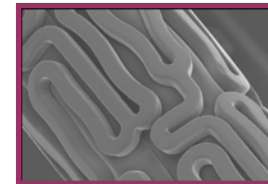


DES in complex patient and lesion subsets

SPIRIT II and III: 1-year pooled patient meta-analysis in vessels <2.765



SPIRIT II and III

Similar inclusion and exclusion criteria: up to 2 *de novo* lesions, maximum of 1 lesion per epicardial vessel
LL ≤28 mm

Meta-analysis of patient level data
n=541
RVD <2.765 mm

XIENCE V
n=376

TAXUS®
n=165

- Independent meta-analysis done by CRF
- SPIRIT II and SPIRIT III have similar inclusion and exclusion criteria
- Pooled, patient level analysis of combined SPIRIT II and SPIRIT III data
- Pre-specified superiority testing on all endpoints

CRF, Cardiovascular Research Foundation; LL, lesion length

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: baseline characteristics (541 randomised patients)

	XIENCE V (n=376 pts)	TAXUS® (n=165 pts)
Age (years)	63.37 ± 10.49	62.24 ± 10.31
Male	63.8% (240/376)	58.8% (97/165)
Diabetes	29.3%	32.5%
– Treated with insulin	7.2%	6.7%
Hypertension	76.1%	77.0%
Hypercholesterolaemia	73.3%	77.5%
Current smoker	21.5%	20.9%
Prior MI	22.1%	20.4%
Unstable angina	21.5%	27.0%

There were no significant differences between the two groups

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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MI, myocardial infarction; pts, patients

SPIRIT II and III pooled meta-analysis: angiographic characteristics (541 lesions in 541 randomised patients)

Lesion Location	XIENCE V (n=376 lesions)	TAXUS® (n=165 lesions)
LAD	43.6%	52.1%
LCX	33.0%	30.3%
RCA	23.1%	17.6%
LMCA	0.3%	0.0%

There were no significant differences between the two groups

**LAD, left anterior descending; LCX, left circumflex; LMCA, left main coronary artery;
RCA, right coronary artery**

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: clinical results

Hierarchical 0–393 days	XIENCE V 366 patients	TAXUS® 159 patients	<i>P</i> *
Cardiac death % (n)	0.8 (3)	0.6 (1)	1.0000
Myocardial infarction % (n)			
Q-wave MI	0.3 (1)	0.0 (0)	1.0000
Non-Q-wave MI	1.6 (6)	4.4 (7)	0.0716
Ischaemia driven TLR % (n)			
CABG	0.0 (0)	0.0 (0)	NA
PCI	2.5 (9)	5.7 (9)	0.0719
MACE % (n)	5.2 (19)	10.7 (17)	0.0369

