



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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on behalf of the EVOLVE II Diabetes Substudy Investigators



Session: New DES and DES comparisons

Date: 17 May 2017

Session Time: 10:30 – 12:00

Location: Room Maillot

Presentation Time: 11:35-11:43

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

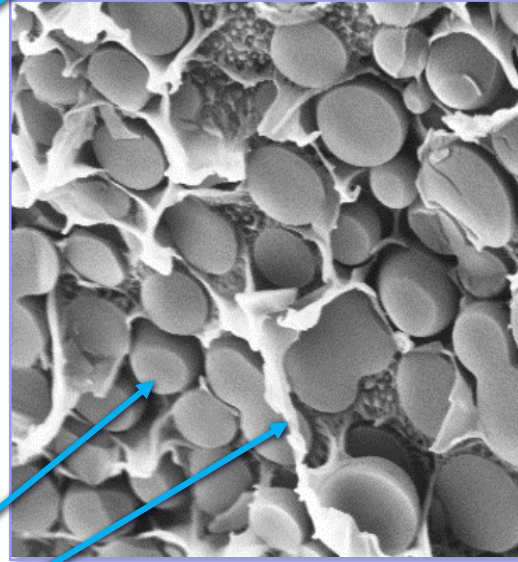
Bioabsorbable-polymer DES have been designed to facilitate arterial healing, reduce inflammation and the risk for late stent thrombosis

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



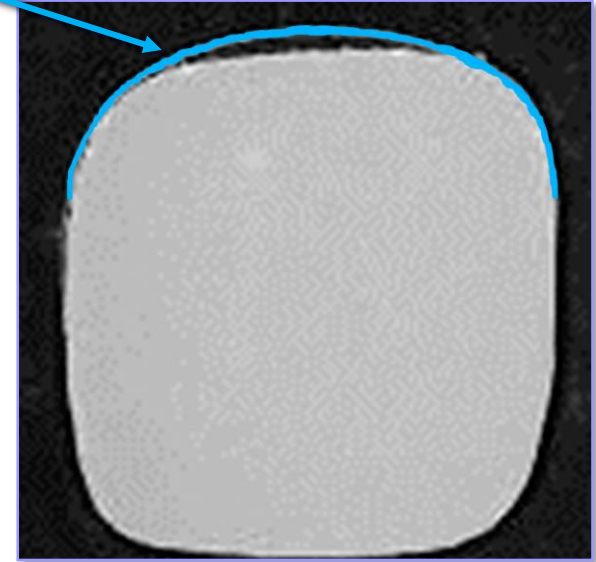
Everolimus Drug
PLGA Polymer

Drug & Polymer Coating



SEM of coating (x5000)

Abluminal (4 μm)



Luminal

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

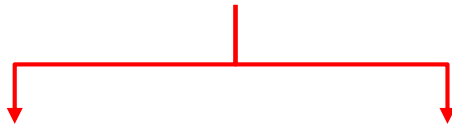
- 100 $\mu\text{g}/\text{cm}^2$
- 3 month release time

EVOLVE II Clinical Program

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

Lesion length ≤ 34 mm, RVD ≥ 2.25 mm ≤ 4.0 , % DS $\geq 50 < 100$
(excluded LM disease, CTO, SVG, ISR or recent STEMI)

