

Mid America Heart Institute Experience

BMS vs. DES

CYPHER[®] vs. TAXUS[®]



Angioplasty
Summit
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SES vs. PES in De Novo Coronary Artery Lesions – The REALITY Trial: A Randomized, Controlled Trial

*Prospective, randomized trial, Aug 2003 – Feb 2004.
1386 pts, angiographic f/u at 8 months, clinical f/u to 12 months
Primary endpoint: In-lesion binary restenosis*

	SES (n=970 lesions)	PES (n=941 lesions)	p-value
Lesion length (mm)	10.96 ± 10.04	17.31 ± 10.09	NS
Total stent length (mm)	22.8 ± 11.8	23.5 ± 11.4	NS
Procedural success (%)	94.9	94.5	NS
8-Month F/U			
In-Stent RS (%)	7.0	8.3	NS
In-Lesion RS (%)	9.6	11.1	NS
In-Stent LL (mm)	0.09 ± 0.43	0.31 ± 0.44	< 0.001
In-Lesion LL (mm)	0.04 ± 0.38	0.16 ± 0.40	< 0.001

SES vs. PES in De Novo Coronary Artery Lesions – The REALITY Trial: A Randomized, Controlled Trial

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1386 pts, angiographic f/u at 8 months, clinical f/u to 12 months
Primary endpoint: In-lesion binary restenosis*

Clinical Events at 12 Months	SES (n = 684)	PES (n = 669)	p-value
Death (%)	2.3	1.3	NS
AMI (%)	5.1	6.0	NS
TLR (%)	6.0	6.1	NS
TVR (%)	2.0	1.8	NS
TVF (%)	12.0	12.9	NS
Stent Thrombosis (%)	0.7	1.9	0.06

SES vs. PES in Pts with CAD: Meta-Analysis of Randomized Trials

Review of six randomized trials, 3669 pts. Jan 2003-Apr 2006
Primary Endpoint: F/U TLR (6-8 months)

	SES (n = 1845)	PES (n = 1824)	OR	p-value
TLR (%)	5.1	7.8	0.64	0.001
Angiographic RS (%)	9.3	13.1	0.68	0.001
Stent Thrombosis (%)	0.9	1.1	0.85	0.62
Death (%)	1.4	1.6	0.85	0.56
Death or AMI (%)	4.9	5.8	0.84	0.23

Conclusion: Pts receiving SES vs. PES had significantly lower risk of RS and TLR

Safety and Efficacy of SES and PES

- ★ Pooled analysis of 4 double-blind trials of SES vs BMS in 1748 pts (RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS)
- ★ Pooled analysis of 5 double-blind trials of PES vs BMS in 3513 pts (TAXUS-I, II, III, IV, V, VI)
- ★ Analysis of Major Clinical Endpoints:

Baseline Data	SES	BMS	p-value	PES	BMS	p-value
Age (yrs)	61.9±11.1	61.9±10.7	NS	62.4±10.8	62.2±10.6	NS
Diabetes (%)	22.2	26.8	0.03	23.2	23.8	NS
RFD (mm)	2.72±0.45	2.72±0.48	NS	2.74±0.51	2.74±0.51	NS
Lesion Length (mm)	13.8±5.7	13.9±5.9	NS	15.1±7.9	15.1±8.0	NS
Total Stent Length (mm)	22.9±9.0	22.5±8.1	NS	24.4±11.2	24.1±11.1	NS

Safety and Efficacy of SES and PES

★ Clinical Outcomes at 4 years: Kaplan-Meier Estimate

Clinical Outcomes	SES	BMS	p-value	PES	BMS	p-value
Stent Thrombosis (%)	1.2	0.6	0.20	1.3	0.9	0.30
>1 - 4 yr post-proc	0.6	0	0.02	0.7	0.2	0.02
Death, all cause (%)	6.7	5.3	0.23	6.1	6.6	0.68
>1 - 4 yr post-proc	5.5	4.6	0.37	4.6	4.9	0.81
AMI (%)	6.4	6.2	0.86	7.0	6.3	0.66
>1 - 4 yr post-proc	2.8	2.2	0.43	2.8	1.8	0.15
TLR (%)	7.8	23.6	< 0.001	10.1	20.0	< 0.001
TVR (%)	12.1	27.5	< 0.001	17.2	24.7	< 0.001

