29th TCTAP2024

The Future of BRS: Insights From the COMPARE ABSORB Trial

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CVRF

Disclosure

In the last 3 years I received,

- Institutional research grants from Abbott Vascular and Sahajanad Medical Technologies (SMT)
- Consultancy and speakers fees from Abbott Vascular, Abiomed, Microport, Terumo and SMT, and
- I’m CERC shareholder (minor)

COMPARE-ABSORB trial

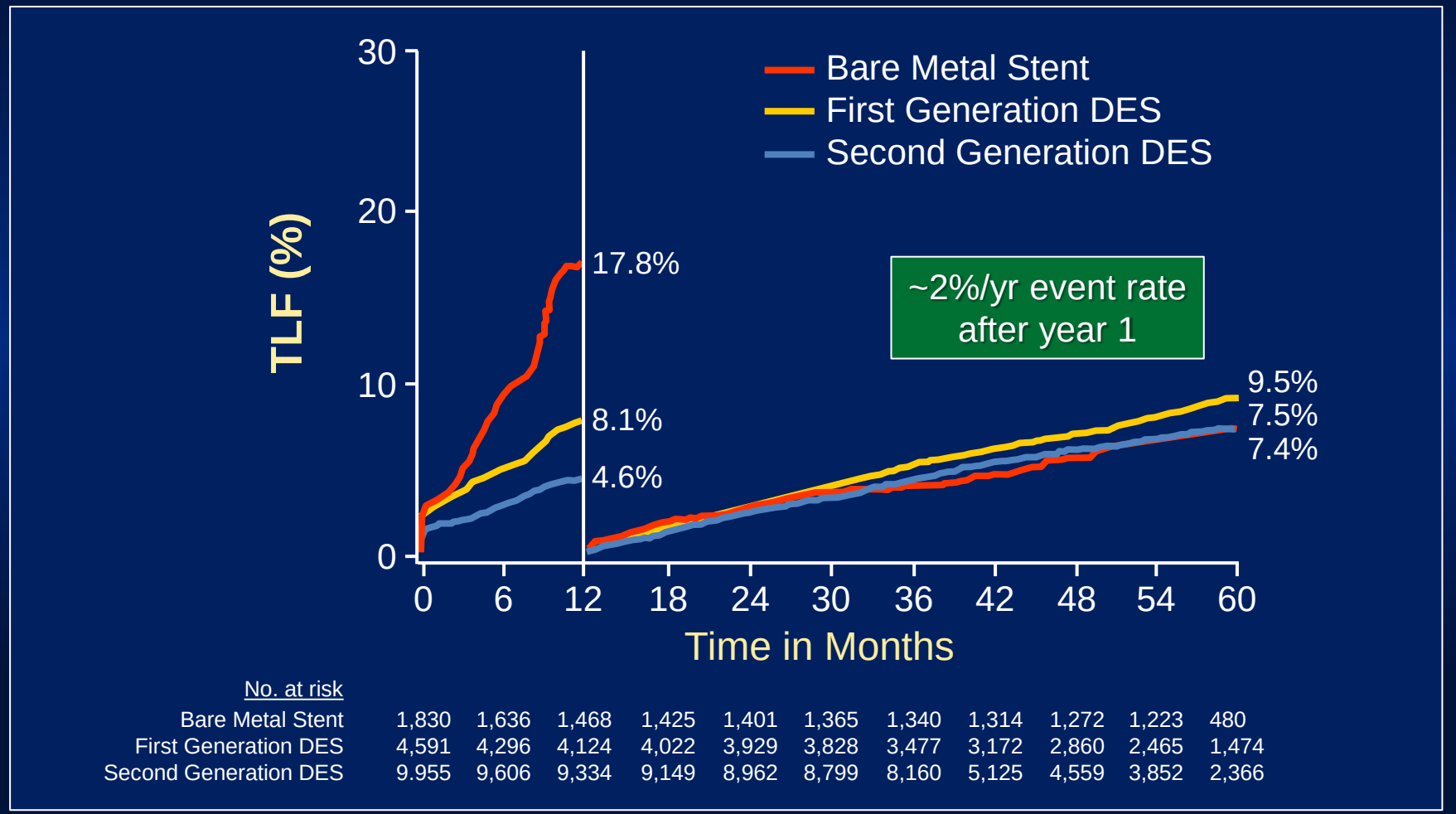
Prospective, single blind, multicenter randomized controlled trial comparing

Xience versus Absorb

in a high-risk patient population for restenosis

17 RCTs, 21,830 patients

TLF Between 0-1 and 1-5 Years by Stent Type (Landmark Analysis)



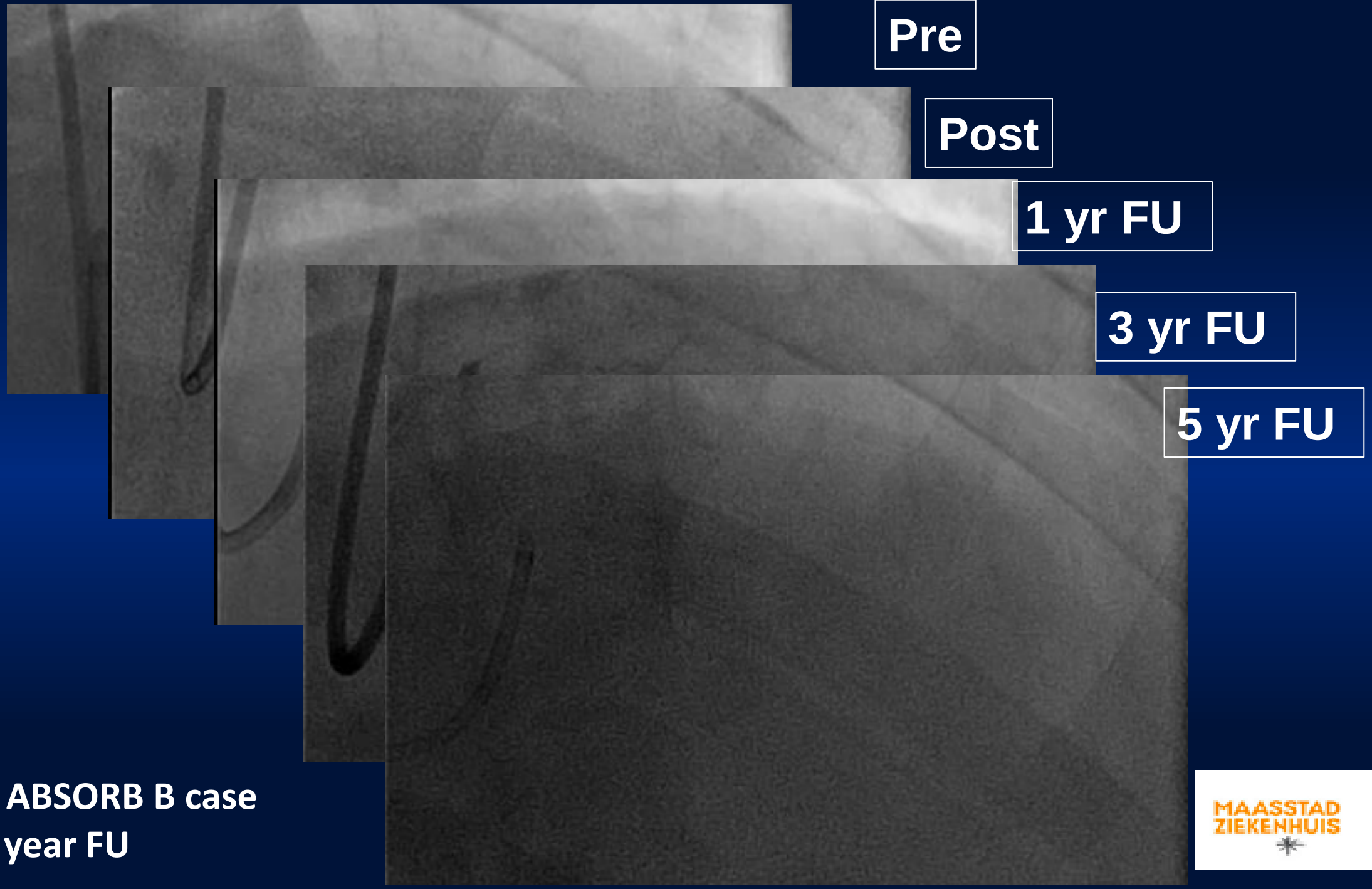
COMPARE I & II and Resolute AC 5-year outcomes