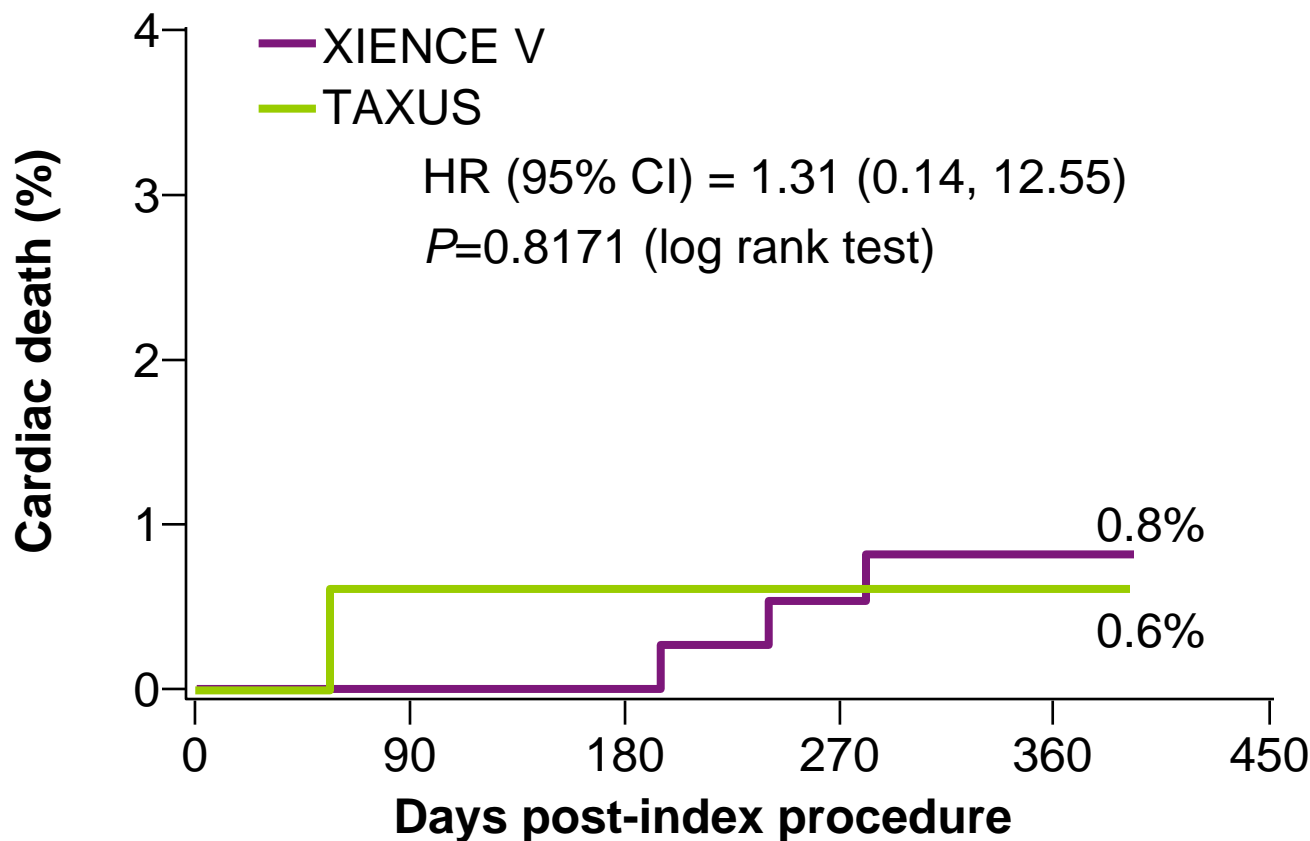
**P*-values for descriptive purposes only, not adjusted for multiple comparisons

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: cardiac death (393 Days)



Number at risk

XIENCE V	376	371	370	364	362	362
TAXUS®	165	161	161	158	158	157

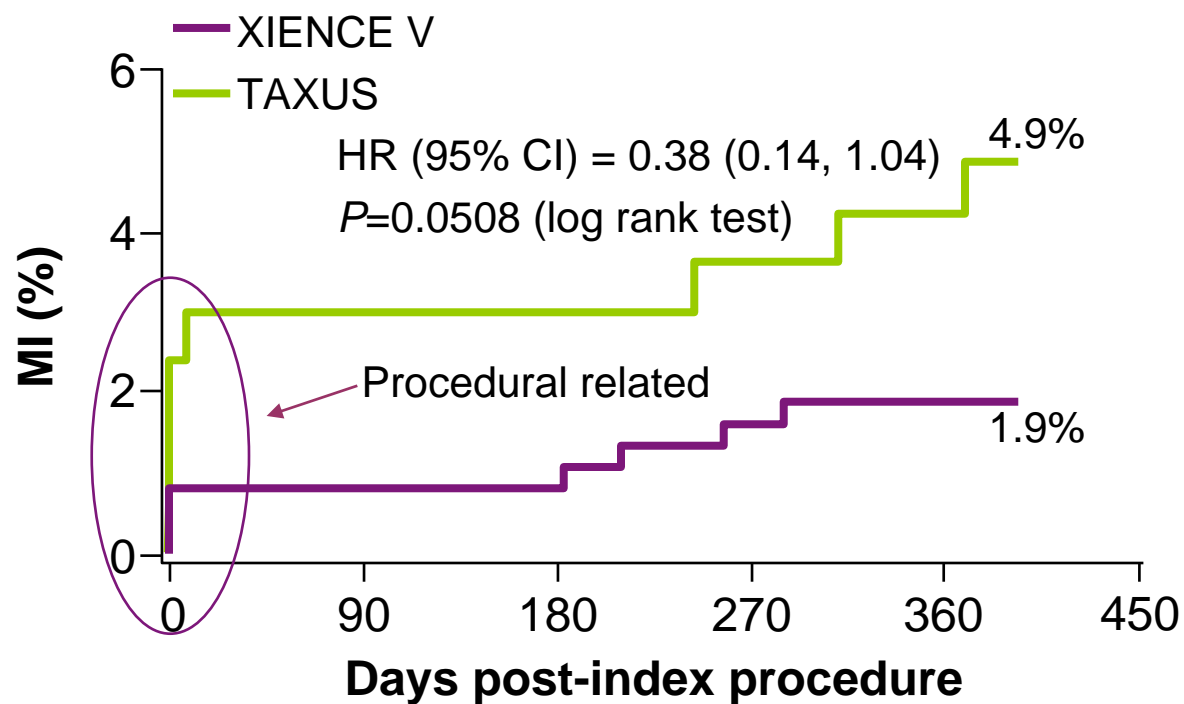
SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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CI, confidence interval; HR, hazard ratio