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

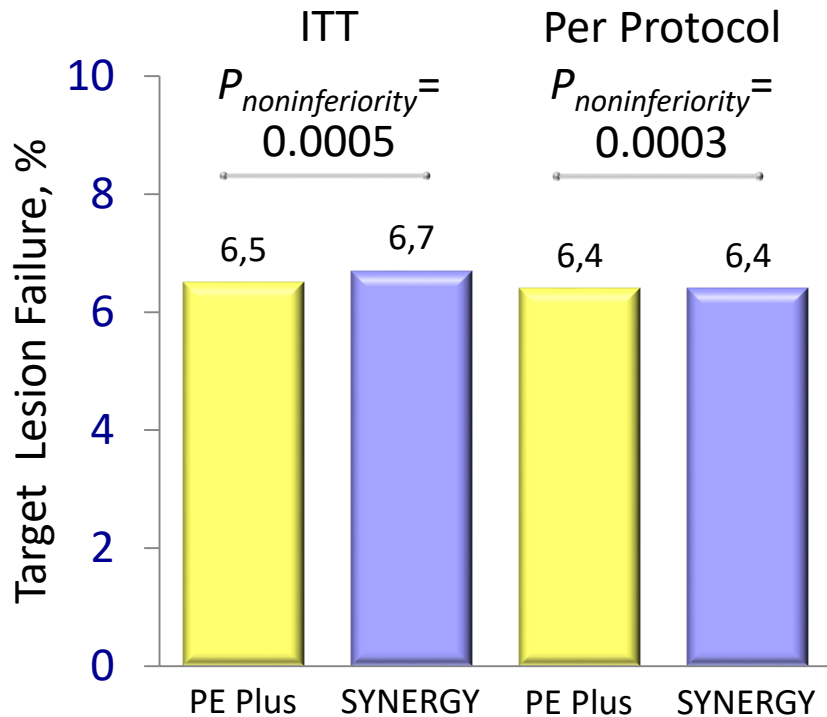
Consecutive, multicentre, single-arm,
non-randomized study

1° Endpoint: TLF at 12 mo

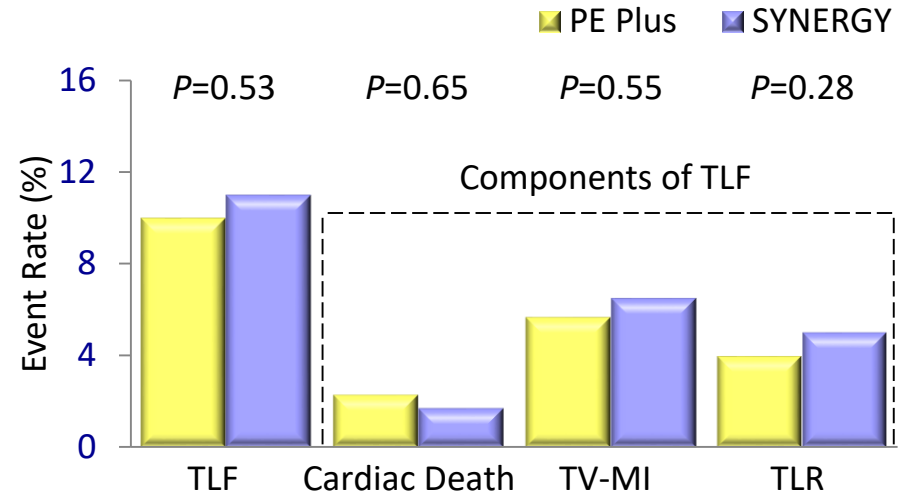
1° endpoint met

Primary Endpoint

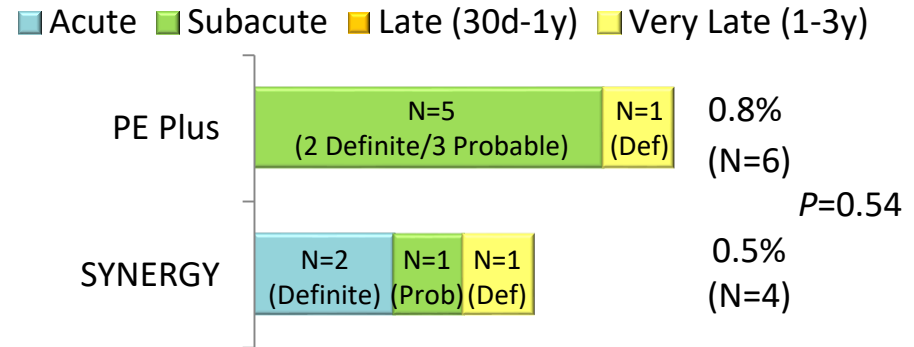
TLF at 1 year



3-year Outcomes (ITT)

