

Clinical Experience with the Xience V stent

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XIENCE V DES Components

**MULTI-LINK VISION®
Stent**



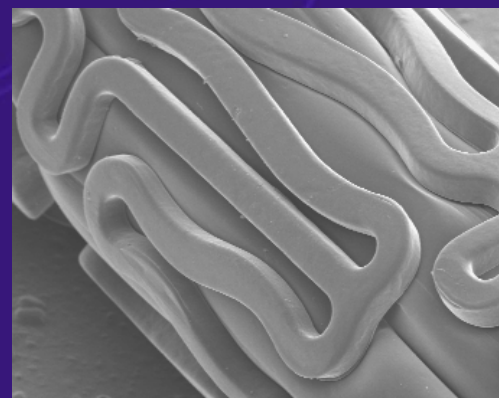
**MULTI-LINK VISION®
Stent Delivery System**



Everolimus

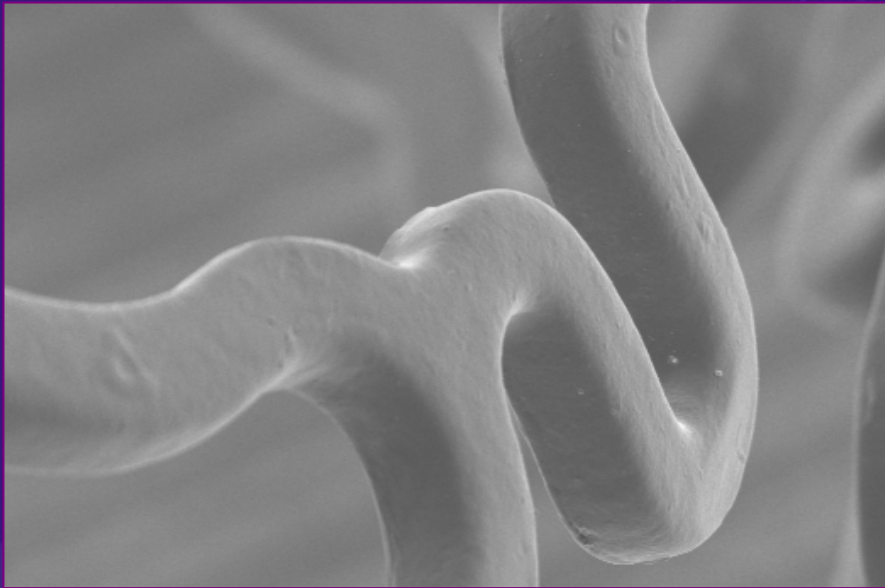


Fluoropolymer

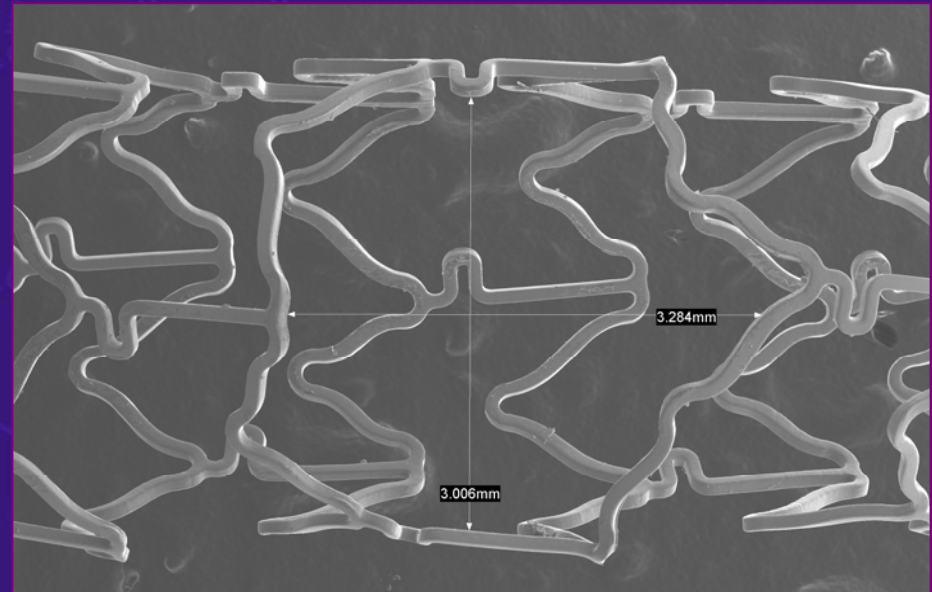


Robust Coating Integrity

- Uniform, consistent coating integrity upon deployment
- Good adhesion to stent due to base layer
- Non-tacky drug matrix prevents “unwanted” adhesions



Nominal Expansion – High Magnification

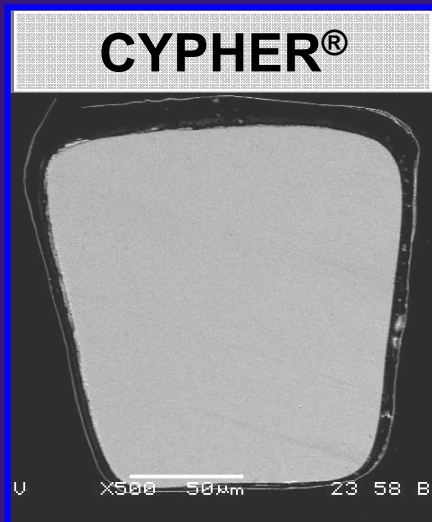


Side Branch Cell Expansion

Acute
Long-Term

Minimal Injury

Minimizing Strut and Polymer Thickness

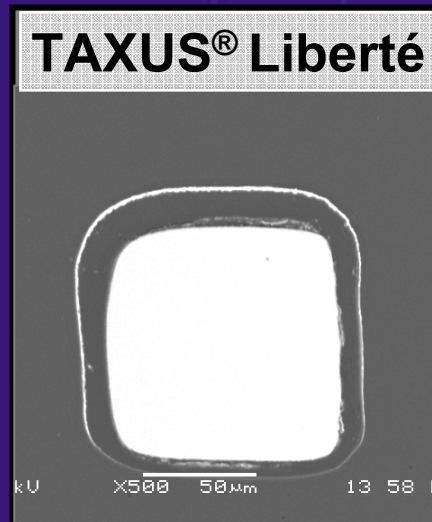


Strut Thickness:

140 µm

Polymer Thickness:

13.7 µm



Strut Thickness:

97 µm

Polymer Thickness:

17.8 µm

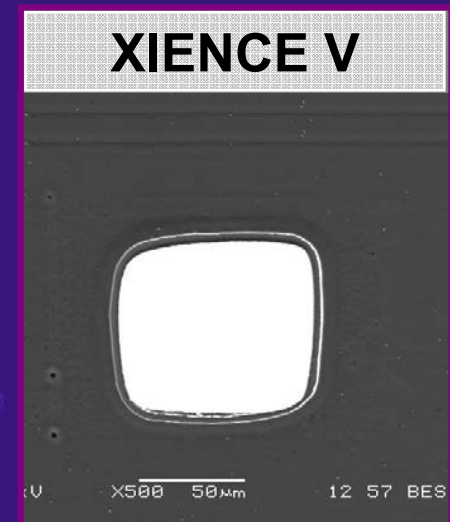


Strut Thickness:

91 µm

Polymer Thickness:

4.8 µm



Strut Thickness:

81 µm

Polymer Thickness:

7.8 µm

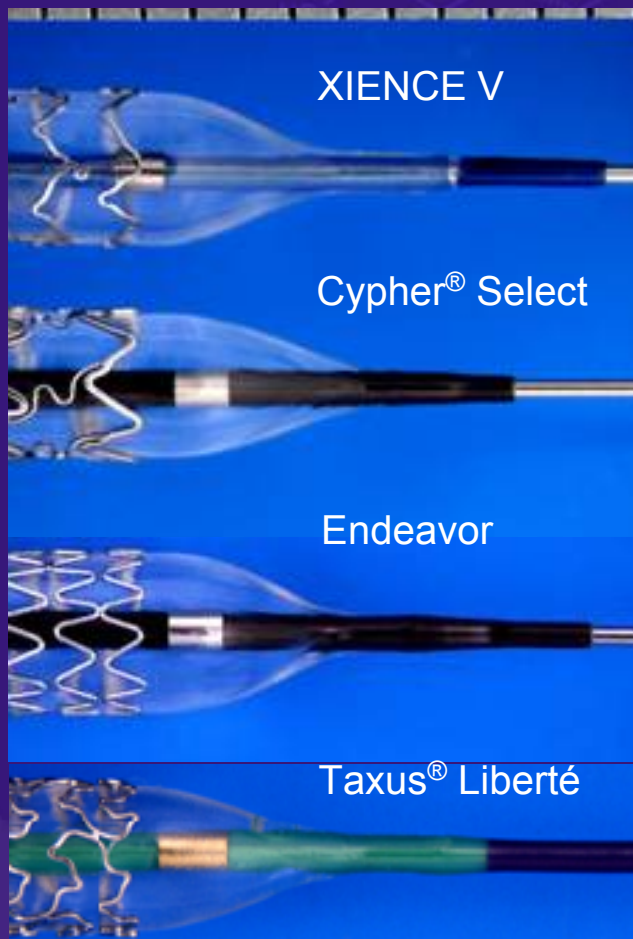
3.0 mm diameter stents, 500x magnification

Data on file at Abbott Vascular.

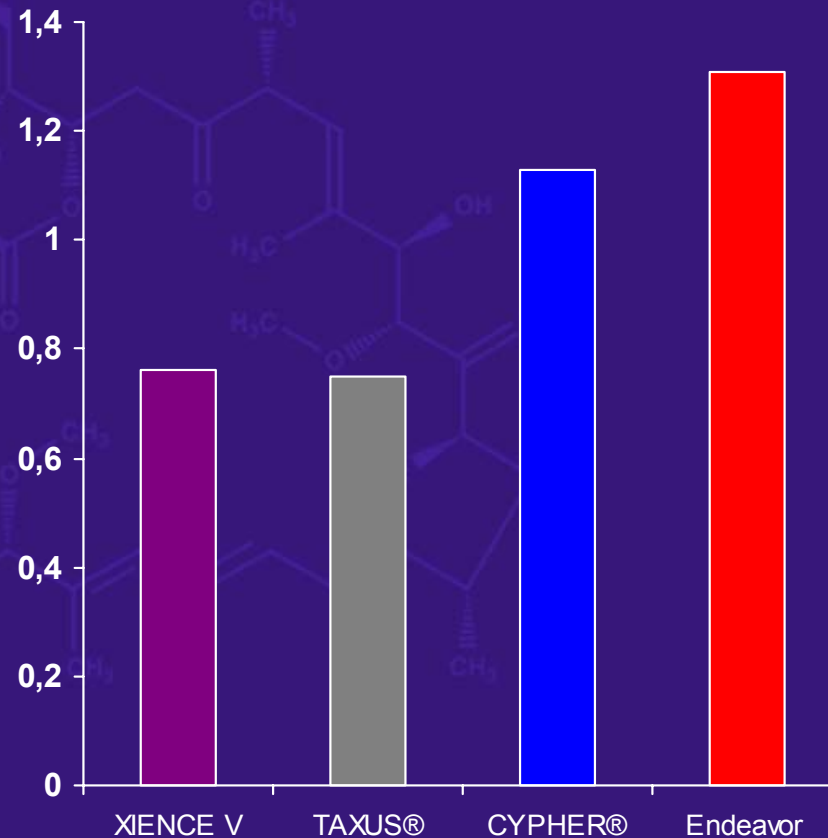
Minimal Vessel Injury

Short, Abrupt Tapers

Acute
Long-Term



Stent-to-Shoulder (mm)

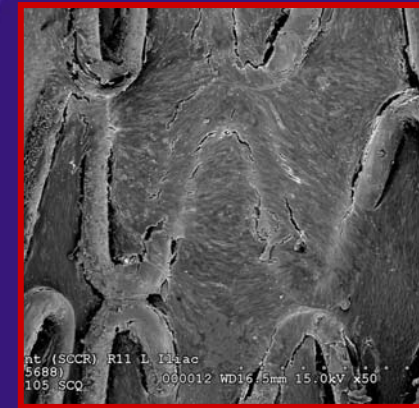
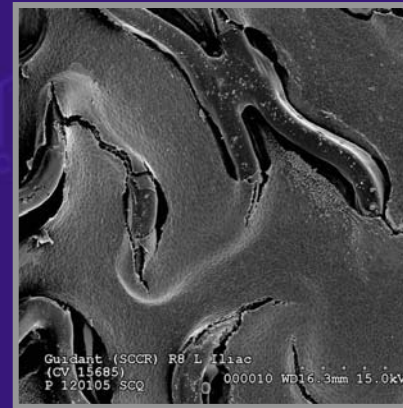
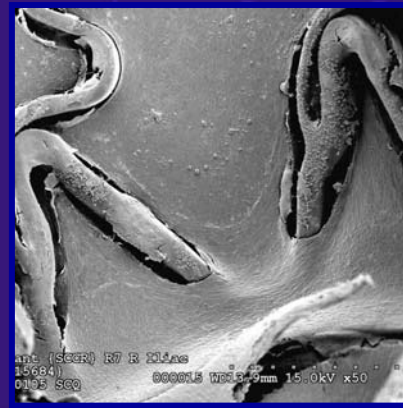
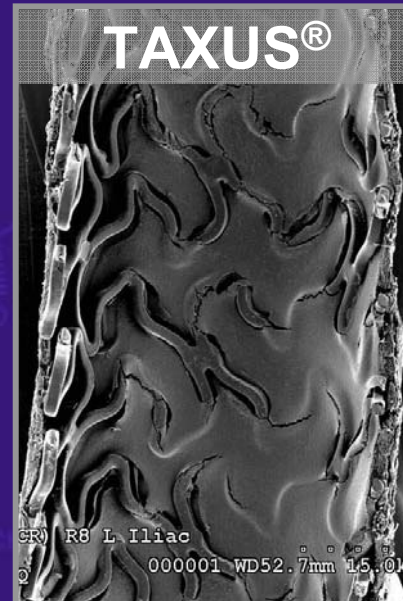
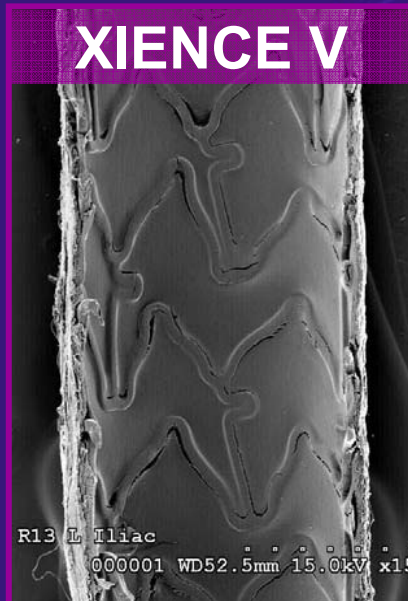


Photos taken by and data on file at Abbott Vascular.
3.0 mm x 18 mm XIENCE™ V , CYPHER® Select, and Endeavor™. 3.0 mm x 20 mm TAXUS® Liberté

Rapid Re-endothelialization

14-Day Rabbit Iliac Study

Acute
Long-Term

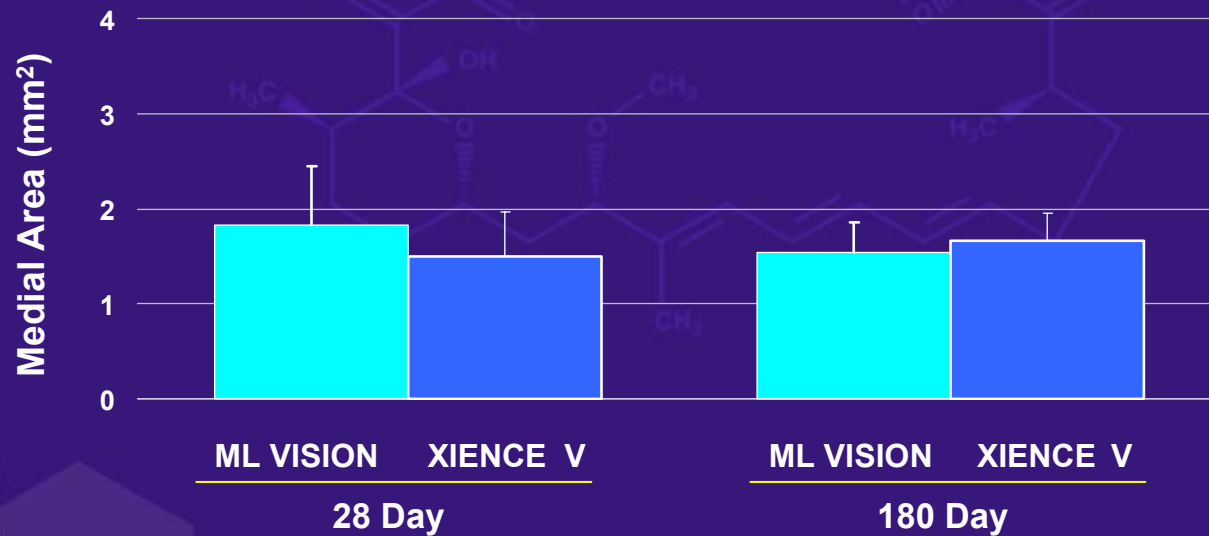
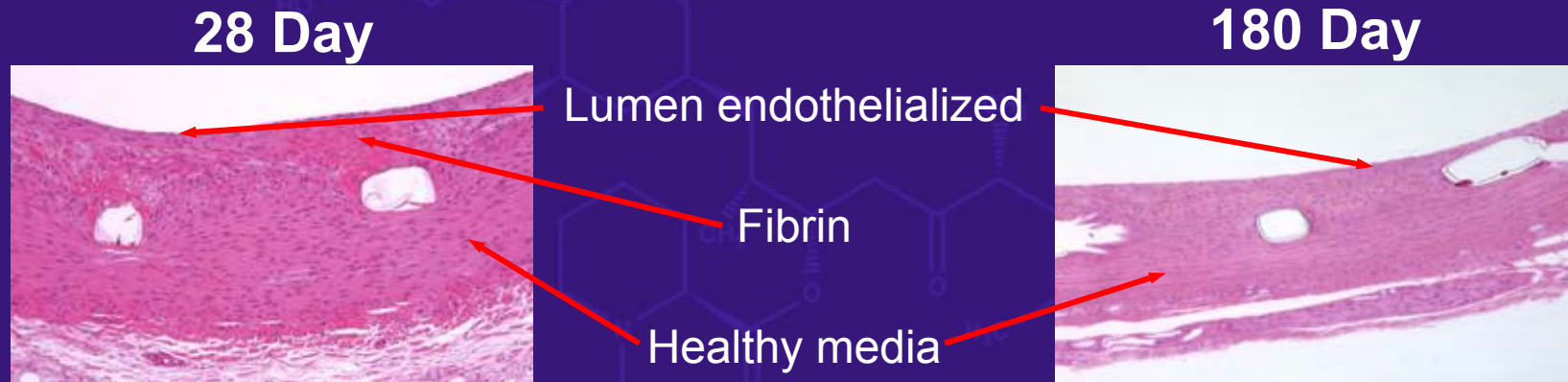


Photos on file at Abbott Vascular.

Rapid Re-endothelialization

Porcine Stent Healing at 28 & 180 Days

Acute
Long-Term



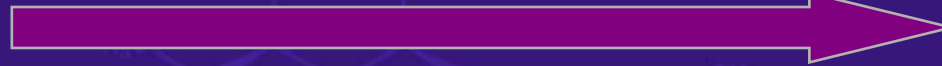
Data on file at Abbott Vascular.

SE2926300 Rev. D

Xience V

The Science of Safety

Acute



Long-Term

- Minimal Injury
- Complete Apposition
- Thromboresistant Materials

- Rapid re-endothelialization
- Functional endothelial layer
- No chronic inflammation
- No persistent fibrin

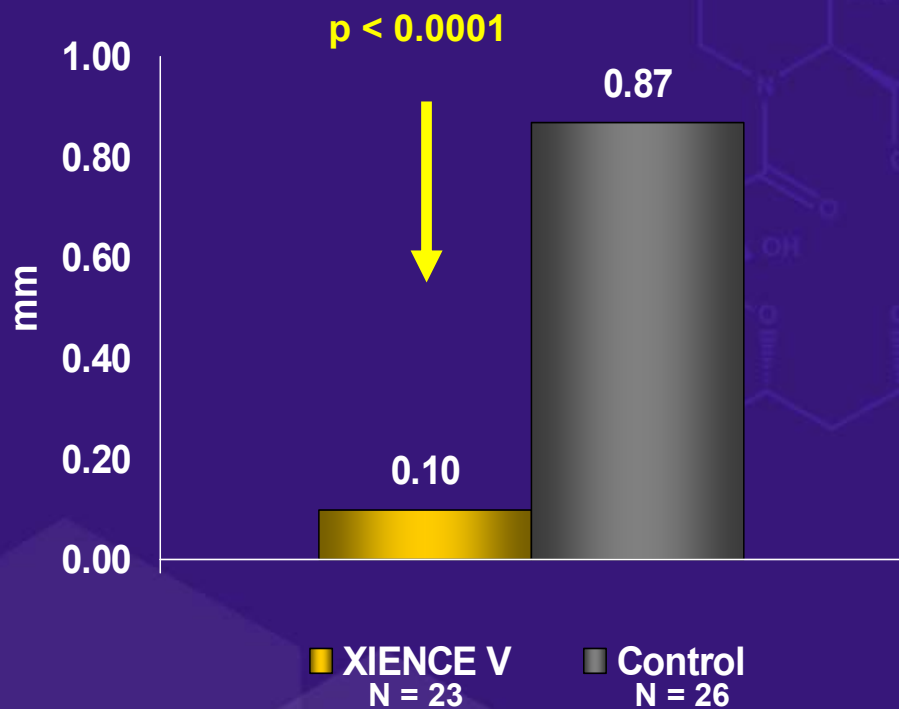
The SPIRIT of XIENCE V

The SPIRIT Family of Trials

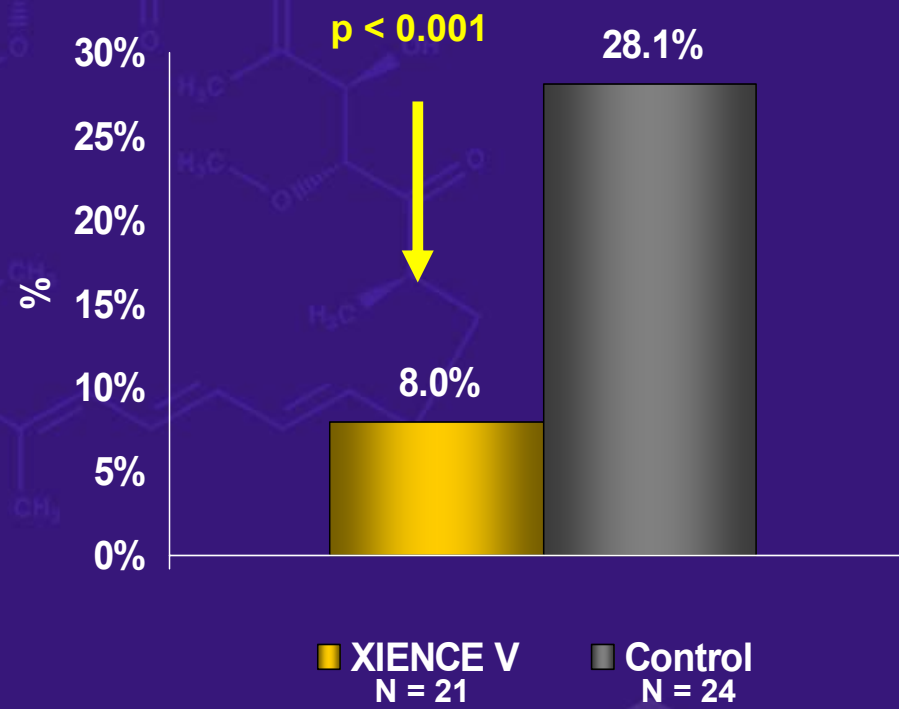
SPIRIT FIRST	SPIRIT II	SPIRIT III	SPIRIT IV	SPIRIT V	XIENCE V SPIRIT WOMEN
Safety & Performance	Clinical Support for CE Launch	US & Japan Approval	US Peri Approval	Post- CE Mark Approval	Post- CE Mark Approval
Europe N = 60	International N = 300	US N = 1,002	US N = 3,690	International N = 3,000	International N = 2,000
				Diabetic study N = 300 Registry N = 2,700	Women only

SPIRIT FIRST 6M Results

SPIRIT FIRST Primary Endpoint In-stent Late Loss



SPIRIT FIRST Percent Volume Obstruction



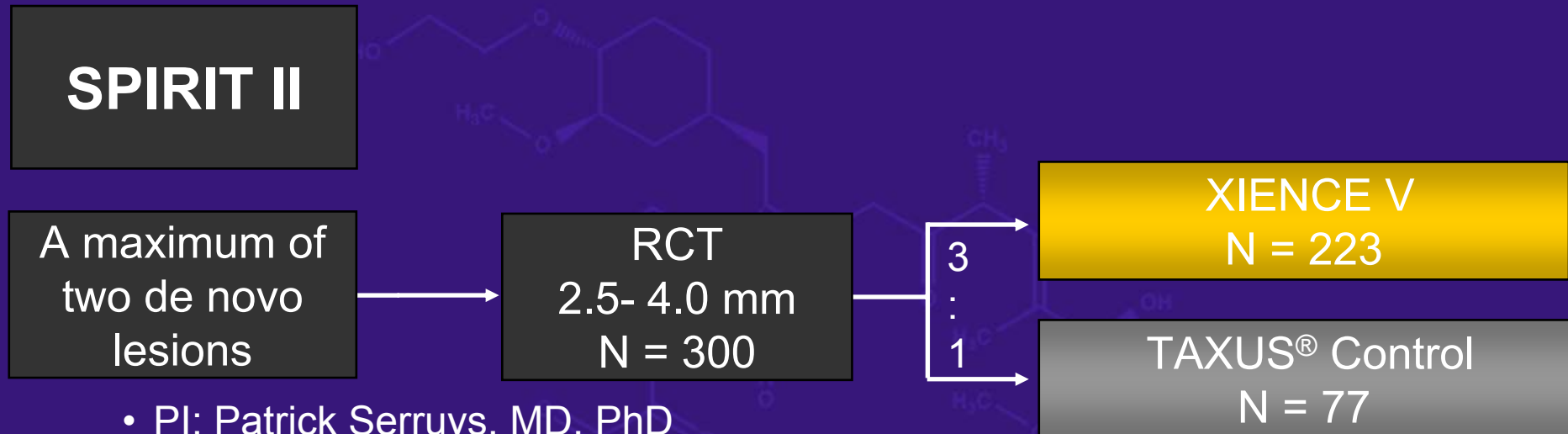
NOTE: IVUS totals are number of lesions.
SOURCE: P. Serruys, et al. *Eurointervention*, 2005,1:1 58-65.

