Outcomes of Absorb Bioresorbable Scaffolds with Improved Technique in an Expanded Patient Population: The ABSORB IV Randomized Trial

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ABSORB IV

Disclosures

- Chairman of the ABSORB global clinical trial program (uncompensated)
- Consultant to Reva, Inc.

ABSORB IV

Background

- First generation Absorb bioresorbable vascular scaffolds (BVS) have been associated with higher rates of TLF and device thrombosis than contemporary metallic DES, in part due to suboptimal technique in early studies
- In addition, prior ABSORB trials excluded commonly treated patient subgroups (e.g. troponin+ NSTEACS)
- We therefore performed the ABSORB IV trial in an expanded patient population, in which avoidance of small vessels was mandated and aggressive pre-dilatation and routine high-pressure post-dilatation were encouraged

Trial Design

NCT01751906

~2,600 pts with SIHD or ACS
1 - 3 target lesions w/RVD
2.5-3.75 mm and LL ≤24 mm

Randomize 1:1
Stratified by diabetes and ABSORB III-like vs. not

ABSORB BVS
N=1,300

Xience EES
N=1,300

BVS technique:
Pre-dil: 1:1; NC balloon recommended
Sizing: IV TNG; QCA/IVUS/OCT strongly recommended if visually estimated RVD ≤2.75 mm and 2.5 mm device intended; <2.5 mm ineligible!
Post-dil: 1:1, NC balloon, ≥16 atm strongly recommended

DAPT for ≥12 months
Clinical/angina follow-up: 1, 3, 6, 9, 12 months, yearly through 7-10 years
SAQ-7 and EQ-5D: 1, 6, 12 months and 3 and 5 years
Cost-effectiveness: 1, 2, and 3 years

Primary endpoints: TLF at 30 days; TLF between 3 and 7-10 yrs (pooled with AIII)
Secondary endpoints: TLF at 1 year; angina at 1 year

No routine angiographic follow-up

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Major Inclusion Criteria

- ≥18 years old
- SIHD, NSTEACS, STEMI >72 hours; troponin pos or neg
- 1, 2 or 3 *de novo* target lesions in up to 2 native coronary arteries (max 2 lesions per artery) ± 1 non-target lesion
- Diameter stenosis ≥50% and <100% with TIMI flow ≥1
  - If DS <70%, abnormal noninvasive or invasive functional test, unstable angina or NSTEMI within 2 weeks, or STEMI >72 hours but ≤2 weeks.
- RVD ≥2.50 mm and ≤3.75 mm (visually estimated)
  - QCA or IVUS/OCT strongly recommended if visually estimated RVD ≤2.75 mm and 2.5 mm device intended
- Lesion length ≤24 mm (visually estimated)

Baseline Characteristics (n=2604)

Characteristic	Absorb (N=1296)	Xience (N=1308)
Age (mean)	63.1 ± 10.1	62.2 ± 10.3
Male	71.5%	72.4%
Race (caucasian)	87.6%	88.7%
Current tobacco use	22.1%	23.3%
Hypertension	78.5%	78.6%
Dyslipidemia	80.0%	79.2%
Diabetes	31.6%	31.9%
Insulin-treated	11.6%	11.1%
Prior MI	18.0%	19.4%
Prior coronary intervention	30.1%	33.3%
Biomarker positive ACS	22.9%	23.2%
BMI (kg/m^2)	30.3 ± 5.9	30.2 ± 6.1

Baseline Characteristics (QCA)

Per lesion	Absorb (N=1296) (L=1446)	Xience (N=1308) (L=1457)
# of target lesions treated	1.1 ± 0.3	1.1 ± 0.3
One	88.4%	88.8%
Two	10.6%	10.7%
Three	0.6%	0.4%
Target lesion		
LAD	43.6%	43.7%
RCA	25.9%	25.9%
LCX	30.5%	30.4%
Lesion length, mm	14.9 ± 6.2	15.1 ± 6.9
>24 mm	9.9%	9.9%
RVD, mm	2.90 ± 0.39	2.89 ± 0.38
<2.25 mm	2.5%	2.9%
MLD, mm	0.82 ± 0.35	0.81 ± 0.34
%DS	71.8 ± 11.2	71.8 ± 10.9