- DM
- Long lesions (>28 mm)
- Bifurcation lesions
- MVD
- CTO

2.5 - 3.5 %/yr event rate after year 1

Madhaven M et al. JACC 2020

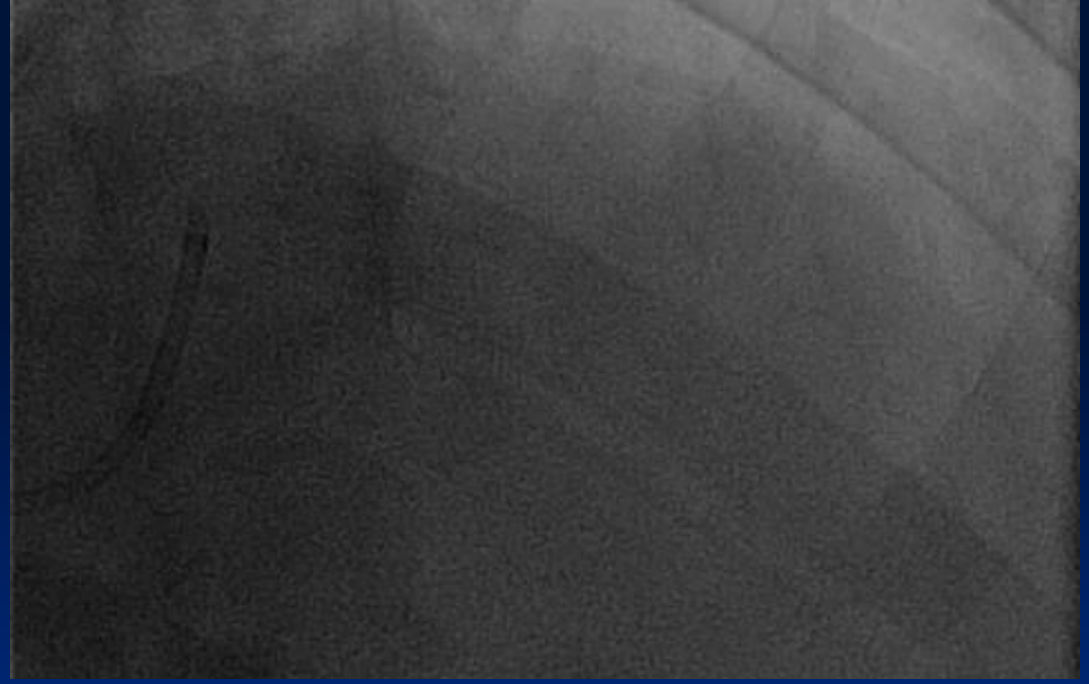
Unpublished

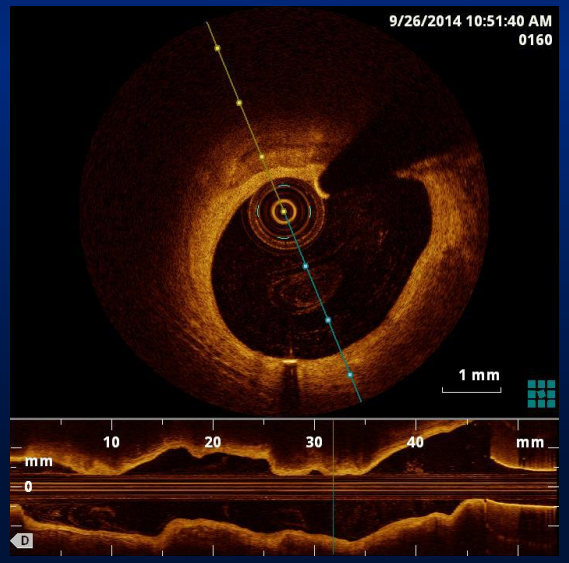


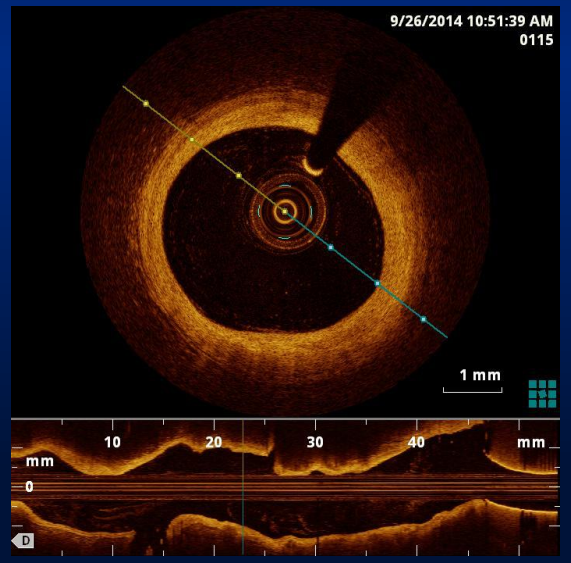
Example ABSORB B case
5 year FU

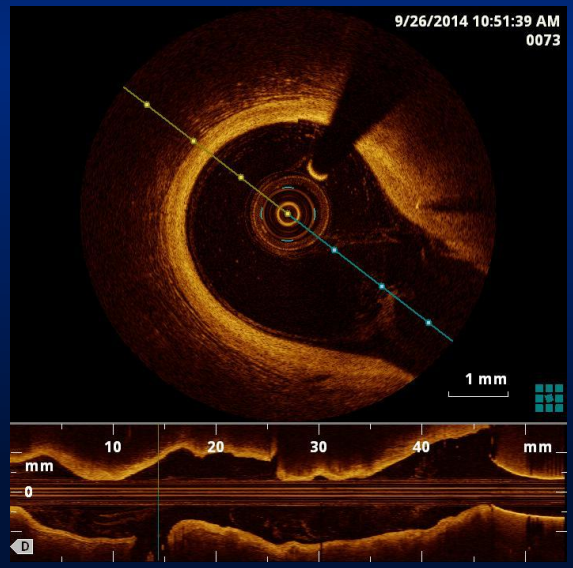
MAASSTAD ZIEKENHUIS

Example ABSORB B case
5 year FU









Proximal marker

Distal marker

….and nothing in between

Rationale for COMPARE ABSORB

- We hypothesised that the use of Bioresorable Vascular Scaffold (BVS) in a high-risk population for re-stenosis might demonstrate better long-term outcomes compared to metallic DES after full BVS resorption