★ Conclusion:

- ST after 1 yr more common in both SES and PES vs BMS.
- SES and PES associated with marked reduction in TLR
- No difference in rates of death or AMI

Outcomes of 6906 Pts Undergoing PCI in the DES Era: The DEScover Registry

★ January - June 2005, 140 medical centers

Outcomes at 1 Year	BMS N = 397	DES N = 6509	p-value
Death (%)	5.9	3.1	0.005
MI (%)	3.5	2.4	NS
Stent Thrombosis (%)	0.8	0.6	NS
Repeat PCI, Any (%)	9.3	8.4	NS
CABG (%)	3.5	1.4	0.0007
TVR (%)	9.5	6.0	0.007
Death/MI (%)	9.0	5.2	0.002

Outcomes of 6906 Pts Undergoing PCI in the DES Era: The DEScover Registry

★ January - June 2005, 140 medical centers

Outcomes	30-Days			1-Year		
	SES	PES	p-value	SES	PES	p-value
	N = 3873	N = 2636		N = 3873	N = 2636	
Death (%)	0.5	0.4	NS	3.3	2.8	NS
MI (%)	1.0	1.3	NS	2.2	2.6	NS
Stent Thrombosis (%)	0.3	0.4	NS	0.5	0.8	0.06
Repeat PCI, Any (%)	1.8	1.8	NS	8.7	7.9	NS
CABG (%)	0.2	0.4	0.07	1.3	1.5	NS
TVR (%)	1.0	1.2	NS	6.3	5.5	NS
Death/MI (%)	1.4	1.6	NS	5.2	5.3	NS



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Patient Demographics	DES N = 1437	BMS N = 4530	p-value
Age (yrs)	64.8 ± 13.0	65.2 ± 12.7	NS
Male (%)	64.1	67.3	0.02
Diabetes (%)	29.8	24.8	< 0.001
Dyslipidemia (%)	84.6	75.2	< 0.001
Renal Insufficiency (%)	8.5	8.6	NS
Prior AMI (%)	42.8	50.0	< 0.001
Prior PCI (%)	28.3	26.1	NS
Prior CABG (%)	15.7	13.7	NS
LVEF < 40% (%)	17.0	20.3	0.01
MVD (%)	69.6	64.7	< 0.001
Acute STEMI (%)	12.1	14.1	NS



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Procedural Characteristics	DES N = 1437	BMS N = 4530	p-value
Single Stent (%)	59.6	60.6	NS
Multiple Stents (%)	40.4	39.4	
Avg Stent Diameter (mm)	3.0 ± 0.3	3.2 ± 0.5	< 0.001
Total Stent Length (mm)	33.4 ± 20.9	27.6 ± 17.1	< 0.001
Avg Stent Length (mm)	19.8 ± 5.4	17.0 ± 5.5	< 0.01
Multiple Vessel Stenting (%)	14.6	8.6	< 0.001
Vessel Stented (%):			
LAD	49.2	43.3	< 0.01
LCX	22.4	18.4	
RCA	37.6	45.2	
SVG	3.9	3.0	
LMCA	2.9	0	



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Drug Eluting Stents: Dec. 2003-Dec. 2005

30-Day Outcomes	DES	BMS	p-value
	N = 1437	N = 4530	
Death (%)	20 (1.5)	76 (3.9)	< 0.001
AMI (%)	5 (0.4)	240 (14.3)	< 0.001
CABG (%)	5 (0.4)	31 (1.6)	0.001
TLR (%)	7 (0.5)	0	0.02
TVR (%)	15 (1.1)	53 (2.8)	0.002
SAT (%)	7 (0.5)	4 (0.2)	NS
Composite (%) (D, AMI, TVR, CABG)	42 (3.2)	212 (10.9)	< 0.001