N= number of patients
L= number of lesions

Procedural Characteristics

Per patient	Absorb (N=1296) (L=1446)	Xience (N=1308) (L=1457)	p-value
Bivalirudin use	26.5%	27.7%	0.52
GP IIb/IIIa inhibitor use	13.4%	12.6%	0.54
Cangrelor use	0.3%	0.5%	0.75
Unassigned device implanted	0.8%	0.4%	0.19
Unplanned overlapping devices	7.8%	6.3%	0.15
Intravascular imaging use	15.6%	12.8%	0.04
Procedure duration (min)	46.2 ± 25.2	38.1 ± 21.1	<0.0001

N= number of patients
L= number of lesions

Procedural Technique

Per Lesion	Absorb (N=1296) (L=1446)	Xience (N=1308) (L=1457)	p-value
Pre-dilatation performed	99.8%	99.2%	0.02
NC/cutting/scoring balloon	43.9%	40.4%	0.06
Balloon/QCA-RVD ratio	1.00 ± 0.12	0.99 ± 0.12	0.22
Pressure (atm.)	12.6 ± 3.5	12.6 ± 3.5	0.99
Study device diameter (mm)	3.05 ± 0.38	3.05 ± 0.39	0.91
Device dia./QCA-RVD ratio	1.06 ± 0.10	1.06 ± 0.09	0.74
Total study device length (mm)	20.5 ± 8.3	20.1 ± 7.9	0.25
Device length/QCA-LL ratio	1.43 ± 0.52	1.42 ± 0.51	0.54
Post-dilatation performed	82.6%	54.1%	<0.0001
NC balloon	98.1%	96.1%	0.007
Balloon diameter (mm)	3.25 ± 0.45	3.26 ± 0.46	0.74
Balloon/QCA-RVD ratio	1.13 ± 0.12	1.12 ± 0.11	0.12
Pressure (atm.)	16.0 ± 3.4	16.4 ± 3.4	0.046
Bailout scaffold/stent required	7.0%	5.7%	0.15

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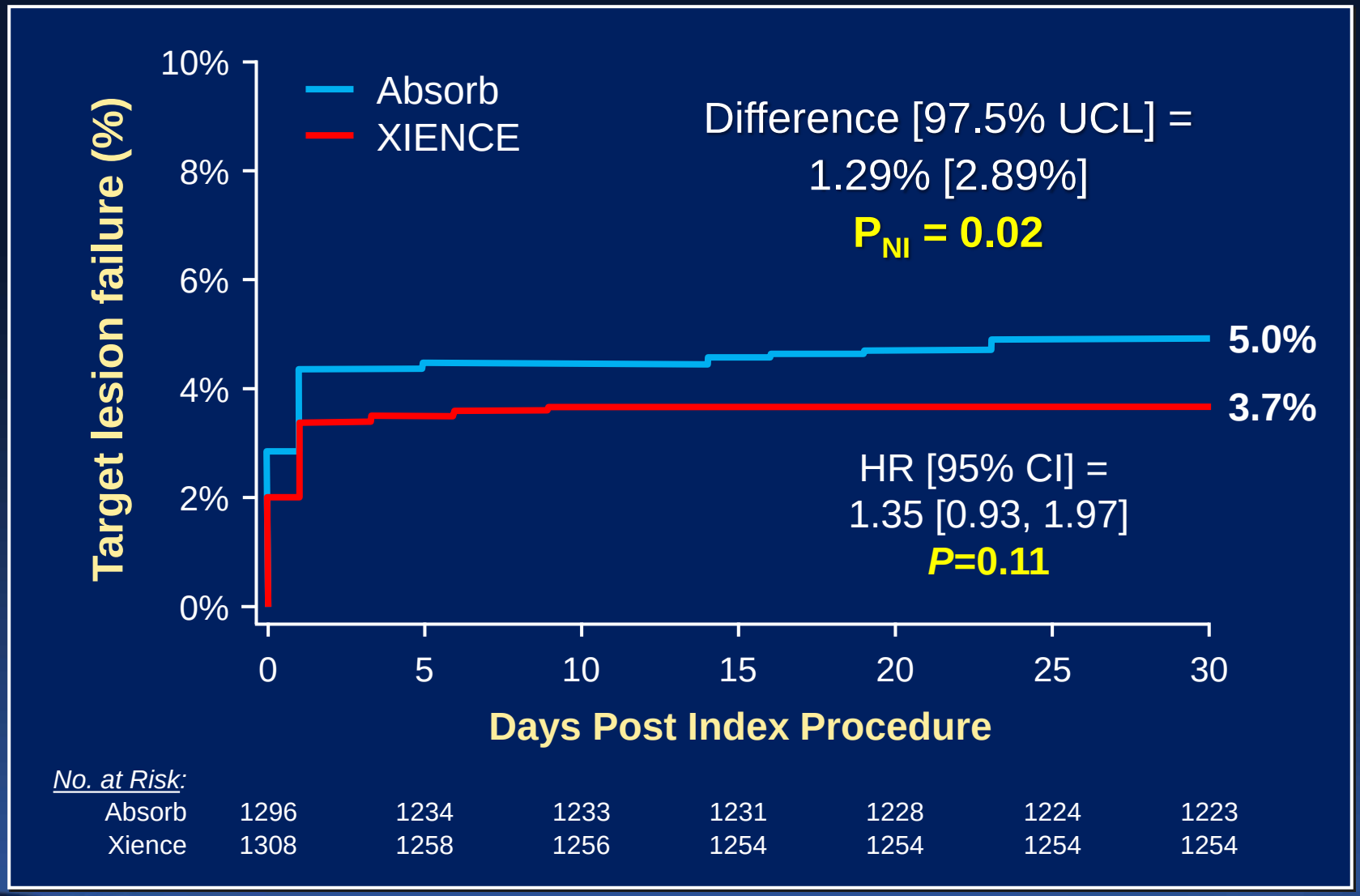
Target Lesion Failure



