CRT 21 Virtual

3-Year Results from the COMPARE-ABSORB trial

Pieter C. Smits
On behalf of the COMPARE-ABSORB investigators

COMPARE-ABSORB

ABSORB bioresorbable scaffold vs. Xience metallic stent for prevention of restenosis following PCI in patients at high risk of restenosis.

MAASSTAD ZIEKENHUIS

CARDIALYSIS
Clinical Trial Management - Core Laboratories

COMPARE ABSORB

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Center for European Research Initiatives in Cardiovascular Medicine

Erasmus MC
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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

Rationale for long-term follow-up

Previous trials with BVS showed an increase in myocardial infarction and device thrombosis rates up to 3 year follow-up

Meta-analysis 4 RCT's

Outcome	Up to 1 year				1 up to 2 years				2 up to 3 years			
	BVS	DES	OR (95% CI)	P	BVS	DES	OR (95% CI)	P	BVS	DES	OR (95% CI)	P
TLF (%)	6.39	5.15	1.24 (0.97–1.58)	0.09	4.43	2.55	1.55 (0.98–2.46)	0.06	1.20	0.34	2.75 (0.97–7.78)	0.06
All-cause mortality (%)	1.17	1.49	0.90 (0.33–2.43)	0.83	1.10	1.73	0.65 (0.4–1.05)	0.08	0.20	1.88	0.14 (0.01–1.46)	0.10
Myocardial infarction (%)	5.15	3.50	1.38 (1.04–1.83)	0.03	2.20	1.01	2.17 (1.30–3.62)	0.003	1.36	0.94	1.18 (0.59–2.37)	0.64
ID-TLR (%)	3.08	2.57	1.26 (0.90–1.77)	0.18	2.87	1.59	1.67 (0.97–2.87)	0.06	2.11	1.02	1.79 (0.62–5.15)	0.28
Def/ prob device thrombosis (%)	1.60	0.61	2.45 (1.35–4.46)	0.03	0.86	0.10	4.75 (1.63–13.82)	0.004	0.53	0.00	3.79 (0.67–21.37)	0.13

*ABSORB II, ABSORB III, ABSORB China, ABSORB Japan. Def/ prob: definite/probable; OR: Odds ratio; ID-TLR: ischemia driven target lesion revascularization; TLF: target lesion failure

Felix et al. PLoS One 2018 13(5): e0197119

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

COMPARE-ABSORB

Inclusion criteria

- Patients with *at least one* of the following:

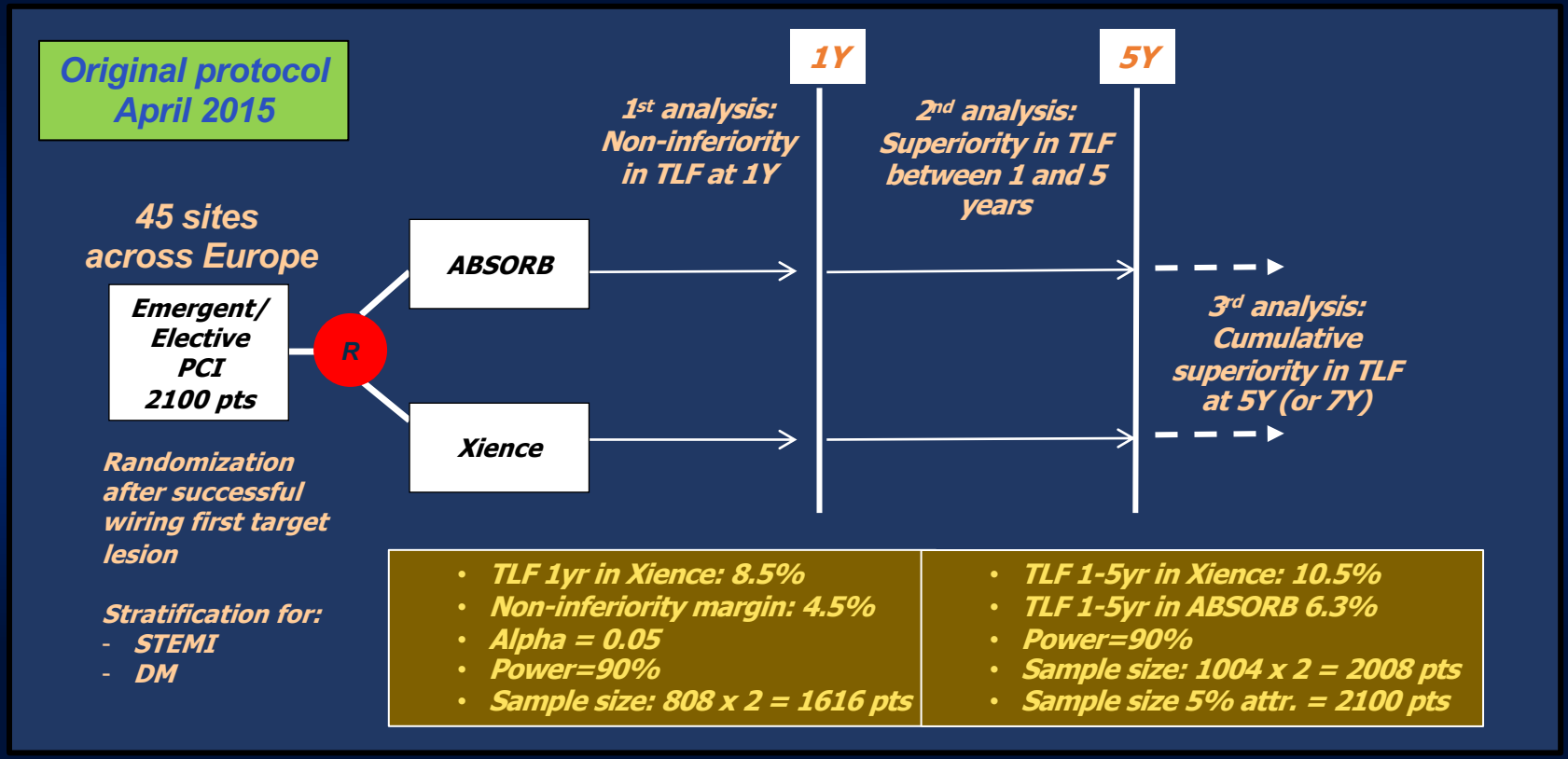
i) High-risk characteristics for restenosis