- Second, a specific BVS implantation technique was never employed in previous BVS RCT's from the start. In COMPARE-ABSORB a dedicated optimal implantation technique for BVS was mandated from the start

Objectives COMPARE ABSORB

- To show non-inferiority between Absorb and Xience on TLF at 1 year
- Secondary objective is to show superiority of Absorb on TLF on the longterm in a landmark analysis
- Tertiary objective is to show superiority of Absorb on TLF on the longterm from the start

Inclusion criteria

Patients with *at least one* of the following:

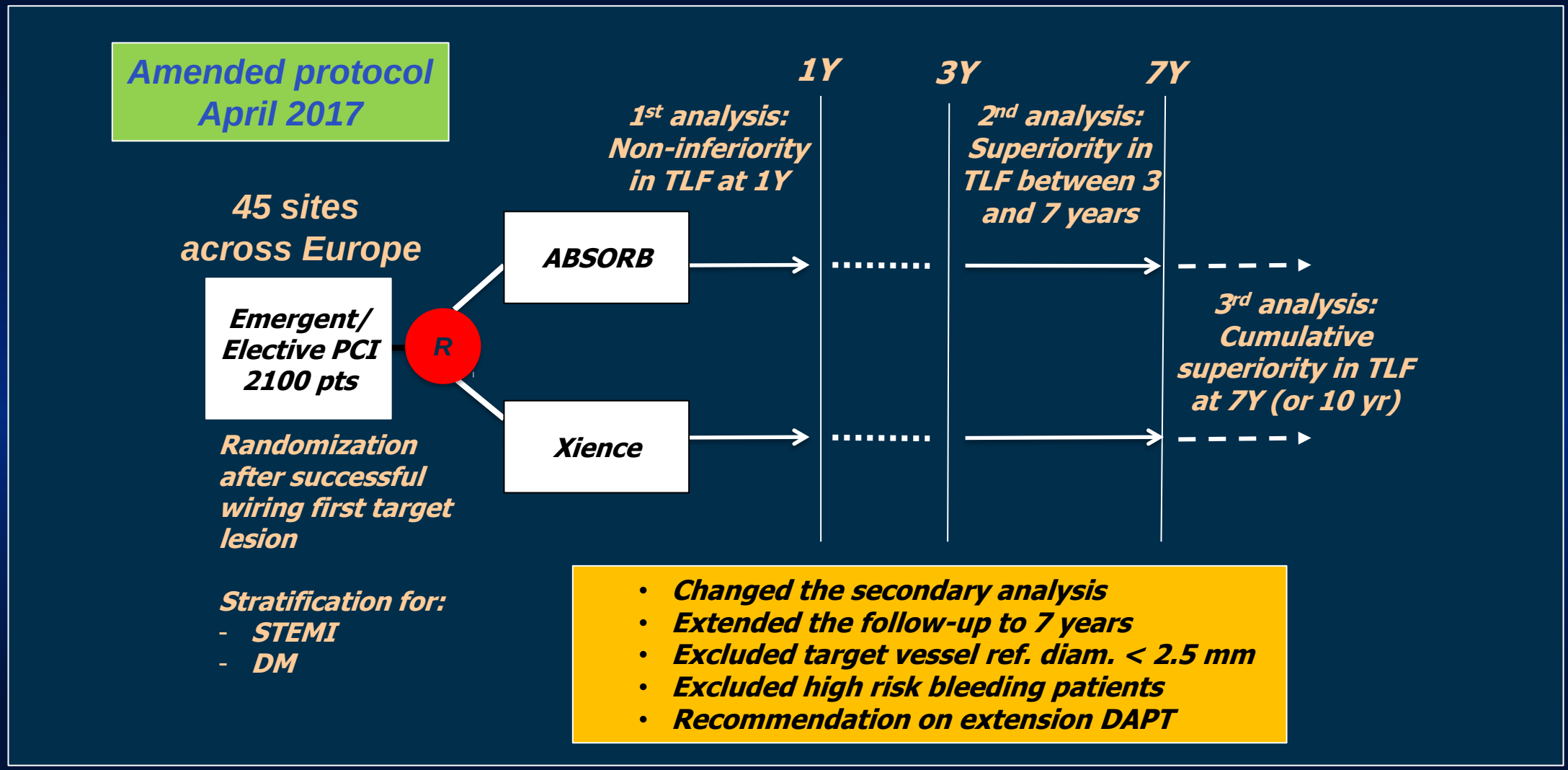
i) High-risk characteristics for restenosis

Known diabetes and/or multivessel disease of which more than one *de-novo* target lesion to be treated with the study scaffold/stent