SPIRIT II and III pooled meta-analysis: myocardial infarction (393 Days)

Reduction in procedural-related myonecrosis with XIENCE V may result from less side-branch compromise as a result of the thinner polymer and total polymer+stent strut width



Number at risk

XIENCE V	376	368	367	358	355	355
TAXUS®	165	157	157	153	152	150

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: stent thrombosis – ARC definite/probable

	XIENCE V	TAXUS®	P*
ARC definite/probable Stent thrombosis (0–393 days)	0.3% (1/362)	1.9% (3/159)	0.2221
Definite stent thrombosis (0–393 days)	0.3% (1/362)	0.6% (1/159)	0.5176
Probable stent thrombosis (0–393 days)	0.0% (0/362)	1.3% (2/159)	0.0927
Early stent thrombosis (≤ 30 day)	0.0% (0/375)	0.6% (1/165)	0.3056
Late stent thrombosis (31 days–393 days)	0.3% (1/362)	1.3% (2/159)	0.2221

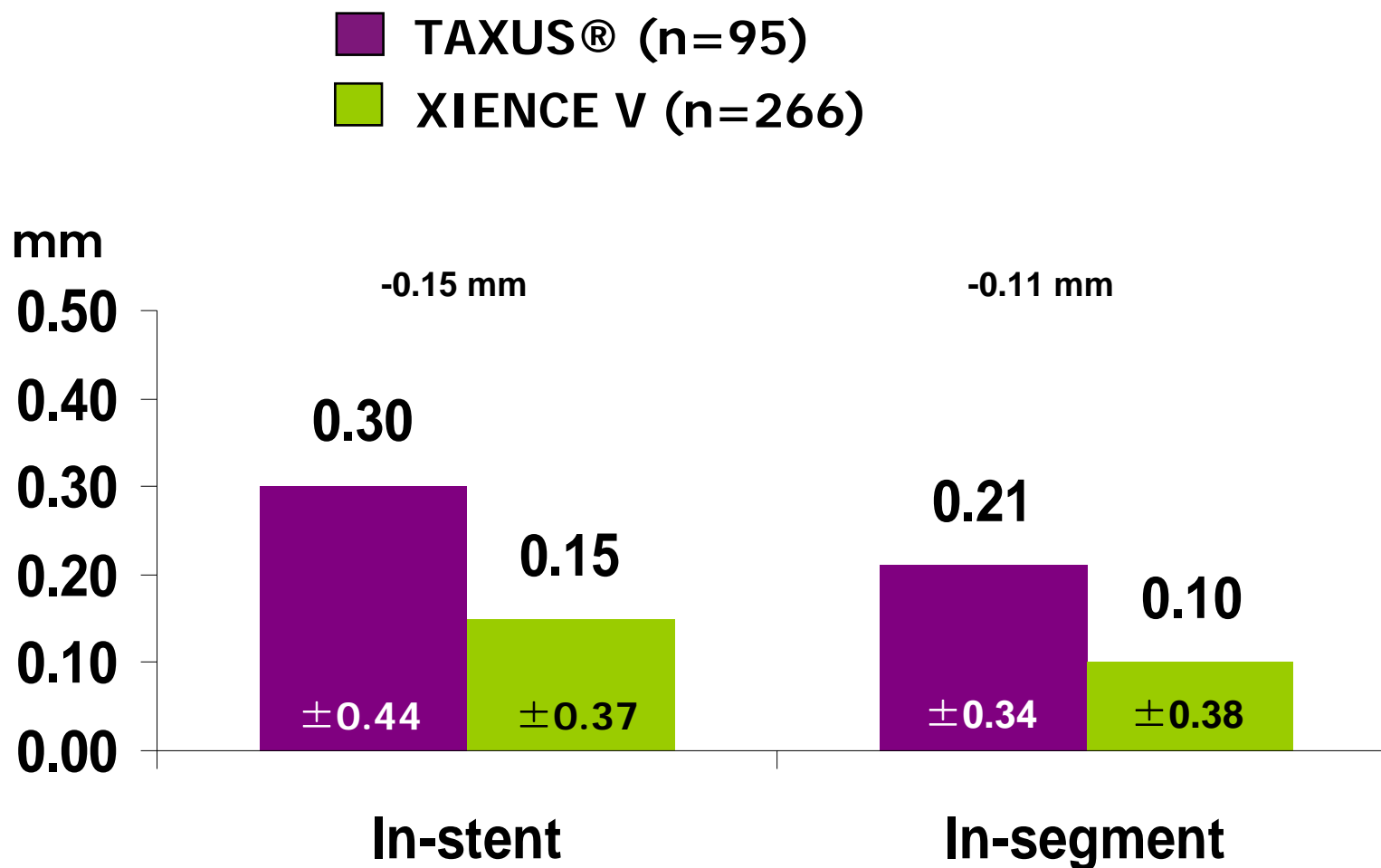
*P-values for descriptive purposes only, not adjusted for multiple comparisons