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

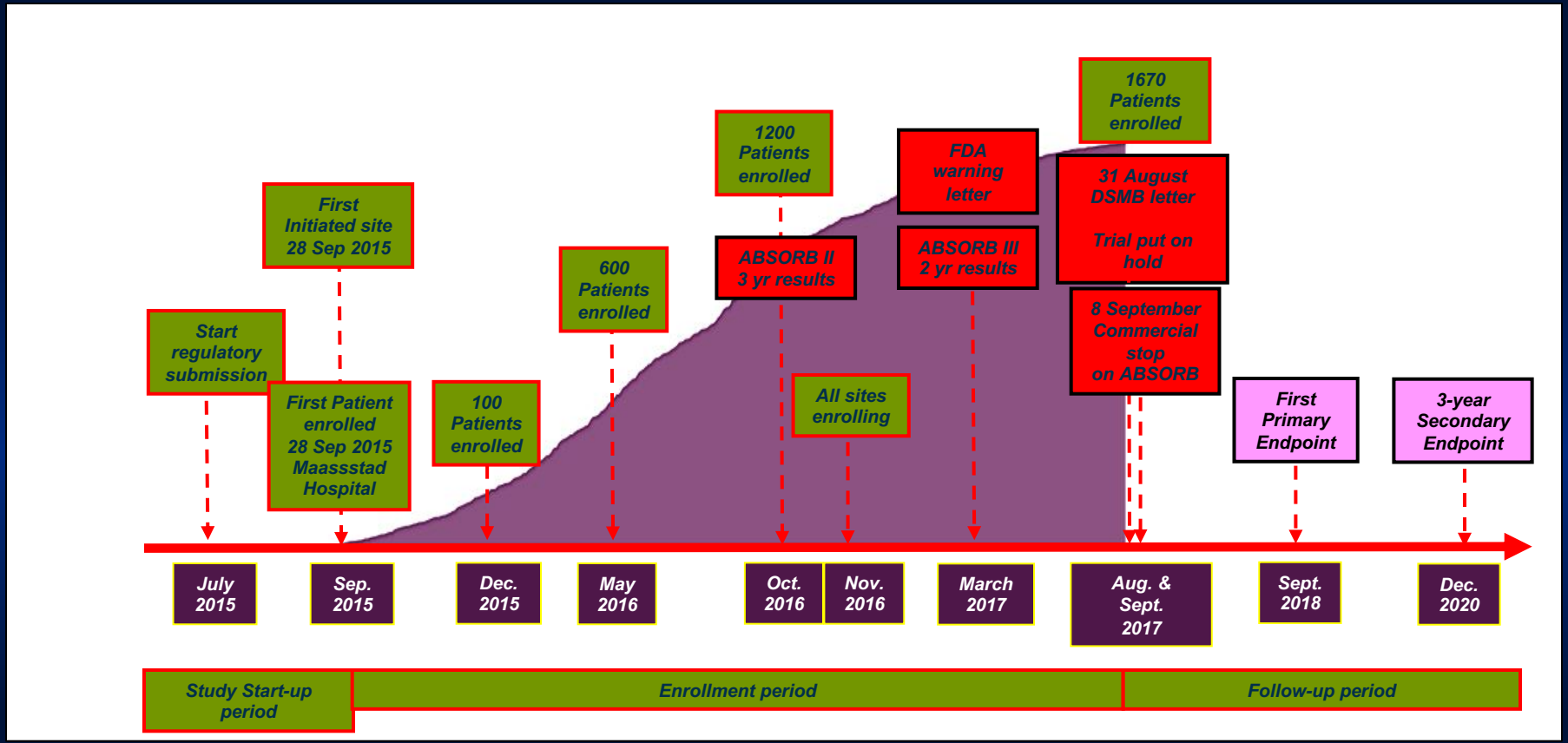
ii) Complex *de-novo* target lesion

- 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 (original)

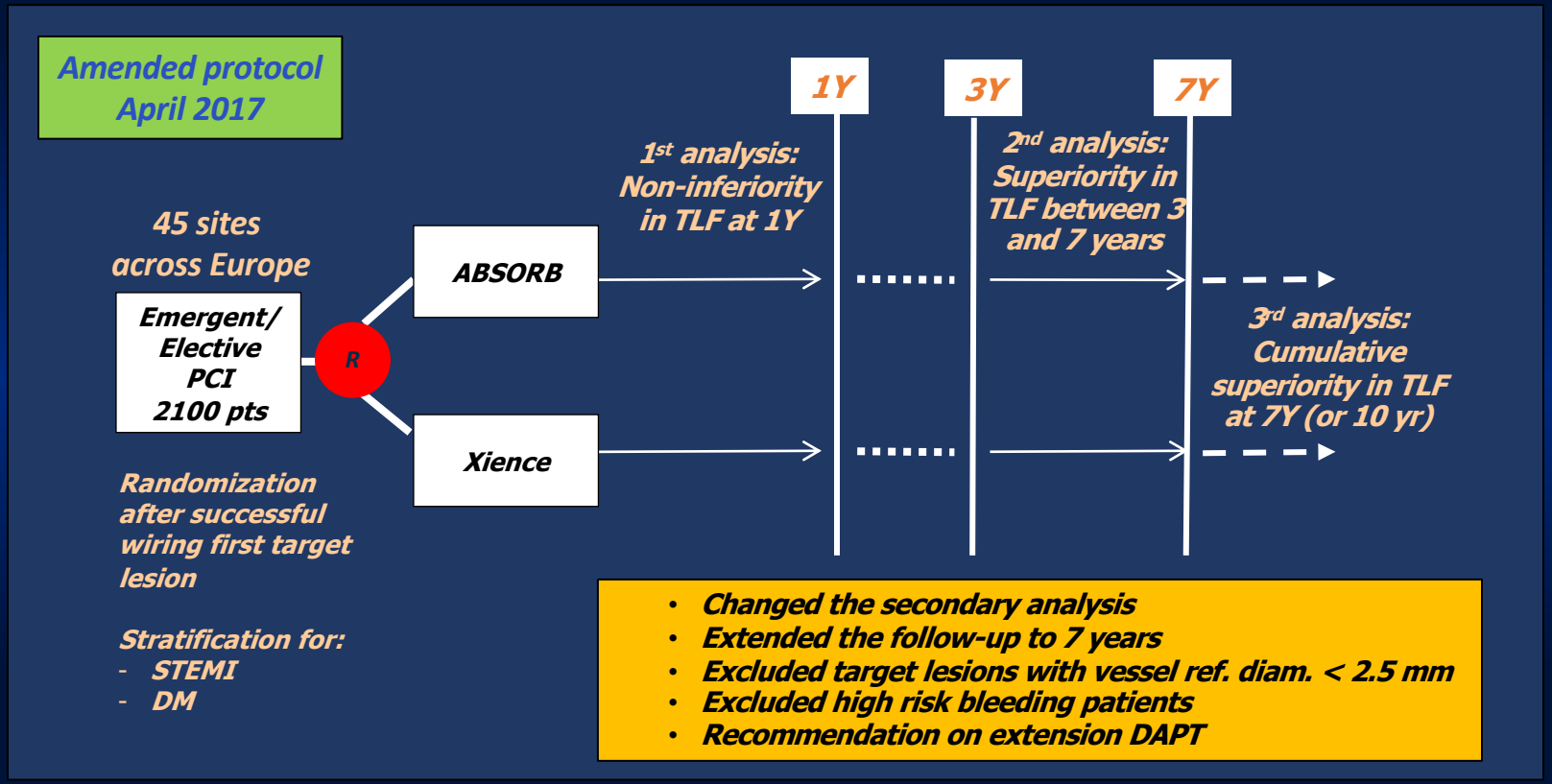


Chang et al. Cardiovasc Revasc Med. 2019 Jul;20(7):577-582



COMPARE ABSORB

Trial design (revised)