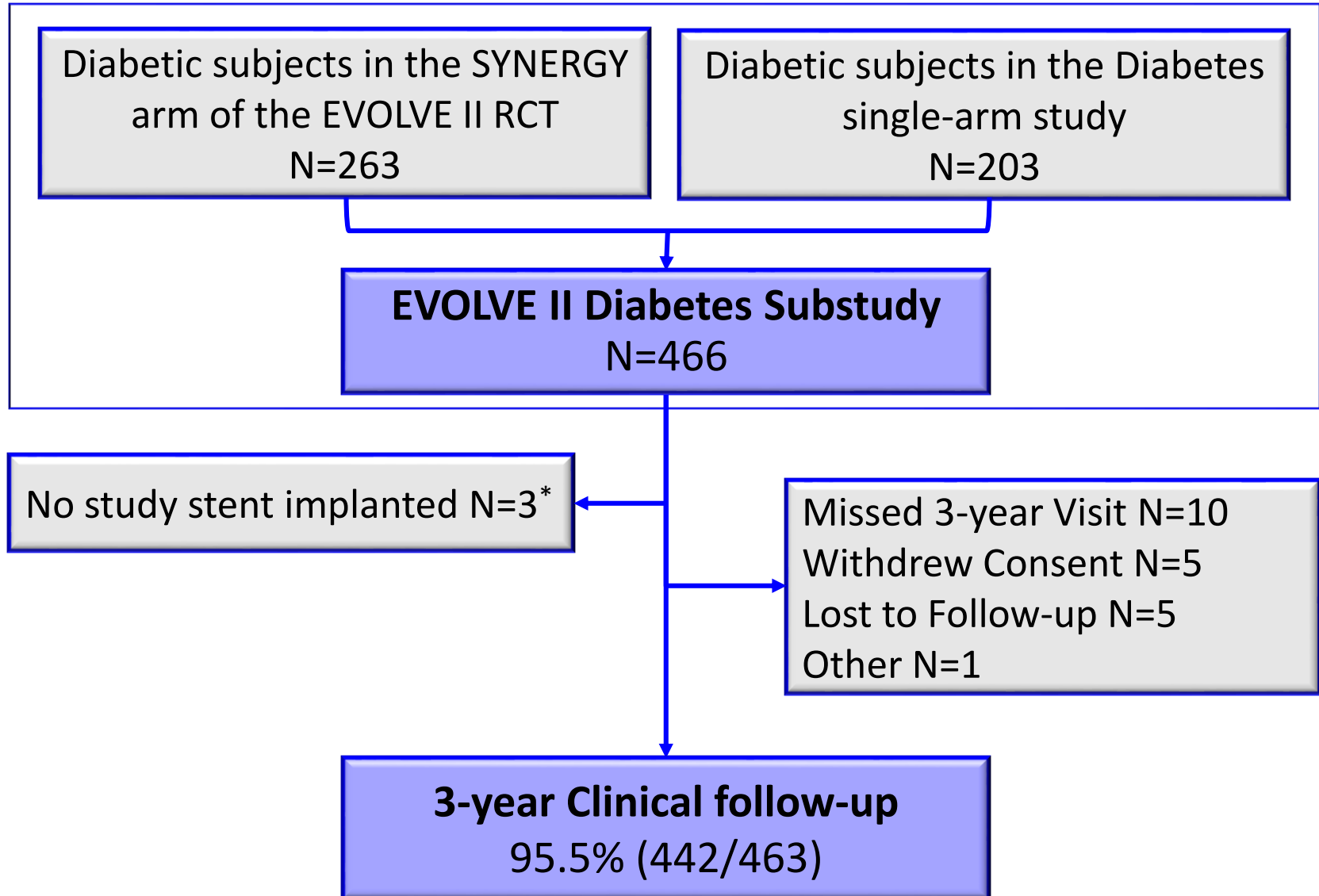


Stent Thrombosis



Noninferiority was proven at 1 year because the one-sided upper 97.5% confidence bound for the difference in TLF is <4.4%