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Patient Demographics	TAXUS N = 563	CYPHER N = 874	p-value
Age (yrs)	64.6 ± 13.9	64.9 ± 12.4	NS
Male (%)	61.3	65.9	0.07
Diabetes (%)	31.8	28.5	NS
Dyslipidemia (%)	83.7	85.2	NS
Renal Insufficiency (%)	9.8	7.7	NS
Prior AMI (%)	41.6	43.6	NS
Prior PCI (%)	35.3	23.8	< 0.001
Prior CABG (%)	19.2	13.4	0.003
LVEF < 40% (%)	16.3	17.5	NS
MVD (%)	69.4	69.7	NS
Acute STEMI (%)	11.0	12.8	NS
Bifurcation (%)	11.0	8.9	NS



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Procedural Characteristics	TAXUS N = 563	CYPHER N = 874	p-value
Single Stent (%)	49.6	69.6	0.005
Multiple Stents (%)	50.4	30.4	
Avg Stent Diameter (mm)	3.0 ± 0.3	3.0 ± 0.4	NS
Total Stent Length (mm)	34.8 ± 22.0	32.5 ± 20.0	0.04
Avg Stent Length (mm)	19.3 ± 5.7	20.2 ± 5.1	0.001
Stent Length > 30 mm (%)	48.4	39.1	< 0.001
Multiple Vessel Stenting (%)	19.5	11.4	< 0.001
Vessel Stented (%): LAD	46.2	51.1	NS
LCX	25.0	20.7	
RCA	37.8	37.5	
SVG	3.9	3.0	
LMCA	3.9	2.2	



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Drug Eluting Stents: Dec. 2003-Dec. 2005

30-Day Outcomes	TAXUS N = 563	CYPHER N = 874	p-value
Death (%)	11 (2.0)	9 (1.2)	NS
AMI (%)	3 (0.6)	7 (0.9)	NS
Q-Wave MI (%)	2 (0.4)	3 (0.4)	NS
Non Q-Wave MI (%)	1 (0.2)	4 (0.5)	NS
CABG (%)	3 (0.6)	2 (0.3)	NS
TLR (%)	4 (0.7)	3 (0.4)	NS
TVR (%)	8 (1.5)	7 (0.9)	NS
SAT (%)	5 (0.7)	2 (0.3)	NS
Composite (%) (D, AMI, TVR, CABG)	21 (3.8)	21 (2.7)	NS



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Drug Eluting Stents: Dec. 2003-Dec. 2005

12-Month Outcomes	TAXUS N = 563	CYPHER N = 874	p-value
Death (%)	28 (5.3)	35 (4.7)	NS
AMI (%)	14 (2.8)	12 (1.7)	NS
Q-Wave MI (%)	5 (1.0)	6 (0.7)	NS
Non Q-Wave MI (%)	9 (1.8)	6 (0.7)	NS
CABG (%)	7 (1.4)	4 (0.6)	NS
TLR (%)	22 (4.4)	18 (2.5)	0.07
TVR (%)	44 (8.7)	46 (6.4)	0.13
SAT (%)	10 (2.0)	3 (0.4)	0.009
Composite (%) (D, AMI, TVR, CABG)	74 (14.0)	82 (11.0)	NS



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Multiple Stent Use: TAXUS 563, CYPHER 874

One Year Outcomes	Multiple Stents N = 284	Single Stent N = 1153	p-value
Death (%)	20 (7.5)	43 (4.3)	0.03
AMI (%)	7 (2.8)	19 (2.0)	NS
Q-Wave MI (%)	4 (1.6)	7 (0.6)	NS
Non Q-Wave MI (%)	3 (1.2)	12 (1.2)	NS
CABG (%)	5 (2.0)	6 (0.6)	0.05
TLR (%)	16 (6.4)	24 (2.5)	0.002
TVR (%)	27 (10.8)	63 (6.5)	0.02
SAT (%)	7 (2.8)	6 (0.6)	0.008
Composite (%) (D, AMI, TVR, CABG)	47 (17.6)	109 (10.8)	0.003