ii) Complex *de-novo* target lesion

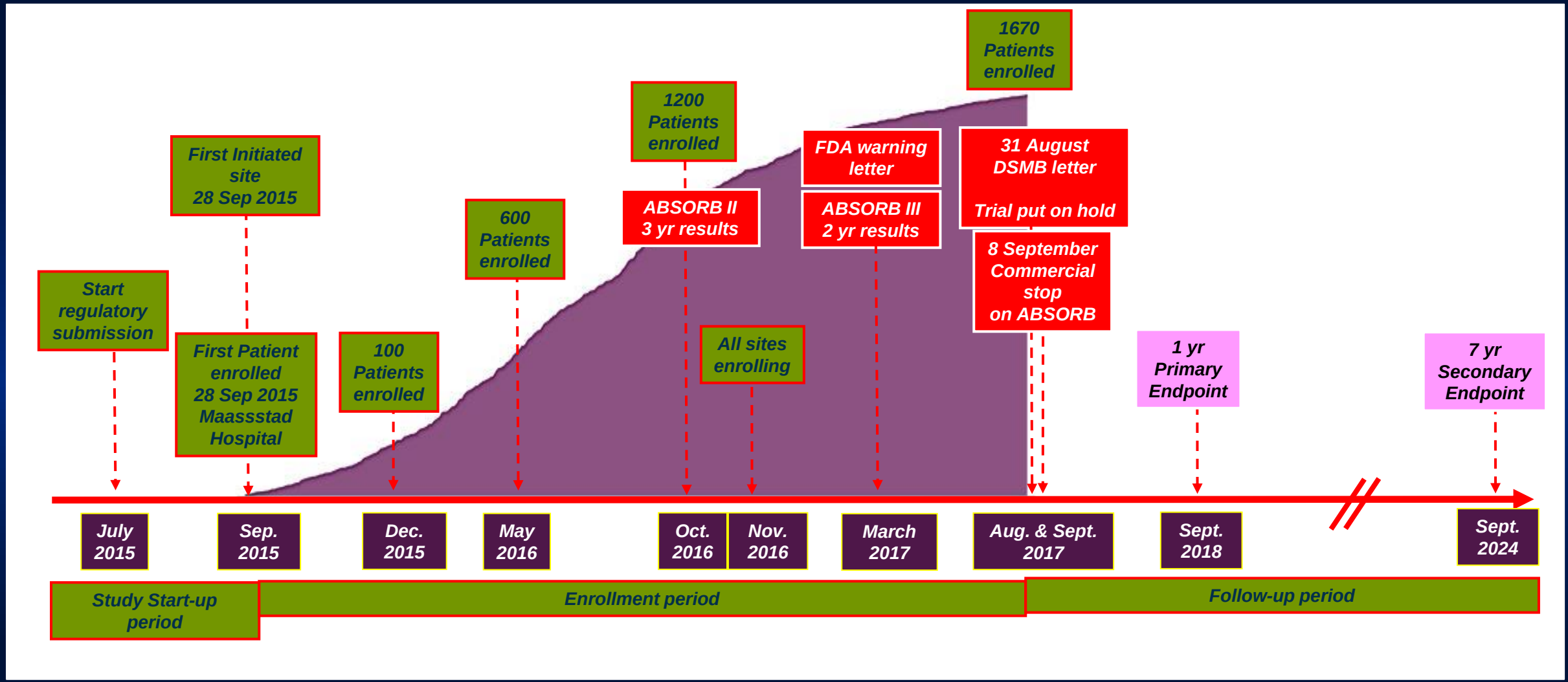
- Lesion length >28 mm
- Small vessels: RVD between 2.25-2.75 mm
- Lesion with pre-existing total occlusion
- Bifurcation with single device strategy

Trial design (revised)



COMPARE ABSORB

Study flow



COMPARE ABSORB

Baseline characteristics

Risk factors	ABSORB 848 patients	XIENCE 822 patients	P value
Age [yr] ± SD	61.9 ± 9.4	62.2 ± 9.0	0.61
Male	79.5% (674)	76.3% (627)	0.13
Diabetes mellitus	34.6% (293)	36.1% (296)	0.57
Current smoker	28.8% (241)	26.9% (217)	0.41
Previous smoker	51.9% (289)	50.1% (280)	0.55
Hypercholesterolemia	66.3% (546)	65.8% (531)	0.88
Hypertension	71.6% (601)	69.2% (567)	0.31
Family history of CAD	36.2% (278)	31.7% (241)	0.07
Previous PCI	27.0% (229)	20.2% (238)	0.38
Previous CABG	1.9% (16)	2.6% (21)	0.41
Previous MI	18.2% (154)	20.2% (166)	0.29
Previous stroke	3.4% (29)	4.8% (39)	0.18
Renal insufficiency	3.9% (33)	6.0% (49)	0.054
LV ejection fraction [%] ± SD	56.4 ± 10.5	56.3 ±10.2	0.83

Baseline characteristics

Indication and treatment	ABSORB 848 patients 1242 target lesions	XIENCE 822 patients 1213 target lesions	P value
Acute coronary syndrome (ACS)	52.1% (442)	48.7% (400)	0.17
STEMI	13.0% (110)	12.5% (103)	0.88
Non-STEMI treatment < 72 hours	13.3% (113)	12.4% (102)	0.57
Multi-vessel treatment	35.7% (303)	37.7% (301)	0.56
Mean target lesions treated ± SD	1.5 ± 0.7	1.5 ± 0.7	0.67
Mean Syntax score ± SD	12.2 ± 7.1	12.2 ± 7.3	0.88
Bifurcation lesions	20.5% (254)	22.2% (269)	0.30
Pre-existing total occlusions	14.6% (181)	13.1% (159)	0.32
Long lesions (>28mm)	25.2% (313)	31.5% (370)	<0.001
Small vessel lesions (>2.25 ≤ 2.75 mm)	22.5% (279)	30.5% (370)	<0.001

Procedural characteristics

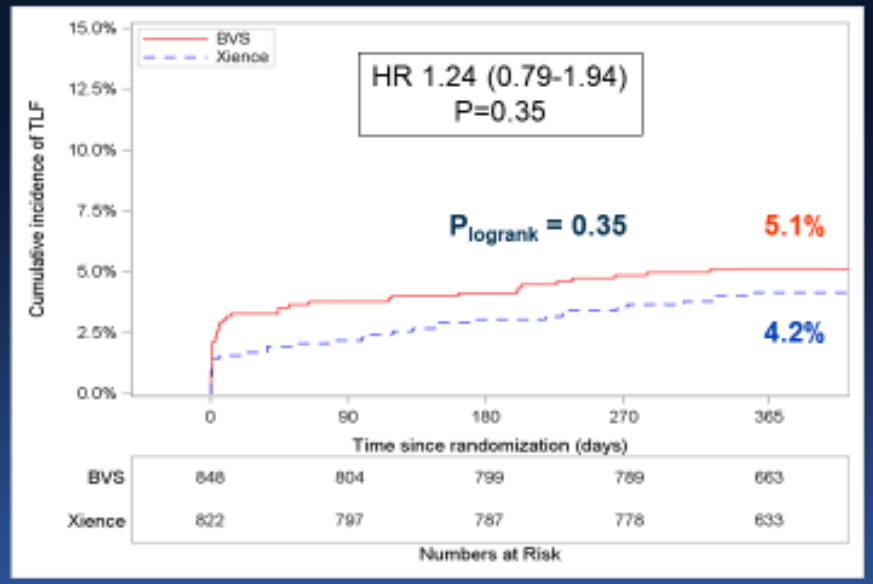
Vessel and lesion treatment	ABSORB 1242 target lesions 1651 scaffolds	XIENCE 1213 target lesions 1553 stents	P value
Pre-dilatation	96.5% (1198)	78.6% (1213)	<0.001
Largest balloon (mm ± SD)	3.0 ± 1.0	3.0 ± 0.7	0.96
Non-compliant balloon used	67.9% (814)	52.9% (504)	<0.001
Max. pressure used (Atm.)	15.3 ± 3.5	14.8 ± 3.4	0.002
Thromboaspiration	2.8% (35)	2.9% (35)	1.00
Rotablator	0.8% (10)	1.0% (12)	0.67
Cutting / scoring balloon	5.8% (72)	2.3% (28)	<0.001
Mean study devices used	1.3 ± 0.7	1.3 ± 0.6	0.07
Post-dilatation	90.7% (1497)	58.3 (906)	<0.001
Non-compliant balloon used	93.0% (1392)	85.5% (775)	<0.001
Largest balloon diameter (mm ± SD)	3.3 ± 0.4	3.3 ± 0.5	0.97
Max. pressure largest balloon (Atm)	17.6 ± 3.7	17.5 ± 3.7	0.76
Max. pressure > 16 Atm	79.7% (1193)	79.5% (720)	0.92