SE2926300 Rev. D

Xience V

SPIRIT II Study Design

SPIRIT II



- PI: Patrick Serruys, MD, PhD
- RCT: Prospective, single blind
- **Primary end point: in-stent late loss at 6 months**
- Stent Size: 2.5 – 4.0 mm; Stent lengths: 8, 18, 28 mm
- Angiographic follow-up: baseline, 180 days (300 patients), and 2 years (152 patients)
- IVUS follow-up: baseline, 180 days and 2 years (152 patients)
- Clinical follow-up at 1, 6, 9 months, 1 and 2 years
- 6 Months clopidogrel for all arms

SPIRIT II Baseline Demographics

	XIENCE V 223 pts	TAXUS® 77 pts
Male (%)	71	79
Mean age (years)	62	62
Previous MI (%)	35	25
Prior intervention at target vessel (%)	4	4
Diabetes mellitus (%)	23	24
Insulin-dependent diabetes (%)	5	7
Hyperlipidemia req. med. (%)	69	75
Hypertension req. med.(%)	67	65
Current Smoker (%)	32	30
Device success (%)	98.8	98.9
Procedure success (%)	99.1	97.4

SPIRIT II Baseline Angiography

	XIENCE V 260 lesions	TAXUS® 91 lesions
Dual lesions treated (%)	17	18
Type B2/C Lesions	78	80
Lesion location		
LAD	41	47
LCX	29	19
RCA	30	34
QCA		
RVD (mm)	2.70*	2.82*
MLD (mm)	1.06	1.14
% DS	61	59
Lesion length (mm)	13.0	13.2

*RVD p = 0.099

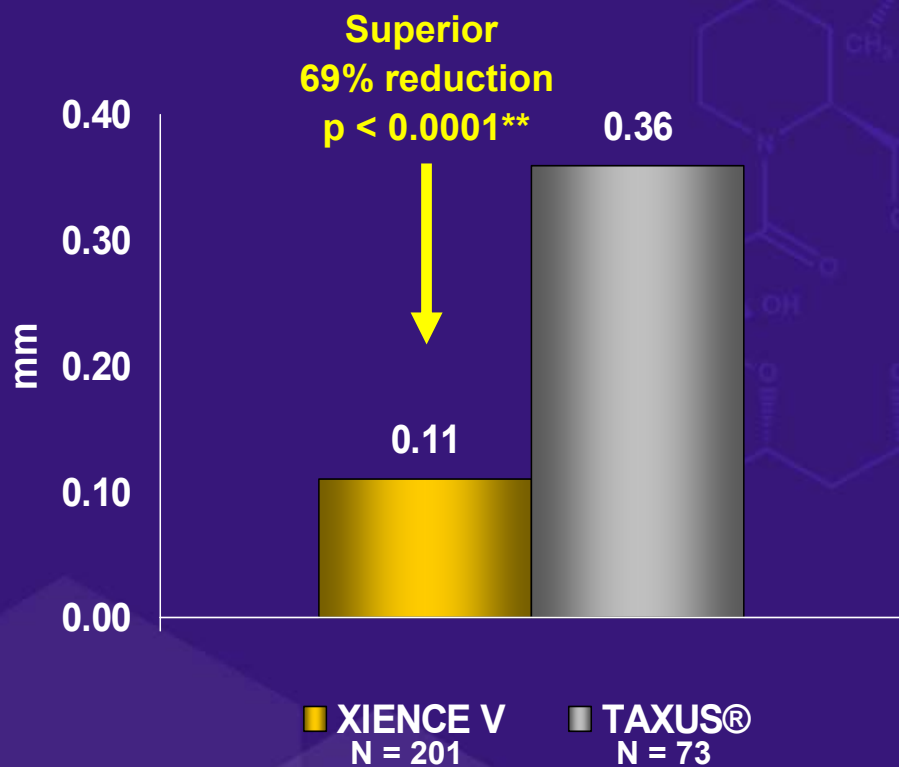
SOURCE: P. Serruys et al., *EuroIntervention* 2006, 2: 286-94. P. Serruys, SPIRIT II Clinical, Angiographic, and IVUS 6M results, ESC 2006.

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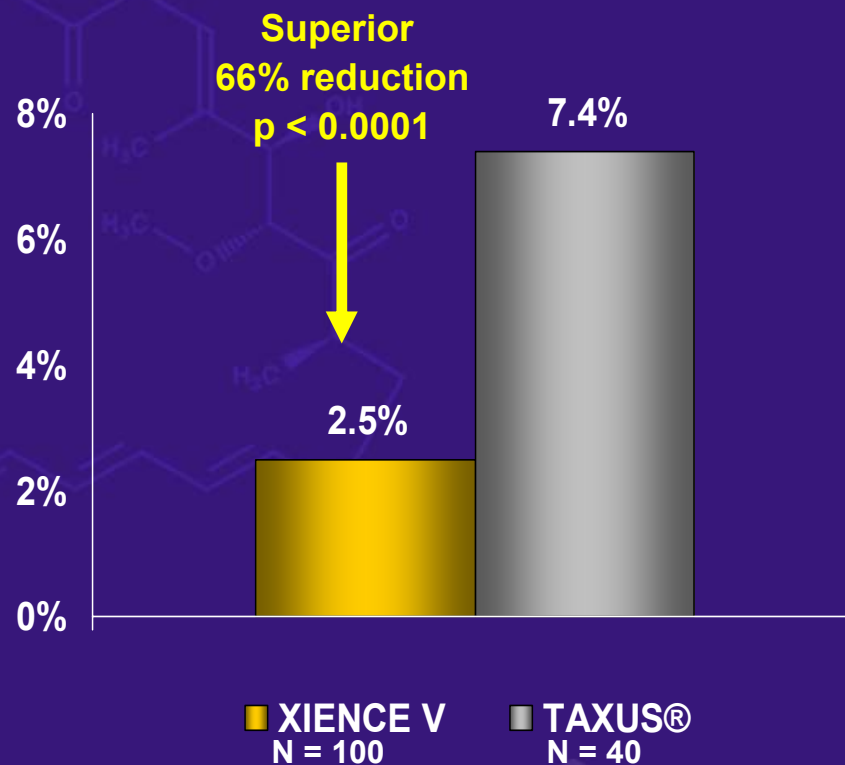
Xience V

SPIRIT II 6M Results

Primary Endpoint In-stent Late Loss*



In-Stent Percent Volume Obstruction



NOTE: IVUS totals are number of lesions.

SOURCE: P. Serruys et al., *EuroIntervention* 2006, 2: 286-94.

*Analysis lesion intent to treat

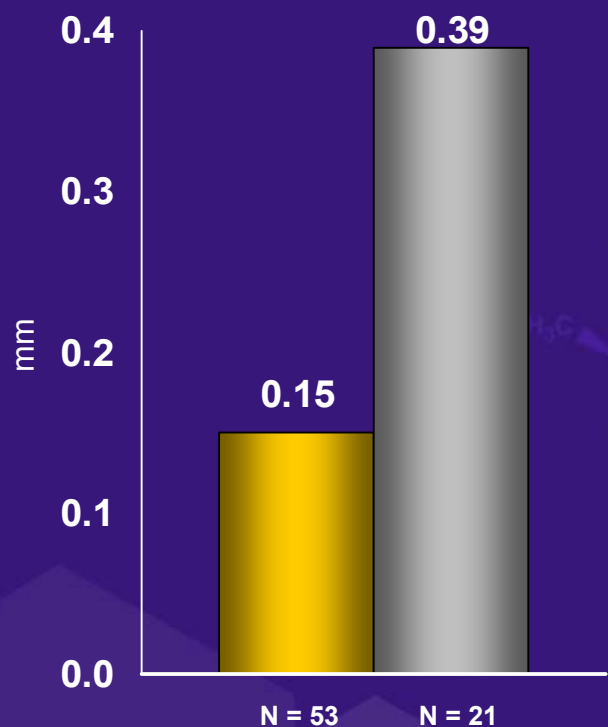
**p value for both non-inferiority (delta 0.16m) and superiority

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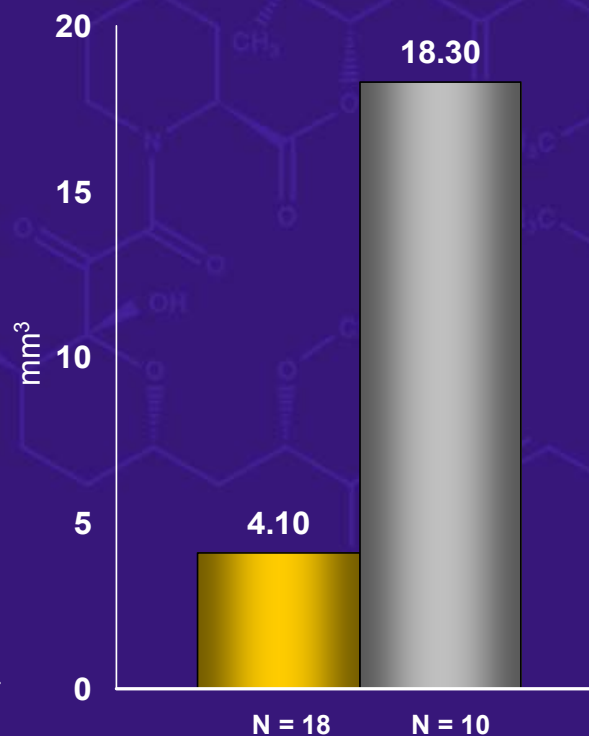
Xience V

SPIRIT II Diabetic Subset – 6M Results

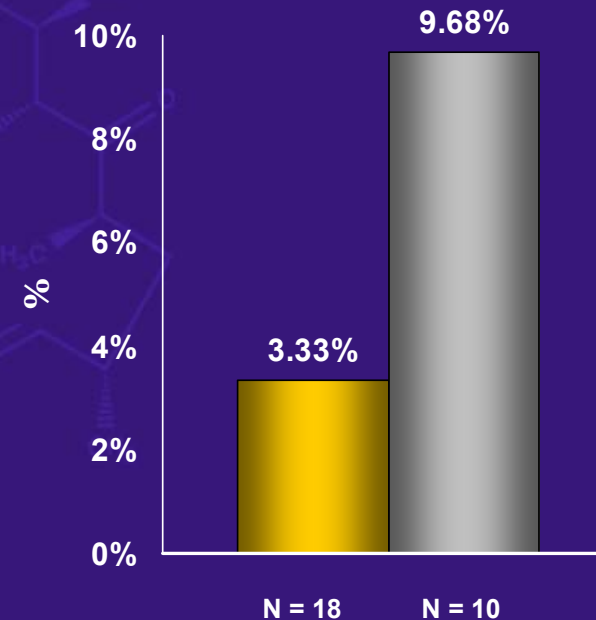
In-stent Late Loss



NIH Volume

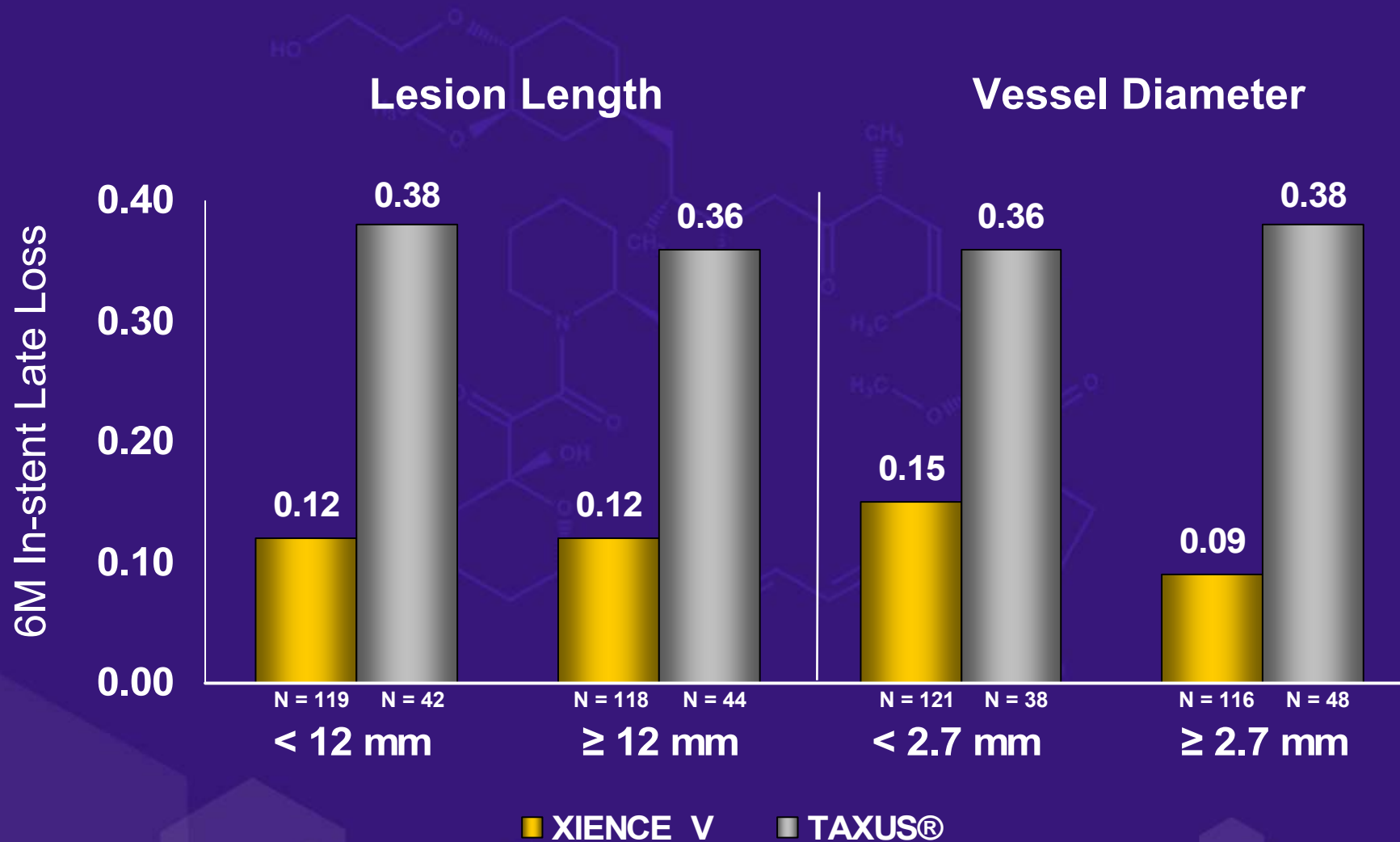


% Volume Obstruction

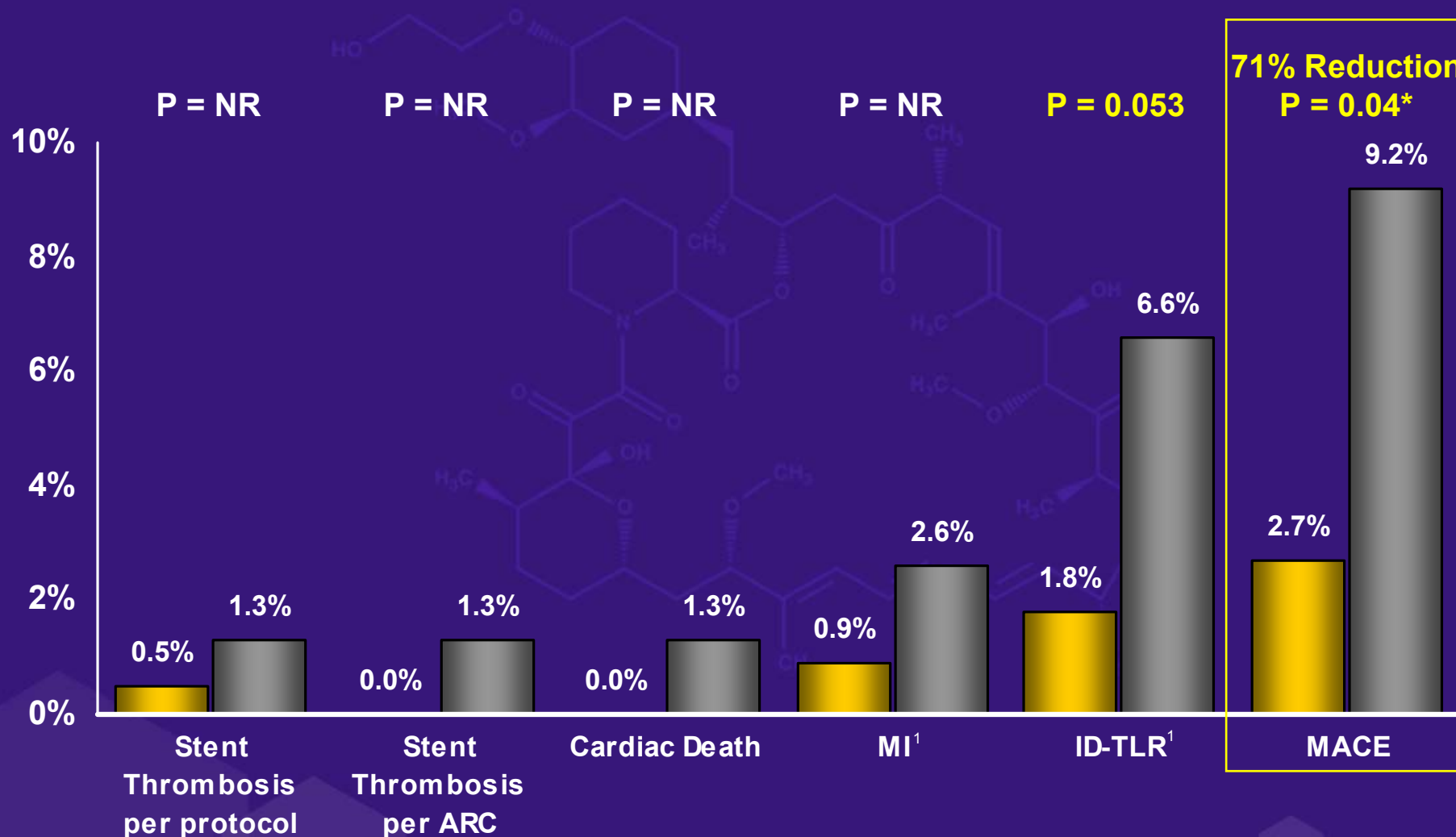


■ XIENCE V ■ TAXUS®

SPIRIT II Lesion Subset Analysis



SPIRIT II 12M Clinical Results



■ XIENCE V N = 220 ■ TAXUS® N = 76

*For descriptive purposes only. 1) Non-hierarchical
SOURCE: P. Ruygrok, SPIRIT II One Year Presentation, ACC 2007.

SPIRIT III RCT Design

SPIRIT III

Up to two de novo lesions, maximum of one lesion per epicardial vessel

Main US RCT
2.5 – 3.75 mm
LL ≤ 28 mm
N = 1,002

2
:
1

XIENCE V
N = 669

TAXUS® Control
N = 333

- PI: Gregg Stone, MD
- RCT: Prospective, single blind
- **Primary end point: In-segment Late Loss at 8M**
- Stent Size: 2.5 – 3.5mm mm; Stent lengths: 8, 18, 28 mm
- Angiographic and IVUS Follow-Up on 564 and 240 pts, respectively
- Clinical follow-up at 30, 180, 270d and 1, 2, 3, 4 and 5 years
- 6 Months clopidogrel for all arms

SPIRIT III Baseline Demographics

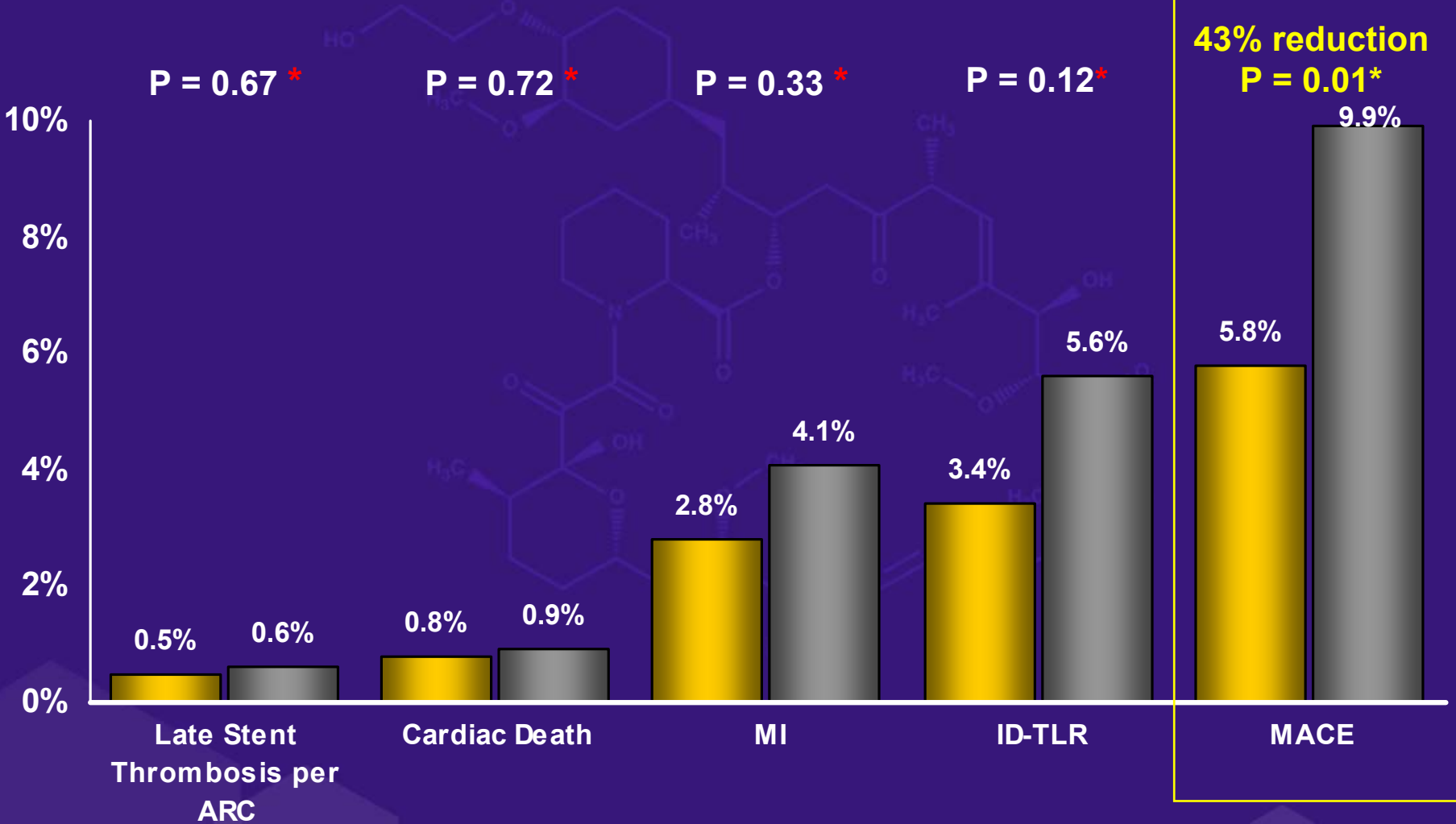
	XIENCE V 669 pts	TAXUS® 333 pts	P-value
Age (in years)	63.2 ± 10.5	62.8 ± 10.2	0.54
Male (%)	70.1	65.7	0.17
Hypertension (%)	76.2	74.0	0.48
Hypercholesterolemia (%)	74.2	71.5	0.36
Diabetes mellitus (%)	29.6	27.9	0.60
Insulin requiring (%)	7.8	5.5	0.19
Current smoker (%)	23.4	22.5	0.81
Prior MI (%)	19.9	18.0	0.49
Unstable angina (%)	18.7	25.1	0.02

SPIRIT III QCA at 8 Months

	XIENCE V 343 lesions	TAXUS® 158 lesions	P-value
RVD (mm)	2.77 ± 0.43	2.78 ± 0.42	0.84
MLD (mm)			
In-segment	2.22 ± 0.53	2.12 ± 0.60	0.08
In-stent	2.56 ± 0.53	2.45 ± 0.65	0.07
*Late Loss (mm)			
In-segment	0.14 ± 0.39	0.26 ± 0.46	0.003
In-stent	0.16 ± 0.41	0.30 ± 0.53	0.002
% Diameter Stenosis			
In-segment	18.8 ± 14.4	22.8 ± 16.4	0.008
In-stent	5.9 ± 16.4	10.3 ± 21.4	0.02
Binary Restenosis (%)			
In-segment	4.7	8.9	0.07
In-stent	2.3	5.7	0.06

*All lesions F/U window ± 28 Days
SOURCE: G.W. Stone, SPIRIT III 9 Month Presentation, ACC 2007.

