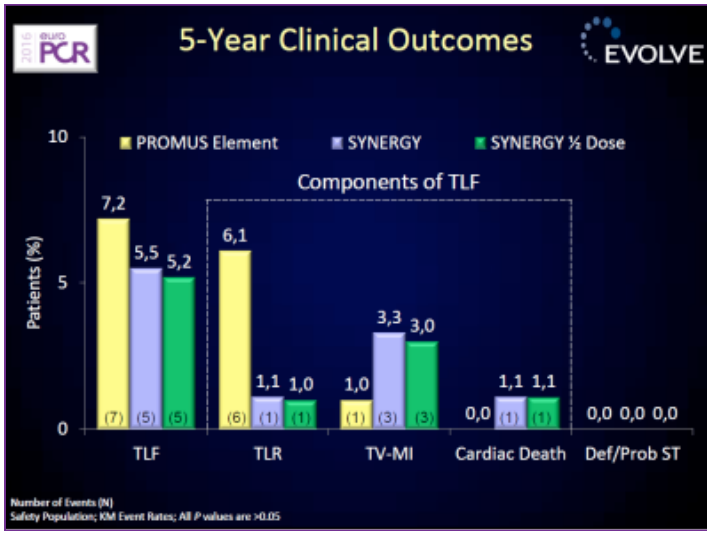
Boston Scientific announces long-term data from the EVOLVE Trial of the SYNERGY™ Stent presented at EuroPCR 2016

Final, 5-year results from the EVOLVE Trial evaluating the Boston Scientific SYNERGY Stent support long-term safety and efficacy for the treatment of patients with de novo coronary artery disease.

The final 5 year results of the EVOLVE Trial reinforce earlier findings of sustained performance of the SYNERGY™ Bioabsorbable Polymer Drug-Eluting Stent System, with no stent thrombosis (ST), a very low target lesion revascularisation (TLR) rate (1.1%) and no significant differences between SYNERGY and control for the key endpoints of target lesion failure (TLF), cardiac death, or myocardial infarction (MI).

These data demonstrate excellent long term outcomes with the SYNERGY stent, which is designed to deliver more rapid and complete arterial healing and to reduce the risk of complications associated with long-term polymer exposure.

The study results were presented today at EuroPCR by Professor Ian Meredith, Ph.D.



Def/Prob ST: 1.1% at 2 years in EVOLVE II Diabetes (466 patients)

Acute ST (≤ 1 day) 0.9%
Subacute ST (2-30 days) 0.2%
Late ST (31-365 days) 0%
Very Late ST (>365 days) 0%

Prof. Ian Meredith presented outstanding results of EVOLVE II 2 year data for diabetics treated with Synergy:No ST after 30 days

About EVOLVE

The EVOLVE Trial is a prospective, randomised, single-blind first human use study of 291 patients with de novo native coronary lesions that was conducted at 29 sites in Europe, Australia and New Zealand. EVOLVE evaluated the non-inferiority of the SYNERGY Stent to a durable polymer control stent. The EVOLVE Trial is part of a rigorous clinical program, which also includes EVOLVE II, a global, multi-centre, randomised, single-blind, non-inferiority pivotal trial. Boston Scientific is continuing to advance the robust clinical program supporting the SYNERGY Stent with the currently enrolling EVOLVE Short Dual Anti- Platelet Therapy (DAPT) Study.

About the SYNERGY Bioabsorbable Polymer Stent

The SYNERGY Stent is the only bioabsorbable polymer stent available to patients in the United States. It features ultrathin stent struts with an abluminal bioabsorbable drug/polymer coating technology that is absorbed shortly after drug elution is complete at three months, thereby eliminating long-term polymer exposure. The SYNERGY Stent received CE Mark in 2012 and was approved for use in the U.S. in 2015 and in Japan in early 2016.

SYNTAX II 30-Day Results: FFR / iFFR and IVUS-guided percutaneous coronary revascularisation with new-generation DES in patients with De Novo three vessel disease

SYNERGY performed very well in SYNTAX II. FFR/iFFR and IVUS Guided PCI for multivessel coronary disease with the SYNERGY Stent (SYNTAX II strategy) results in statistically significant lower MI and ST rates at 30 days when compared to the control of the SYNTAX I trial:

- Def/Prob ST: 0.4% in Syntax II at 30 day vs 2.5% in Syntax I (p=0.019)
- MI rate: 0.2 in Syntax II vs vs 4.1% in Syntax I (p<0.001)

About the Syntax II:

The SYNTAX II trial is a multicentre, all-comers, open-label, single-arm trial aiming to recruit 450 patients with de novo three-vessel CAD in approximately 25 European interventional cardiology centres. All patients will be selected and treated following the SYNTAX II strategy, which includes: a) establishing the appropriateness of revascularisation utilising the SYNTAX score II as a clinical tool to allow objective decision making by the Heart Team, b) ischaemia-driven revascularisation based on functional intracoronary assessment, c) implantation of the new-generation everolimus-eluting platinum chromium coronary stent with thin struts and abluminal bioabsorbable polymer coating to promote rapid vessel healing, d) intravascular ultrasound-guided DES implantation, and e) treatment at centres with expertise in CTO recanalisation. The primary endpoint is a composite of the major adverse cardiac and cerebral events (MACCE) rate at one-year follow-up compared to the historical PCI arm of the SYNTAX trial. An exploratory endpoint will be MACCE at five-year follow-up compared to the historical surgical arm of the SYNTAX trial.