Cutlip DE *et al.* *Circulation*. 2007;115;2344-2351

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: late loss



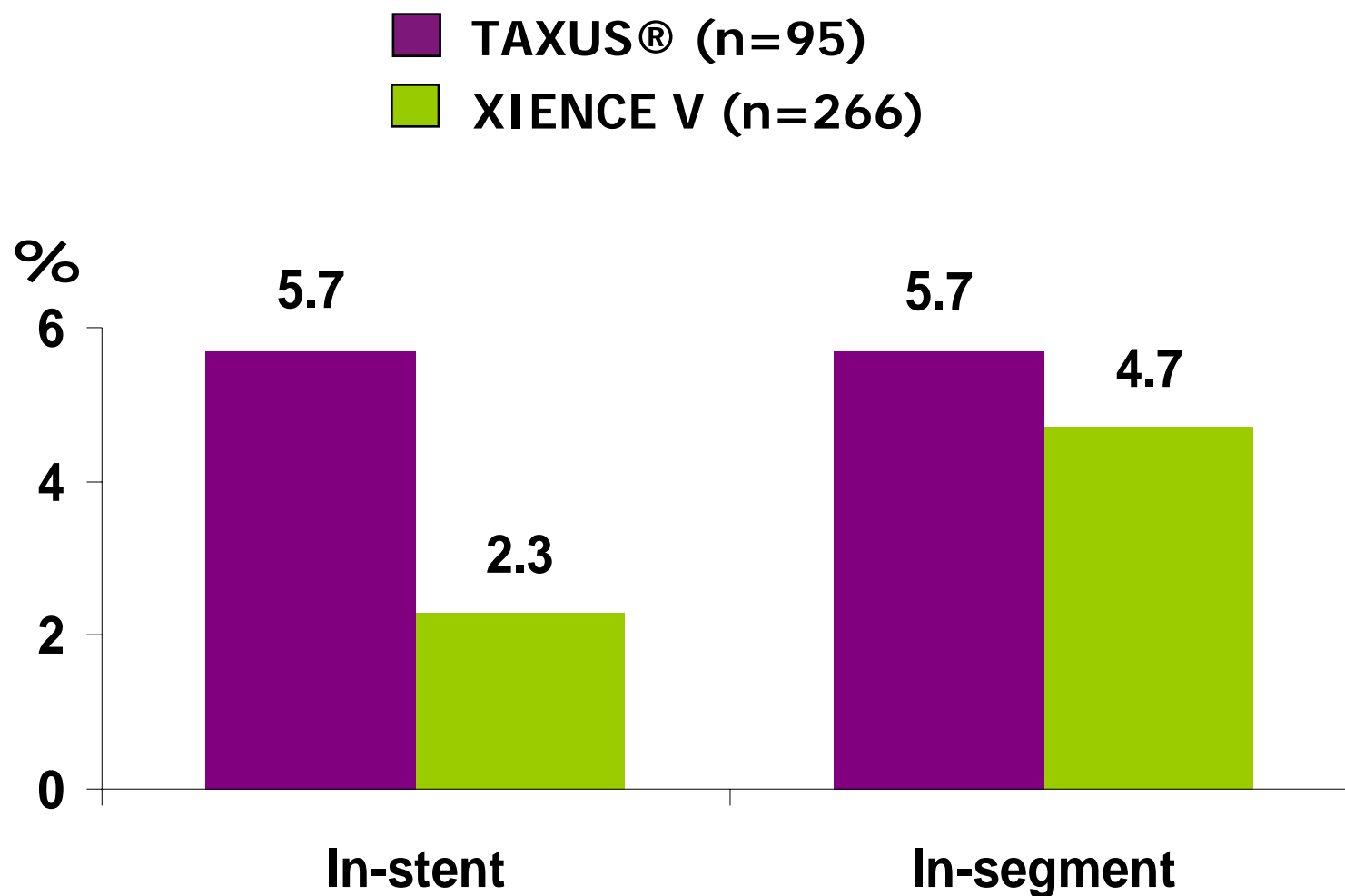
SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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Angiographic F/U: SPIRIT II= 6 mos; SPIRIT III= 8 mos