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Diabetic Patients: TAXUS 563, CYPHER 874

One Year Outcomes	Diabetes N = 428	No Diabetes N = 1009	p-value
Death (%)	28 (7.3)	35 (3.9)	0.01
AMI (%)	10 (2.8)	16 (1.9)	0.30
Q-Wave MI (%)	1 (0.3)	7 (0.8)	0.45
Non Q-Wave MI (%)	7 (2.0)	8 (0.9)	0.15
CABG (%)	3 (0.8)	8 (0.9)	NS
TLR (%)	18 (5.1)	22 (2.6)	NS
TVR (%)	37 (10.3)	53 (6.1)	0.01
SAT (%)	4 (1.1)	9 (1.0)	NS
Composite (%) (D, AMI, TVR, CABG)	65 (17.1)	91 (10.2)	< 0.001



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Drug Eluting Stents: Dec. 2003-Dec. 2005

Multiple Vessel Stenting: TAXUS 563, CYPHER 874

1-Year Outcomes	Multiple Vessels N = 210	Single Vessel N = 1227	p-value
Death (%)	12 (6.3)	51 (4.7)	NS
AMI (%)	3 (1.7)	23 (2.2)	NS
Q-Wave MI (%)	2 (1.1)	9 (0.9)	NS
Non Q-Wave MI (%)	1 (0.6)	14 (1.4)	NS
CABG (%)	2 (1.1)	9 (0.9)	NS
TLR (%)	8 (4.5)	32 (3.1)	0.03
TVR (%)	24 (13.3)	66 (6.3)	0.001
SAT (%)	2 (1.1)	11 (1.1)	NS
Composite (%) (D, AMI, TVR, CABG)	34 (18.0)	122 (11.3)	0.009



Temporal Rates of Stent Thrombosis

	In-Hosp	30-d	3-mth	6-mth	9-mth	1-Year
CYPHER	0	2 (0.3)	2 (0.3)	2 (0.3)	3 (0.4)	3 (0.4)
TAXUS	2 (0.4)	4 (0.7)	5 (0.9)	8 (1.5)	10 (1.9)	10 (2.0)

Timing of Stent Thrombosis in the Real World: Comparison of Bare Metal vs Drug Eluting Stents

10,732 pts; January 1994-March 2006
9,637 with BMS, 926 with DES and 173 with both

Stent Thrombosis (ST)	BMS	DES	Total	p-value
Total	118 (0.12%)	22 (0.24%)	140	
Early (< 30d)	85 (72%)	11 (50%)	96	0.04
Late (30d-6 mths)	256 (22%)	1 (1%)	27	
Very Late (> 6 mths)	7 (6%)	10 (45%)	17	< 0.0001



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Drug Eluting Stents: TAXUS 563, CYPHER 874

Multivariate Predictors for Events at 1 Year

O.R.

p-value

For TVR

Total Stent Length 1.015 (1.003-1.027) 0.014

1 mm increase in length = 2% increase in TLR

10 mm increase in length = 15% increase in TLR

For TLR

Total Stent Length 1.020 (1.005-1.035) 0.008



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Drug Eluting Stents: TAXUS 563, CYPHER 874