2018

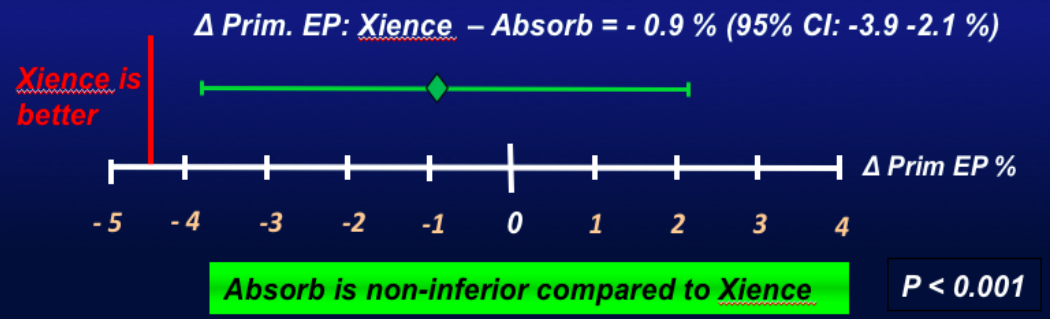
1 year results

TLF @ 1 year

Cardiac death, target vessel myocardial infarction, clinically-indicated target lesion revascularization

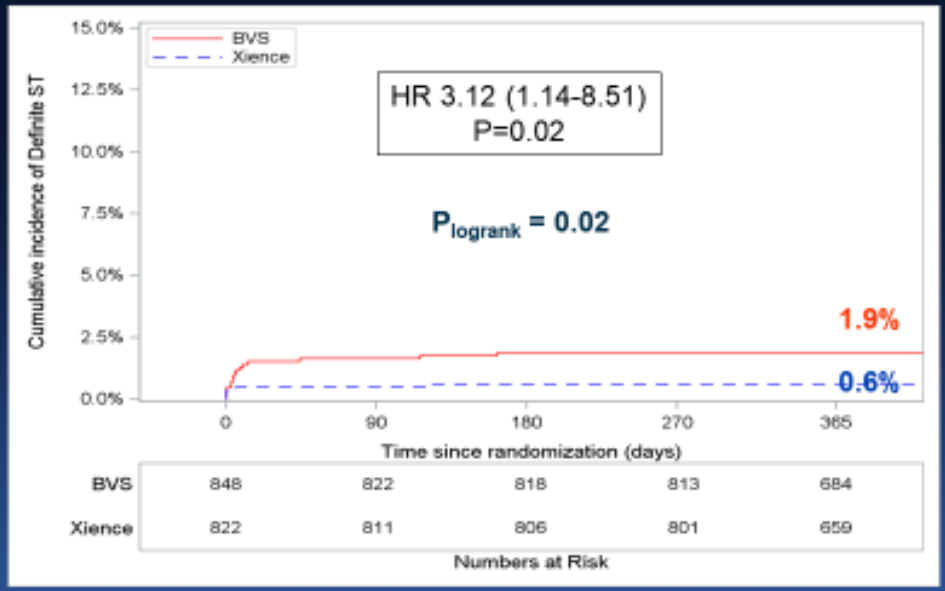


tct2017 Cardiovascular Research Foundation



Stent/Scaffold Thrombosis @ 1 year

Definite Stent/Scaffold Thrombosis (ARC definition)



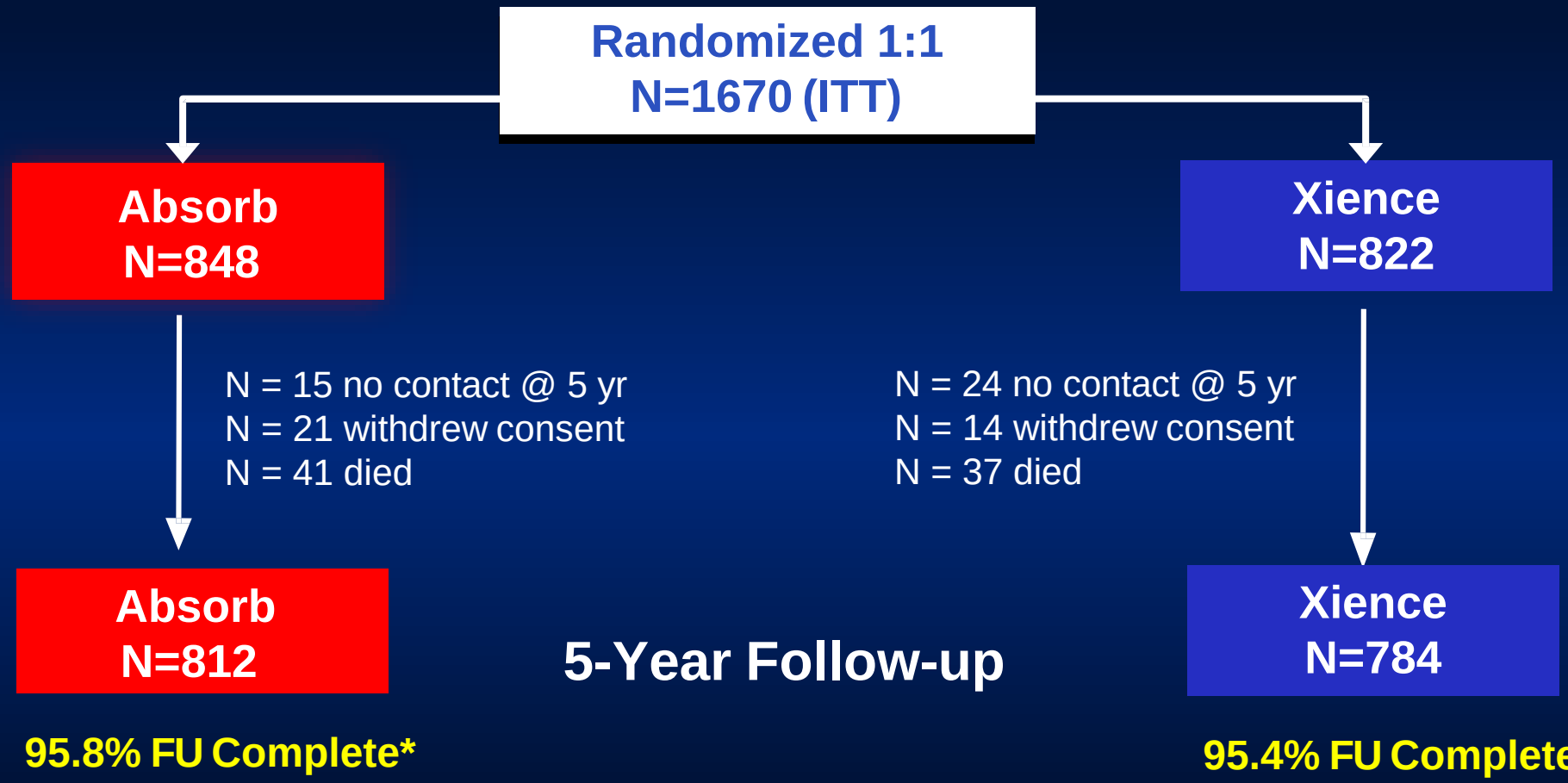
tct2018 Cardiovascular Research Foundation