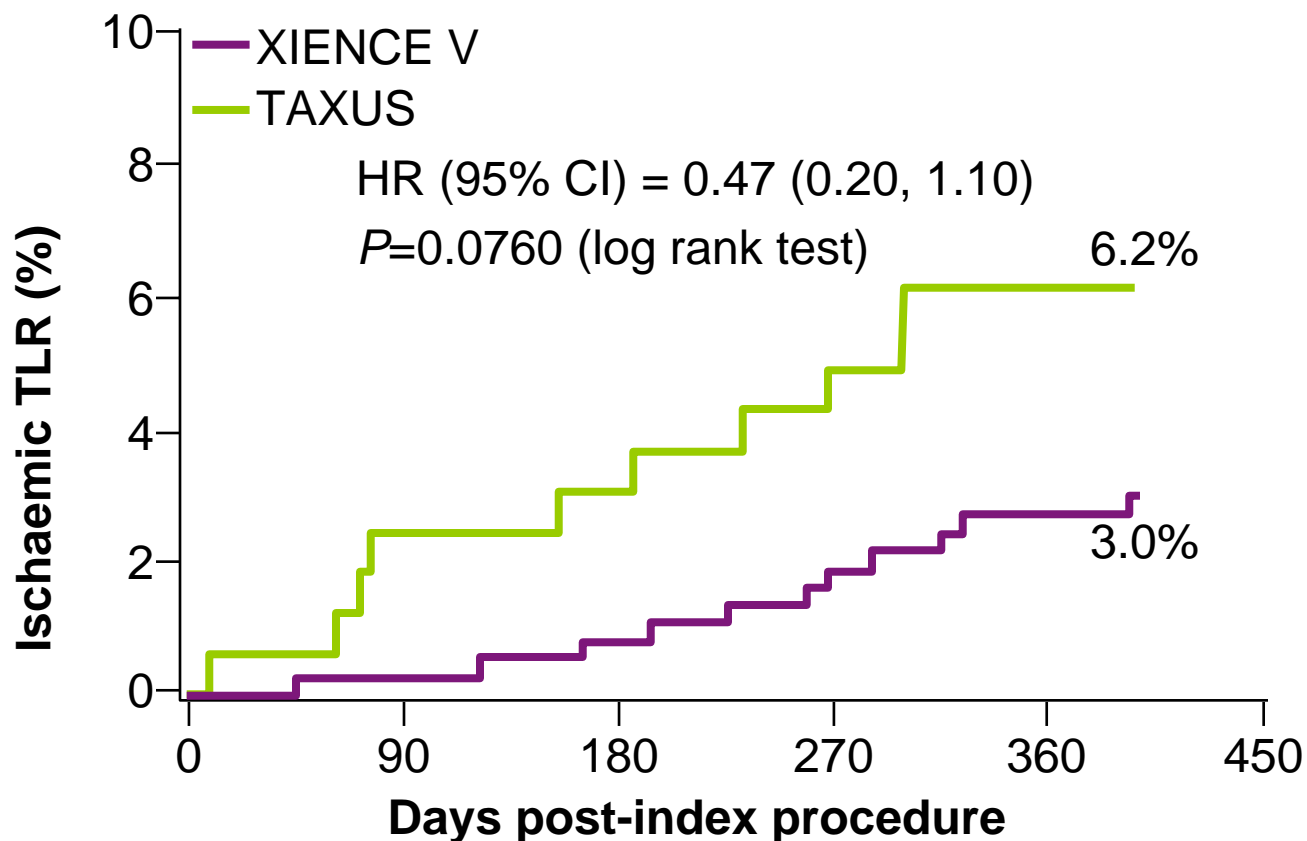
SPIRIT II and III pooled meta-analysis: binary restenosis



SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: ischaemic TLR (393 Days)