SPIRIT III 12M Clinical Results



*For descriptive purposes only.

SOURCE: G.W. Stone, SPIRIT III 12 Month Presentation, TCT 2007.

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SE2926300 Rev. D

SPIRIT II + III Pooled Meta-Analysis

SPIRIT II + III

Similar inclusion and exclusion criteria: Up to two de novo lesions, maximum of one lesion per epicardial vessel
2.5 – 3.75 mm*
LL ≤ 28 mm

Meta-Analysis of Patient Level Data
N = 1,302

XIENCE V
N = 892

TAXUS® Control
N = 410

- Presented by Gregg Stone, MD at PCR, 5/22/07
- 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

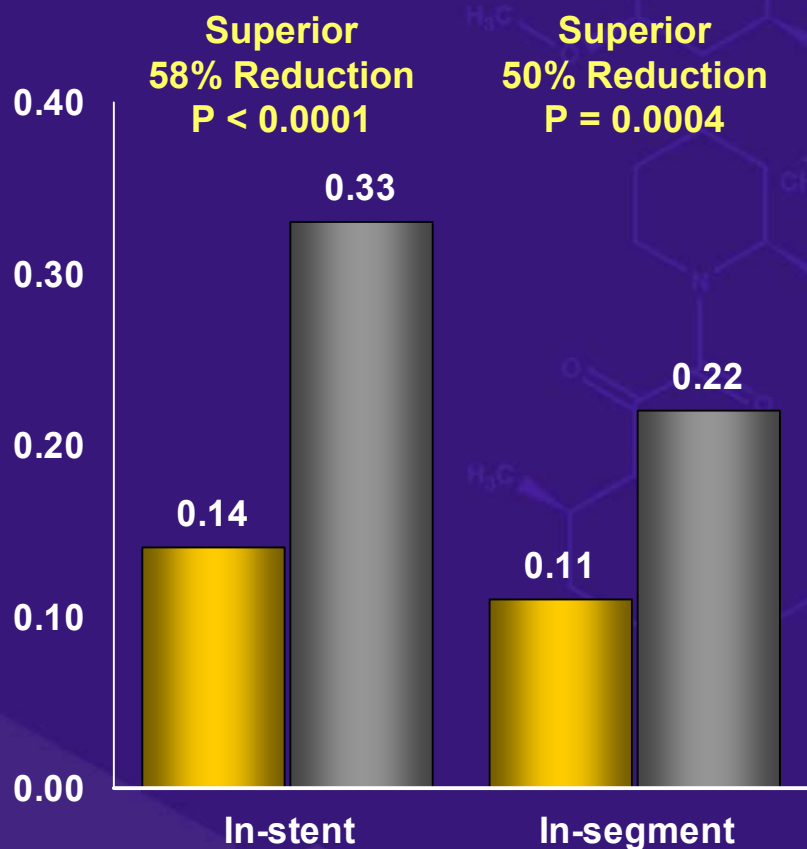
SPIRIT II + III Baseline Demographics

	XIENCE V 892 pts	TAXUS® 410 pts
Age (years)	62.9 ± 10.5	62.6 ± 10.1
Male (%)	70.3	68.2
Diabetes (%)	27.9	27.1
– Treated with Insulin (%)	7.1	5.7
Hypertension (%)	74.0	72.3
Hypercholesterolemia (%)	72.8	72.1
Current smoker (%)	25.3	23.8
Prior MI (%)	23.7	19.3
Unstable angina (%)	20.8	26.5

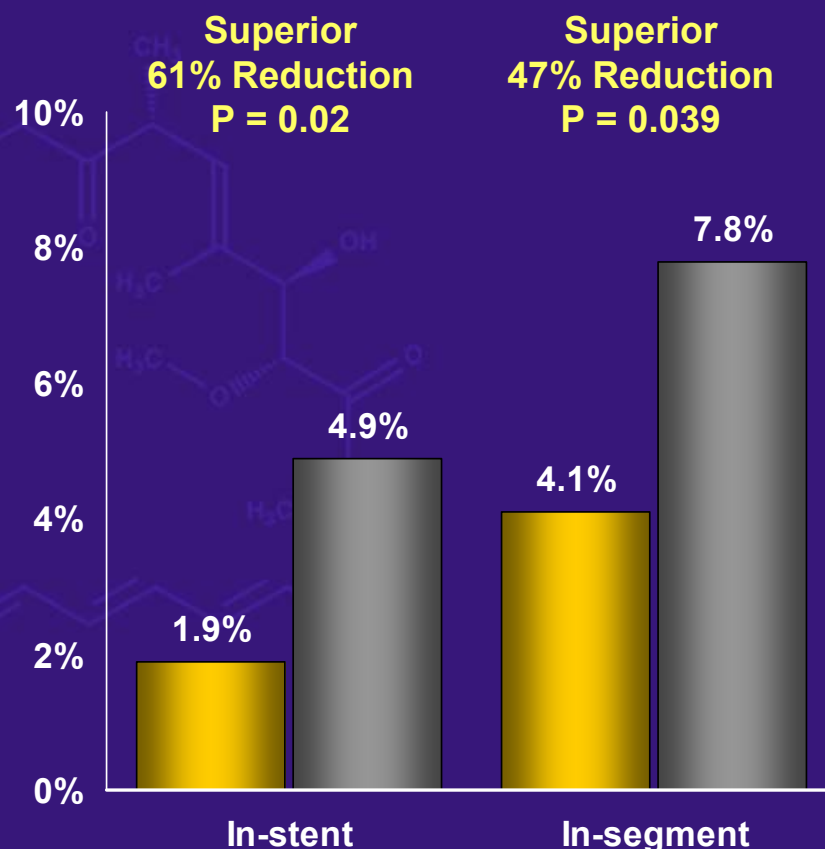
There were no significant differences between XIENCE V and TAXUS®

SPIRIT II + III Angiographic Results

Late Loss



Binary Restenosis



■ XIENCE V N = 581

■ TAXUS® N = 244

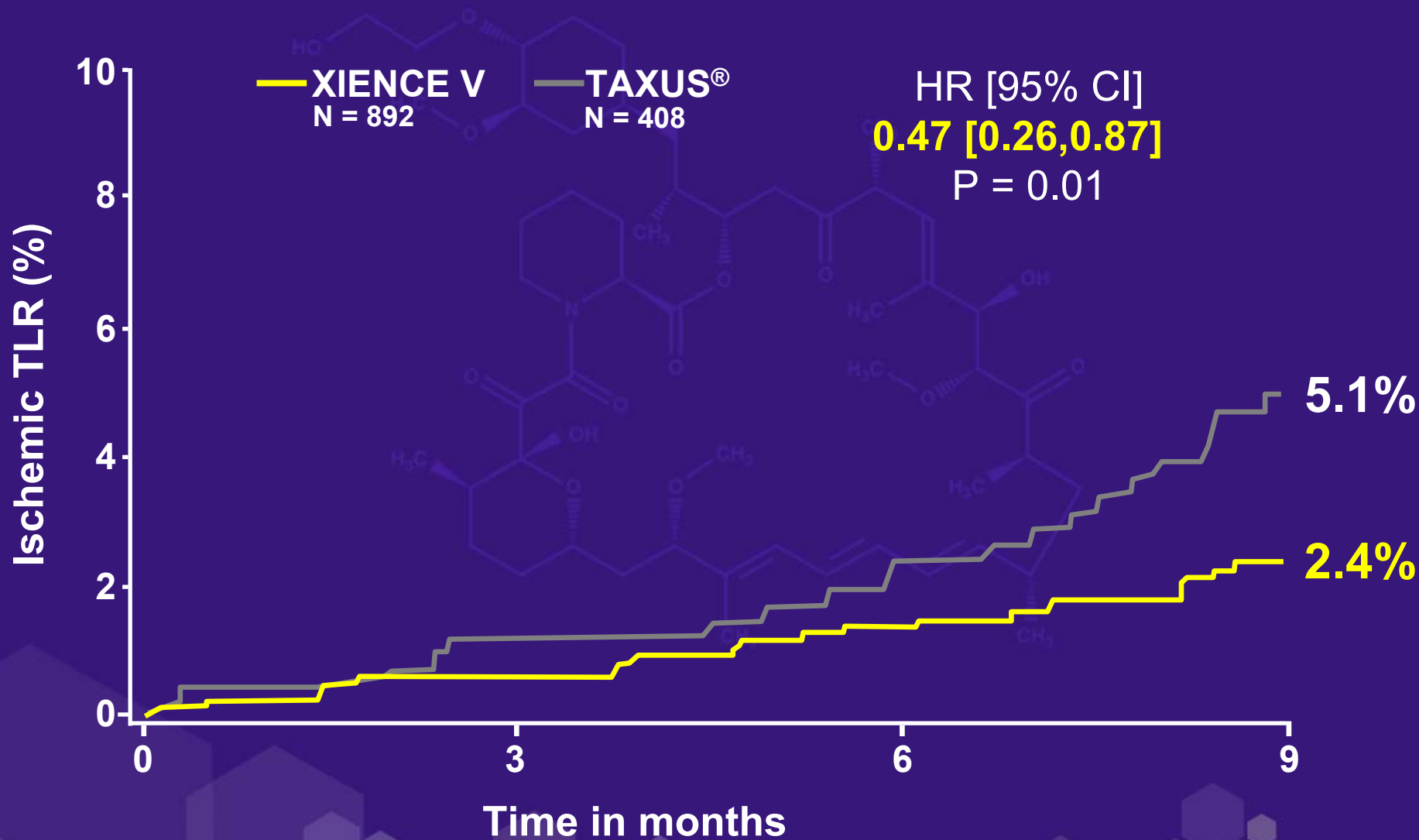
SOURCE: G.W. Stone, SPIRIT II + III Meta-Analysis, PCR 2007.

NOTE: This analysis was performed by the SPIRIT III investigator and is meant for descriptive purposes only. Please note that the data had different angiographic follow-up time points (6 months vs. 8 months).

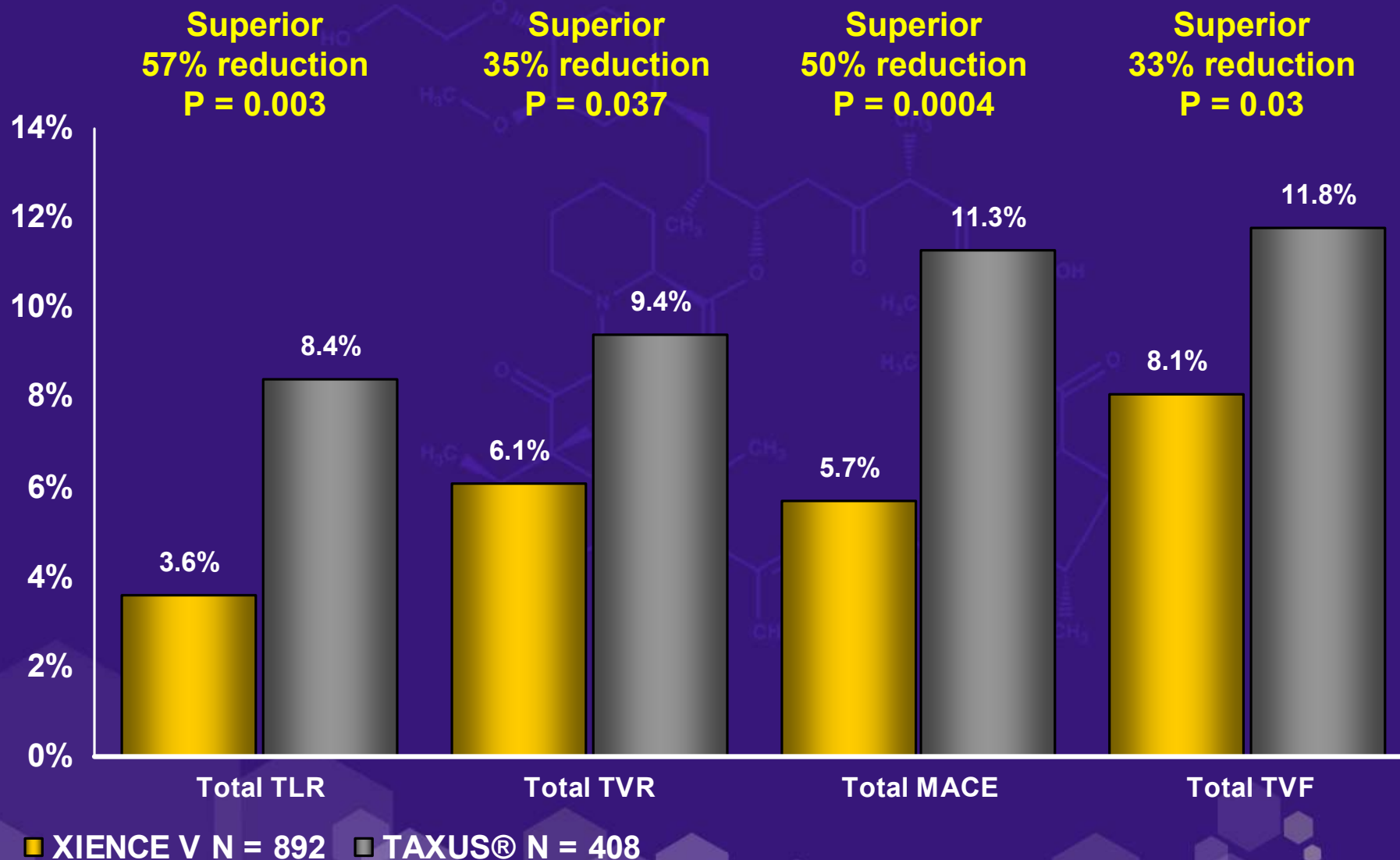
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XIENCE V

SPIRIT II + III ID-TLR Results – 9M

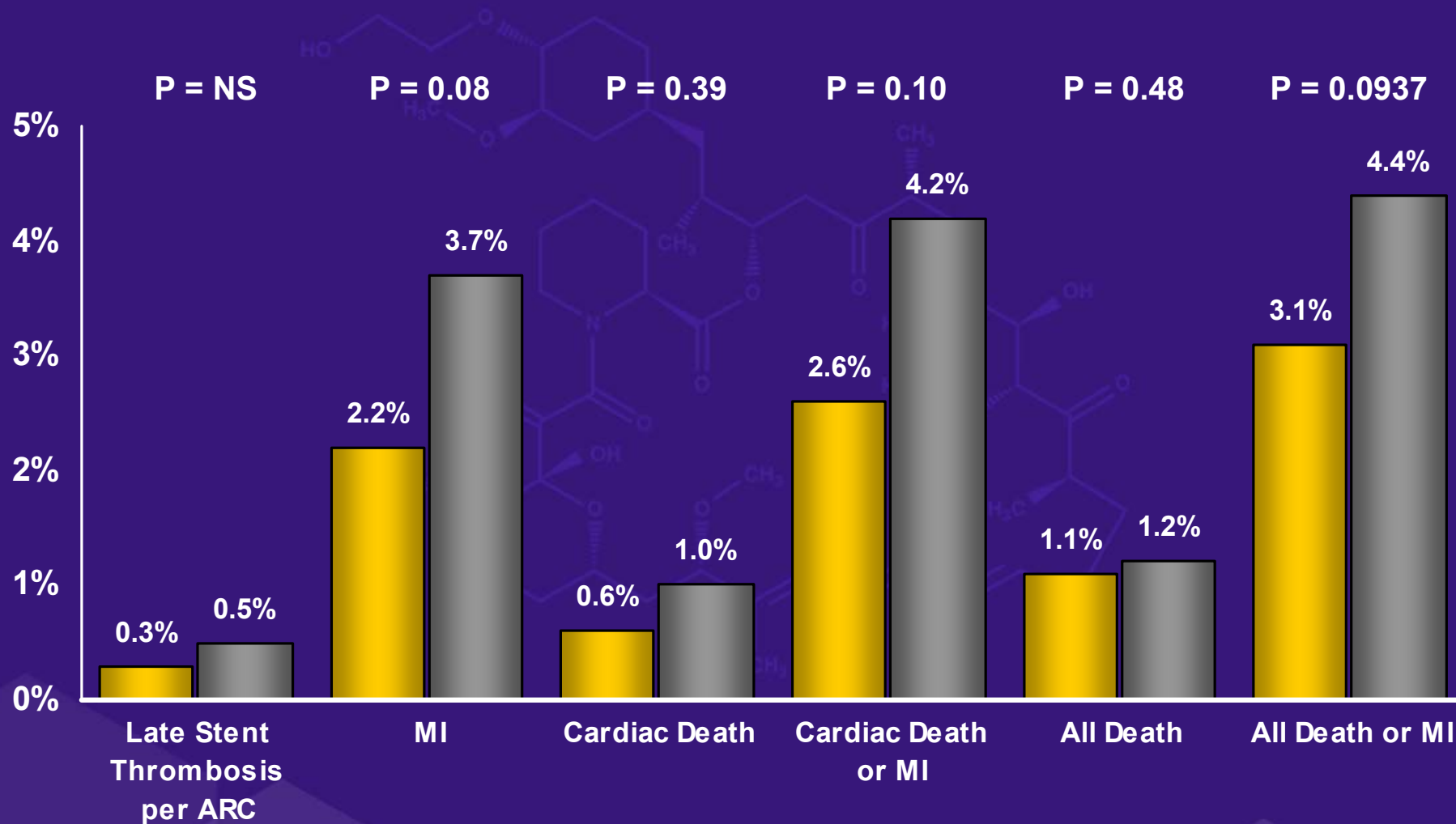


SPIRIT II + III Total Events – 9M



SOURCE: G.W. Stone, SPIRIT II + III Meta-Analysis, PCR 2007.

SPIRIT II + III Safety Results – 12M



SOURCE: PW Serruys, SPIRIT II + III Meta-Analysis, TCT 2007.

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Xience V

12M SPIRIT II + III Pooled Meta-analysis

Stent Thrombosis

	XIENCE V	TAXUS®	p
Acute stent thrombosis %	0.1 (1/892)	0.0 (0/407)	ns
Sub-acute stent thrombosis %	0.2 (2/890)	0.0 (0/407)	ns
Late stent thrombosis %	0.3 (3/866)	0.8 (3/394)	ns

Stent thrombosis was categorized as acute (≤ 1 day), subacute (> 1 day ≤ 30 days) and late (> 30 days) and was defined as any of the following:

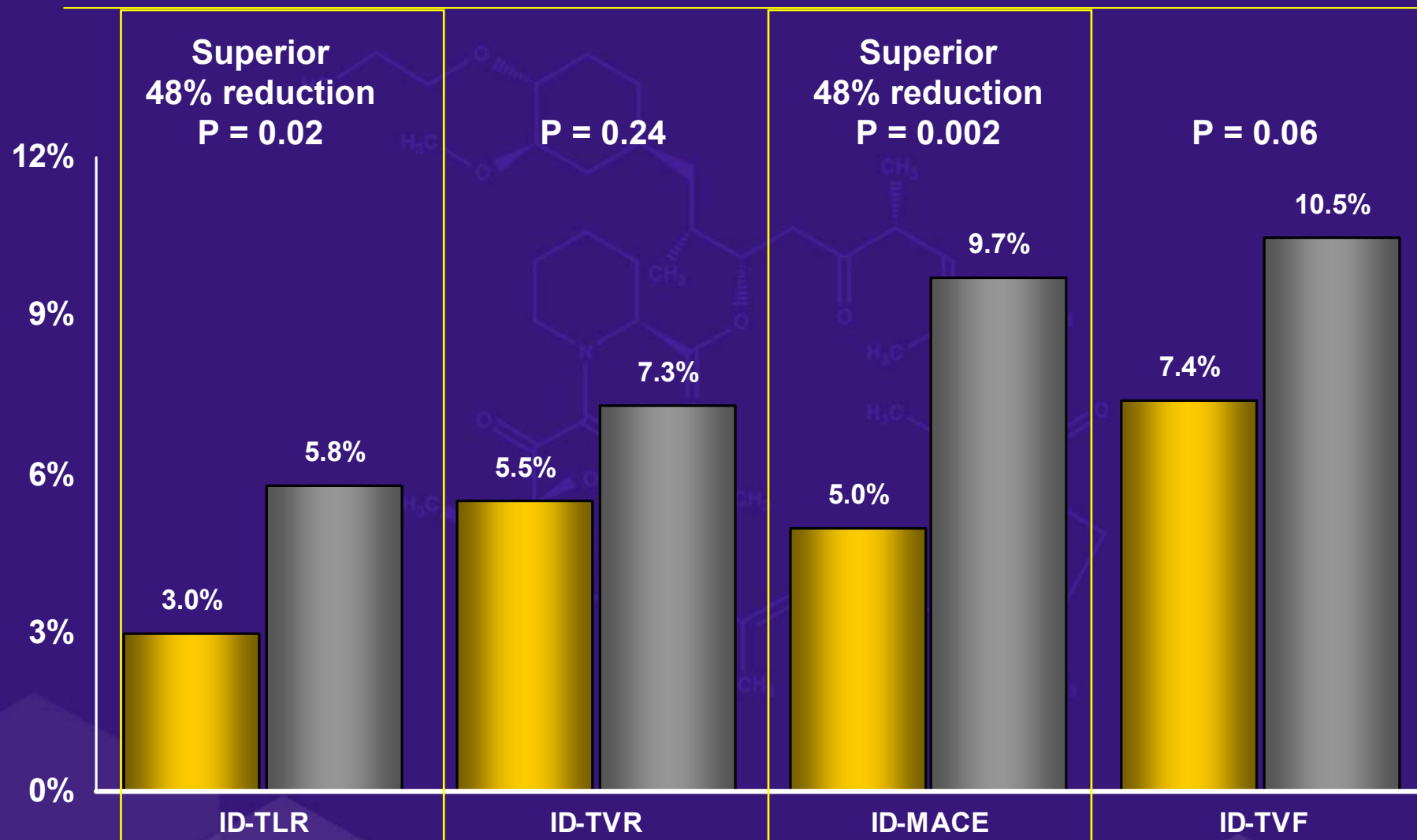
- Clinical presentation of acute coronary syndrome with angiographic evidence of stent thrombosis (angiographic appearance of thrombus within or adjacent to a previously treated target lesion)
- In the absence of angiography, any unexplained death, or acute MI (ST segment elevation or new Q-wave)* in the distribution of the target lesion within 30 days
- AMI that cannot be distinctly attributed to a non-target vessel during CEC adjudication will also be considered in the composite for stent thrombosis
- **p values for descriptive purposes only, not adjusted for multiple comparisons**

SOURCE: PW Serruys, SPIRIT II + III Meta-Analysis, TCT 2007.

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Xience V

SPIRIT II + III Ischemic Events, 12M



■ XIENCE V N = 873 ■ TAXUS® N = 397

SOURCE: PW Serruys, SPIRIT II + III Meta-Analysis, TCT 2007.