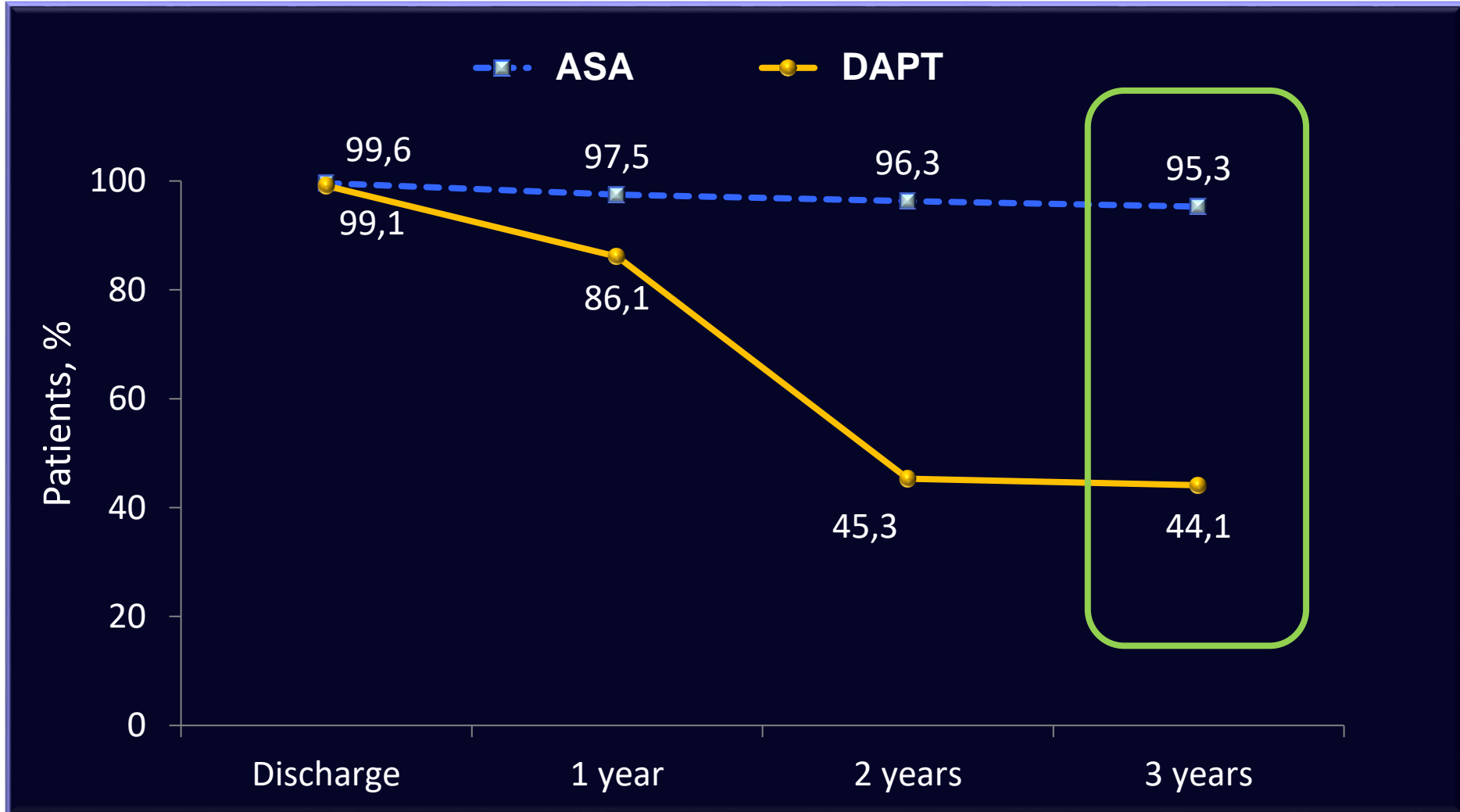
EVOLVE II Diabetes Patient Disposition



*Patients who did not receive a study stent were only followed through 1 year (safety population)