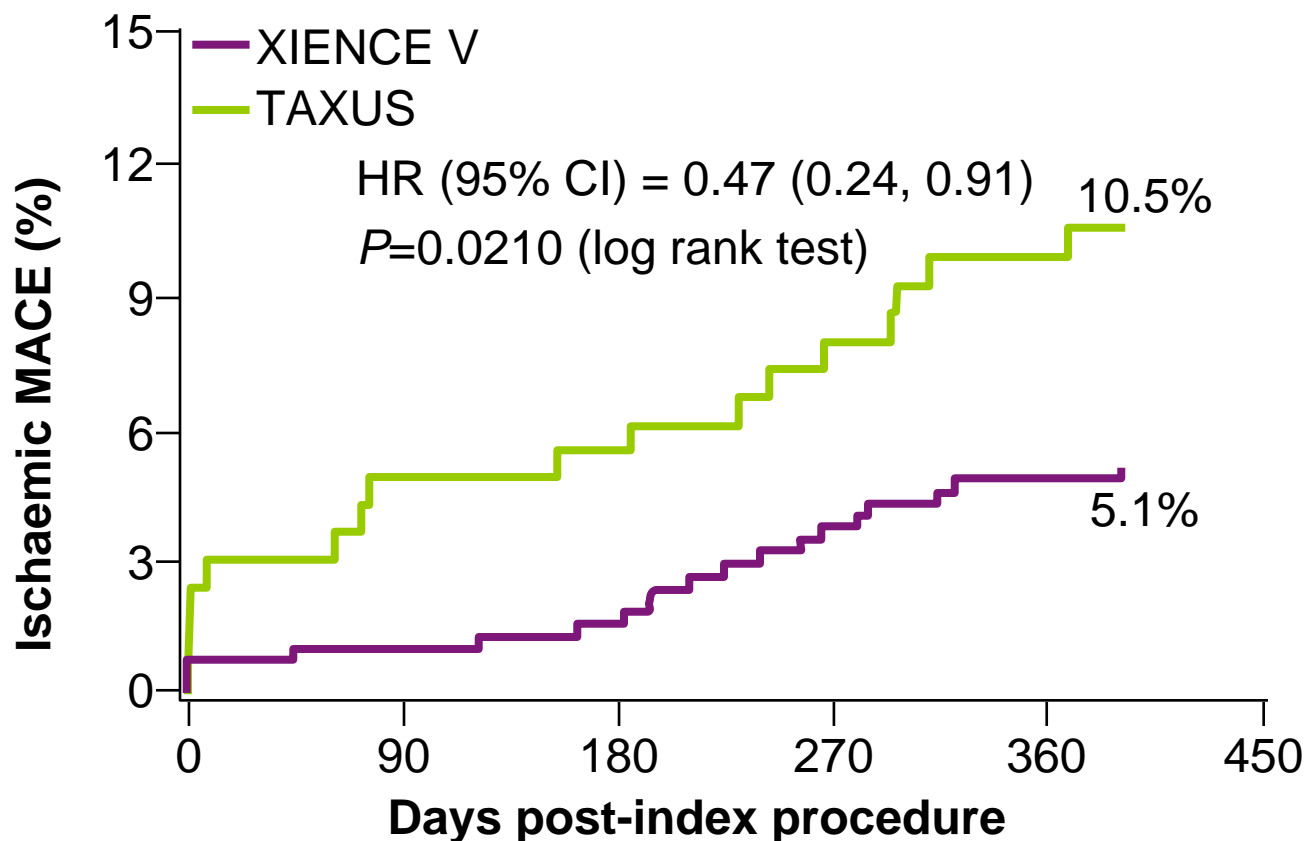
Number at risk

XIENCE V	376	370	367	357	352	351
TAXUS®	165	158	157	151	149	148

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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SPIRIT II and III pooled meta-analysis: ischaemic MACE (393 Days)



Number at risk

XIENCE V	376	367	364	352	347	346
TAXUS®	165	154	153	146	143	141

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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EURO PCR08 Conclusions

- Compared to a first generation paclitaxel-eluting stent (TAXUS®), use of a second generation everolimus-eluting stent (XIENCE V) in coronary vessels <2.765 mm resulted in, at 393-day F/U:
 - Similar rates of death and stent thrombosis
 - Significantly less major adverse cardiac events
 - Significant reduction in late loss and binary restenosis
 - Significant reduction in target lesion revascularisation

SOURCE: Antonio L Bartorelli, SPIRIT II and III Meta-analysis – 1-year, RVD <2.765, PCR 2008.

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