12M SPIRIT II + III Pooled Meta-analysis

Conclusions :

Compared to the TAXUS® paclitaxel-eluting stent, the XIENCE V Everolimus eluting stent results in:

- Similar rates of death and stent thrombosis
- Significant reduction in late loss and binary restenosis
- Significant reduction in target lesion revascularization
- Significantly less major adverse cardiac events

SPIRIT IV Trial Design

SPIRIT IV

Up to three de novo lesions, maximum of two lesions per epicardial vessel

Main US RCT
2.5 - 4.25 mm*
LL ≤ 28 mm
N = 3,690

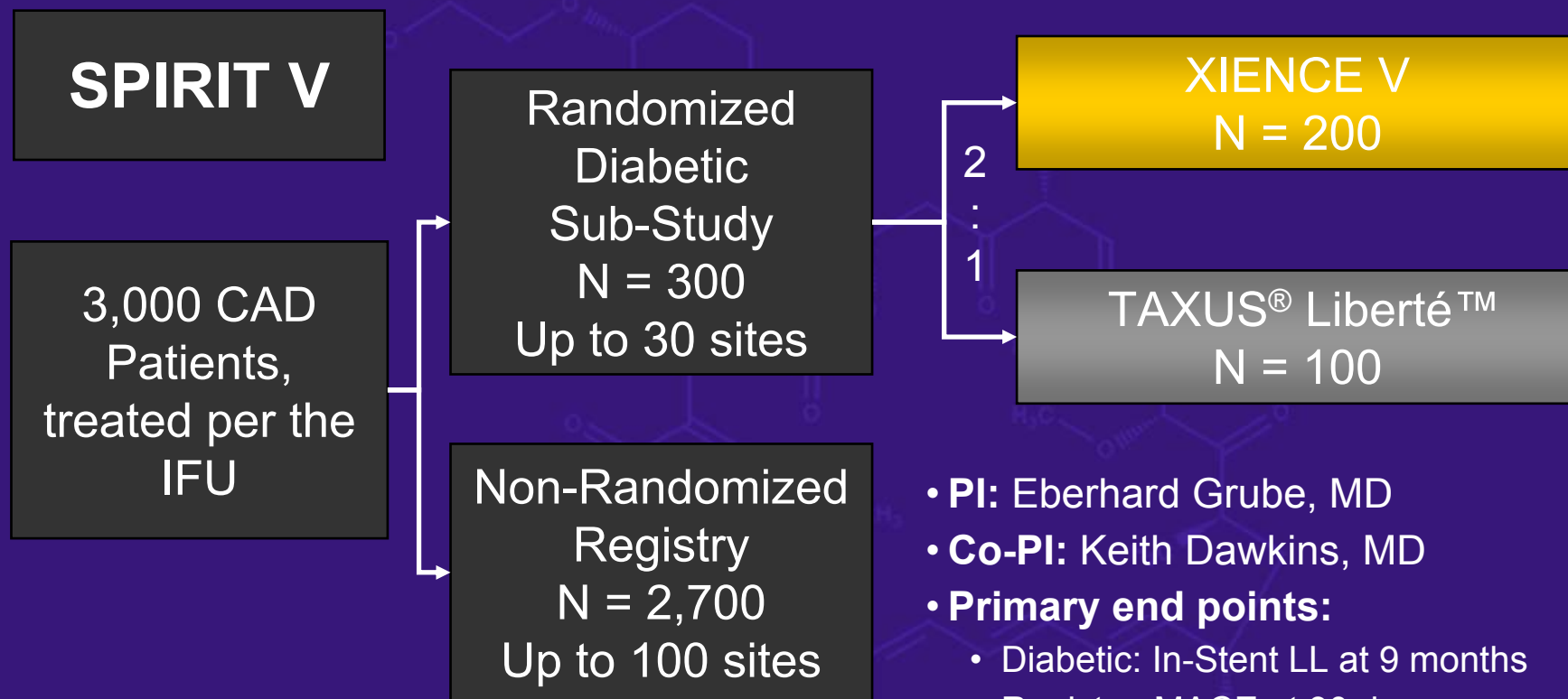
2
:
1

XIENCE V
N = 2,460

TAXUS® Control
N = 1,230

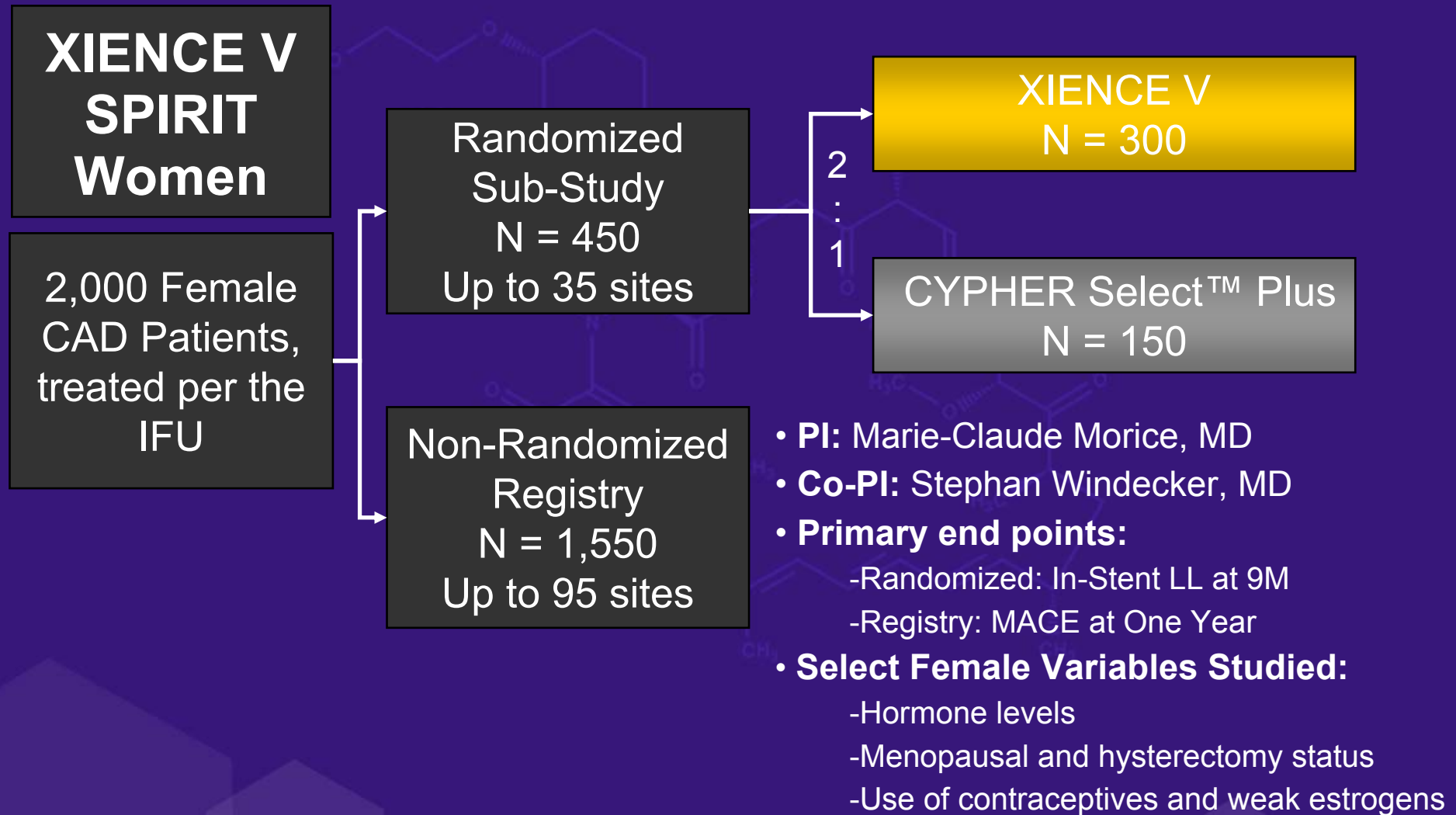
- PI: Gregg Stone, MD
- RCT: Prospective, single blind
- **Primary end point: MACE at 9 months**
- Stent Size: 2.5 – 4.0* mm; Stent lengths: 8, 18, 28 mm
- Enrollment Started: August 2006
- Clinical follow-up at 30, 180, 270d and 1, 2, 3, 4 and 5 years
- 6 Months clopidogrel for all arms

SPIRIT V Trial Design

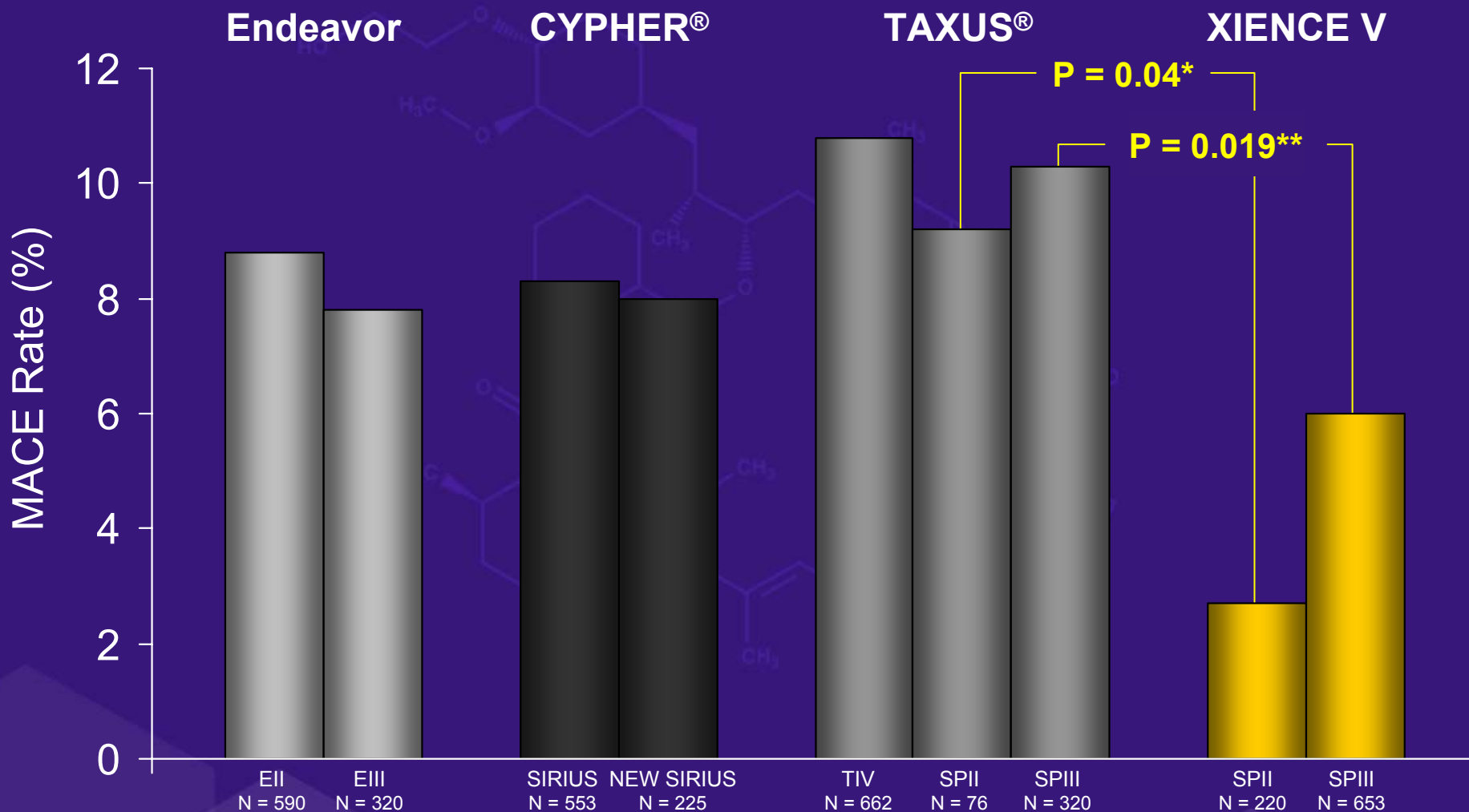


- **PI:** Eberhard Grube, MD
- **Co-PI:** Keith Dawkins, MD
- **Primary end points:**
 - Diabetic: In-Stent LL at 9 months
 - Registry: MACE at 30 days
- **Stent diameters:** 2.5 – 4.0 mm
- **Stent lengths:** 8, 12, 15, 18, 23, 28 mm
- **Enrollment Started:** October 2006

XIENCE V SPIRIT Women Trial Design



DES 12 Month MACE Comparison



*For descriptive purposes only. **Post hoc analysis value unadjusted for multiple comparisons, and for descriptive purposes only.

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SOURCES: **EII & EIII**: Anthony Gershlick, et al., American Journal of Cardiology 2007; 100[suppl]: 45M-55M. **SIRIUS**: David R. Holmes et al.,

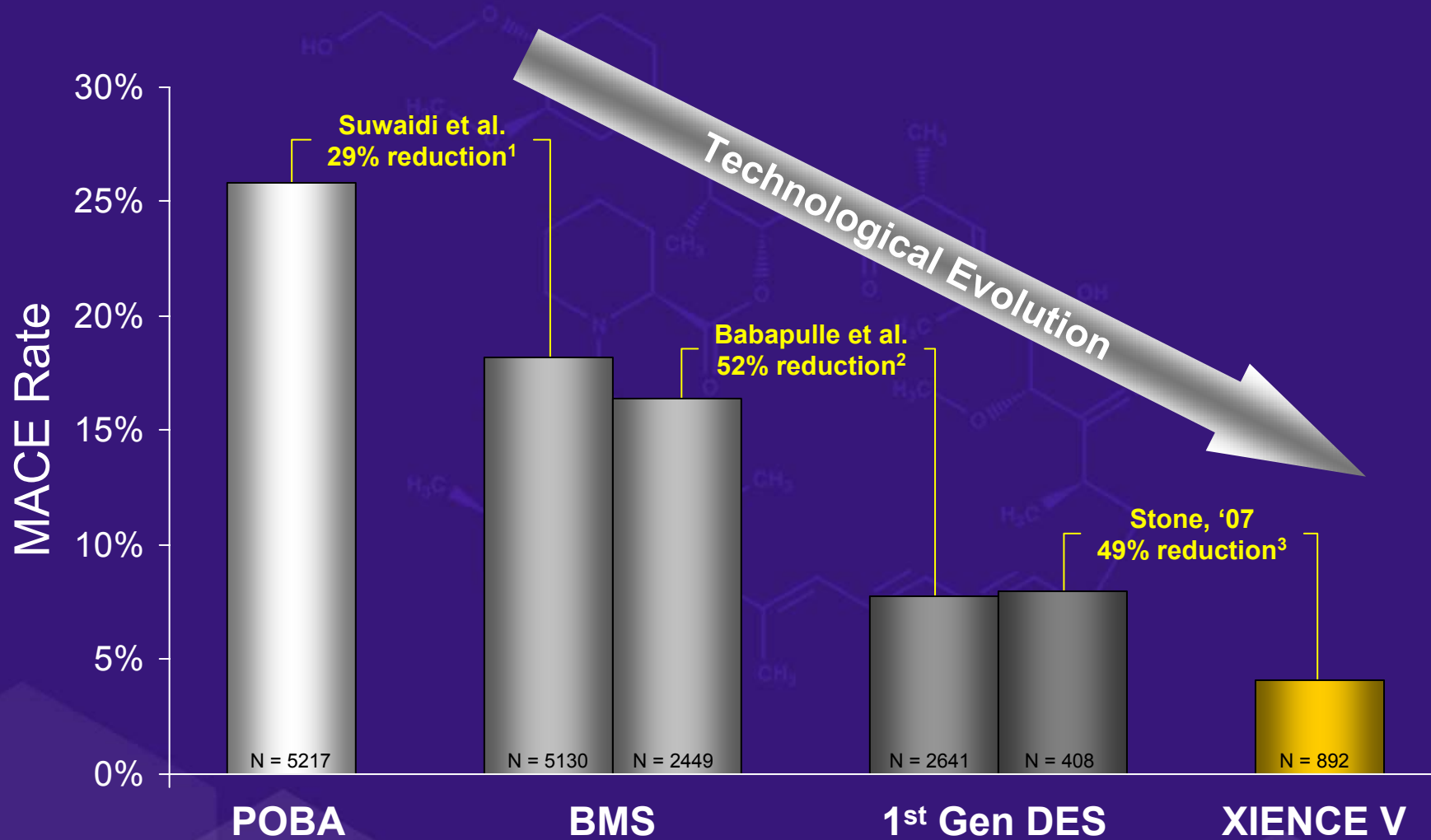
Circulation 2004; 109; 634-640. **NEW SIRIUS**: Michael Schluter et al., Journal of American Cardiology 2005; 45: 1;10-13. Value is a % representation of the composite MACE for predilatation and direct stenting. **TIV**: Gregg W Stone, et al., Circulation 2004; 109; 1942-1947.

SP II: P. Ruygrok, SPIRIT II One year, ACC 2007. **SP III**: Data on file at Abbott Vascular - SPIRIT III One year data.

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Xience V

Historical Meta-Analyses



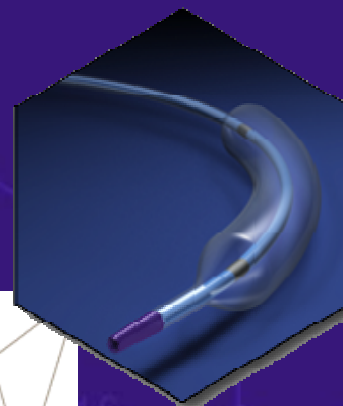
SOURCES: 1) Suwaidi et al. American Heart Journal 2004; 147; 815-22.
2) Babapulle et al. Lancet 2004; 364: 583-91. 3) G.W. Stone, SPIRIT II+III Meta Analysis, PCR 2007.

XIENCE V: State of the Art Platform

MULTI-LINK VISION
Stent



MULTI-LINK VISION
Stent Delivery System

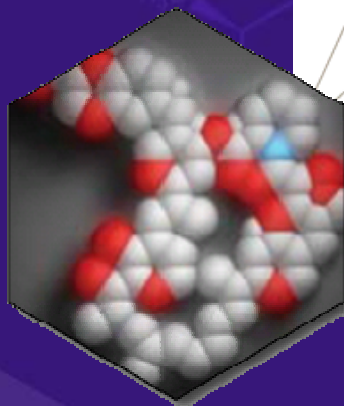


Deliverability

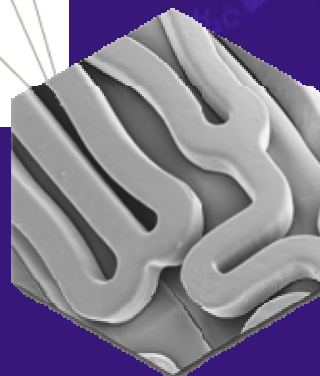
Efficacy

Safety

Everolimus



Fluoropolymer



BMS Body of Data

State of the Art Platform

REVE Registry	VISION Registry	Da Vinci Registry	BASKET 6M	RISICO Registry
Post Marketing Study of ML VISON	Pre-Market Study of ML VISON for Safety & Efficacy	Post Marketing Study of ML VISON	3 rd Generation BMS vs. 1 st Generation DES	Post Marketing Study of ML MINI-VISON
France N = 518	US N = 267	Germany N = 1,289	Switzerland N = 826	Italy N = 143
Death, MI & TLR	Death, MI & TLR	Death, MI & CABG or PTCA in any vessel	Cardiac Death, MI & TVR	Death, MI & TVR

REVE Registry Design

State of the Art Platform

REVE

1-3 Native, de novo Lesions
≤ 25mm

Registry
2.0- 4.0 mm
N = 518

ML VISION
CoCr

- PI: Dr. Thierry Corcos, MD
- **Primary end point: TLR at 6M**
- Stent Size: 2.0mm – 4.0 mm
- Stent Lengths: 8 mm-28 mm; mean: 17.2 mm
- Secondary Endpoints: In-Hospital and 6M MACE

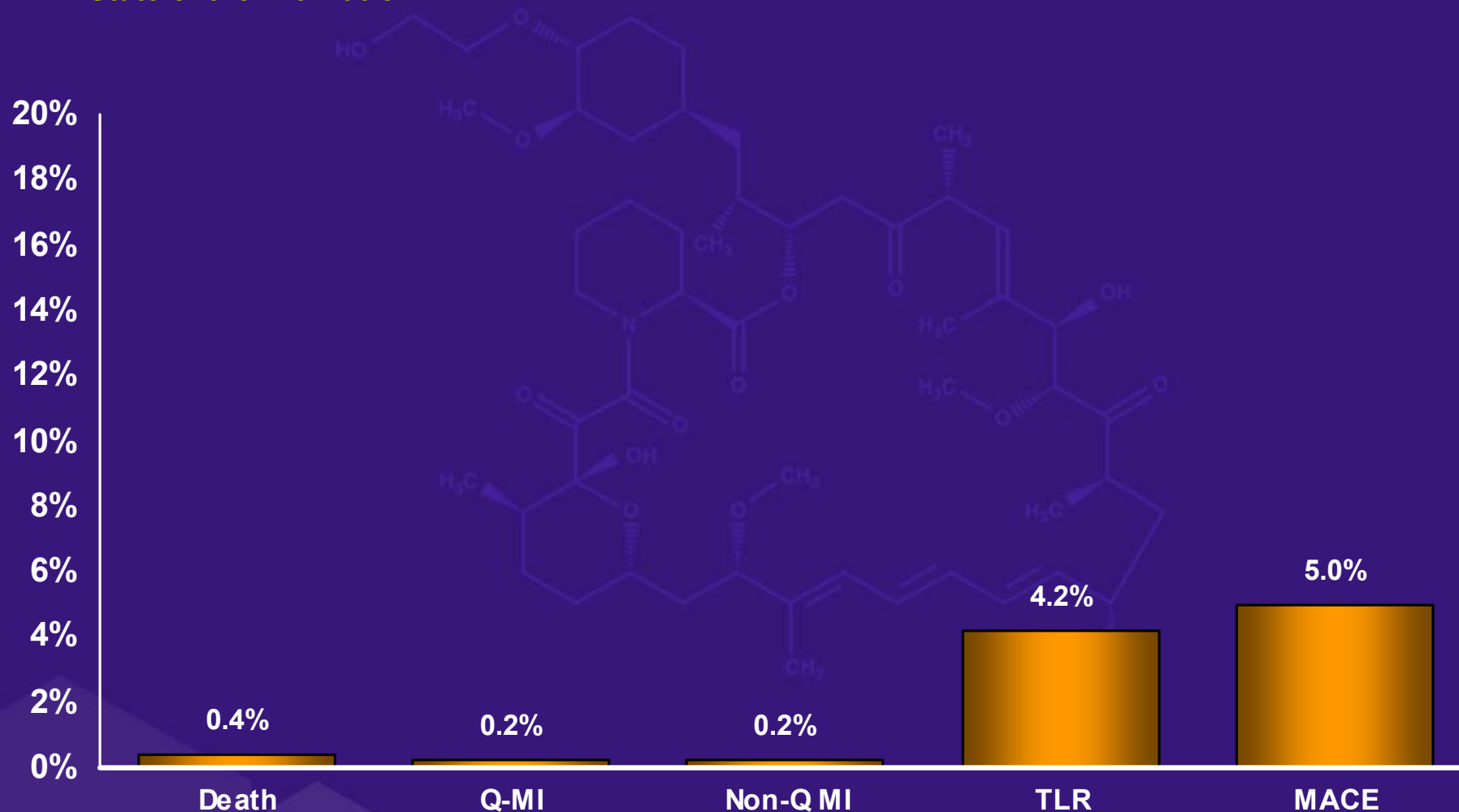
REVE Baseline Demographics

State of the Art Platform

Male (%)	68
Mean age (years)	77
Previous PCTA + Stent (%)	16
Previous PCTA (%)	4
Current Smoker (%)	28
Diabetes mellitus (%)	17
Hypertension (%)	49

REVE Registry 6M Results

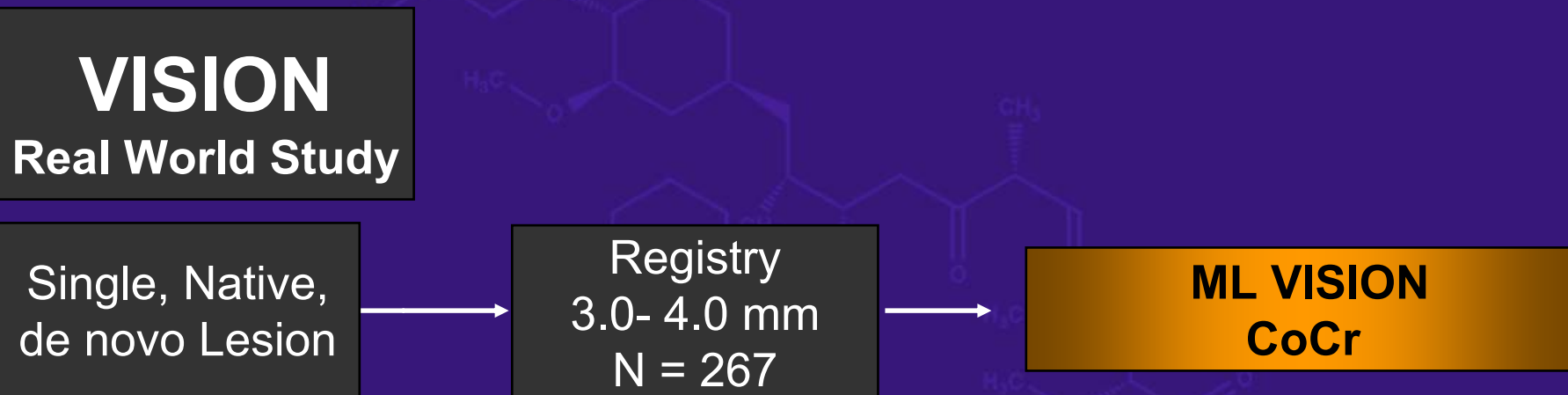
State of the Art Platform



■ ML VISION/MINI VISION, N = 518

ML VISION Registry Design

State of the Art Platform



- PI: Dean Kereiakes, MD
- **Primary end point: TVF at 6M**
- Stent Size: 3.0mm – 4.0 mm
- Stent Lengths: 8 mm-28 mm; mean: 17.2 mm
- 81% Angiographic Follow-Up