Chang et al. Cardiovasc Revasc Med. 2019 Jul;20(7):577-582

Base-line 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
L V ejection fraction [%] ± SD	56.4 ± 10.5	56.3 ±10.2	0.83

Base-line 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

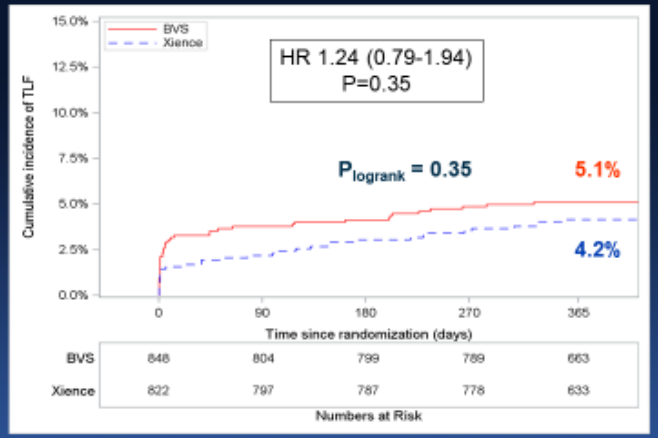
Vessel and lesion treatment	ABSORB 1242 target lesions 962 procedures	XIENCE 1213 target lesions 904 procedures	P value
Pre-dilatation	96.5% (1198)	78.6% (1213)	<0.001
Largest balloon (mm ± SD)	3.0 ± 1.0	3.0 ± 0.7	0.96
Non-compliant balloon used	67.9% (814)	52.9% (504)	<0.001
Max. pressure used (Atm.)	15.3 ± 3.5	14.8 ± 3.4	0.002
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
IVUS performed post	14.3% (138)	14.3% (129)	1.0
OCT performed post	9.4% (90)	2.7% (24)	<0.001

2018

1 year results

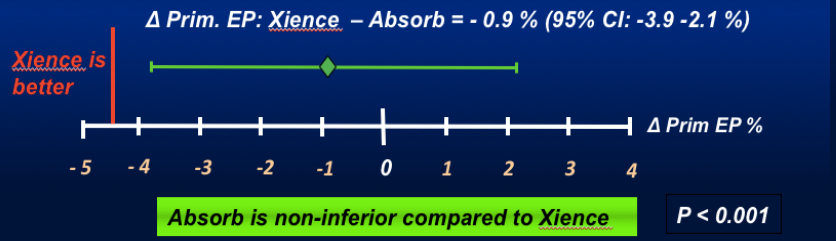
TLF @ 1 year

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



tct2017

Cardiovascular Research Foundation

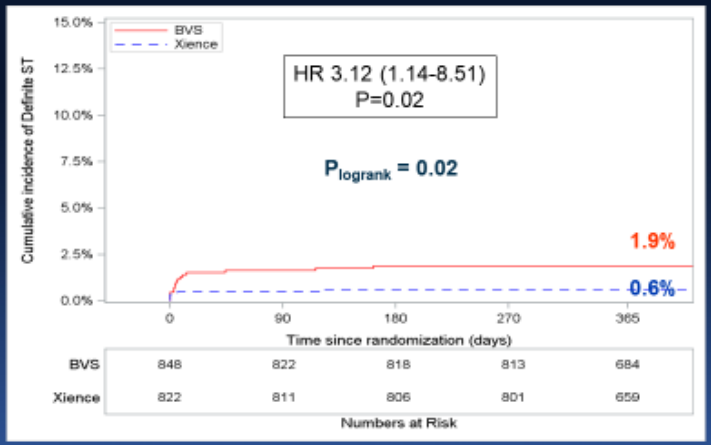


Absorb is non-inferior compared to Xience

P < 0.001

Stent/Scaffold Thrombosis @ 1 year

Definite Stent/Scaffold Thrombosis (ARC definition)