Smits et al. EuroIntervention 2020;16:645-653

Current Objectives

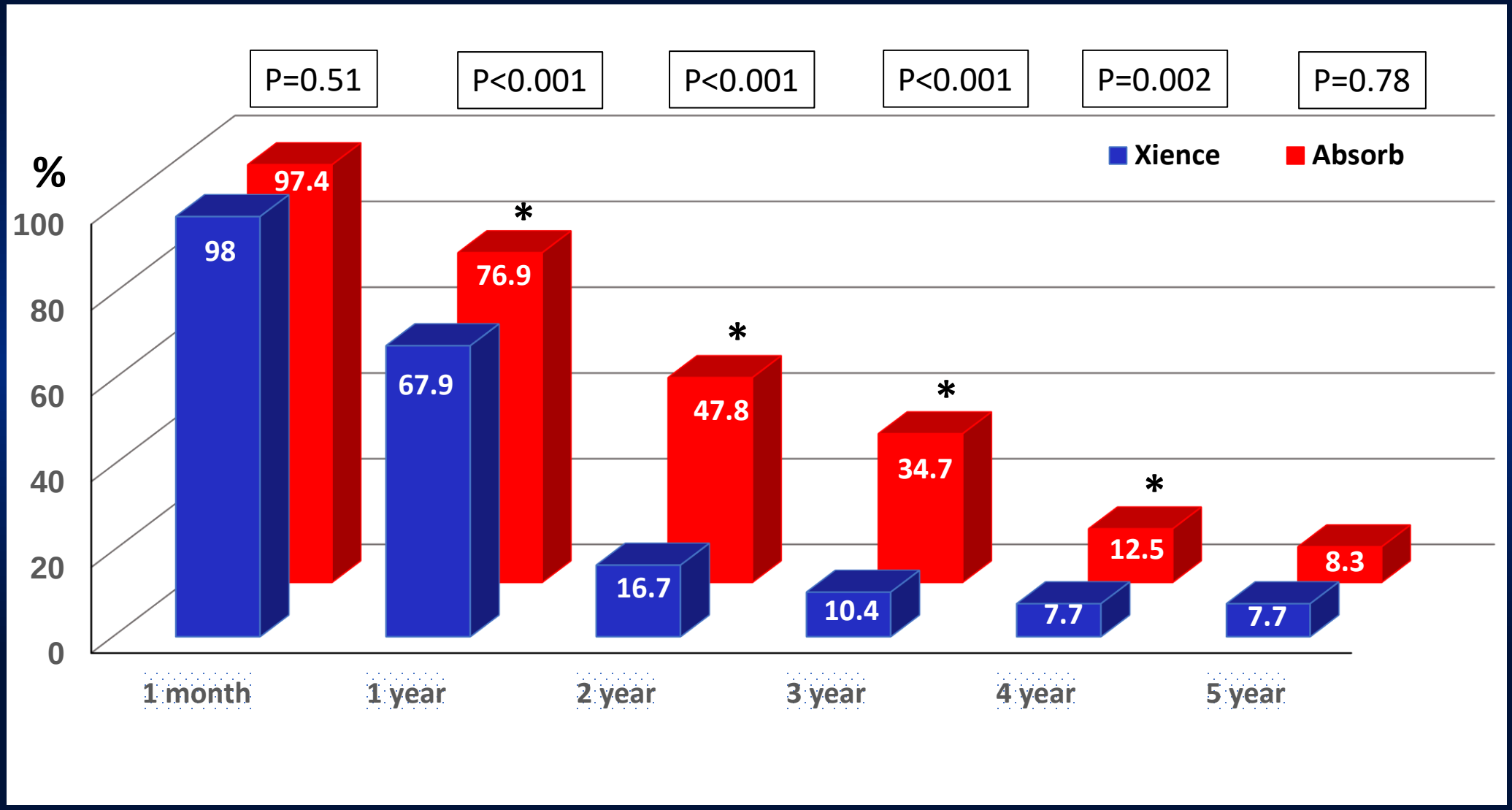
- To show the interim 5-year longterm results
- To observe if the dedicated implantation protocol (PSP) resolved the issue of very late scaffold complications?