ABSORB IV

30-Day Endpoints (i)

	Absorb (N=1296)	Xience (N=1308)	p-value
TLF (CD, TV-MI, ID-TLR)	5.0% (64)	3.7% (48)	0.11
TVF (CD, MI, ID-TVR)	5.1% (66)	3.7% (48)	0.07
PoCE (death, MI, revasc)	5.2% (67)	4.1% (53)	0.17
- Death	0.1% (1)	0.1% (1)	0.99
- MI	4.5% (58)	3.6% (47)	0.25
- TV-MI	4.4% (57)	3.6% (47)	0.29
- Non-TV-MI	0.1% (1)	0.1% (1)	0.99
- Peri-procedural MI	3.8% (49)	3.4% (44)	0.55
- Non-peri-procedural MI	0.8% (10)	0.2% (3)	0.049
- Q-wave MI	0.5% (6)	0.2% (2)	0.15
- Non-Q-wave MI	4.1% (53)	3.5% (46)	0.44

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Data are KM estimates (n events)

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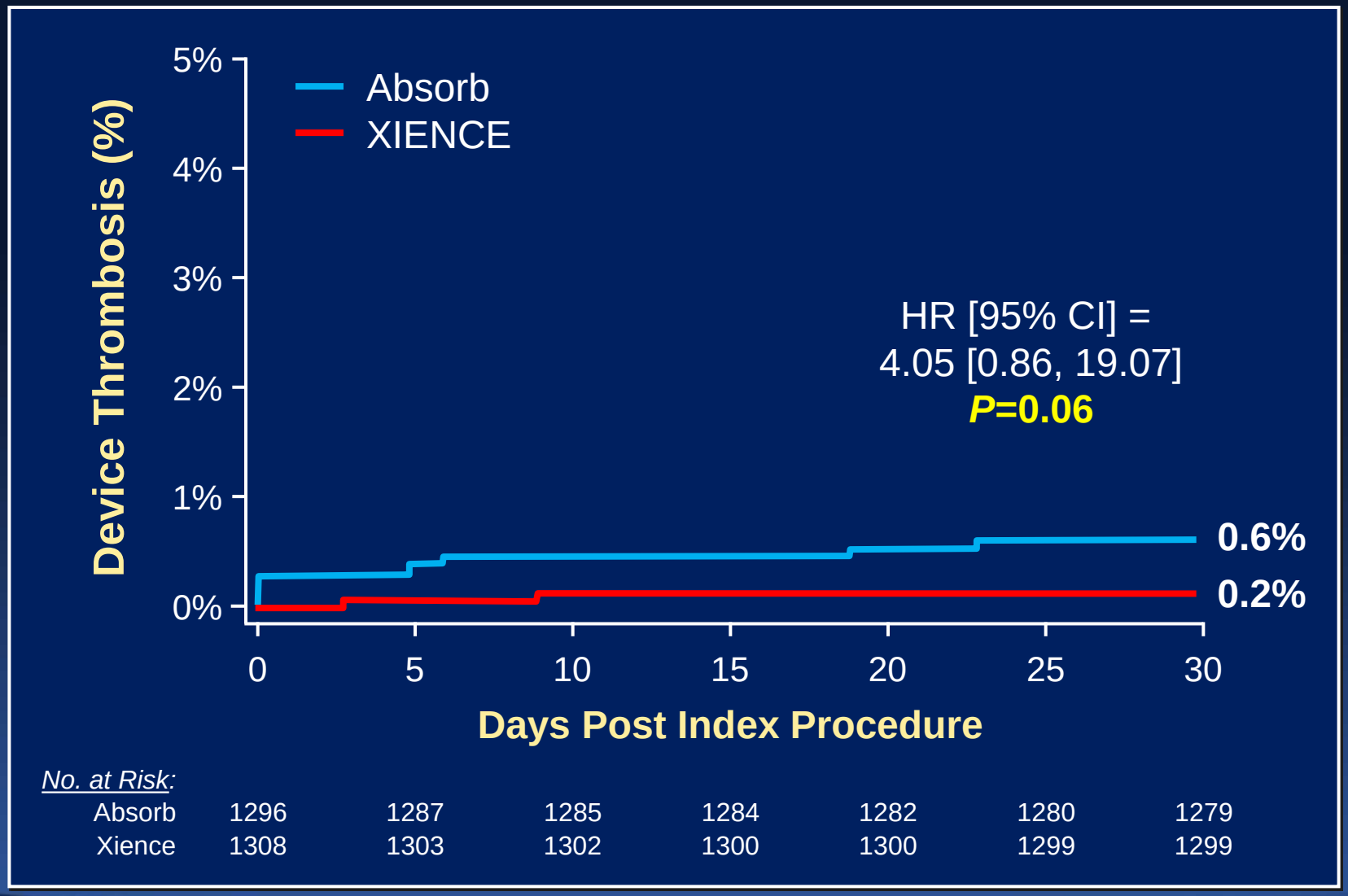
30-Day Endpoints (ii)