tct2018

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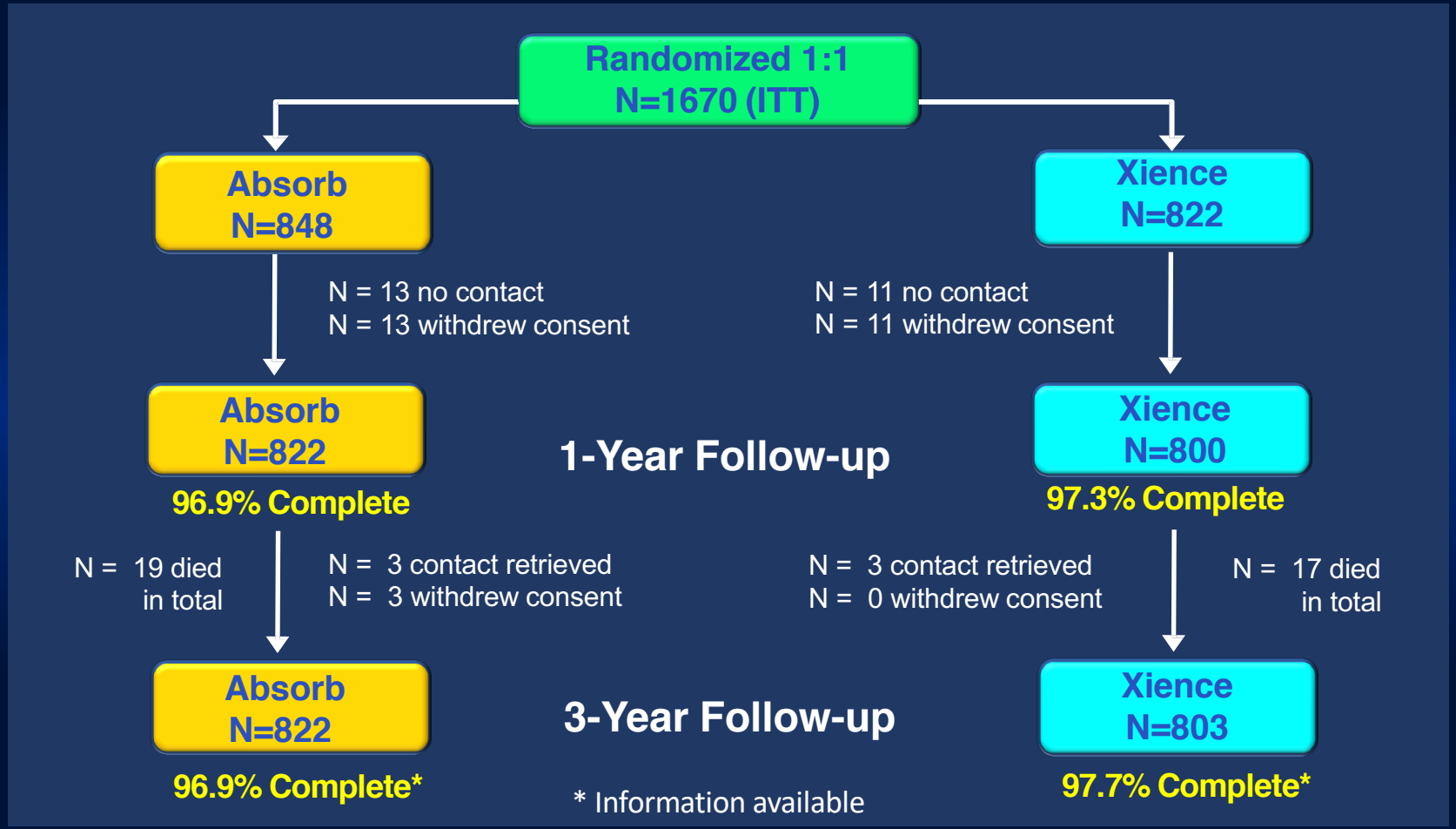
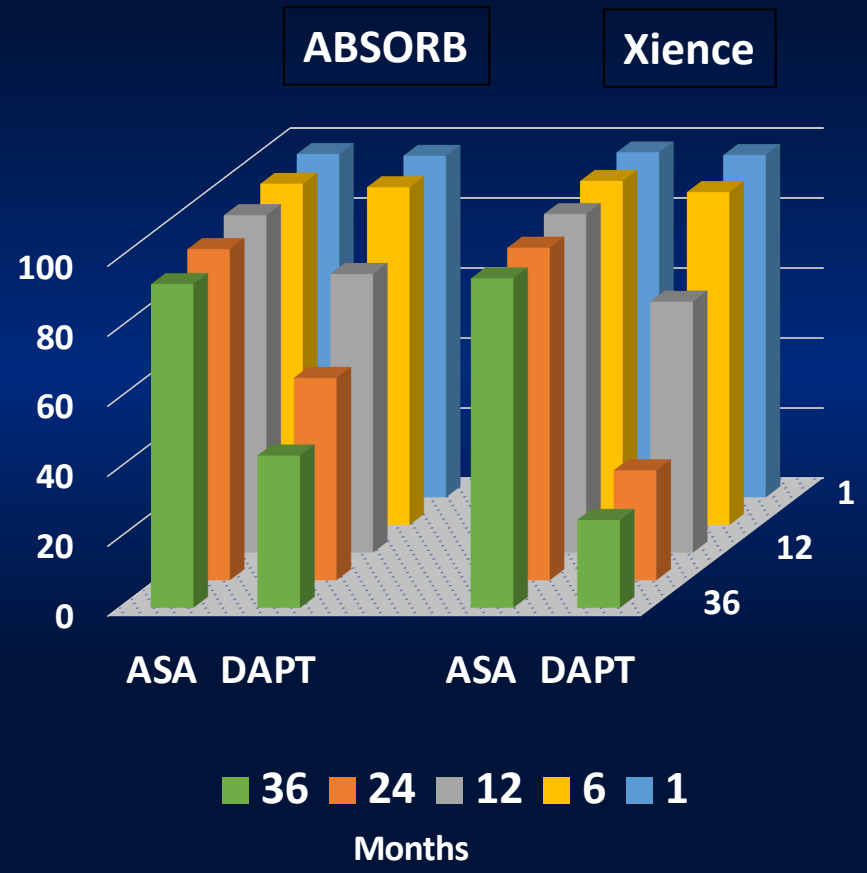
Smits et al. EuroIntervention 2020;16:645-653