Study Flow and 5 yr Follow-up

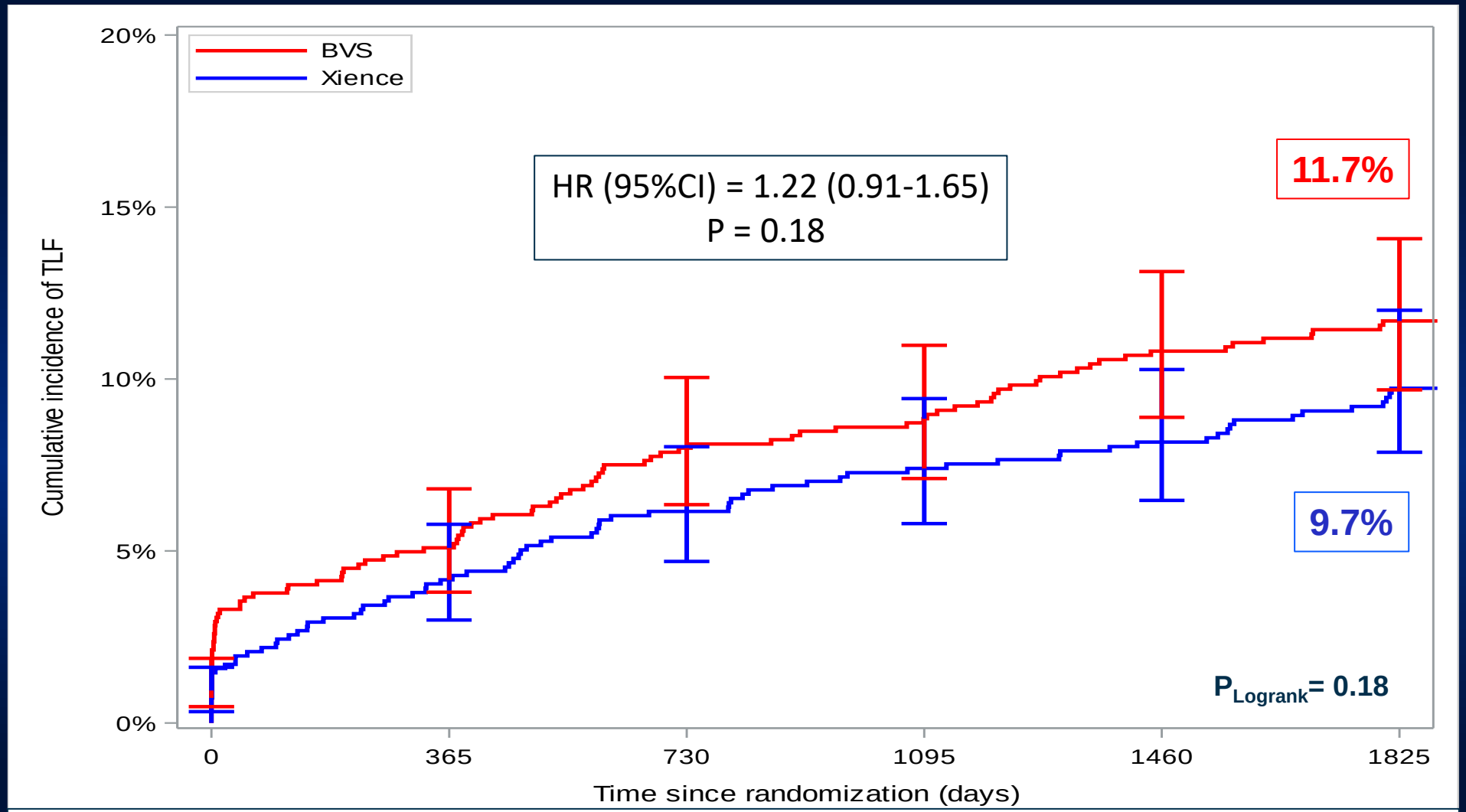


* Information available

DAPT usage

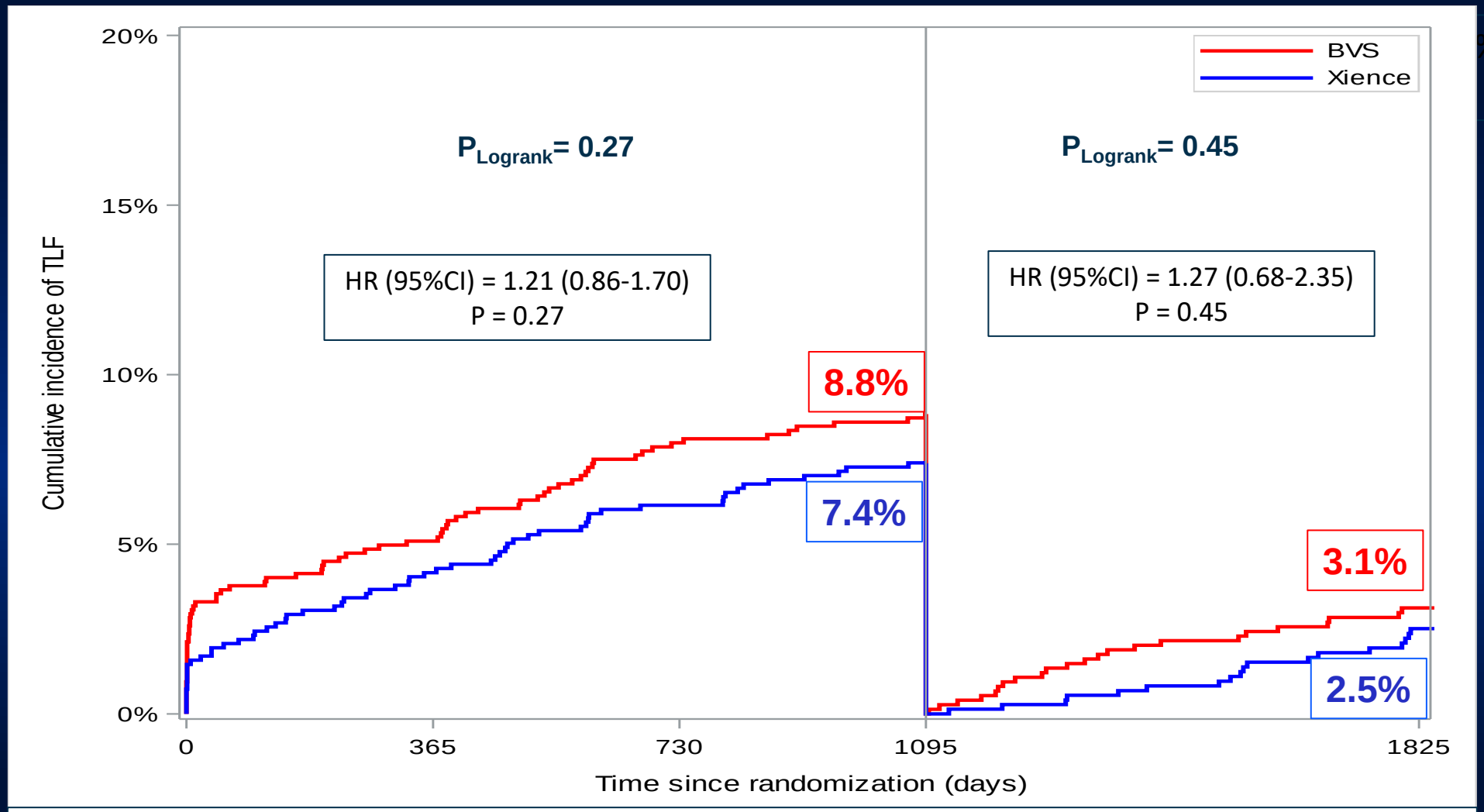

P=0.51
P<0.001
P<0.001
P<0.001
P=0.002
P=0.78
Xience
Absorb
%
100
80
60
40
20
0
98
97.4
67.9
76.9
16.7
47.8
10.4
34.7
7.7
12.5
7.7
8.3
*
*
*
*
1 month
1 year
2 year
3 year
4 year
5 year

Kaplan-Meier-Plot Primary Endpoint: TLF (DoCE)



Nr. at risk	848	790	759	746	724	630
	822	776	752	736	717	635
Nr. events	8	35	24	7	16	7
	6	28	16	10	6	12

