

ANGIOPLASY SUMMIT 2016 TCT ASIA PACIFIC



Seoul, Korea: 26-29 April 2016

BSC Symposium SYNERGY: heal with confidence

Synergy: real life outcomes on Complex PCI

Speaker - 19'

Antonio Colombo

Centro Cuore Columbus and S. Raffaele Scientific Institute, Milan, Italy

SYNERGY Stent Synchronous Drug Release & Polymer Absorption





EVOLVE I SYNERG

BP-DES Stents vs. CoCr EES: Design

Trial Name	Bioabsorbable Polymer Stent	Absorption Kinetics	Trial Design
BIOFLOW II	Orsiro ^{~~}	NR	Non-inferiority (vs. CoCr EES)
COMPARE II	Nobori®	6 to 9 months	Non-inferiority (vs. CoCr EES)
EVOLVE	Synergy™	4 months	Non-inferiority (vs. PtCr EES)
ISAR-Test-4	Jactax	3 months	Non-inferiority (vs. SES/CoCr EES)
NEXT	Nobori®	6 to 9 months	Non-inferiority (vs. CoCr EES)
TARGET I	Sparrow limus-eluting stent	6 to 9 months	Non-inferiority (vs. CoCr EES)

Bangalore et al. BMJ 2013; 347:f6625

EVOLVE II Pivotal Trial Design





DAPT (ASA + clopidogrel, ticlopidine, prasugrel, ticagrelor) ≥ 6 months or longer as tolerated

EVOLVE II Primary Endpoint: 12-month TLF : ITT Population





Noninferiority is proven because the one-sided upper 97.5% confidence bound for the difference in 12-month TLF is <4.4%

*One-sided 97.5% Farrington-Manning Upper Confidence Bound (UCB)

Patient Disposition and Antiplatelet Medication Usage





*After the first year of follow-up, only patients who received study stents were followed (No study stent implanted: PROMUS ELEMENT Plus arm n=9 and SYNERGY arm n=3). 2 year ASA: P=0.27; DAPT P=0.31 Kereiakes et al. Circ Cardiovasc Interv 2015





DAPT duration

With new generation DES DAPT duration is not stent dependent; DAPT duration is patient dependent

> DAPT duration should be tailored according to the atherosclerosis burden and to the risk of bleeding of the patient





ITT Population; Patients who did not receive a study stent were censored at 1 year; KM Event Rates; log-rank P values

TLF and Components at 2 years





ITT Population; Patients who did not receive a study stent were censored at 1 year; KM Event Rates; Per protocol spontaneous MI is defined as rise and/or fall of cardiac biomarkers with ≥1 value >99th percentile of the URL + evidence of myocardial ischemia. Peri-PCI MI is defined as ≥1 of the following: i) biomarker elevations within 48 hours of PCI (based on CK-MB >3X URL), ii) new pathological Q waves, or iii) autopsy evidence of acute MI

Additional Outcomes at 2 years





Stent Thrombosis at 2 years Definite/Probable : ITT Population





No definite ST in the SYNERGY arm after 24 hours





ITT; Patients who did not receive a study stent were censored at 1 year; KM Event Rate; log-rank P values

ST Landmark Analysis Definite/Probable ST after 24 hours





[†]Day 715 – Definite ST: Patient was not compliant to aspirin and was not taking at P2Y₁₂ inhibitor at time of presentation ST occurring between 0 and 1 years have been previously reported in Kereiakes et al. Circ Cardiovasc Interv 2015

ITT; Patients who did not receive a study stent were censored at 1 year; KM Event Rate; log-rank P values





Rotational Atherectomy for severe calcified lesion involving LM bifurcation

87 y.o Male

<u>Baseline angiogram</u>



<u>Baseline angiogram</u>



Severe Calcification

Procedure



Rota 1.5mm







Synergy 3.5x32mm

Synergy 3.0x12mm

KBI 3.5mm/3.0mm













Baseline angiogram





ON, XT-R tried several channels -> Failed

Retrograde via Septal







SION black + Corsair

Fielder FC, GAIA2nd, PILOT200, PILOT50



Reverse CART -> Externalization

SC 3.0mm/ SC 3.5mm/ NC 3.0mm

Synergy 3.0x38mm

Synergy 3.5x38mm

KBT SC2.5mm/2.5mm



Synergy 3.0x12mm

KBT SC2.5mm/2.5mm



Final angiogram







A Case treated with Hybrid Mini-Crush Stenting (combination of BVS and DES) for bifurcation lesion



72y, Male Stable angina, DM, Cr = 1.5 mg/dl Pre-angiogram





distal LCx: CTO (small)

Diagonal branch: 90% stenosis Medina (0,0,1)









PCI procedure Hybrid (mini) crush stenting (LAD BRS/D1 DES)





1. Pre-dilatation to D1: NC φ3.0x12mm 10atm **2.** DES to D1: Synergy φ3.0x16mm 10atm **3.** Crush: NC φ3.5x12mm 14atm Wire recross 4. Post-dilatation to D1: NC φ3.0x12mm 18atn **5.** Kissing balloon: (LAD) NC φ3.5 8atm / (D1) NC φ3.0 8atm 6. BRS to LAD: Absorb φ3.5x28mm 12atm Post-dilatation to LAD: NC φ3.5 and φ4.0 No Final Kiss



Final angiogram







Final IVUS images (LAD pullback)





Conclusions

Synergy DES highly deliverable

Safety and efficacy not inferior to second generation DES

Preliminary data regarding DAPT show that short term therapy may be acceptable