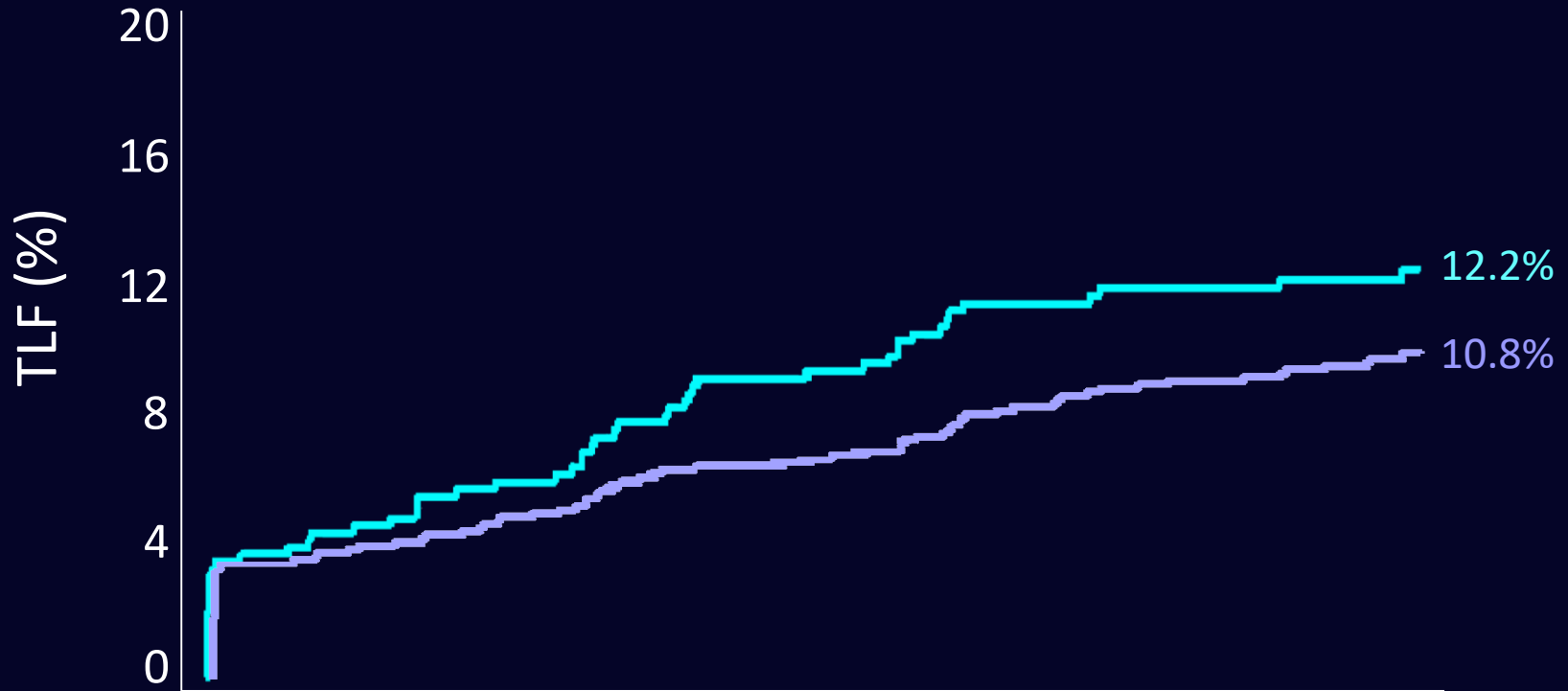
What were the essential results?

Antiplatelet Medication Usage



Safety population; Patients were treated with one of the following P2Y₁₂ inhibitors (clopidogrel, ticlopidine, prasugrel, or ticagrelor) for at least 6 months following the index procedure. ASA=acetylsalicylic acid; DAPT=dual antiplatelet therapy

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



	No. at risk	0	12	24	36 Months
— SYNERGY DM		463	434	402	279
— SYNERGY RCT		845	795	758	540