Study Flow and Follow-up

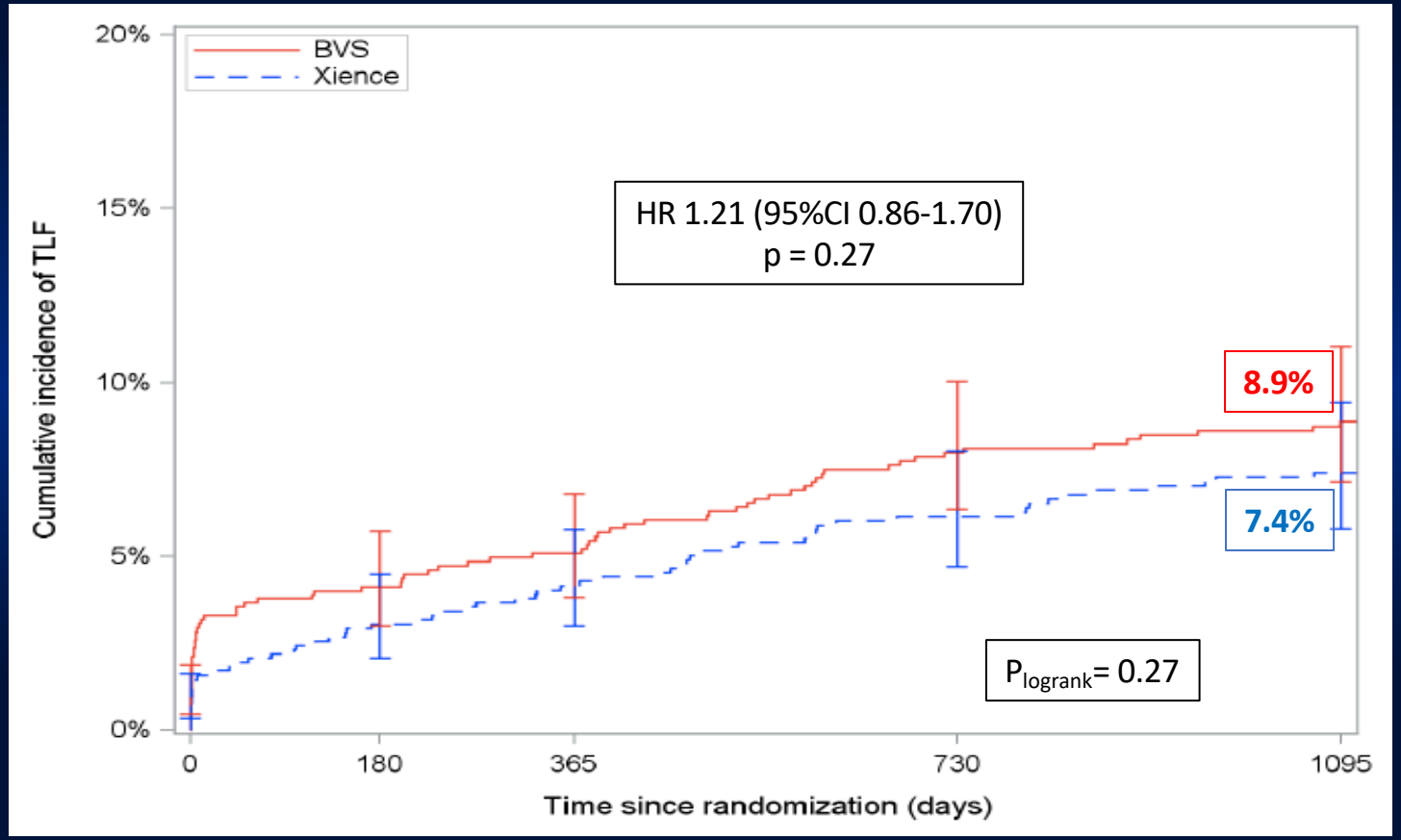


DAPT usage

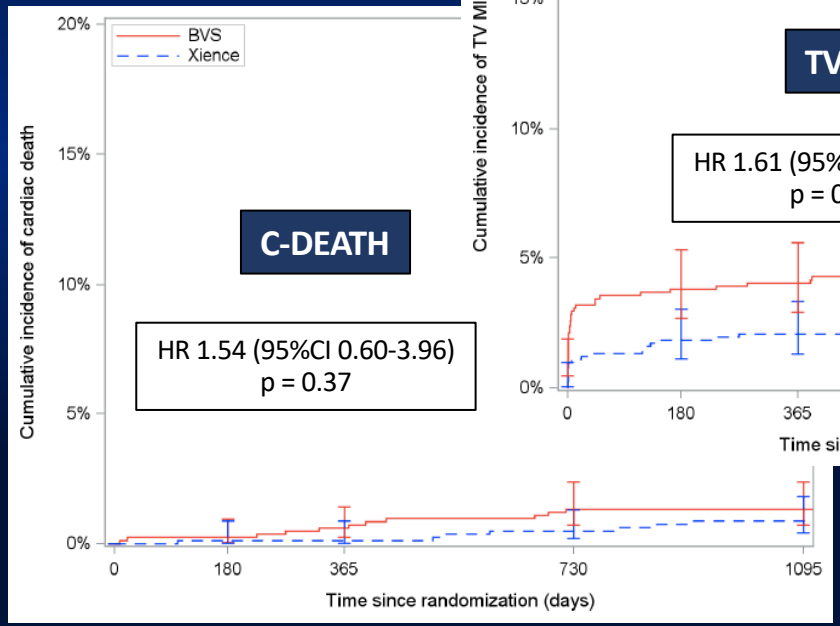


Characteristic	Absorb (N = 848)	Xience (N = 822)	p-Value
DAPT (ASA + Clopi or Tica or Prasu)	43.5%	25.1%	<0.001
ASA	92,5%	94.1%	0.23
Clopidogrel	33.9%	19.1%	<0.001
Ticagrelor	13.1%	8.6%	0.005
Prasugrel	2.6%	1.4%	0.11
OAC + ASA or Clopi or Tica or Prasu	4.0%	2.4%	0.09