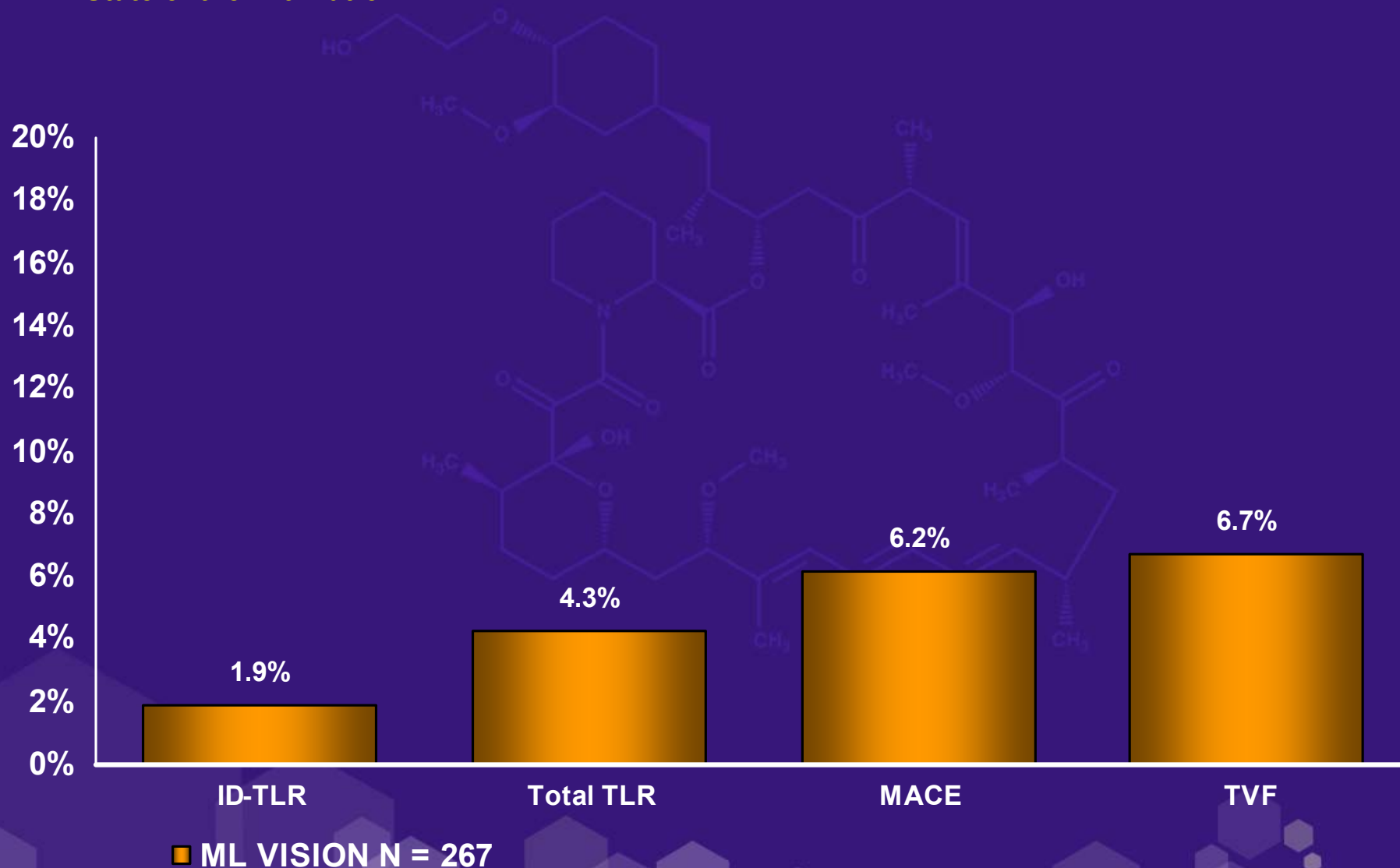
ML VISION Registry Baseline Demographics

State of the Art Platform

Male (%)	68
Mean age (years)	64
Previous MI (%)	33
Current Smoker (%)	24
Diabetes mellitus (%)	23
Hypercholesterolemia (%)	64
Hypertension (%)	61

ML VISION Registry 6M Results

State of the Art Platform



DaVinci Registry Design

State of the Art Platform

DaVinci Real World Study

Native de novo
Lesion \leq
30mm

Registry
2.75- 4.0 mm
N = 1,289

ML VISION
CoCr

- PI: Christian W. Hamm, MD
- Registry: Prospective, Internet Based
- **Primary end point: TVF at 9M**
- Stent Size: 2.75mm – 4.0 mm (mean 3.2 ± 0.3 mm)
- Stent Lengths: 8mm-28mm (mean 14.8 ± 4.8 mm)
- 88.1% Complex Lesions
- 98% Clinical F/U at 9M

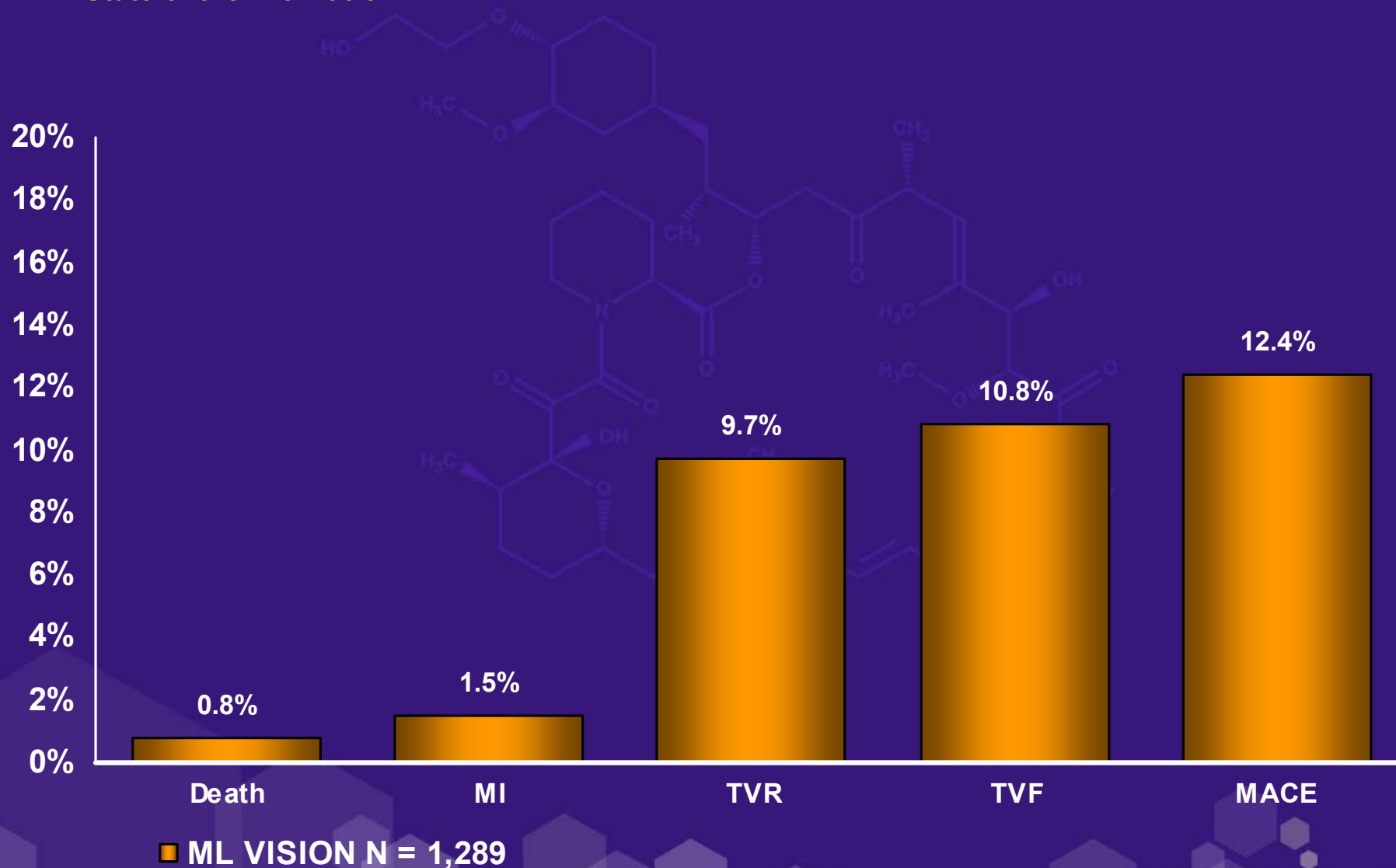
DaVinci Baseline Demographics

State of the Art Platform

Male (%)	76
Mean age (years)	66
Previous MI (%)	28
Previous PCI (%)	31
Current Smoker (%)	21
Diabetes mellitus (%)	26
Hypercholesterolemia (%)	84
Hypertension (%)	84

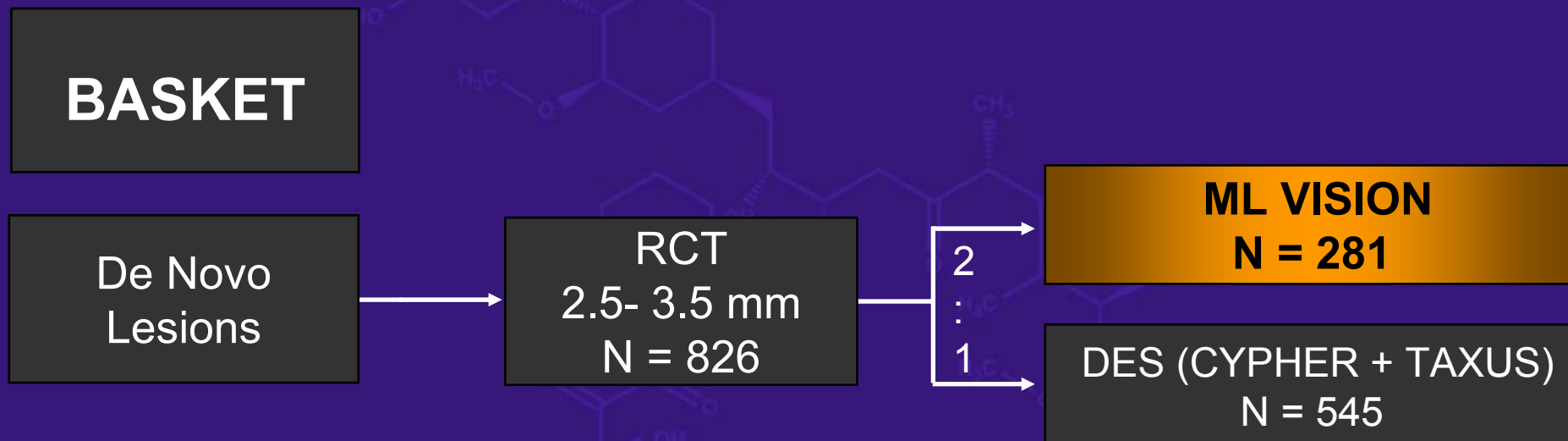
DaVinci Primary Endpoint: 9M TVF

State of the Art Platform



BASKET 6M Study Design

State of the Art Platform



- PI: Christoph Kaiser, MD
- RCT: Prospective, single blind
- **Primary end point: Cost Effectiveness after 6M w/ effectiveness defined as reduction of MACE**
- Stent Size: 2.5 – 3.5 mm; Stent lengths: 8 mm-32 mm
- 6 Months clopidogrel for all arms

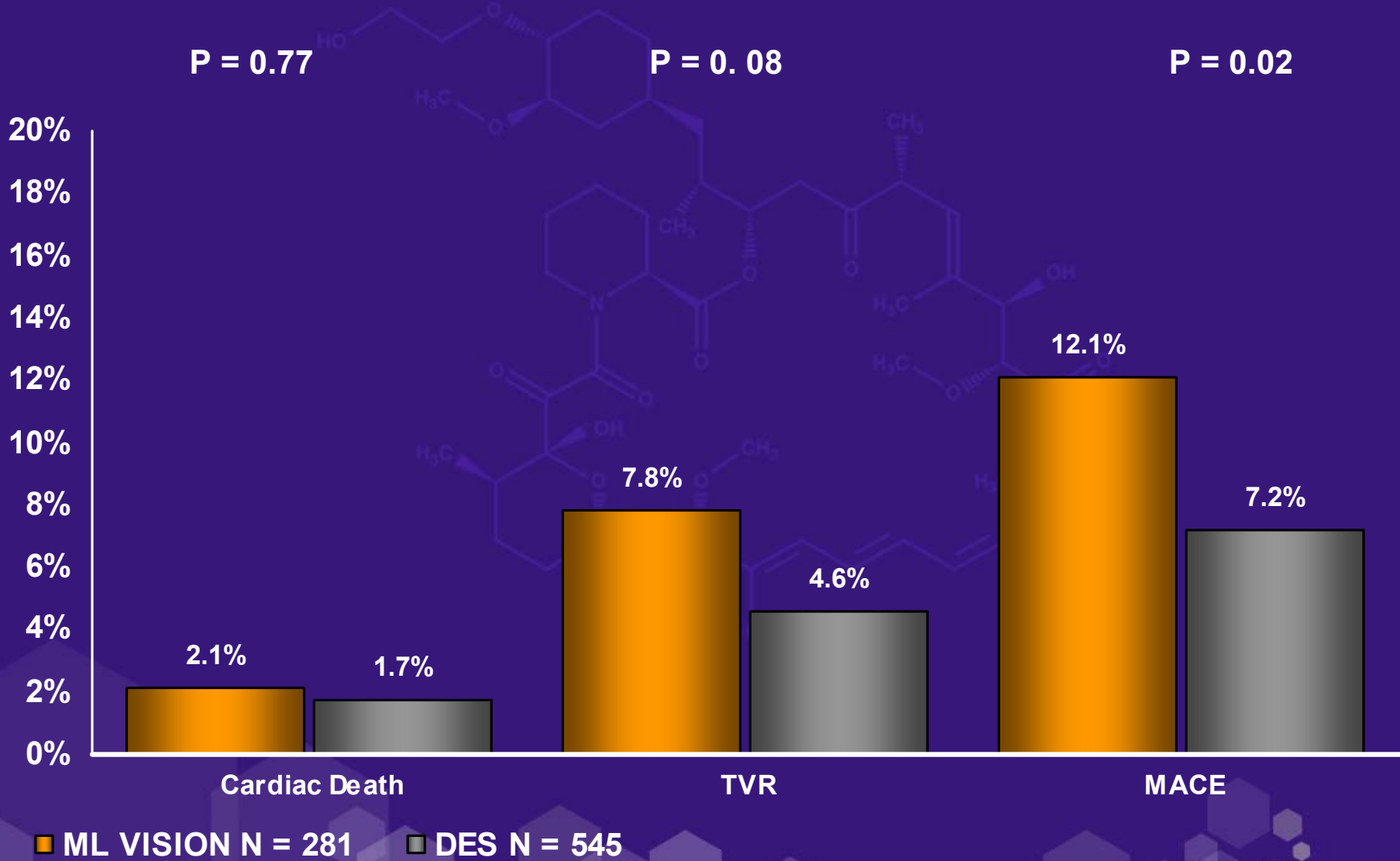
BASKET Baseline Demographics

State of the Art Platform

	DES 545 pts	ML VISION 281 pts
Male (%)	78	79
Mean age (years)	64	64
Previous MI (%)	28	27
Previous PCI (%)	17	15
Current Smoker (%)	27	31
Diabetes mellitus (%)	17	21
Hypercholesterolemia (%)	75	75
Hypertension (%)	65	68
Procedure success (%)	98	96

BASKET 6M Total Events

State of the Art Platform



SOURCE: Kaiser C et al. Lancet: v366 Sept 10, 2005 921-929

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RISICO Registry Design

State of the Art Platform

RISICO
Real World Study

Native, De
Novo Lesion

Registry
 $\leq 2.75\text{mm}$
N = 143

ML MINI-VISION
CoCr

- PI: Colombo A., MD
- Web based, Real World Registry
- **Primary end point: Angiographic success without MACE prior to hospital discharge**
- **Secondary Endpoint: MACE at 6M**
- RVD: ≤ 2.75 mm; Lesion lengths: 15 mm-23 mm

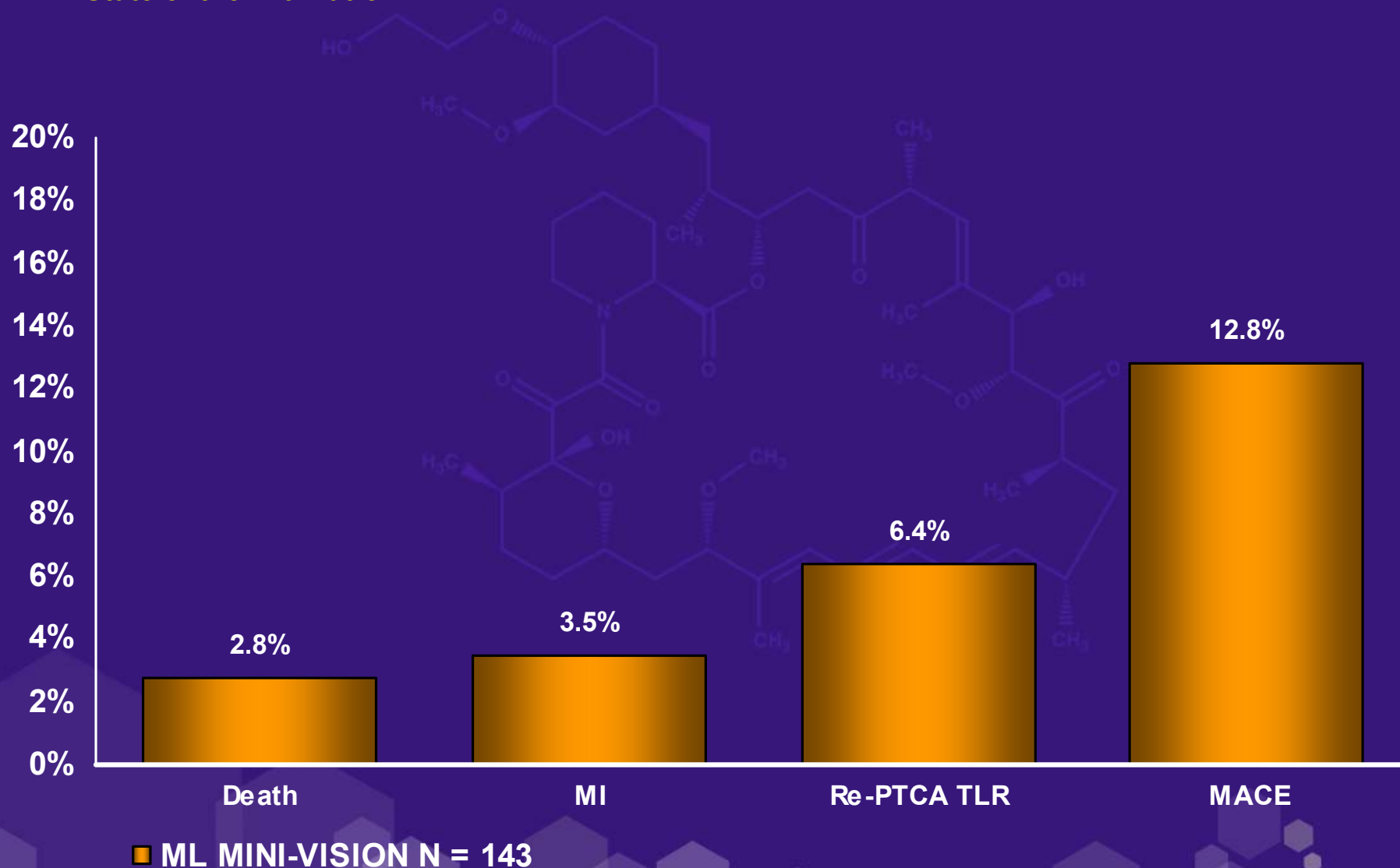
RISICO Baseline Demographics

State of the Art Platform

Male (%)	76
Mean age (years)	67
Previous MI (%)	12
Previous CABG or PCI (%)	22
Current Smoker (%)	22
Diabetes mellitus (%)	22
Hypercholesterolemia (%)	62
Hypertension (%)	70

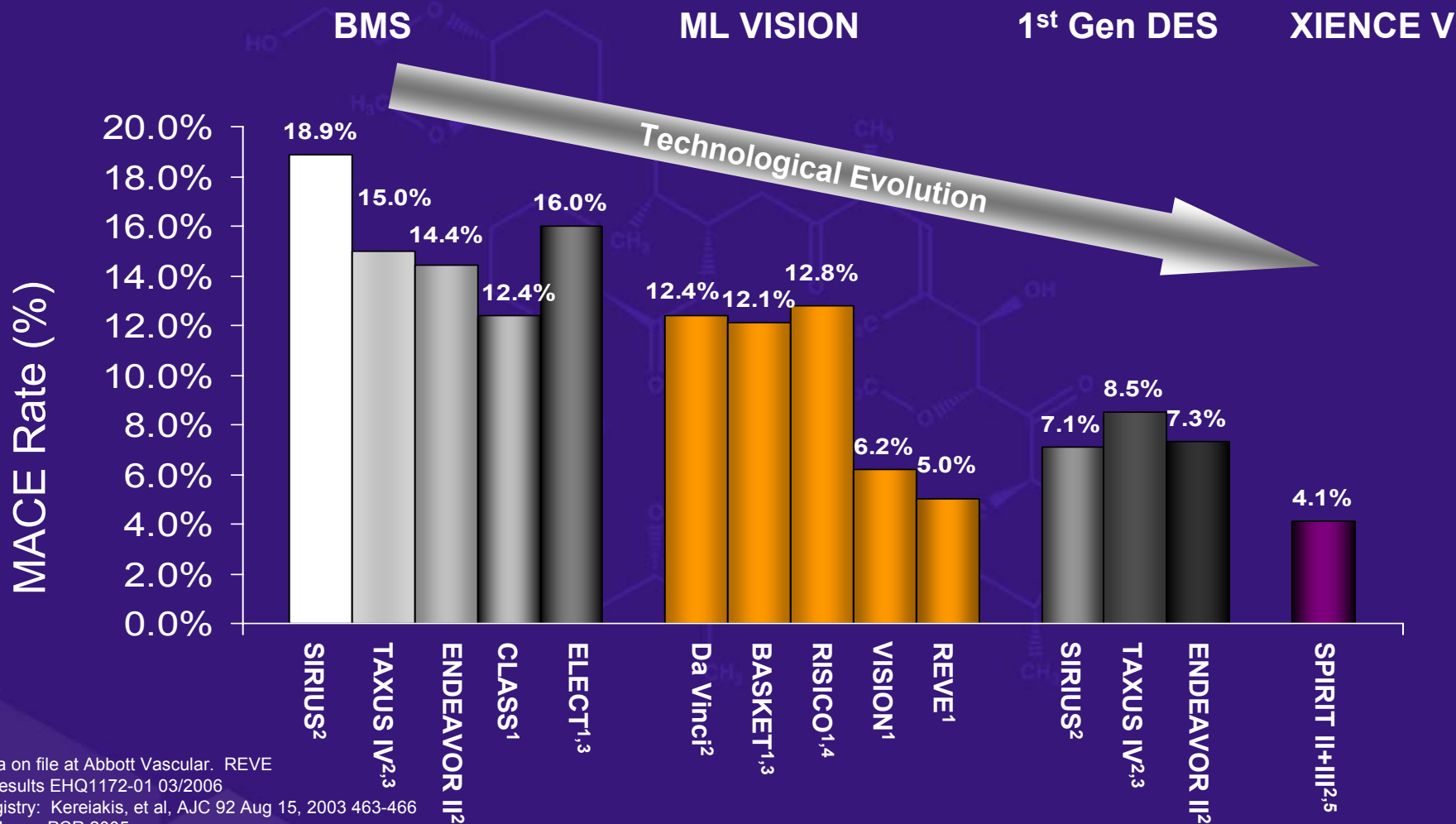
RISICO 6M Results

State of the Art Platform



MACE Results BMS/VISION/DES

State of the Art Platform



SOURCES:

