Outcomes after PCI with a bioabsorbable polymer-coated, everolimus-eluting coronary stent in patients with diabetes: three-year results from the EVOLVE II Diabetes Substudy

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Potential conflicts of interest

Speaker's name: Dr. Martine Gilard

☑️ I have the following potential conflicts of interest to report:

Receipt of consultation fees from Boston Scientific Corporation, Edwards, Medtronic, Bayer, Astra-Zeneca, GE, Abbott
Diabetic patients are more likely to experience poorer clinical outcomes following PCI.

Bioabsorbable-polymer DES have been designed to facilitate arterial healing, reduce inflammation and the risk for late stent thrombosis.

Favorable 2-year clinical outcomes were observed in diabetic patients implanted with the SYNERGY stent (EVOLVE II Diabetes Substudy).
SYNERGY Stent

Platform
Platinum chromium
• 74 µm (0.0029in) strut thickness
↑ Visibility, strength, flexibility, conformability
↓ Recoil

Polymer Coating
Bioabsorbable PLGA
• Abluminal
• 4 µm thick
• 85:15 ratio

Drug
Everolimus
• 100 µg/cm²
• 3 month release time
EVOLVE II Clinical Program

What did we study?

Patients with ≤3 native coronary artery lesions in ≤2 major epicardial vessels;

Lesion length ≤34 mm, RVD ≥2.25 mm ≤ 4.0, % DS≥50<100
(excluded LM disease, CTO, SVG, ISR or recent STEMI)
**EVOLVE II Clinical Program**

**EVOLVE II Randomized Cohort**
- PROMUS Element Plus N=838
- SYNERGY N=846

**RCT Design**
Prospective, multicentre, single-blind, 1:1 randomised, noninferiority trial
1° Endpoint: TLF at 12 mo
1° endpoint met

**EVOLVE II Diabetes Substudy**
*Diabetic Patients from:*
- SYNERGY cohort EVOLVE II RCT N=263
- Single-arm Diabetes Study N=203

**EVOLVE II Diabetes Substudy Design**
Consecutive, multicentre, single-arm, non-randomized study
1° Endpoint: TLF at 12 mo
1° endpoint met
Noninferiority was proven at 1 year because the one-sided upper 97.5% confidence bound for the difference in TLF is <4.4%.
Diabetic subjects in the SYNERGY arm of the EVOLVE II RCT
N=263

Diabetic subjects in the Diabetes single-arm study
N=203

EVOLVE II Diabetes Substudy
N=466

No study stent implanted N=3*

Missed 3-year Visit N=10
Withdrawed Consent N=5
Lost to Follow-up N=5
Other N=1

3-year Clinical follow-up
95.5% (442/463)

*Patients who did not receive a study stent were only followed through 1 year (safety population)
Safety population; Patients were treated with one of the following P2Y_{12} inhibitors (clopidogrel, ticlopidine, prasugrel, or ticagrelor) for at least 6 months following the index procedure. ASA=acetylsalicylic acid; DAPT=dual antiplatelet therapy
What were the essential results?

EVOLVE II Diabetes 3-year TLF
EVOLVE II RCT & Diabetes Substudy

Kereiakes ACC 2017; Safety population; DM=Diabetes Mellitus
What is important?
Clinical Outcomes at 3 years

Kereiakes ACC 2017; Safety population; KM event rates; Spontaneous MI defined as the rise and/or fall of cardiac biomarkers with ≥1 value >99th percentile of the upper reference limit (URL) with ≥1 of the following: symptoms of ischemia, ECG changes, and/or evidence of loss of myocardium. Peri-PCI MI defined by any of the following: i) CK-MB >3X URL within 48 hours, ii) new pathological Q waves, iii) autopsy evidence.
The 3-year data provides evidence supporting safety and efficacy of the SYNERGY stent in patients with diabetes mellitus

**EVOLVE II Diabetes Substudy** is a consecutive, multicentre, single-arm, non-randomized study, with the SYNERGY stent in medically-treated diabetic patients

Low clinical event rates were maintained through 3 years, with TLF 12.2% and all-cause death 4.4%

The ARC definite/probable ST rate through 3 years was low (1.1%), with no ST reported after 30 days