3-year TLF
C-Death, TV-MI, CI-TLR

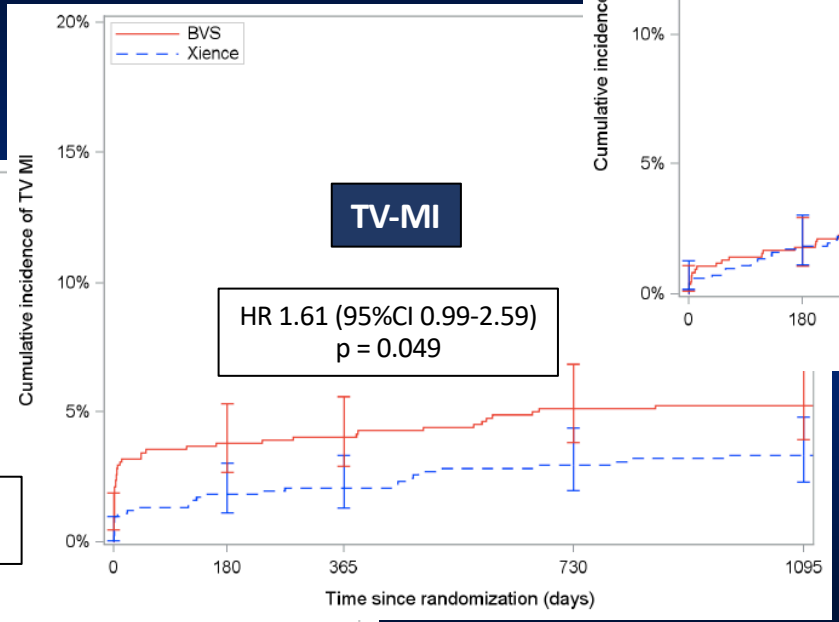


Components of TLF



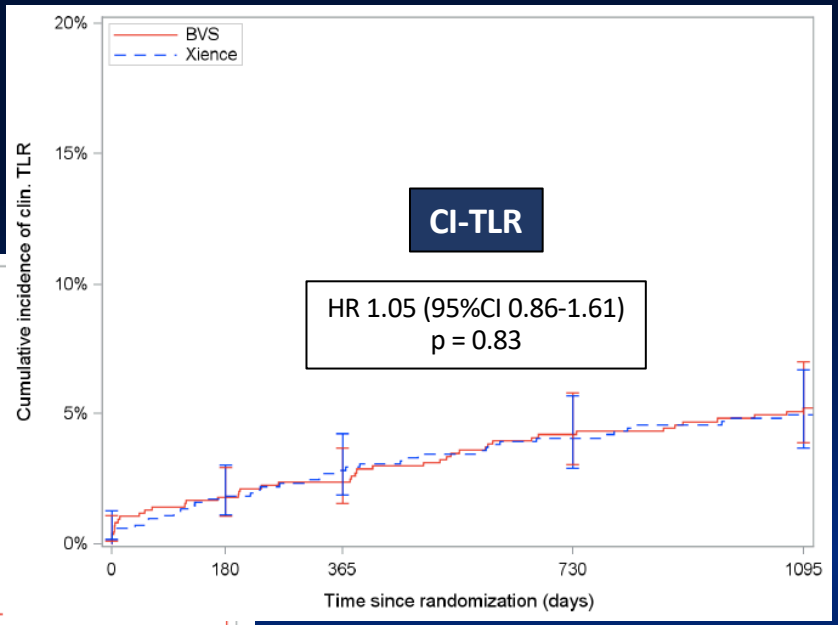
C-DEATH

HR 1.54 (95%CI 0.60-3.96)
p = 0.37



TV-MI

HR 1.61 (95%CI 0.99-2.59)
p = 0.049

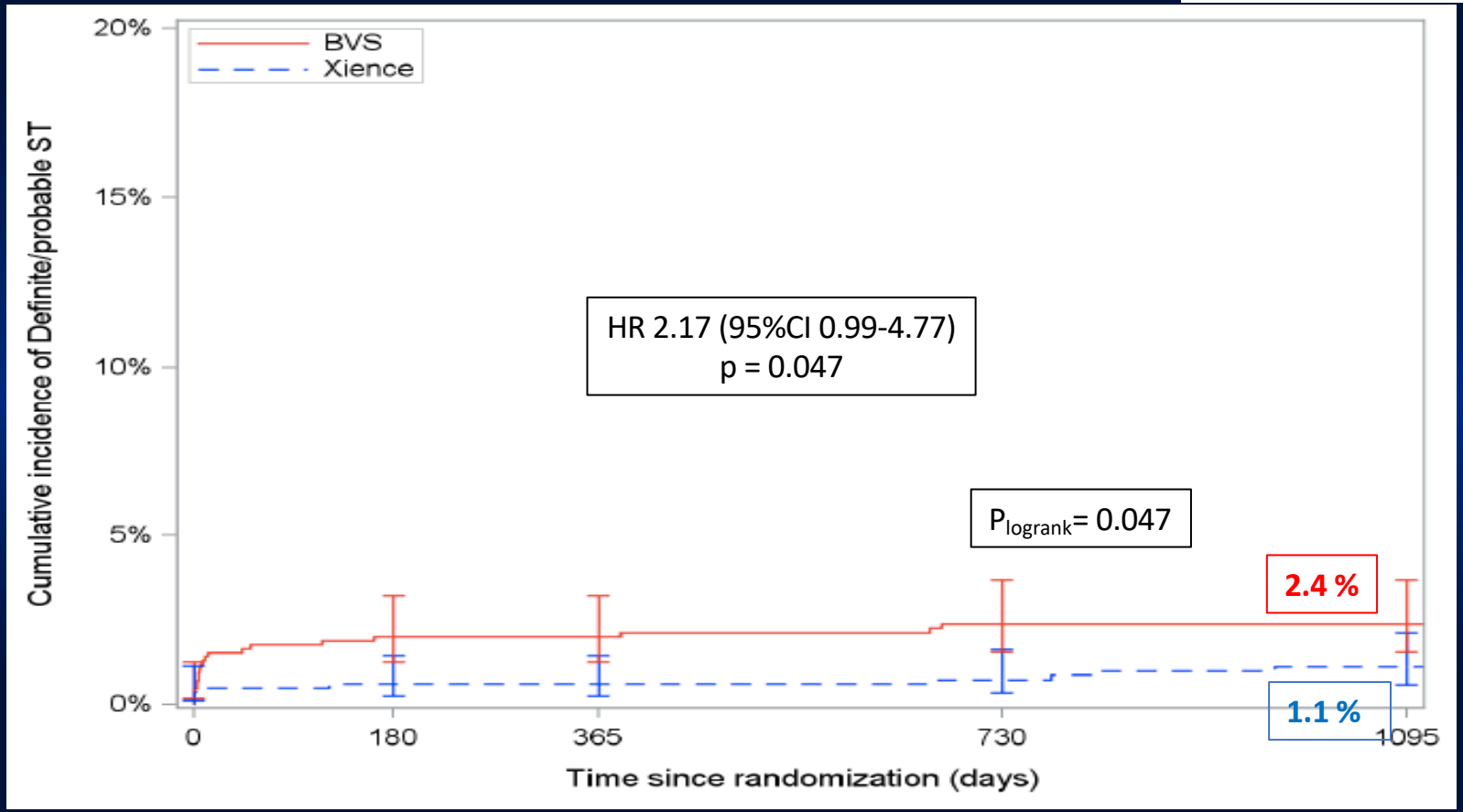


CI-TLR

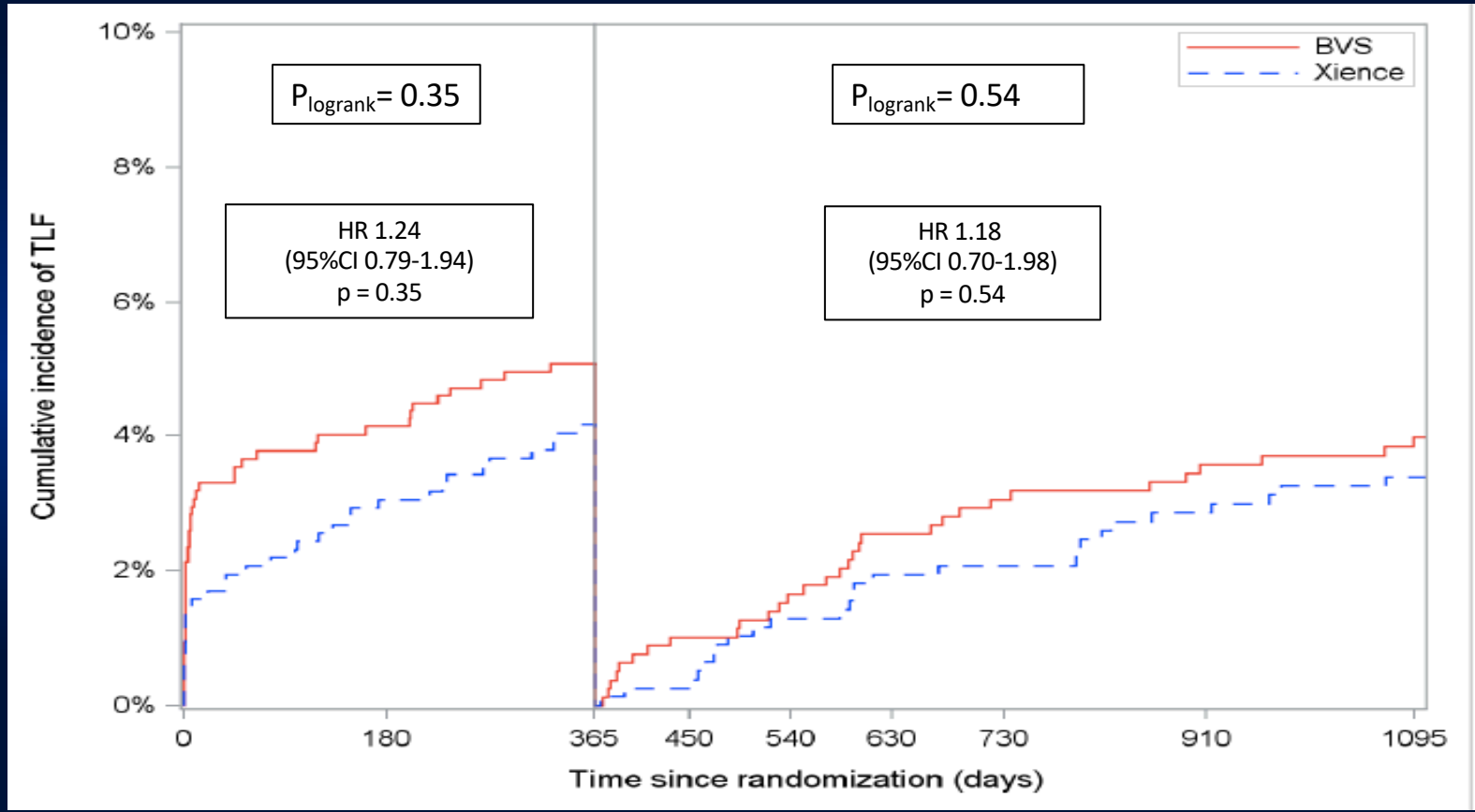
HR 1.05 (95%CI 0.86-1.61)
p = 0.83

COMPARE ABSORB

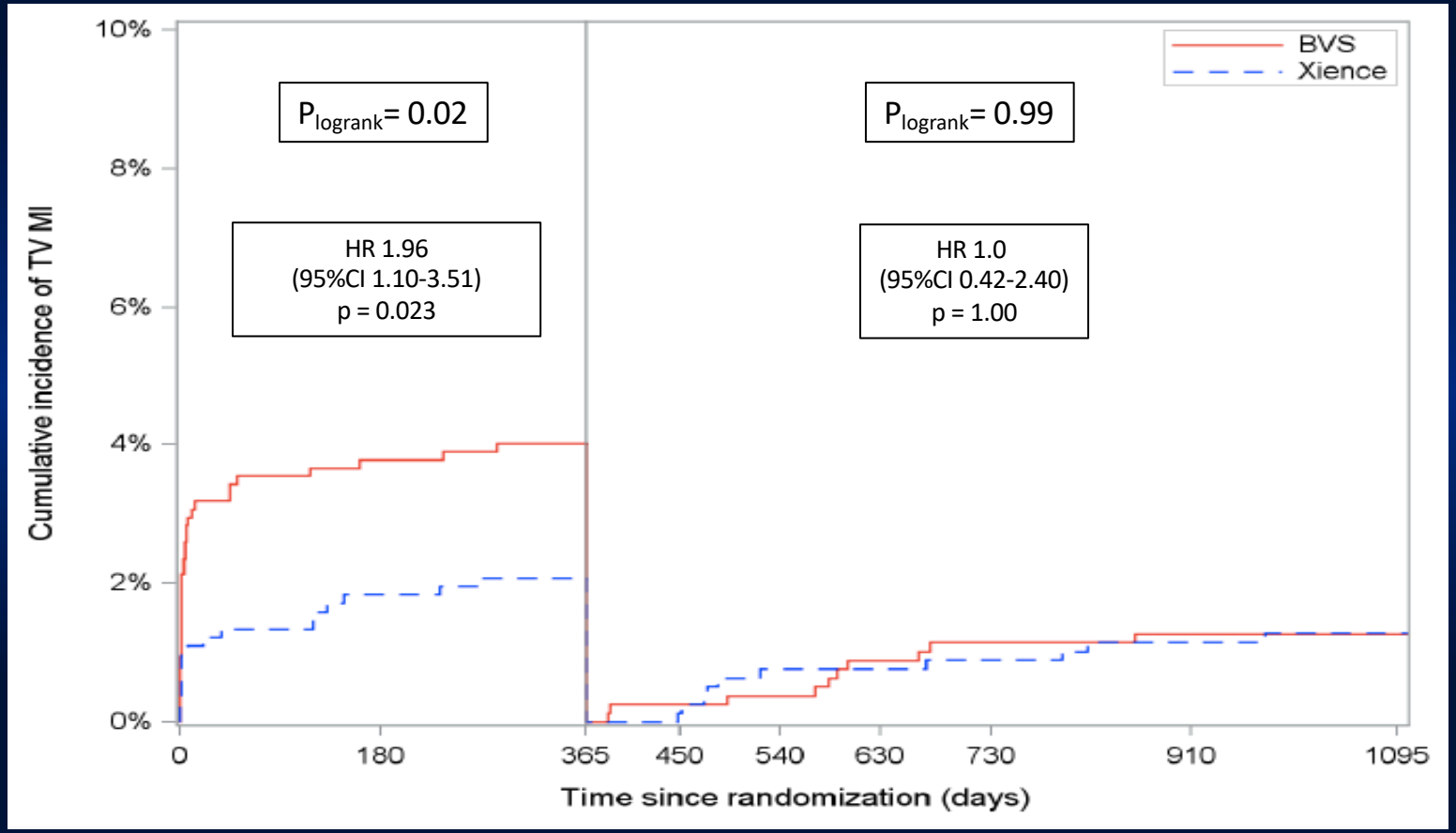
Definite and probable device thrombosis



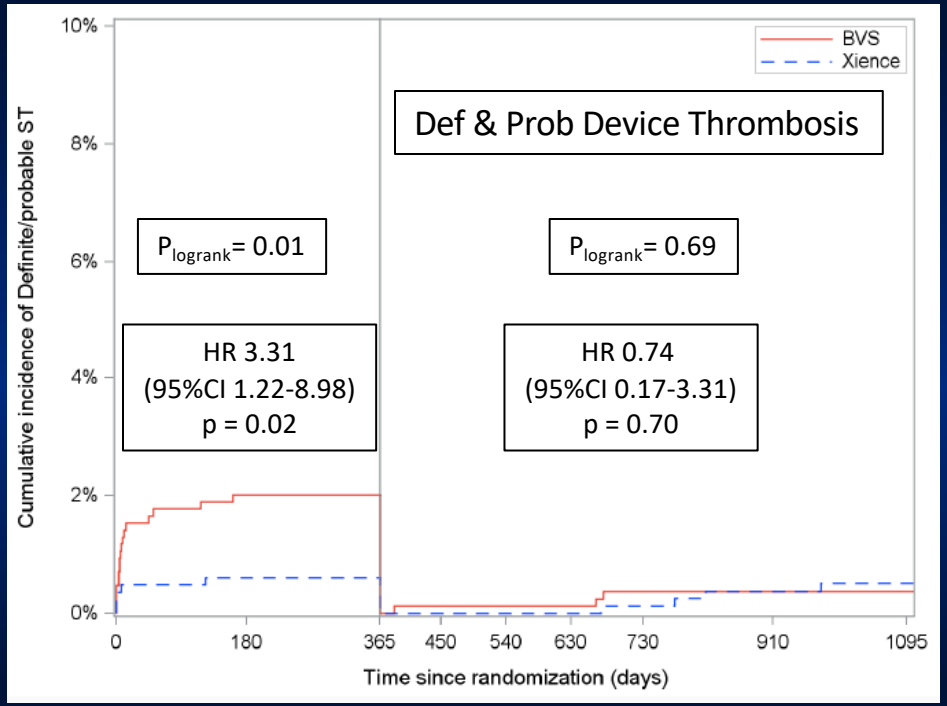