Multivariate Predictors for Events at 1 Year

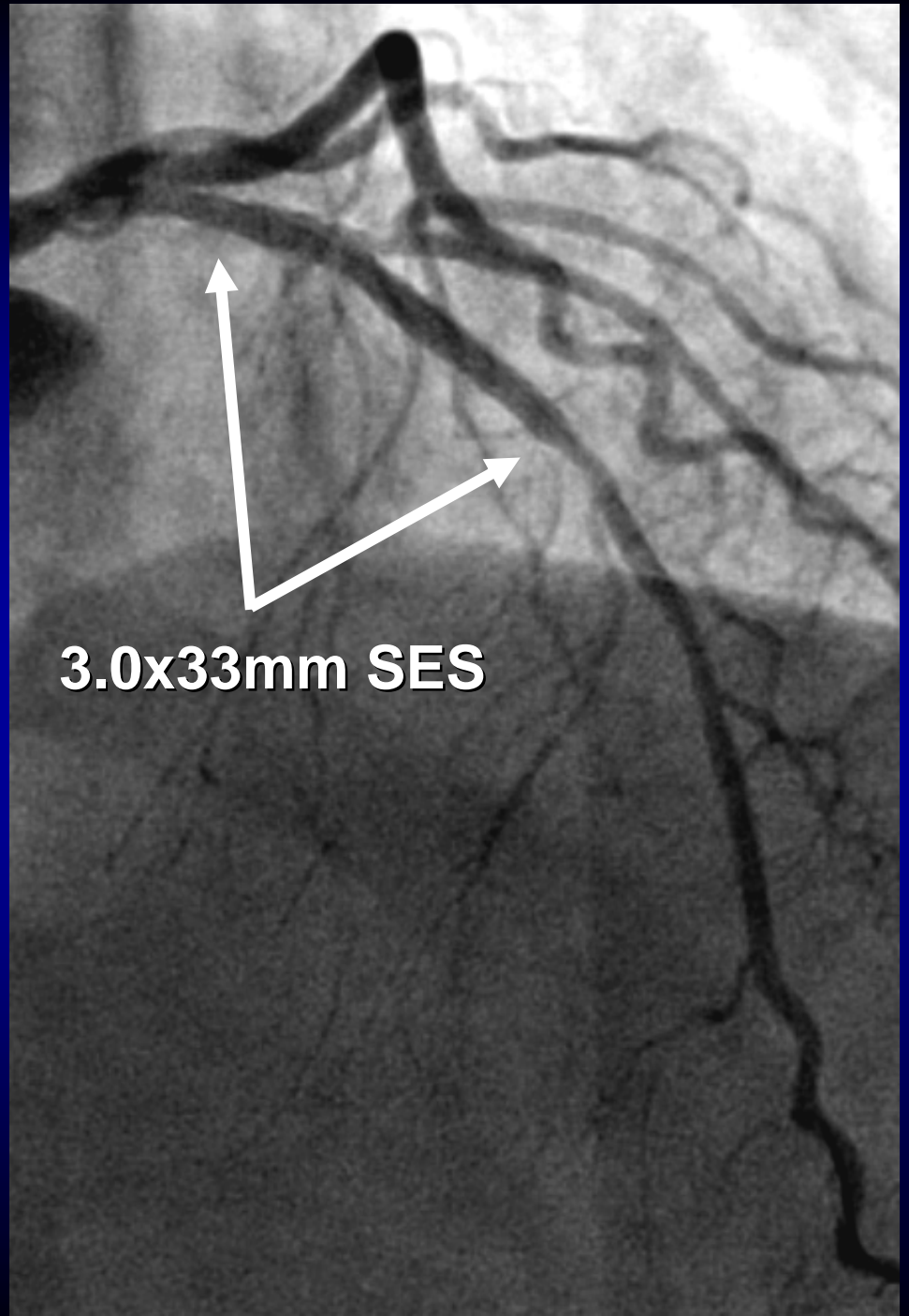
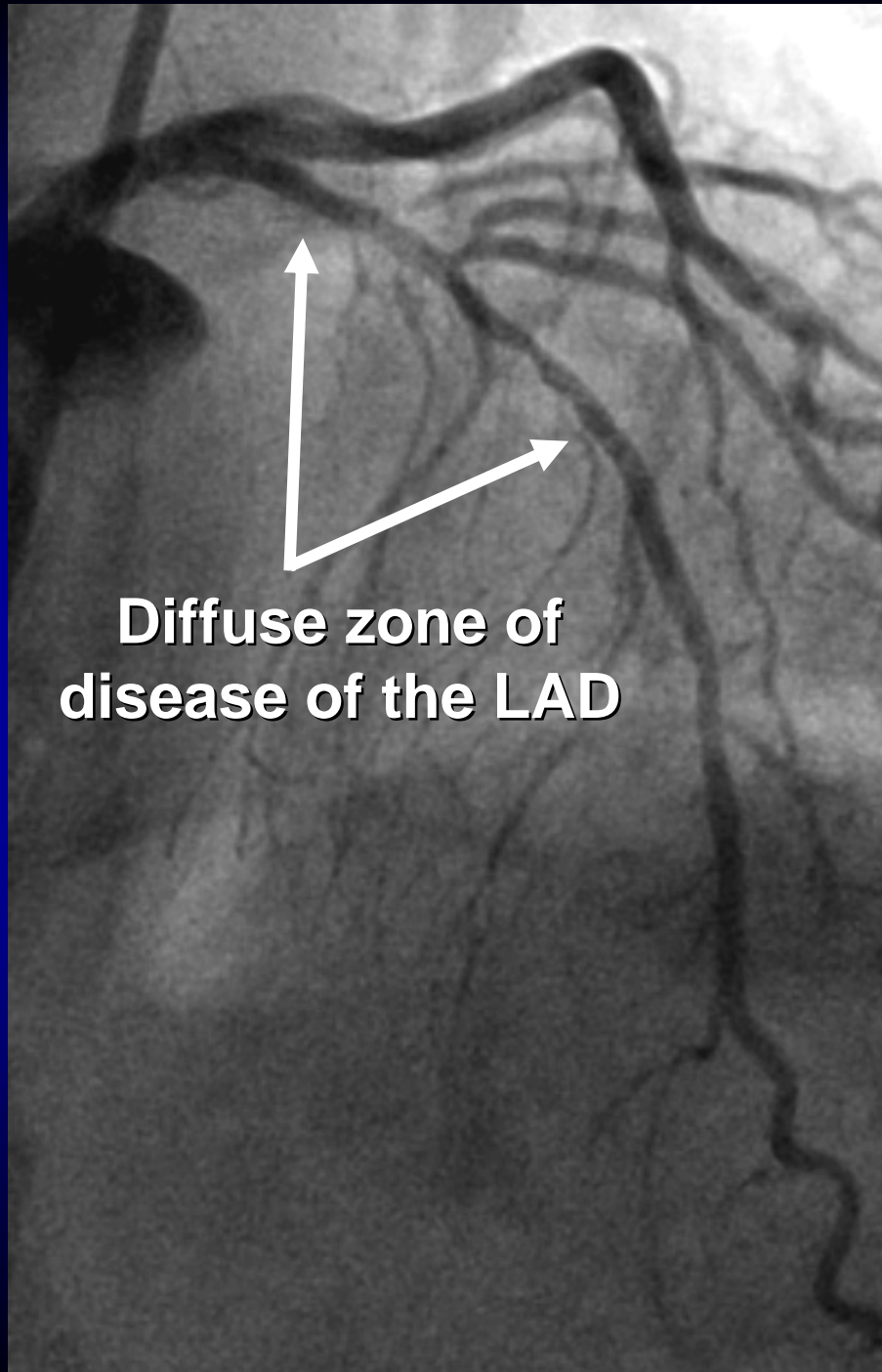
O.R. **p-value**

For Death

Age	1.042 (1.007-1.079)	0.01
Dyslipidemia	0.372 (0.151-0.921)	0.03
Creatinine > 1.5	11.712 (4.924-27.859)	< 0.0001
Total Stent Length	1.017 (1.001-1.033)	0.03

For Composite Endpoint (D, AMI, TVR, CABG)

Creatinine > 1.5	4.550 (1.402-8.619)	< 0.0001
Total Stent Length	1.167 (1.054-1.293)	0.003





Mid America Heart Institute Experience
Drug Eluting Stents: Dec. 2003-Dec. 2005

Conclusions

★ At 12-month follow up:

- Increased incidence of ST with PES vs SES**
- No difference in death/MI or composite endpoint**
- Increased incidence of TLR, TVR, ST in multiple stent use and multiple vessel stenting**
- Increased TVR in diabetic patients**
- Total stent length predictive of TVR, TLR, Death, and Composite Endpoint**