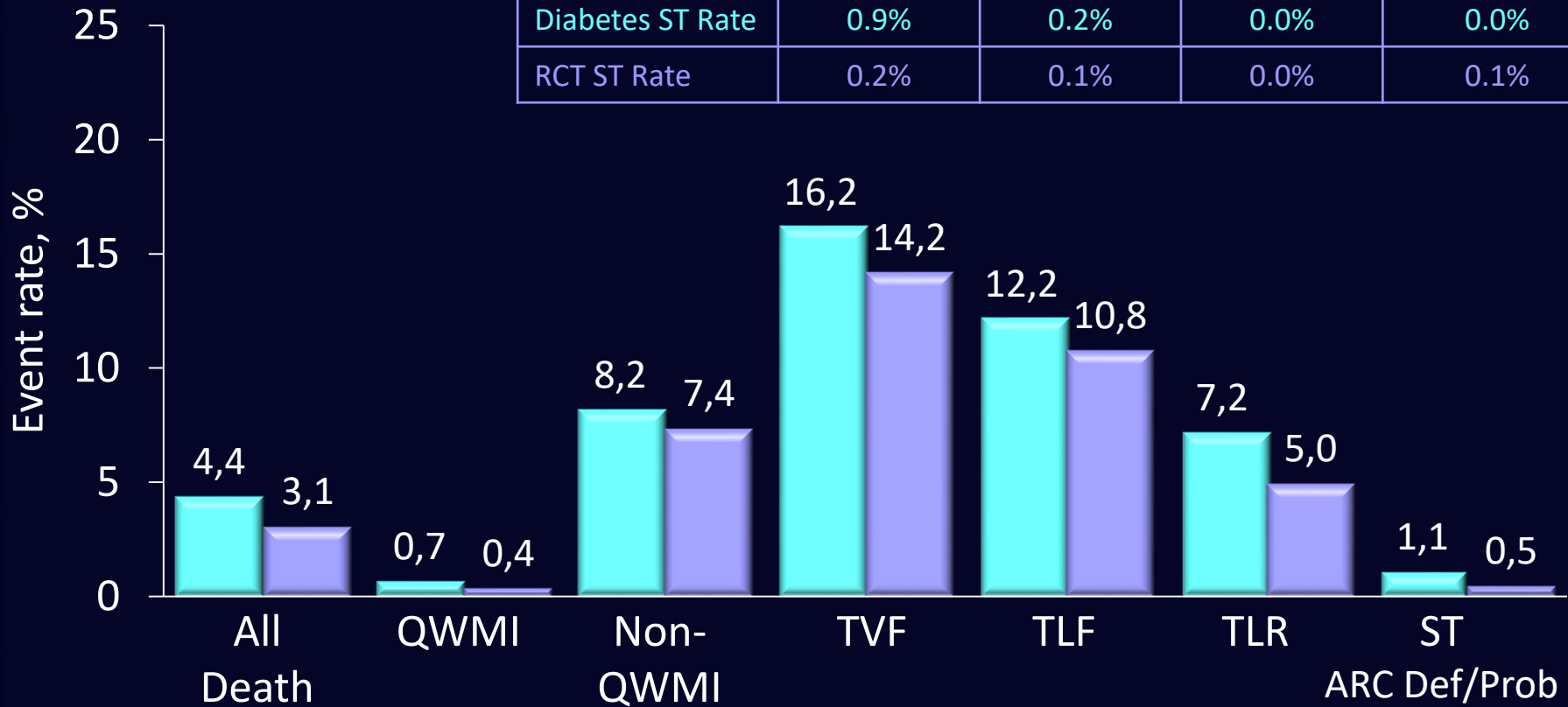
What is important?

Clinical Outcomes at 3 years

■ EVOLVE II Diabetes Substudy

■ EVOLVE II RCT: SYNERGY arm

Time Period	0-1 days	2-30 days	31-365 days	366-1095 days
Diabetes ST Rate	0.9%	0.2%	0.0%	0.0%
RCT ST Rate	0.2%	0.1%	0.0%	0.1%



Kereiakes ACC 2017; Safety population; KM event rates; Spontaneous MI defined as the rise and/or fall of cardiac biomarkers with ≥ 1 value >99 th 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

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**

The 3-year data provides evidence supporting safety and efficacy of the SYNERGY stent in patients with diabetes mellitus