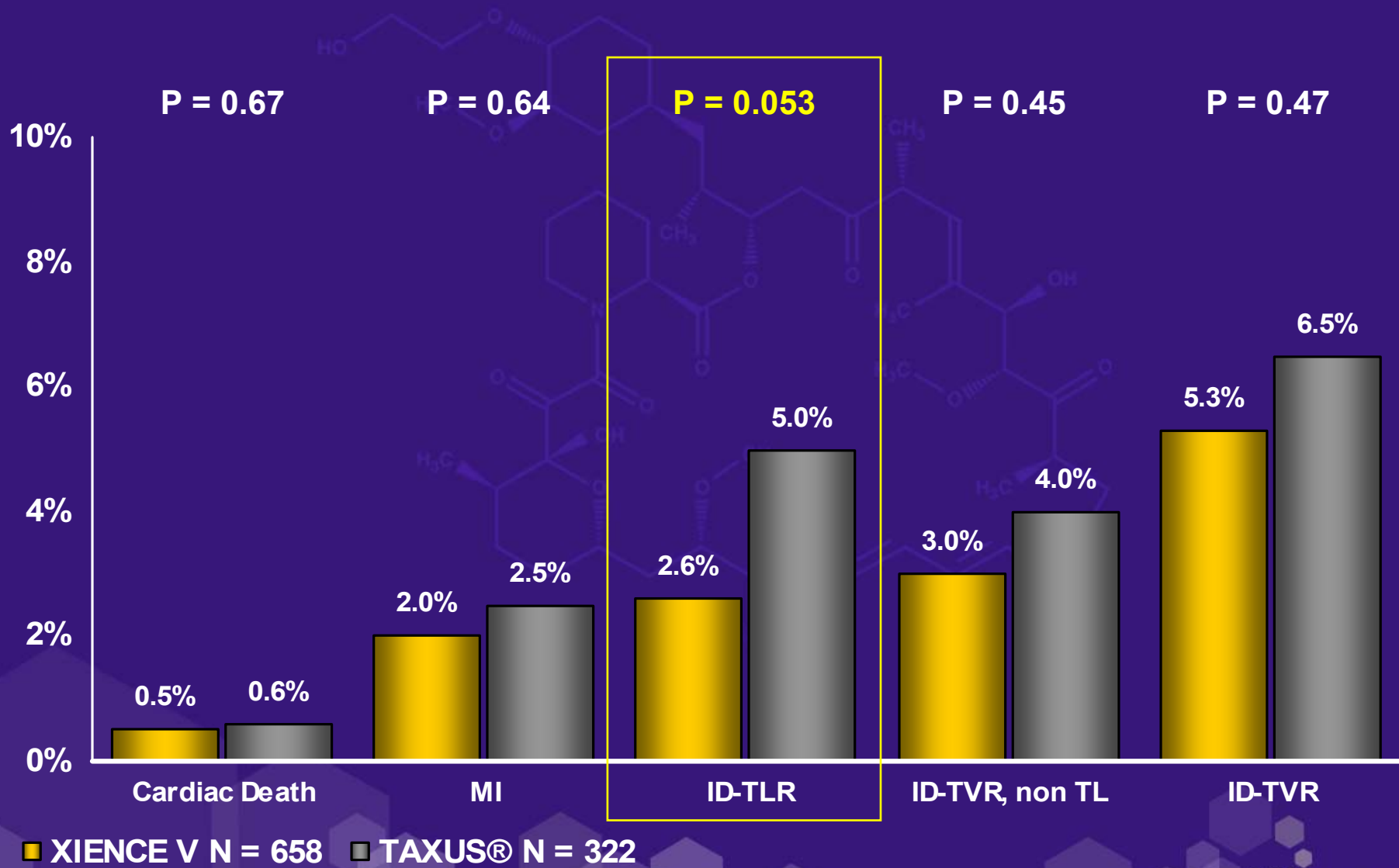
REVE: Data on file at Abbott Vascular. REVE Registry Results EHQ1172-01 03/2006
 VISION Registry: Kereiakis, et al, AJC 92 Aug 15, 2003 463-466
 DaVINCI: Hamm PCR 2005
 BASKET: Kaiser C., et al Lancet: v366 Sept 10, 2005 921-929
 RISICO Sangiorgi G., MD, Poster Presentation, GISE Congress, Italy, Oct06
 SIRIUS: Moses, et al, NEJM Oct 2, 2003 v349 #14
 TAXUS IV: Stone, et al, NEJM Vol. 350, No. 3, Jan 15, 2004
 ENDEAVOR II: Circulation. 2006; 114:798-806
 ELECT: Hermiller TCT 2004
 CLASS: AJC 2006; 97:349-352

MACE = Death, MI & TLR
¹ 6 month follow up
² 9 month follow up
³ MACE= Cardiac death, MI & TVR
⁴ MACE = Death, MI & TVR
⁵ MACE = Cardiac Death, MI & ID-TLR

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Xience V

SPIRIT III 9M TVF Components



XIENCE V Stent Thrombosis Rates

Per Protocol Definitions



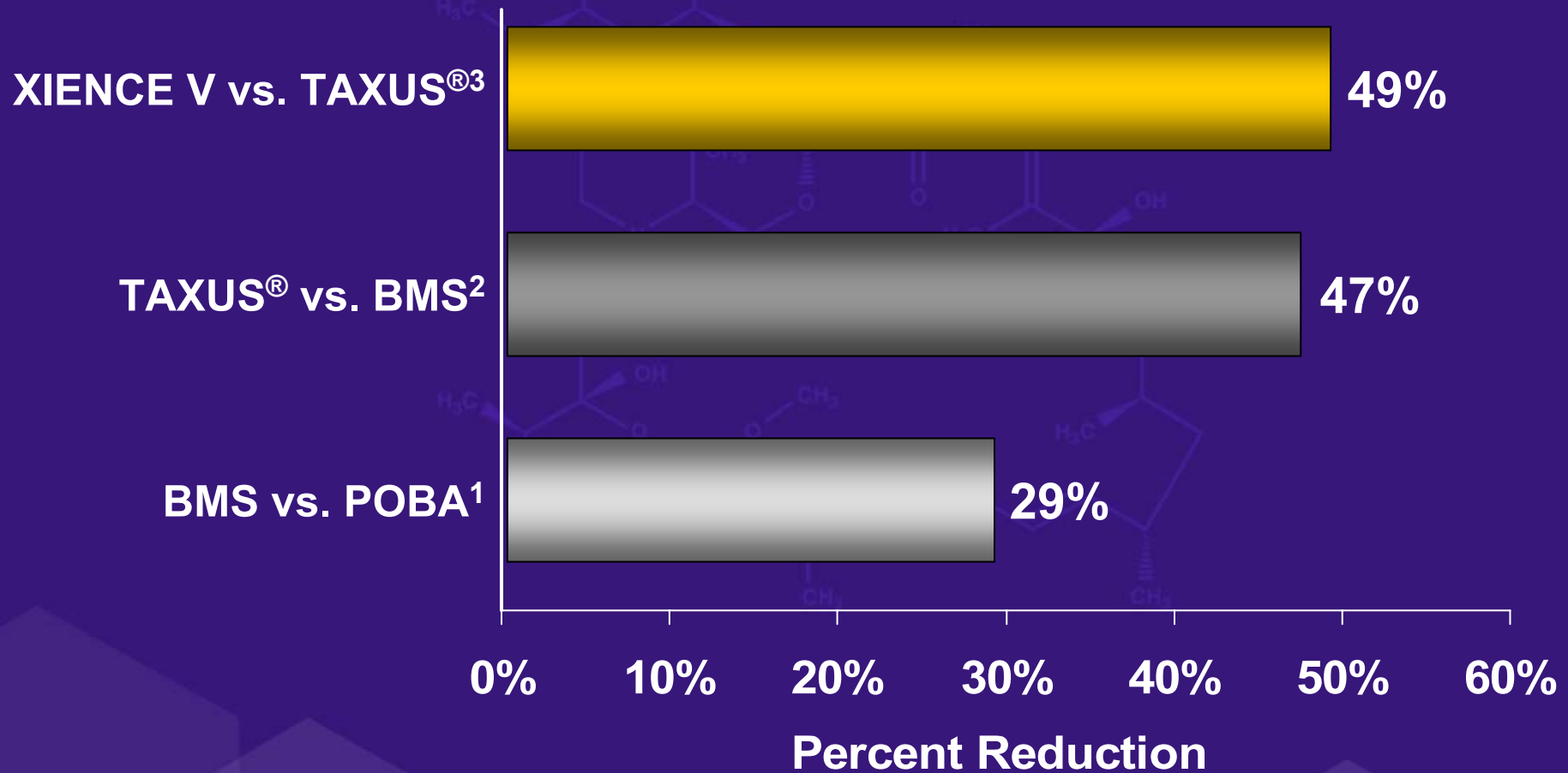
XIENCE V Stent Thrombosis Rates

Per ARC Definitions



Historical MACE Comparison

Historical MACE Reduction



SOURCES: 1) Suwaidi et al. American Heart Journal 2004; 147; 815-22.
2) Babapulle et al. Lancet 2004; 364: 583-91. 3) G.W. Stone, SPIRIT II + III Meta-Analysis, PCR 2007.

Appendix



BMS Body of Data

State of the Art Platform

**VIVE
Registry**

Post
Marketing
Study of ML
VISON

China
N = 429

Death, MI &
TLR

**Da Vinci
Registry**

Post
Marketing
Study of ML
VISON

Germany
N = 1,289

Death, MI &
CABG or
PTCA in
any vessel

**Ortolani
Trial**

3rd Generation
BMS vs. 1st
Generation
DES

Italy
N = 104

No MACE
Results

**REVE
Registry**

Post Marketing
Study of ML
VISON

France
N = 518

Death, MI &
TLR

**VISION
Registry**

Pre-Market
Study of ML
VISON for
Safety &
Efficacy

US
N = 267

Death, MI &
TLR

**BASKET
6M**

3rd Generation
BMS vs. 1st
Generation
DES

Switzerland
N = 826

Cardiac Death,
MI & TVR

**RISICO
Registry**

Post
Marketing
Study of ML
MINI-VISON

Italy
N = 143

Death, MI &
TVR

VIVE Registry Design

State of the Art Platform

VIVE

Native, De
Novo Lesion or
Re-stenosed

Registry
2.25- 4.00mm
N = 429

ML VISION
CoCr

- PI: Huang Cong-xin., MD
- Web based, Real World Registry
- **Primary end point: 6M TLR**
- **Secondary Endpoint: SAE and MACE at 6M**
- Lesion length: 15 mm-23 mm

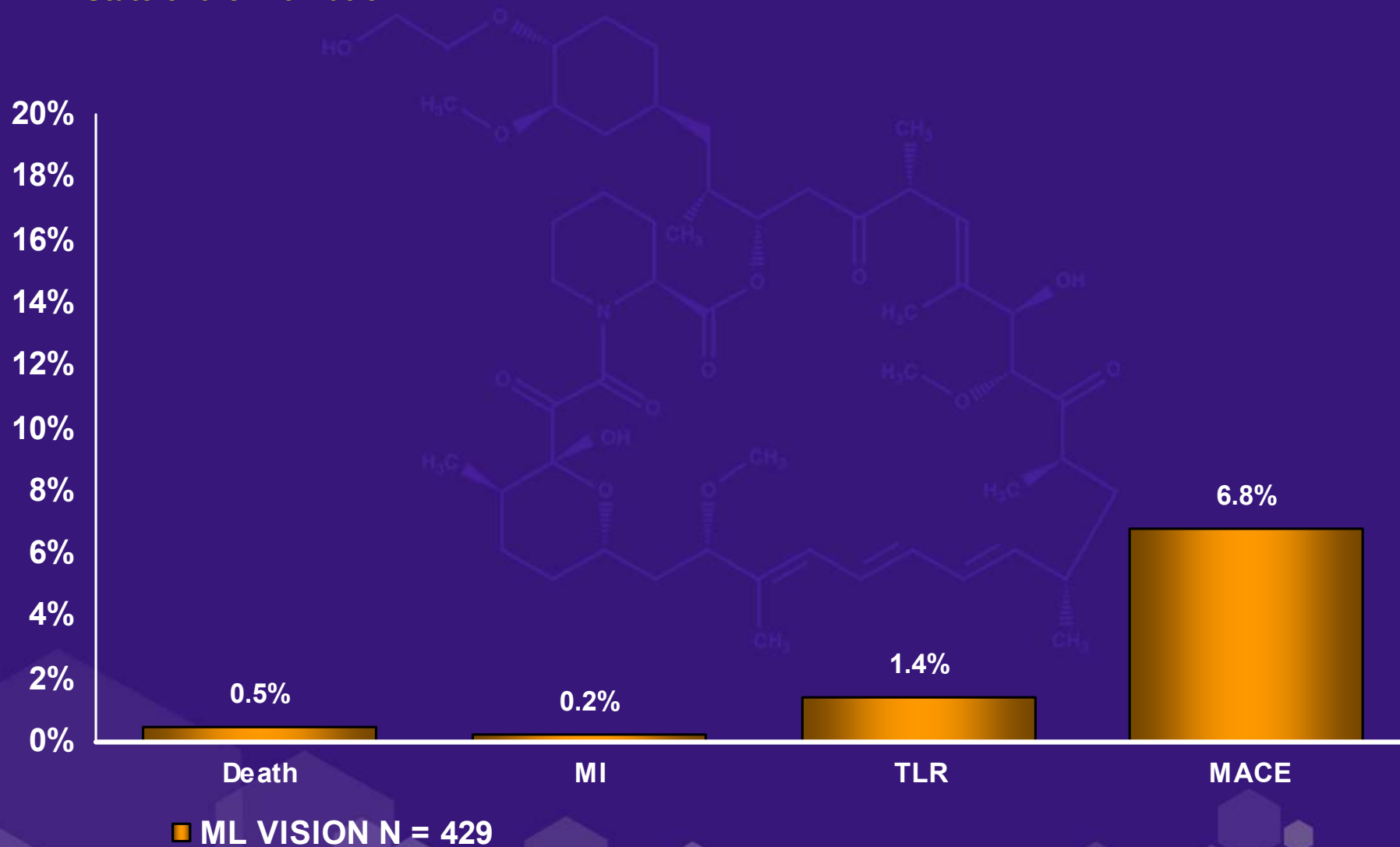
VIVE Baseline Demographics

State of the Art Platform

Male (%)	77
Mean age (years)	61
Previous MI (%)	35
Previous PCI (%)	10
Current Smoker (%)	28
Diabetes mellitus (%)	28
Hypercholesterolemia (%)	62
Multi Vessel Disease (%)	38

VIVE 6M Results

State of the Art Platform



BASKET 18M Study Design

State of the Art Platform

**BASKET
18M F/U**

826
Consecutive
Patients

RCT
2.5- 3.5 mm
N = 826

2
:
1

**ML VISION
N = 281**

DES (CYPHER + TAXUS)
N = 545

- PI: Christoph Kaiser, MD
- RCT: Prospective, single blind
- **Primary end point: Cost Effectiveness after 6M w/ effectiveness defined as reduction of MACE**
- Stent Size: 2.5 – 3.5 mm; Stent lengths: 8 mm-32 mm
- 6 Months clopidogrel for all arms

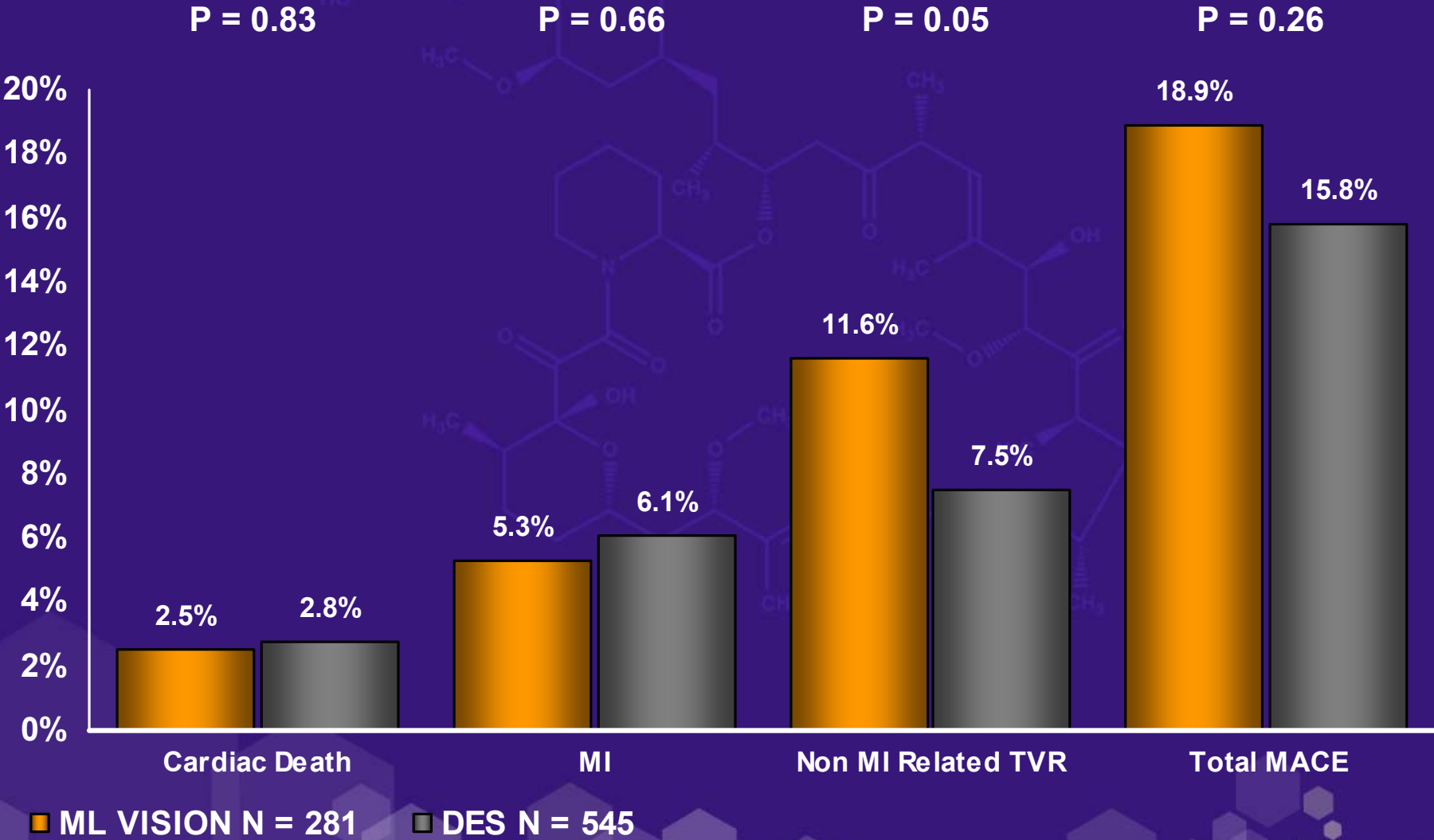
BASKET Baseline Demographics

State of the Art Platform

	DES 545 pts	ML VISION 281 pts
Male (%)	78	79
Mean age (years)	64	64
Previous MI (%)	28	27
Previous PCI (%)	17	15
Current Smoker (%)	27	31
Diabetes mellitus (%)	17	21
Hypercholesterolemia (%)	75	75
Hypertension (%)	65	68
Procedure success (%)	98	96

BASKET 18M Total Events

State of the Art Platform

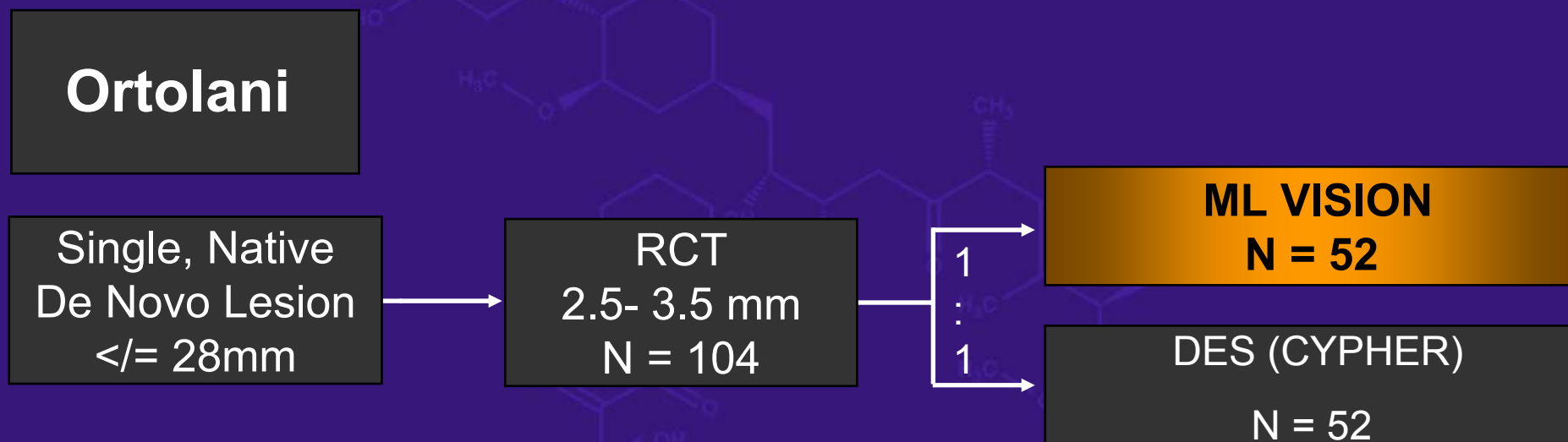


SOURCE: Kaiser C et al. ESC 2006

Ortolani Trial Design

State of the Art Platform

Ortolani



- PI: Ortolani P., MD
- RCT: Prospective, single blind
- **Primary end point: 9M In-Segment Late Loss**
- Stent Size: 2.5 – 3.5 mm; Stent lengths: 8mm-32mm
- 6 Months clopidogrel for all arms
- 94% Angiographic Follow-up

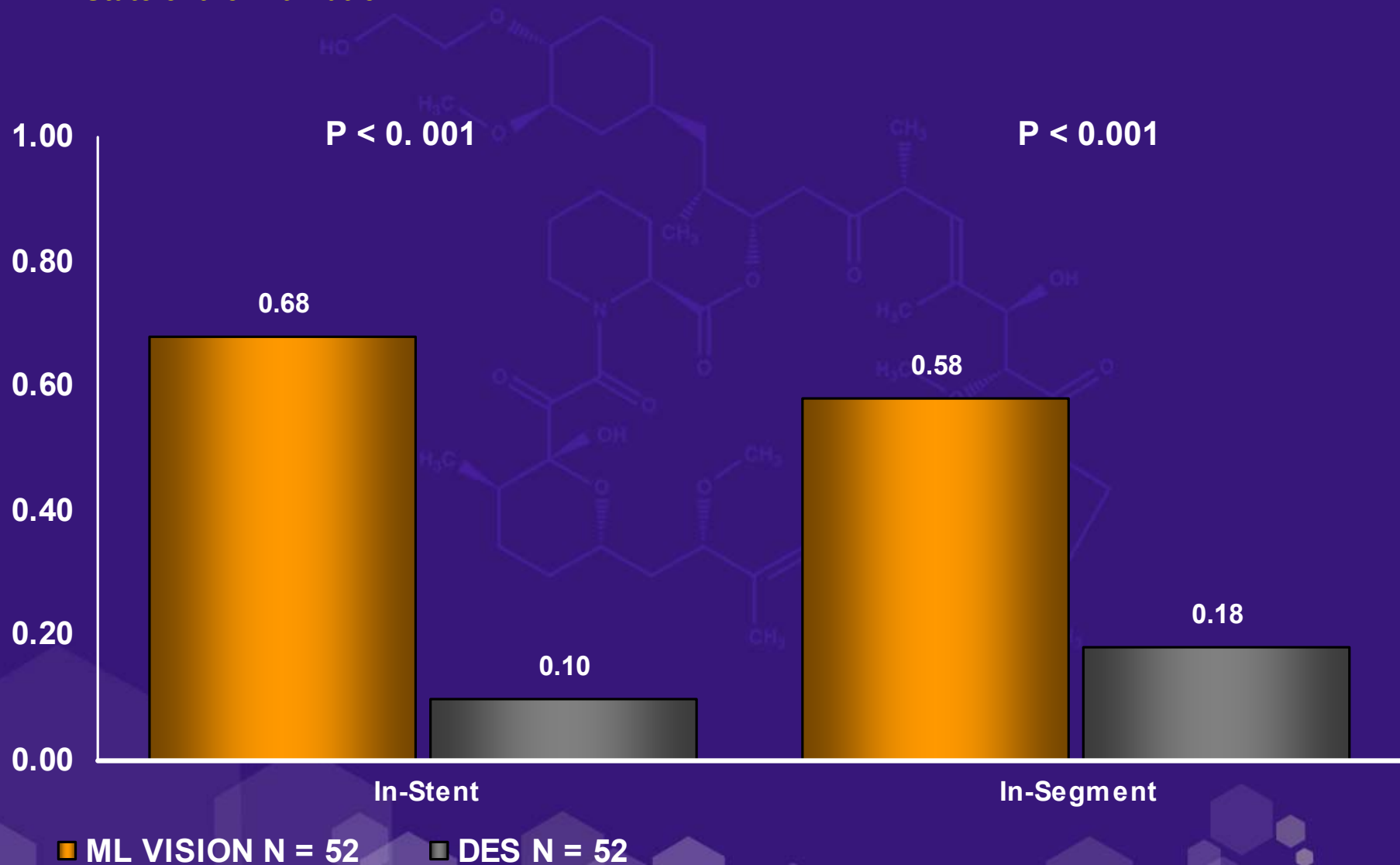
Ortolani Baseline Demographics

State of the Art Platform

	DES (CYPHER) 52 pts	BMS (ML VISION) 52 pts
Male (%)	73	79
Mean age (years)	65	66
Previous MI (%)	25	33
Previous PCI (%)	12	21
Current Smoker (%)	52	60
Diabetes mellitus (%)	15	17
Hypercholesterolemia (%)	79	81
Hypertension (%)	60	73
Procedure success (%)	98	98