	Absorb (N=1296)	Xience (N=1308)	p-value
All revascularization	1.5% (19)	0.6% (8)	0.03
ID-revascularization	1.4% (18)	0.6% (8)	0.046
- ID-TVR	1.2% (16)	0.2% (3)	0.003
- ID-TLR	1.0% (13)	0.2% (3)	0.01
- ID-TVR, non-TLR	0.4% (5)	0.1% (1)	0.10
- ID-non-TVR	0.4% (5)	0.5% (6)	0.78

Data are KM estimates (n events)

Device Thrombosis



Device Thrombosis

ABSORB IV vs. ABSORB III

1918/2604 pts (73.7%) enrolled in ABSORB [illegible] like";
686 were not (20.8% troponin+ ACS, 0.5[illegible] mbus)

ABSORB IV 1-year results at TCT 2018!

ABSORB III vs. ABSORB IV
Optimal PSP Technique (BVS pts)

	ABSORB III		ABSORB IV	
PSP technique	Lesions (N=1385)	Patients (N=1322)	Lesions (N=1446)	Patients (N=1296)
Pre-dilatation:[1]	72.3%	71.6%	45.7%	47.2%
Sizing:[2]	80.6%	80.0%	95.8%	96.3%
Post-dilatation:[3]	9.9%	9.5%	14.3%	15.2%
All PSP	4.8%	4.6%	7.4%	8.0%

[1]Performed in all lesions with a balloon to QCA-RVD ratio ≥1:1; [2]QCA-RVD ≥2.25 mm - ≤3.75 mm for all treated lesions; [3]Performed with a non-compliant balloon at ≥18 atm. and with nominal diameter larger than the nominal scaffold diameter, but not >0.5 mm larger, in all treated lesions

Summary and Conclusions (1)

- Absorb BVS was non-inferior to Xience CoCr-EES for TLF at 30 days (primary endpoint met)
  - The relative rates of TLF and device thrombosis between BVS and CoCr-EES were similar in the non-ABSORB III-like pts (mostly troponin positive) and the more stable ABSORB III-like pts
- Compared to ABSORB III, reducing the number of very small vessels treated in ABSORB IV substantially reduced the device thrombosis rate with BVS, but also with CoCr-EES

Summary and Conclusions (2)

- Rates of non-peri-procedural MI and ID-TLR at 30 days were greater with BVS than with CoCr-EES, and a trend toward greater stent thrombosis with BVS was present
- These data, which are largely consistent with those from earlier ABSORB trials, emphasize the need for advancements in device technology and standardized technique to further improve the early safety profile of BVS