Landmark analysis @ 3-year: TLF



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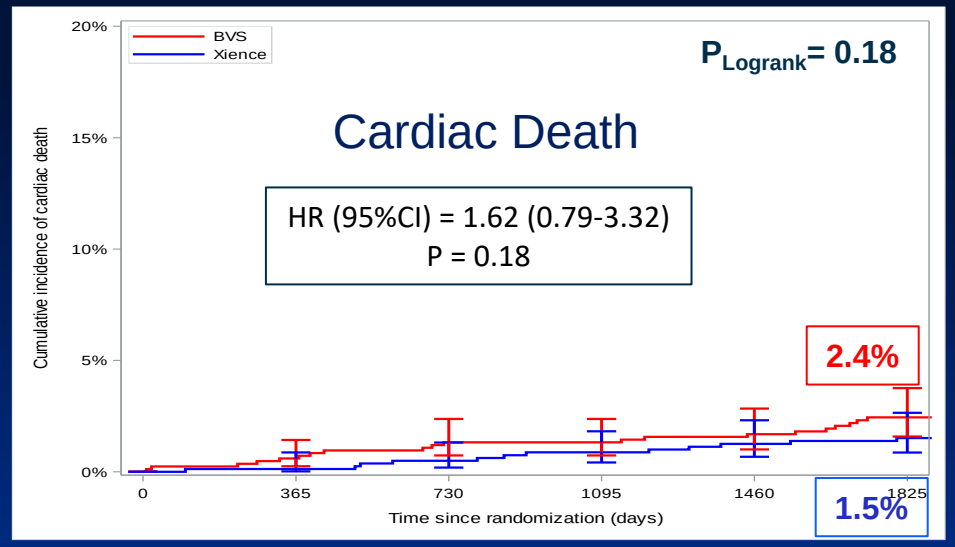
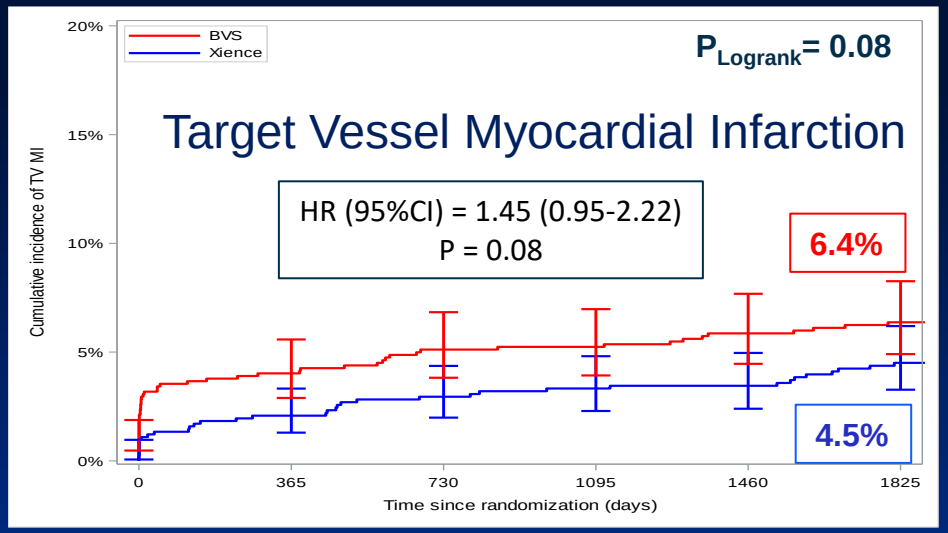
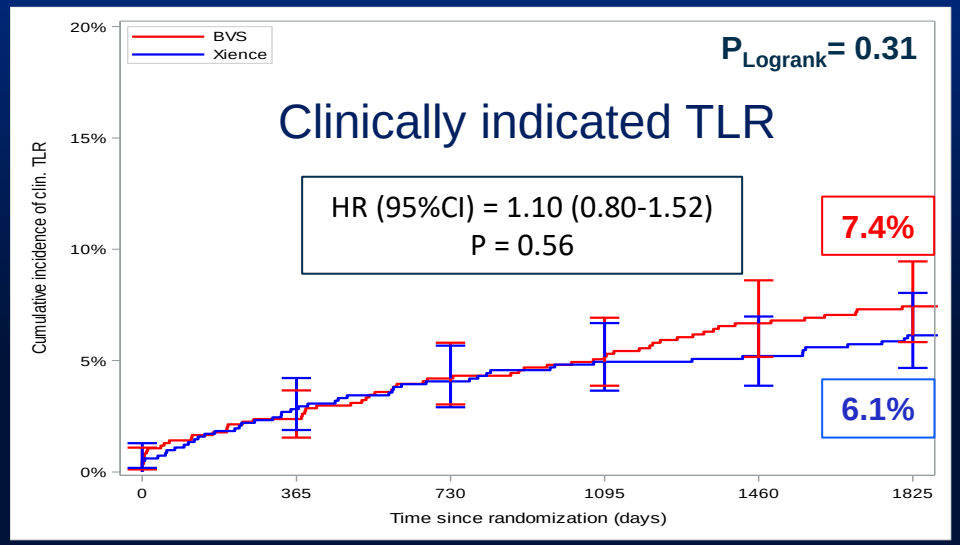
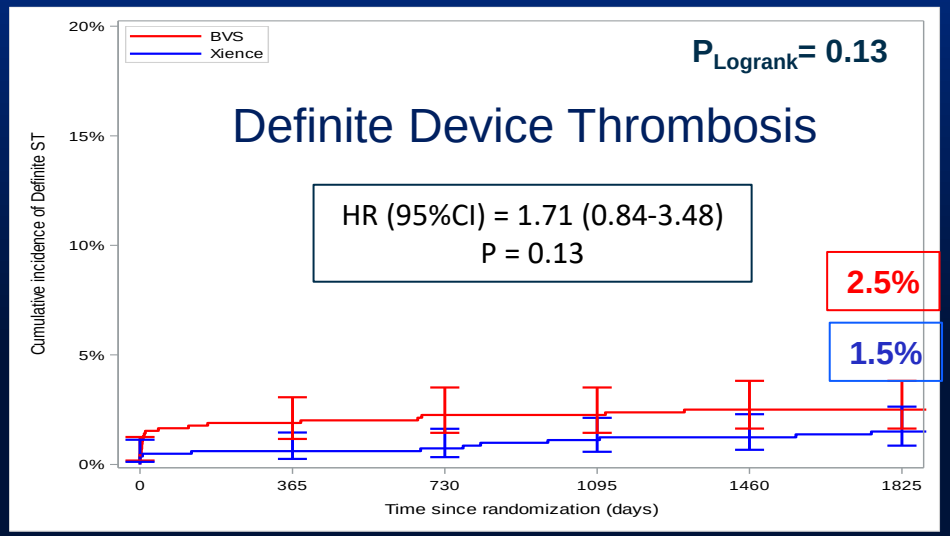
Kaplan-Meier-Plots









Summary

- At 5-year follow-up there were no significant differences between Absorb and Xience, though the event rates for Absorb remained numerically higher in this PCI population at high risk for restenosis

- Very late ischemic events were not prevented with the PSP implantation protocol, despite higher DAPT rates in the Absorb arm

- Between 3 and 4 year follow-up a small increase of events occurred in the Absorb arm, mainly driven by target lesion revascularizations

Trial Organisation

- Grant giver : Abbott Vascular
- Grant receiver and trial sponsor: Maasstad Hospital, Rotterdam
- Trial conductor : CERIC, Geneva
- CRO : CERC, Paris
- Corelab and Statistics : Cardialyis, Rotterdam
- DSMB : Stefan James, Eric Boersma, Michel Bertrand
- Senior Consultant : Patrick Serruys
- Lead Clinical Trial Managers: Ute Windhovel, Tatamo Rakotoary, Ria van Vliet

MAASSTAD ZIEKENHUIS

Ceric Center for European Research Initiatives in Cardiovascular Medicine

CERC Cardiovascular European Research Center

CARDIALYSIS Clinical Trial Management - Core Laboratories

Key features of COMPARE-ABSORB

Specific patient population and implantation technique

- To study a patient population which potentially might benefit the most by the vascular restoration therapy concept on the long term

- Selection of specific patients and complex lesions not investigated in previous RCT's like: STEMI, acute non-STEMI, bifurcations and long lesions and CTO's

- PSP implantation technique from the start
  - Mandatory pre-dilatation 1:1 balloon – artery ratio
  - IVUS / OCT / QCA guidance for treatment target vessels < 2.75 mm highly recommended
  - Mandatory high pressure (> 16 atm.) post-dilatation
  - Usage off NC balloons up to 0.50 mm larger than the scaffold for post-dilatation highly recommended