Boston Scientific announces new data from the RESPOND study of the LOTUS™ Valve presented at EuroPCR2016

Outcomes from this post market study of more than 1,000 patients demonstrate the safety and efficacy of transcatheter aortic valve implantation (TAVI) with the LOTUS™ Valve in routine clinical practice.

Results from the RESPOND Study evaluating the Boston Scientific LOTUS™ Valve demonstrated excellent outcomes of key safety and efficacy endpoints through 30 days post implant procedure. Building on previously presented interim results with 250, 500 and 750 patients, the new RESPOND data from the full trial population of more than 1,000 patients continue to support the use of the LOTUS™ Valve in routine clinical practice. The data show excellent device performance, a strong safety profile and extremely low rates of paravalvular leak (PVL) which is associated with long-term survival.

The data from the post-market study were presented by Professor Volkmar Falk, M.D., Director of the Department of Cardiothoracic Vascular Surgery at the German Heart Center in Berlin.

Highlights from the RESPOND Study include

- All-cause mortality at 30 days post-procedure was 2.2% in the as-treated population
- Disabling stroke at 30 days post-procedure occurred in 2.2% of patients
- Permanent pacemaker (PPM) implantation rate at 30 days was 30 percent
- Correct positioning of one valve in proper location was 99.7%
- Major vascular complications observed in only 2.1% of patients
- Less PVL than reported with competitive valve
    - No/trivial PVL in 91.9 percent of patients and mild PVL in 7.7% of patients at hospital discharge
    - Moderate PVL was only 0.3% and there was no severe PVL
    - PVL with Lotus similar to rates seen with surgical valve replacement

About RESPOND

The RESPOND Registry is a prospective, open label, single arm, multi-centre, observational post market study. Clinical follow-up is at discharge, 30 days, 1 year and annually through five years. It features a primary endpoint of all-cause mortality at 30 days and 1 year, plus secondary endpoints using current Valve Academic Research Consortium guidelines and definitions. Echocardiographic data and key clinical events are independently adjudicated. These measures are designed to increase the quality of the collected data and address inconsistencies with site-reported data commonly observed in post market studies.

About the LOTUS™ Valve

The Lotus Valve System is a differentiated next-generation TAVI device, consisting of a pre-attached, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. It is the first device of its kind that offers controlled mechanical expansion, which allows the valve to be fully deployed, assessed and then released, providing unparalleled control during the procedure. The early valve function provides hemodynamic stability throughout the procedure and if necessary, the valve can be completely repositioned at any time prior to release. The device also features a unique Adaptive Seal™ designed to minimize the incidence of paravalvular regurgitation, which has been identified as a predictor of mortality in multiple clinical trials.

New data from the EWOLUTION registry presented at EuroPCR 2016 confirms safety of the Boston Scientific WATCHMAN™ Left Atrial Appendage Closure device

Three-months outcomes on more than 1000 patients across Europe focus on post-procedural drug regimen, impact of centre experience and peri-device leakage.

The three-month results from the EWOLUTION Registry on WATCHMAN Outcomes in Real-Life Utilization found that LAA closure with the Boston Scientific WATCHMAN™ device has a high success rate in complete LAA closure with low periprocedural risk, independently of implanting physicians' experience, thus confirming the safety of the device.

Dual antiplatelet therapy following the implant also appears to be safe.

The data from the prospective multicentre registry was presented by Professor Martin. W. Bergmann, head Interventional Cardiology at Cardiologicum Hamburg, Germany.

Highlights include:

- The implant procedure was successful in 98.5 % of cases.
- Independent of centre experience, 99% of implanted devices presented no or minimal (≤5mm) peri- device leakage at the first follow-up, assessed by periprocedural transesophageal echocardiogram (TEE).
- Device or procedure related serious adverse events (SAE) rates at 92 days were similar if patients were treated with warfarin or DAPT (2.6 % vs. 4.8 %, respectively).
- Rates for bleeding SAE were also similar if warfarin or DAPT was used post-implantation (4.8 % vs. 3.6 %, respectively).
- Following WATCHMAN implantation, 6 % of patients received no anticoagulation, 27 % received oral anticoagulation (16 % warfarin and 11 % novel oral anticoagulants, NOACs), 60 % received dual antiplatelet therapy (DAPT) and 7 %of patients were on single antiplatelet therapy.
- Stroke (0.4 %) and bleeding (4.1 %) rates were low overall and did not vary by post-implantation medications.