1-year landmark analysis: TLF

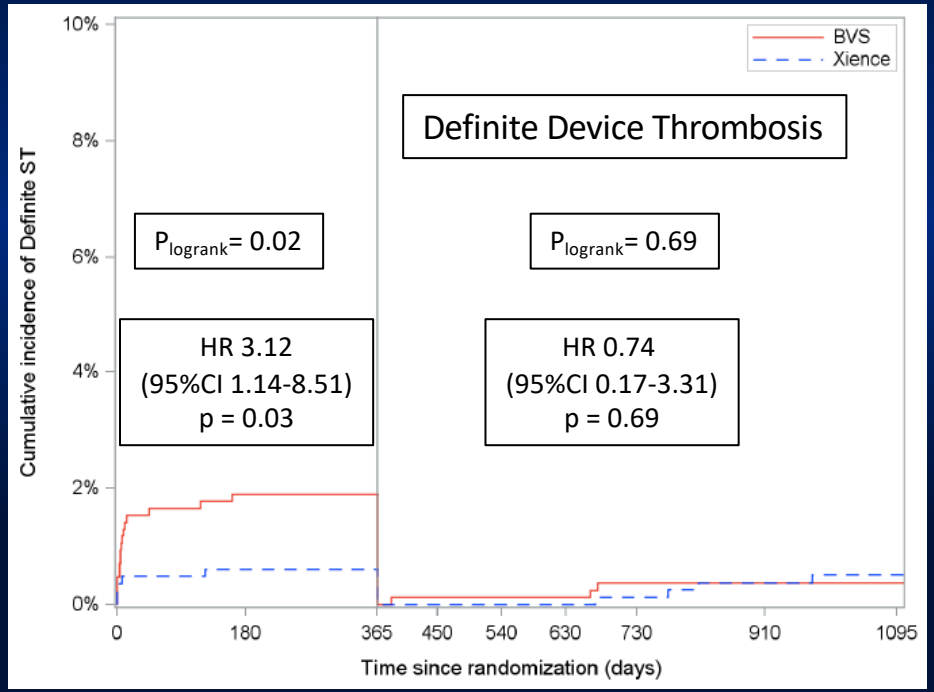


1-year landmark analysis: TV-MI



1-year landmark analysis: device thrombosis





Conclusions

- In a more-comer population at high-risk for restenosis Target Lesion Failure (TLF) rates were not significant different between Absorb and Xience (8.9% versus 7.4%, p=0.27) at 3 year follow-up

- In the 1-year landmark analyses, TLF, TV-MI and Device Thrombosis (definite and def&prob) rates were similar for both devices beyond 1 year