Ortolani Trial 9M Late Loss

State of the Art Platform



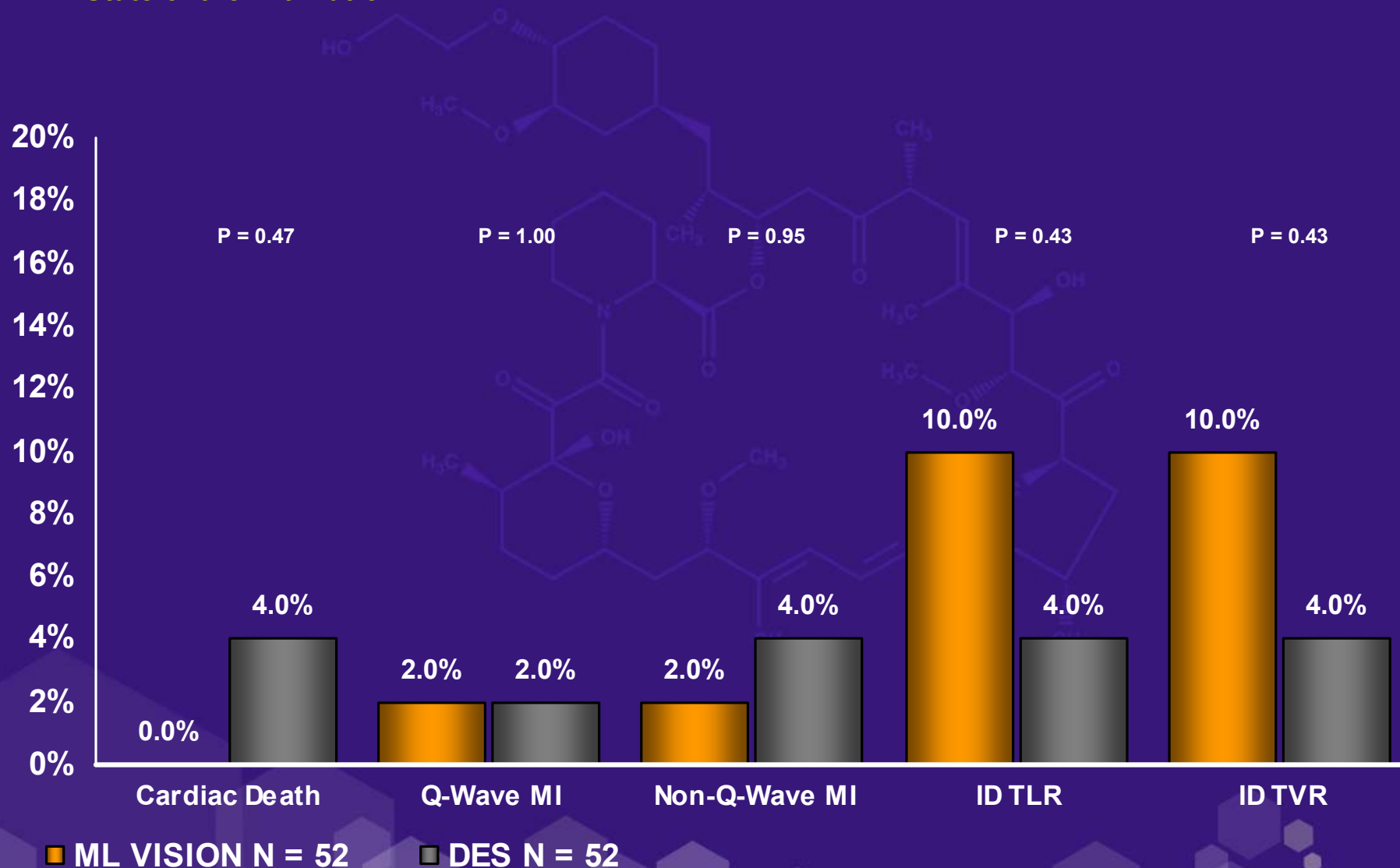
Source: Ortolani, P., et al., CCI., 69:790-798 2007 Moliterno, D., CCI 69:799-800 2007

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Xience V

Ortolani Trial 12M Results

State of the Art Platform

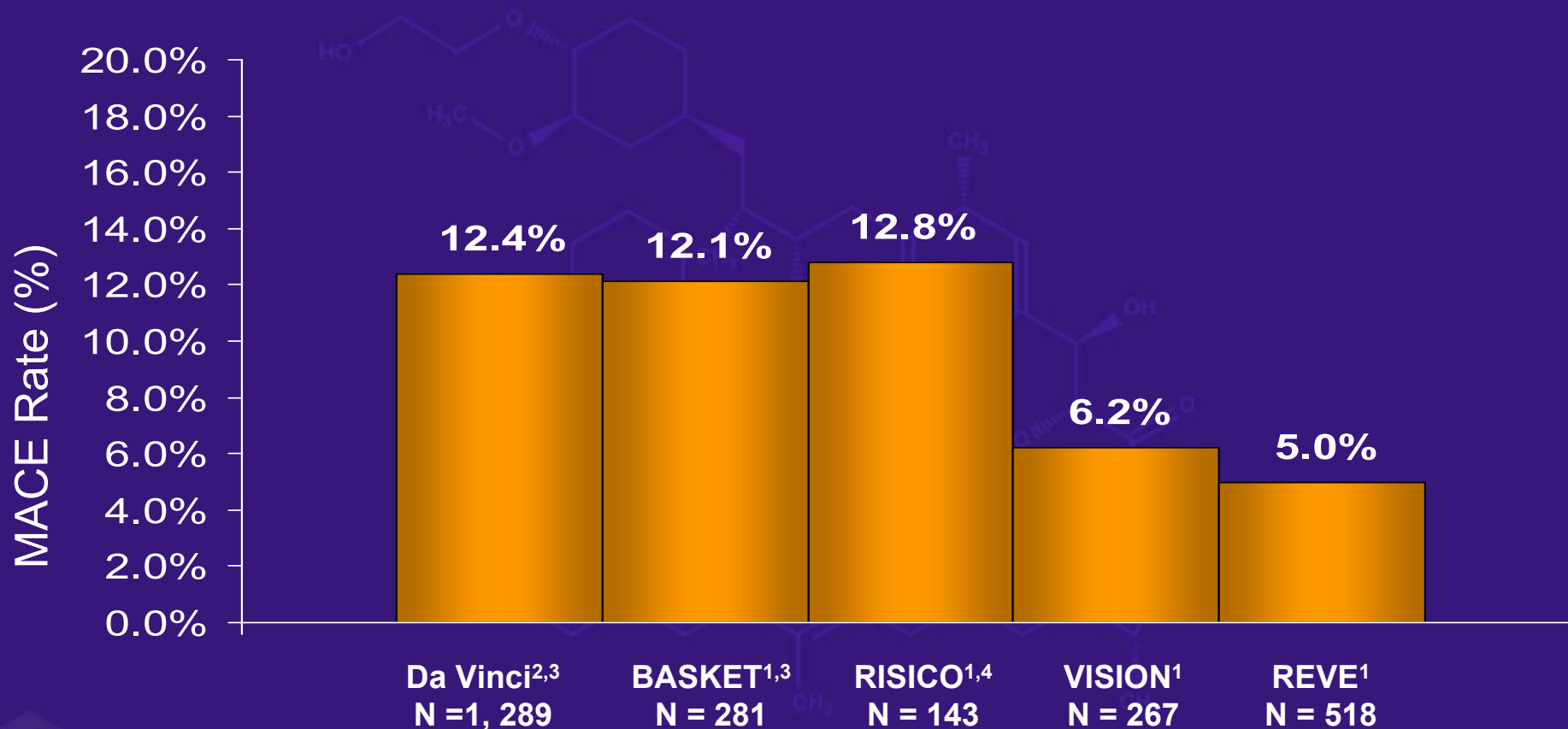


Source: Ortolani, P., et al., CCI., 69:790-798 2007 Moliterno, D., CCI 69:799-800 2007

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Xience V

MACE Results ML VISION



SOURCES:

- Da VINCI Registry , Hamm C., MD, EuroPCR05
- BASKET Trial, Kaiser C., MD Lancet 2005; 366:921-29
- RISICO Registry, Sangiorgi G., MD, Poster Presentation, GISE Congress, Italy, Oct06
- REVE Registry , Corcos T., MD, 8ème Congrès Francophone de Cardiologie interventionnelle, Paris, October 2006
- VISION Registry , Kereiakes D., MD, AJC v92: 463-466, Aug03

MACE = Death, MI & TLR

¹ 6 month follow up

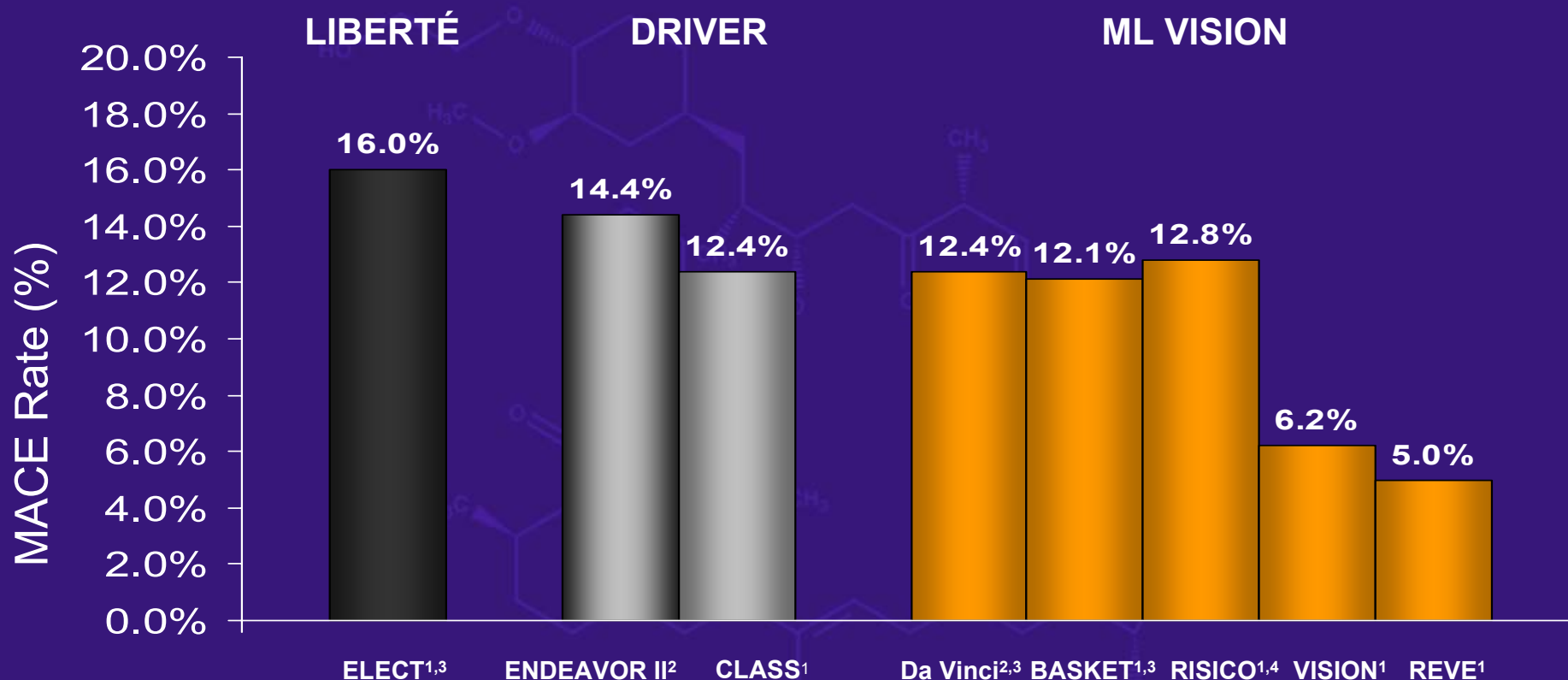
² 9 month follow up

³ MACE= Cardiac death, MI & TVR

⁴ MACE = Death, MI & TVR

Results from different clinical trials are not directly comparable. Information provided here for educational purpose only.

BMS MACE Results



SOURCES:

- Da VINCI Registry , Hamm C., MD, EuroPCR05
- BASKET Trial, Kaiser C., MD Lancet 2005; 366:921-29
- RISICO Registry, Sangiorgi G., MD, Poster Presentation, GISE Congress, Italy, Oct06
- REVE Registry , Corcos T., MD, 8ème Congrès Francophone de Cardiologie interventionnelle, Paris, Oct06
- VISION Registry, Kereiakes D., MD,, AJC v92: 463-466, Aug03
- ENDEAVOUR II: Circulation. 2006; 114:798-806
- ELECT, Hermiller, Presentation, TCT 2004 - CLASS: AJC 2006; 97:349-352

MACE = Death, MI & TLR

¹ 6 month follow up

² 9 month follow up

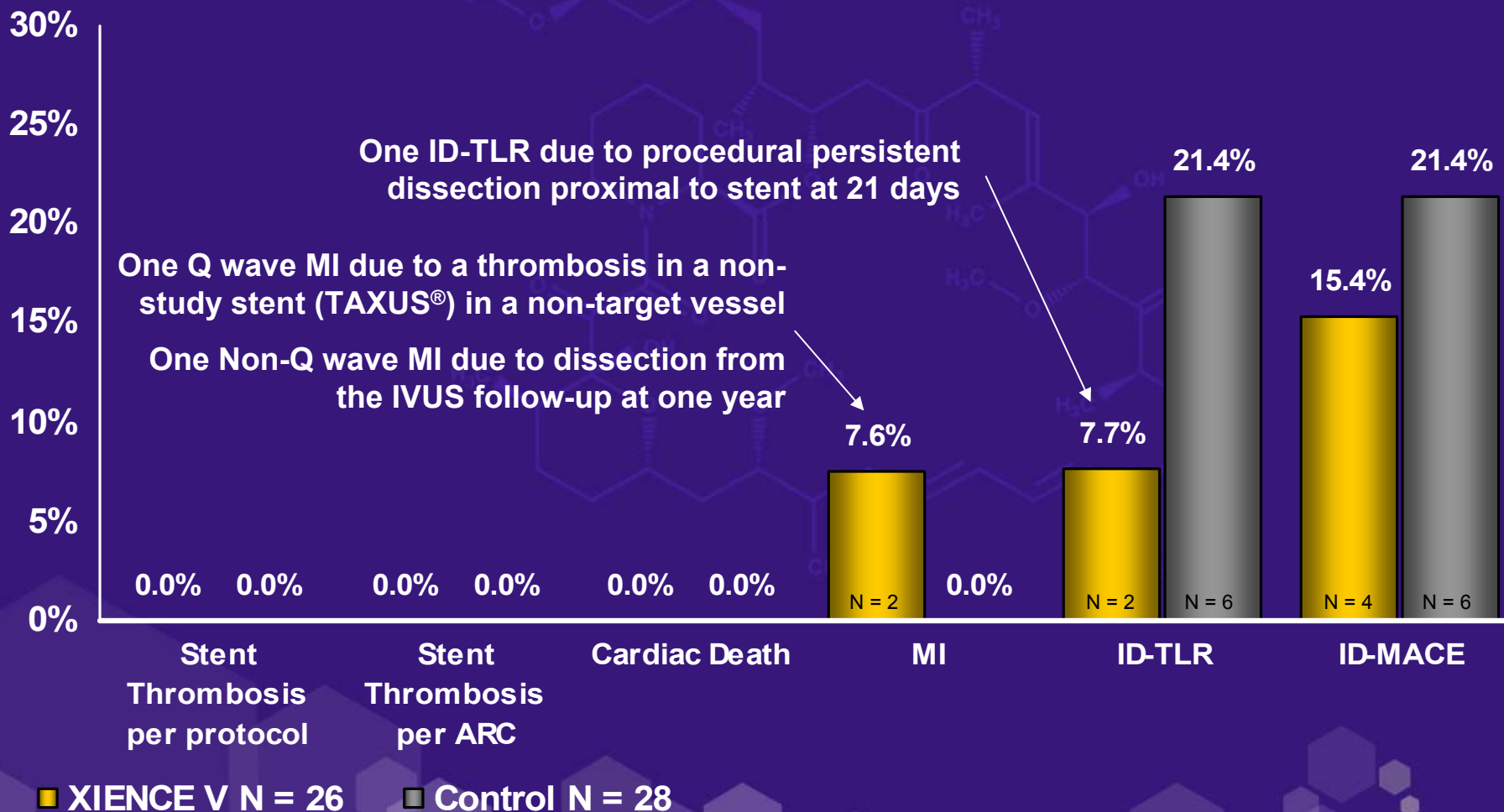
³ MACE= Cardiac death, MI & TVR

⁴ MACE = Death, MI & TVR

Results from different clinical trials are not directly comparable. Information provided here for educational purpose only.

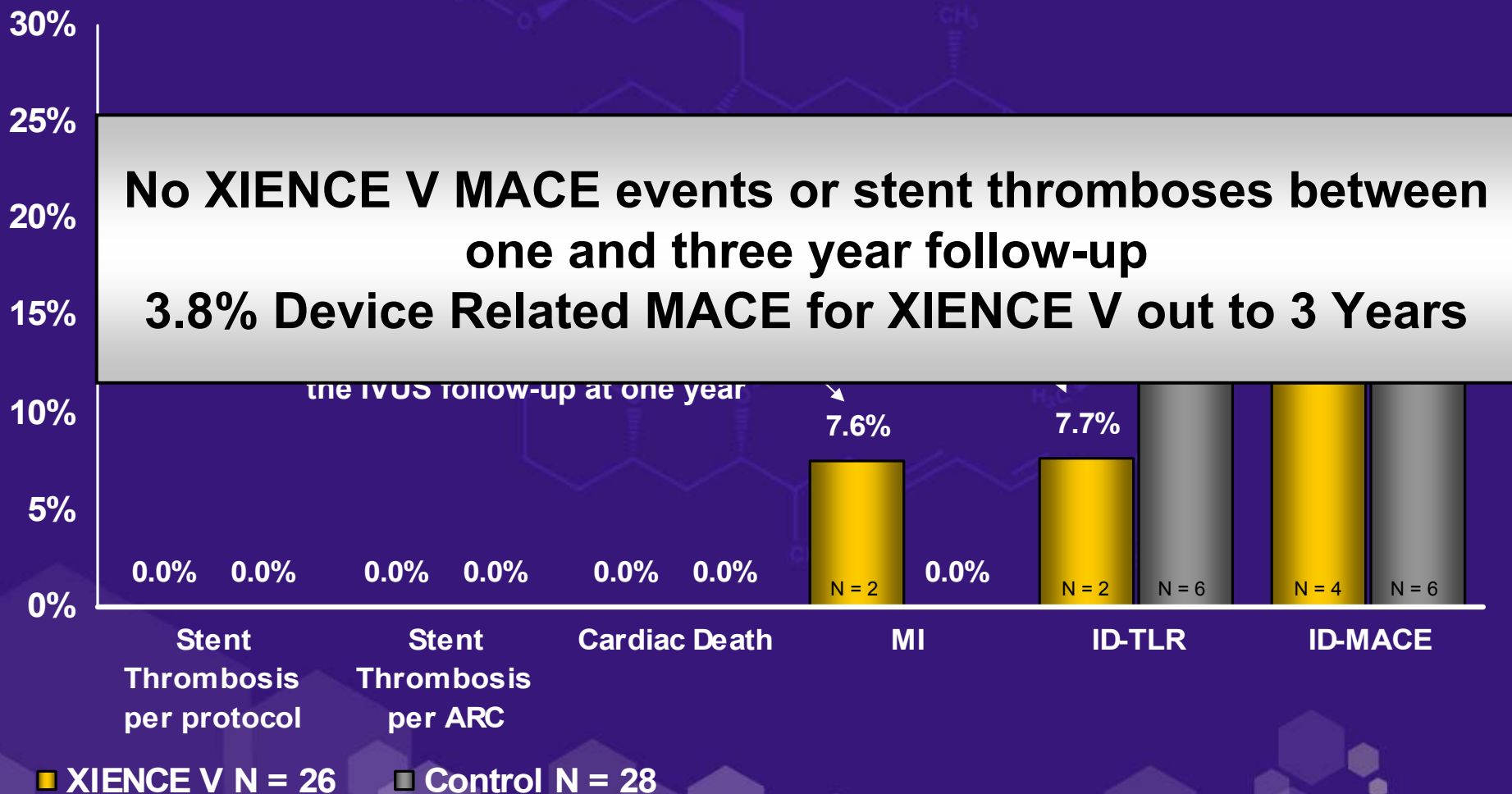
SPIRIT FIRST 12M Clinical Results

There were no significant differences between XIENCE V and Control



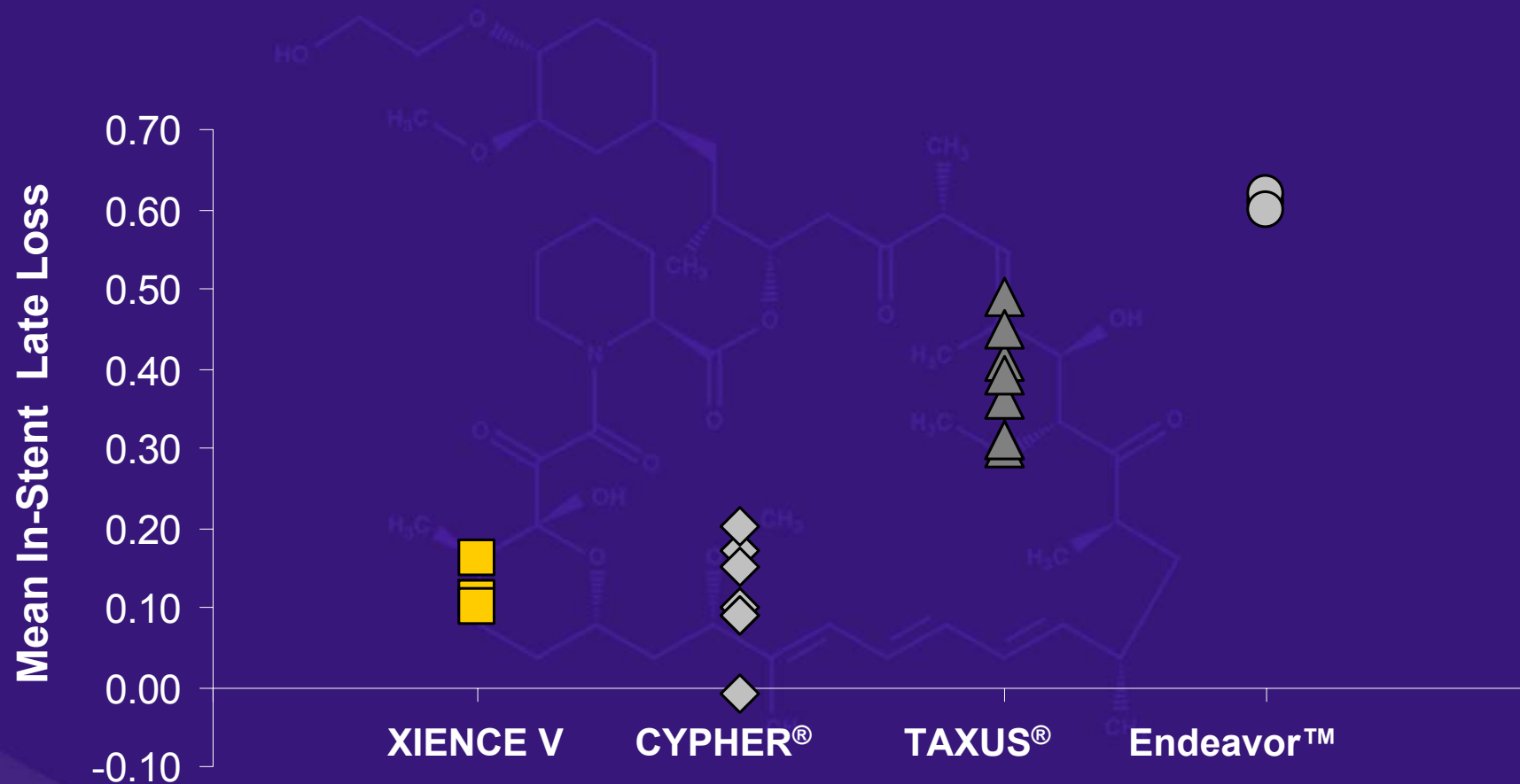
SPIRIT FIRST 12M Clinical Results

There were no significant differences between XIENCE V and Control



SOURCE: Tsuchida et al. *EuroIntervention* 2005 1:266-72. G.W. Stone, SPIRIT II + III Meta-Analysis, PCR 2007.