About EWOLUTION

EWOLUTION included 72 % of patients contraindicated to oral anticoagulation, different from previous trials. The majority of patients therefore received dual antiplatelet therapy following the procedure rather than oral anticoagulation. Currently, more than 1000 patients are part of the registry, whose real-world results are expected to complement the amount of randomised clinical trial data, the largest available for a LAAC device.

You can download the clinical article **"Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry"** (Lucas V.A. Boersma, Boris Schmidt, Timothy R. Betts, Horst Sievert, Corrado Tamburino, Emmanuel Teiger, Evgeny Pokushalov, Stephan Kische, Thomas Schmitz, Kenneth M. Stein, Martin W. Bergmann on behalf of the EWOLUTION investigators) in the European Heart Journal.

The Educational Corner

You were not able to attend EuroPCR? Here you can see the webcasts of Boston Scientific Symposiums

Expanding treatment options in LAA closure patients – Watchman

Chairpersons:
T. FELDMAN, D. HILDICK-SMITH

Objectives:
- To learn which patients benefit from LAA and how to balance best the risk of stroke and bleeding
- To know the latest clinical data and guidelines for LAA closure
- To understand the expected benefits of Watchman in complex anatomies.

Click here to see the Webcast

The Synergy stent: expanding treatment options in complex PCI

Chairpersons:
K.G. OLDROYD, F.J. NEUMANN

Objectives:
- To recognise how biodegradable polymer DES design may impact DAPT duration and clinical outcomes
- To learn how the Synergy stent is being used in complex patient subsets
- To understand the current clinical evidence, latest available clinical data and interventional cardiology pipeline

Click here to see the Webcast

The Lotus™ Valve: simplifying treatment strategies and optimising outcomes in the real world

Chairpersons:
I. MEREDITH, T. FELDMAN

Objectives:
- To recognise key features and procedural aspects of the Lotus™ valve
- To learn how paravalvular leak can be minimised despite anatomical complexities
- To understand the current clinical evidence, latest clinical data and pipeline

Click here to see the Webcast

Learn from 2 Cases Studies

Case Study 1

FFR-GUIDED PCI WITH NEW COMET™
FFR PRESSURE GUIDEWIRE REVEALS THE TRUE PICTURE
Clinica Montevergine, Mercogliano, Italy
Federico II University, Naples, Italy

Key Learnings

This case highlights:
- New Asahi co-developed COMET™ FFR Pressure guidewire's ability to assess and perform PCI with multiple devices and reconnections
- How FFR guidance changes treatment strategy and alerts the operator to the need for further intervention in sub optimal PCI - where ischemia is still present

Download Case Study

Case Study 2

A TALE OF 4 BIFURCATIONS WITH SYNERGY™ STENT
Dr. Owens, Royal Victoria Hospital Belfast, UK

Key Learnings

This case highlights:
- Interventional strategies to deal with complex bifurcation disease in a patient presenting with cardiogenic shock
- How a robust knowledge of stent characteristics allow for full revascularisation in patients with complex disease
- The importance of stent choice where DAPT duration considerations are important

Download Case Study

Join the Complex PCI community to get regular clinical updates

Disclaimer

* The polymer is gone when it's no longer needed, shortly after the drug is completely eluted at three months, which minimizes polymer exposure in the vessel.1,2

1. Eppihimer M, PhD. Impact of Polymer Type and Location on Stent Thrombogenicity and Endothelial Cell Coverage. EuroPCR 2014
2. Chen YL, PhD, Foss A, PhD, Eppihimer M, PhD, et al. Characterization of In Vivo Poly(DL-lactic-co-glycolic acid) Bioabsorption from a Drug-Eluting Stent. EuroPCR 2012
3. Stent_MECD_Technical _Report; PDM doc.91019938
4. Data on file at Boston Scientific. Bench testing performed by Boston Scientific Corporation. Bench test results not necessarily indicative of clinical performance
5. SYNERGY Stent Systems DFU
6. SORT OUT VIII presentation by Ida Riise Balleby, MD at PCR 2015; 2 month OCT Analysis presentation by J. M. de la Torre, MD at TCT 2014; TIMELESS presentation by Juan Granada, MD, at CRT 2015; Burgos-Santander study presentation by J. M. de la Torre, MD at PCR 2015
7. SYNERGY is designed with a low initial polymer load, abluminal coating and bioabsorbable polymer which may reduce the risk of thrombosis and the need for prolonged dual antiplatelet therapy. In selected higher risk patients where the physician determines that the risks outweigh the benefits of continued DAPT, it may be reasonable to interrupt or discontinue therapy after 1 month based on low stent thrombosis rates and no observed increased risk for stent thrombosis as shown in the current literature.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. This material is not for use in the U.S, France and Japan.