- Whether the absence of increased risk of very-late scaffold thrombosis and TV-MI was prevented by a dedicated implantation technique or prolonged DAPT remains to be determined

- Follow-up of 7-10 year within COMPARE-ABSORB will show whether Absorb has long-term advantages above the metallic Xience stent

Steering Committee

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Trial Organisation

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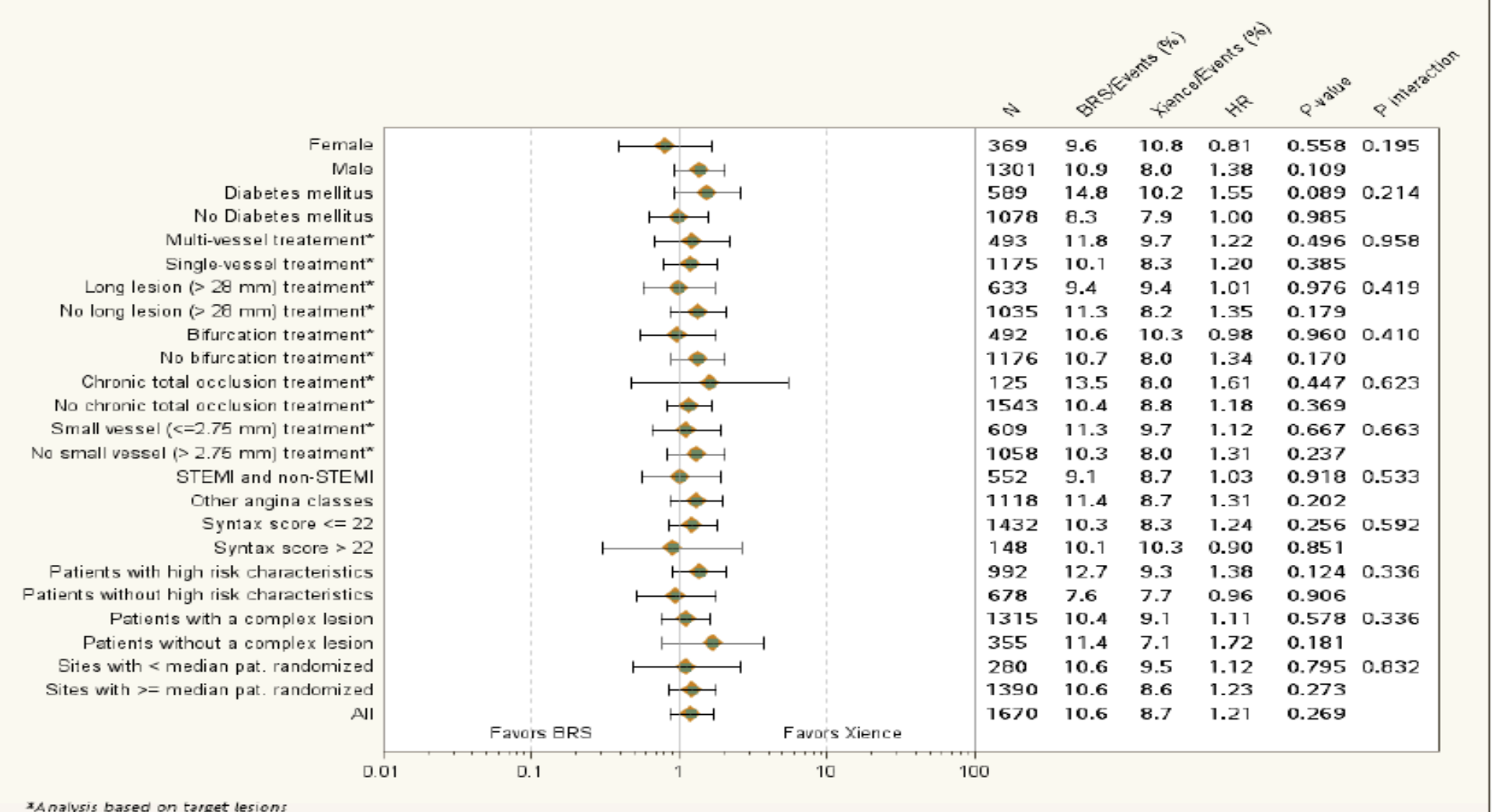

Analysis based on target lesions