In-Stent Late Loss Across DES

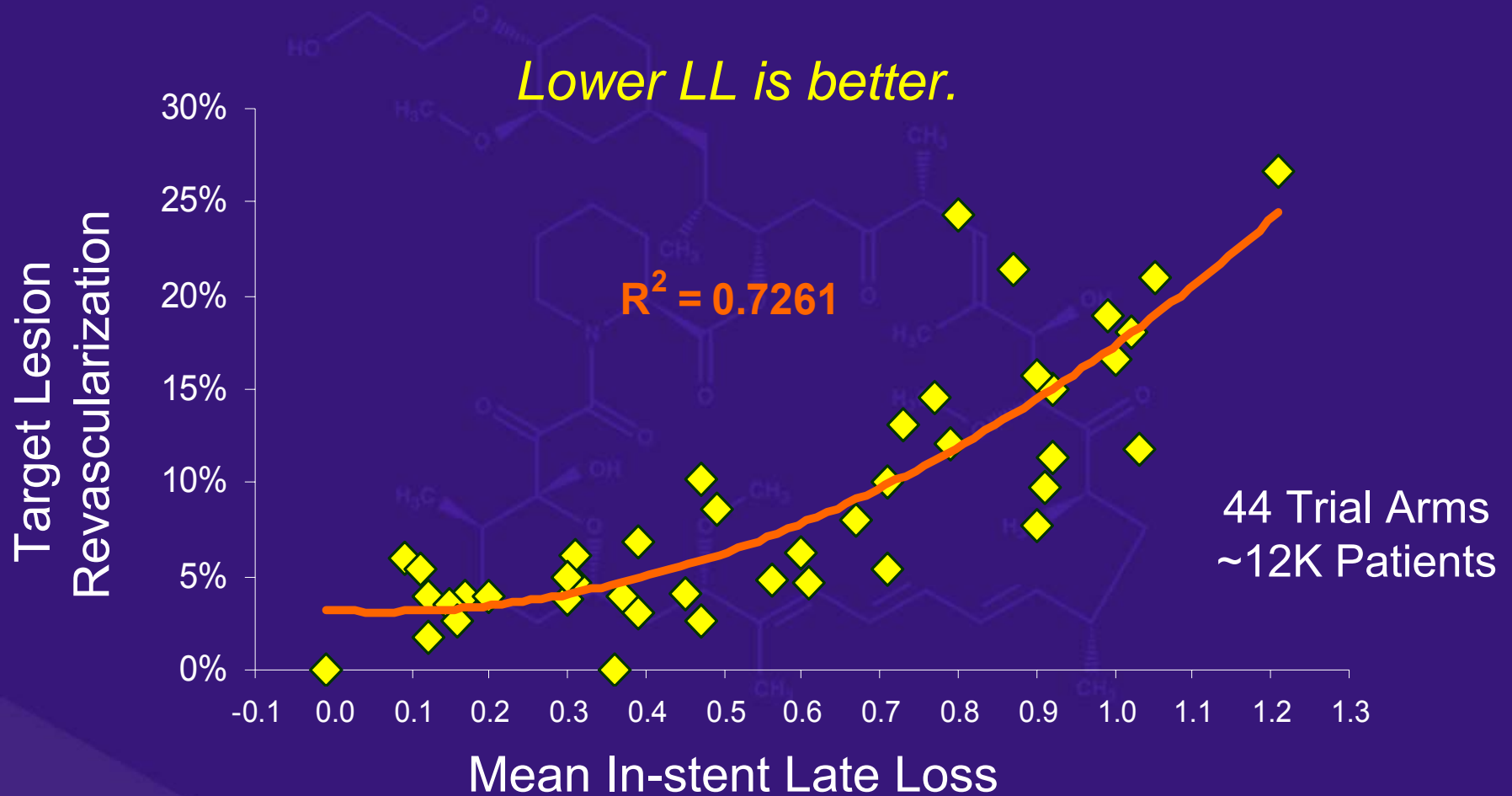


NOTE: Results from different clinical trials are not directly comparable. Information provided for educational purposes only.
SOURCE: In-Stent LL Endpoints for SPIRIT FIRST 6M, SPIRIT II, SPIRIT III, FIM, RAVEL, SIRIUS, C-SIRIUS, E-SIRIUS, TAXUS I, TAXUS II SR, TAXUS IV, TAXUS V, ATLAS, REALITY, ENDEAVOR I, ENDEAVOR II, ENDEAVOR III.

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Xience V

Late Loss vs. TLR Relationship



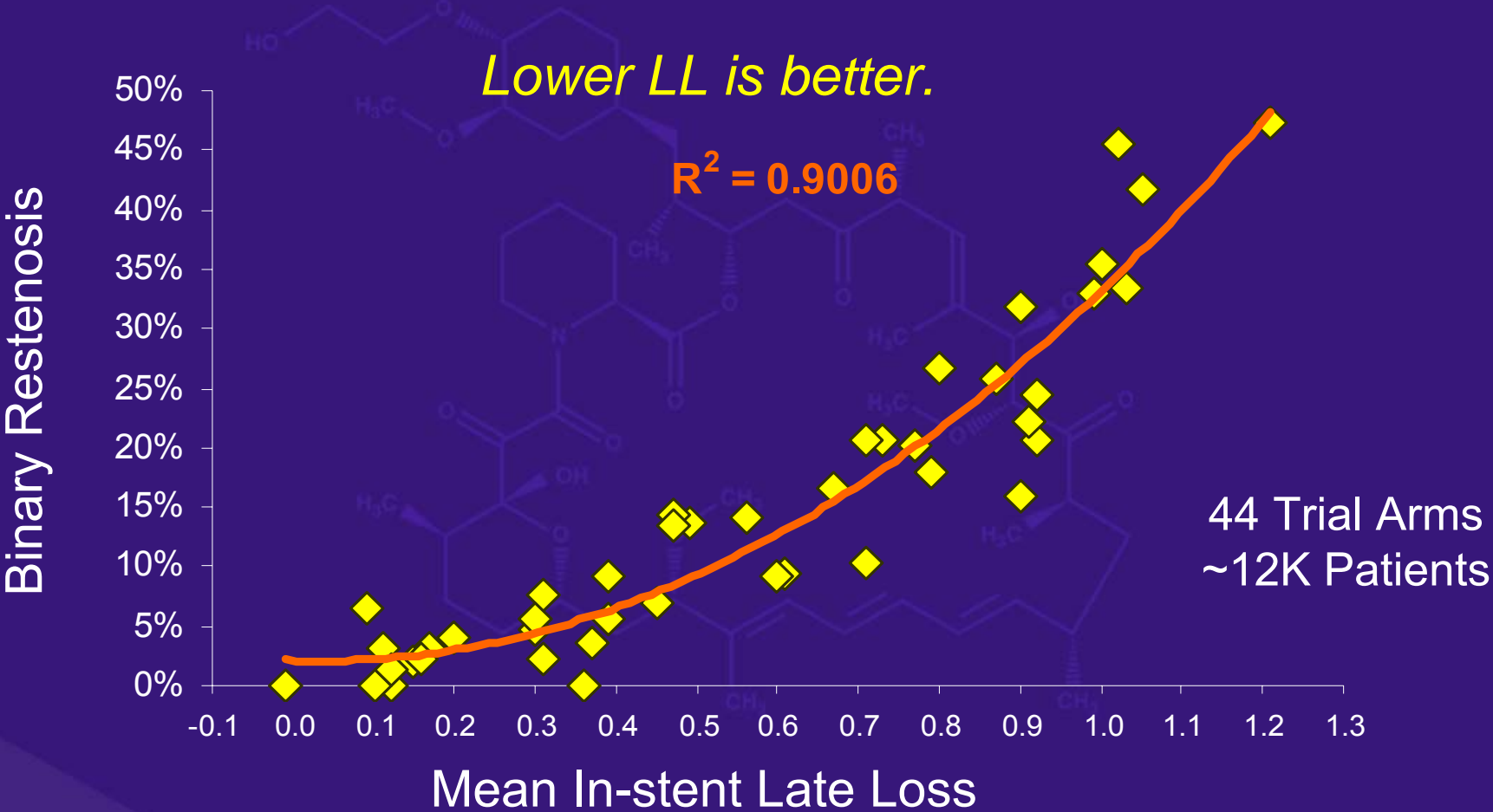
NOTE: Results from different clinical trials are not directly comparable. Information contained herein for educational purposes only.

SOURCES: GR-II, TAXUS I, TAXUS II, TAXUS IV, TAXUS V, TAXUS VI, ASCENT, REALITY, SIRIUS, RAVEL, E-SIRIUS, C-SIRIUS, ELUTES, ENDEAVOR II, ENDEAVOR III, ENDEAVOR II-CA, ZOMAXX I, SPIRIT I, SPIRIT II, SPIRIT III

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Xience V

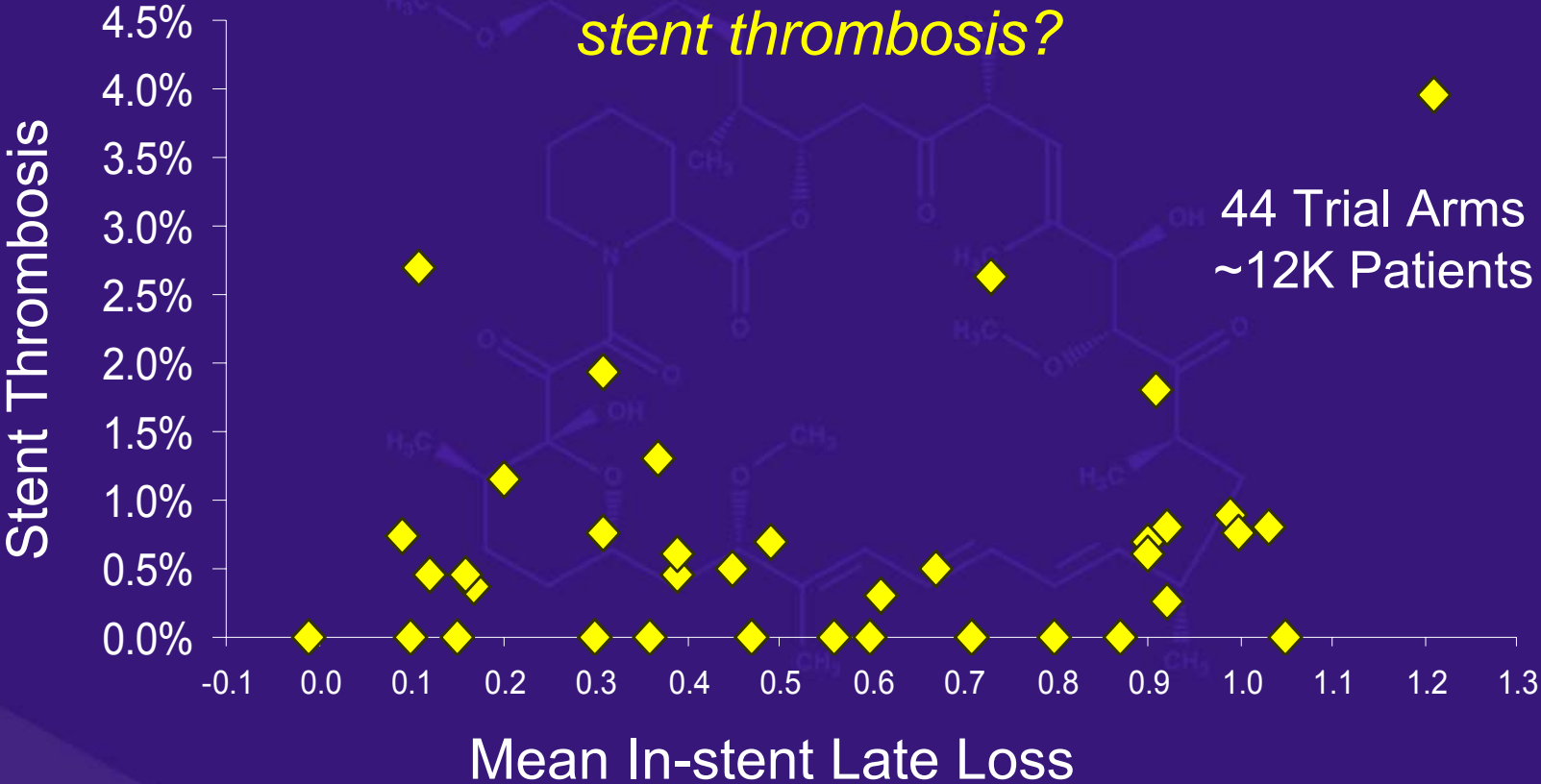
Late Loss vs. Restenosis Relationship



NOTE: Results from different clinical trials are not directly comparable. Information contained herein for educational purposes only.
SOURCES: GR-II, TAXUS I, TAXUS II, TAXUS IV, TAXUS V, TAXUS VI, ASCENT, REALITY, SIRIUS, RAVEL, E-SIRIUS, C-SIRIUS, ELUTES, ENDEAVOR II, ENDEAVOR III, ENDEAVOR II-CA, ZOMAXX I, SPIRIT I, SPIRIT II, SPIRIT III

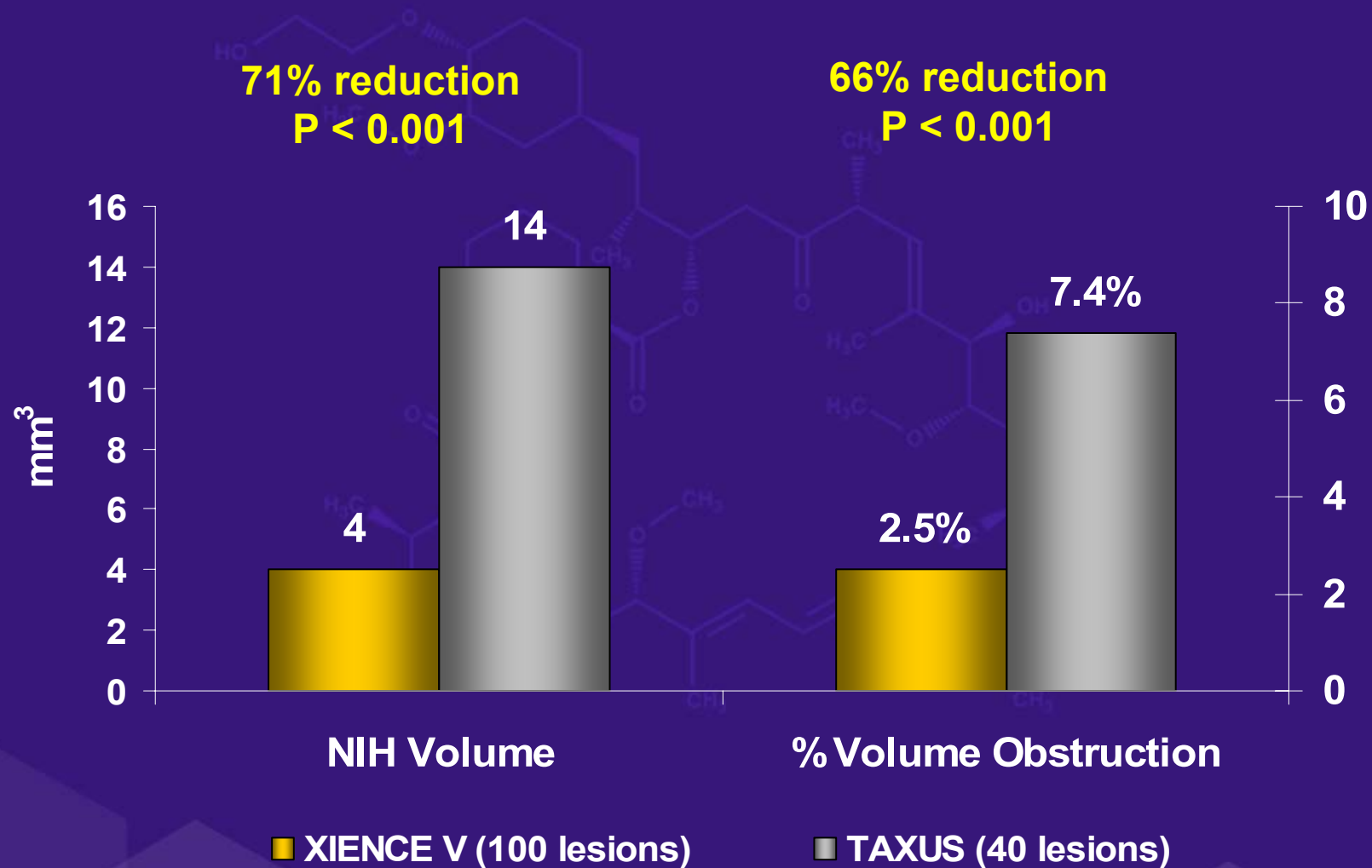
Late Loss vs. ST Relationship

Is there a relationship between LL and stent thrombosis?

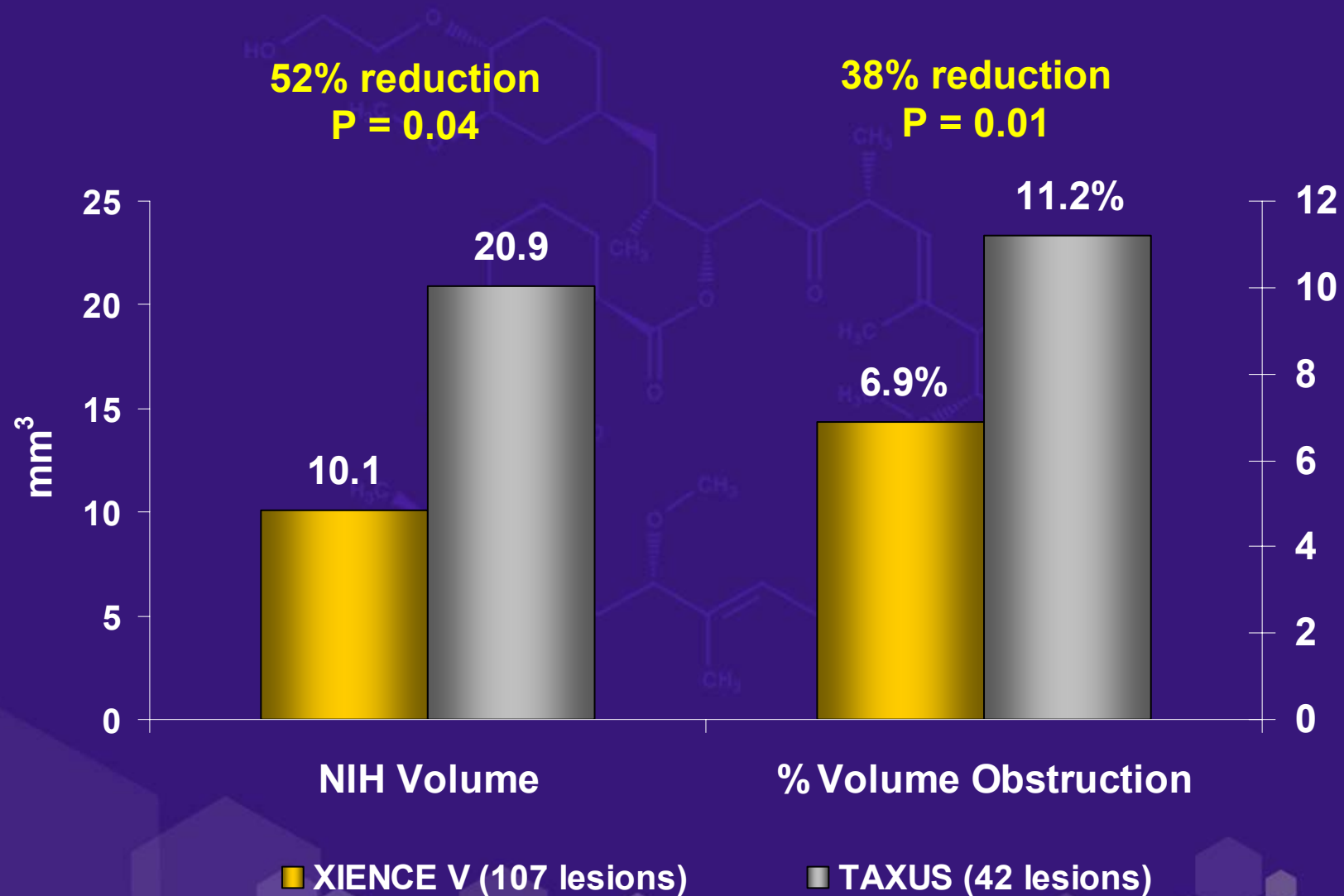


NOTE: Results from different clinical trials are not directly comparable. Information contained herein for educational purposes only.
SOURCES: GR-II, TAXUS I, TAXUS II, TAXUS IV, TAXUS V, TAXUS VI, ASCENT, REALITY, SIRIUS, RAVEL, E-SIRIUS, C-SIRIUS, ELUTES, ENDEAVOR II, ENDEAVOR III, ENDEAVOR II-CA, ZOMAXX I, SPIRIT I, SPIRIT II, SPIRIT III

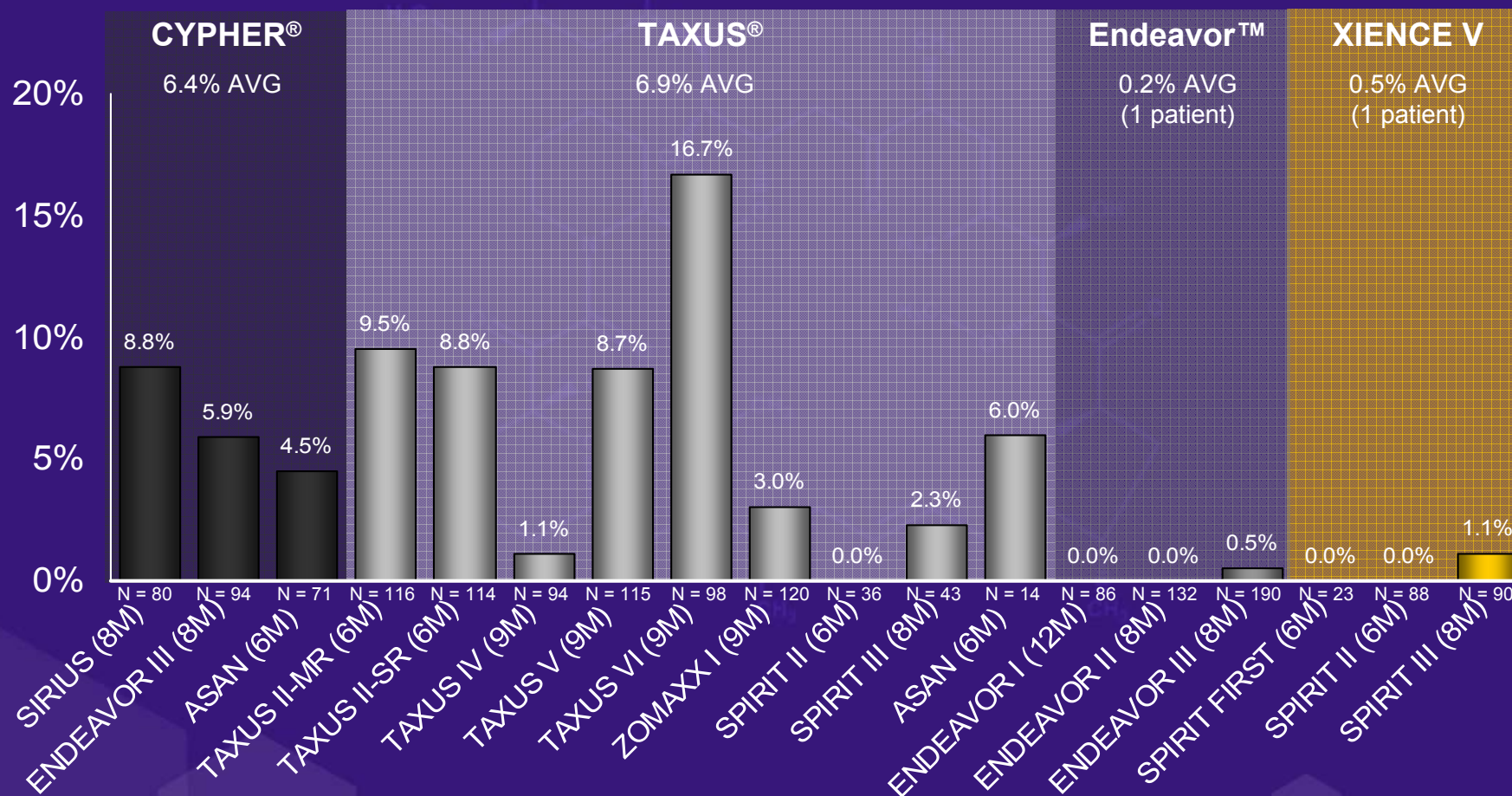
SPIRIT II IVUS Results



SPIRIT III IVUS Results



Late Acquired Incomplete Apposition Rates



Note: Results from different clinical trials are not directly comparable. Information contained herein for educational purposes only.

SOURCE: SIRIUS, ASAN, TAXUS II, TAXUS IV, TAXUS V, TAXUS VI, ENDEAVOR I, ENDEAVOR II, ENDEAVOR III, SPIRIT FIRST, SPIRIT II, and SPIRIT III.

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Xience V