

Comparisons of Drug Eluting to Bare Metal Stents: Findings from the NHLBI-Dynamic and the DEScover Registries

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Presenter Disclosure Information

- **Consultant:**
 - ◆ **Cordis**
 - ◆ **Abbott Vascular (Chair, ZoMaxx I and II DSMB)**
- **Research support: Cordis, Boston Scientific, Abbott Vascular, NHLBI**
- **Speaker bureau: None**
- **Travel/meeting attendance: None**

Scope of Discussion

- **Databases**

- ◆ DEScover

- ◆ NHLBI Dynamic Registry

- **Bare-metal compared to drug-eluting stents**

- ◆ Unselected patients

- ◆ Standard vs. off-label use



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Study Design

- Prospective/observational study
- 140 clinical sites in the US
- Each site to enroll at least 60 consecutive patients undergoing PCI:
 - Target - 7,500 patients
 - Enrollment period: December 2004 – June 2005
- Exclusion criteria: refusal or inability to provide written informed consent and/or HIPAA authorization

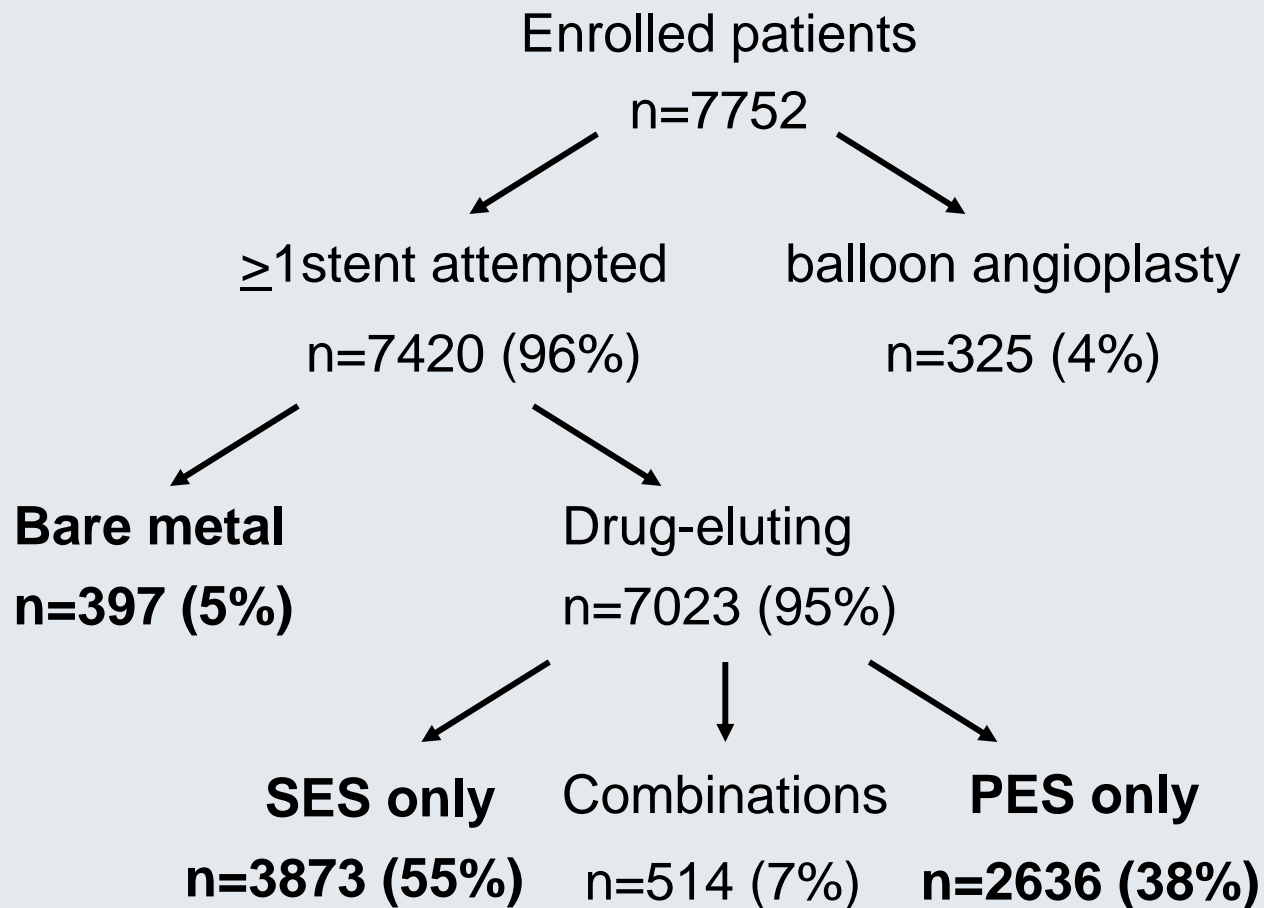


Data Collection and Management

- Web-based training of data coordinators
 - Abt Associates
- Web-based electronic case report form
 - Outcome Science
- Data collection
 - In-hospital: data coordinators
 - Follow-up: centralized telephone contact
- Data analysis
 - University of Pittsburgh, Principal Investigator Kevin E. Kip Ph.D
- Sponsor
 - Cordis Corporation



- Death
 - All cause mortality
- Myocardial infarction
 - Evolutionary ST-segment elevation, or
 - New Q-waves or LBBB, or
 - CK>2 ULN and elevated CK-MB or troponin
- Stent thrombosis
 - Acute (0-24 hours), sub-acute (>24 hours – 30 days), or late (>30 days)
 - Classified as definite or probable (composite presented)
 - Adjudicated by an independent events committee
- Angiographic characteristics were evaluated at the clinical sites





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Baseline Characteristics

	BMS Group (n=397)	SES Group (n=3873)	PES Group (n=2636)	P BMS vs. DES	P SES vs. PES
Age, mean, SD (years)	66.0, 11.9	63.6, 12.0	64.7, 11.6	0.001	0.0009
Male, %	69.8	67.5	68.4	0.42	0.45
Diabetes, %	32.2	32.7	30.5	0.86	0.06
Current smoking, %	27.6	24.3	25.2	0.20	0.40
Hypertension, %	75.2	75.7	75.7	0.82	0.99
Hypercholesterolemia, %	73.0	75.9	76.6	0.16	0.55
Prior myocardial infarction, %	28.4	27.1	27.5	0.58	0.53
Prior coronary bypass, %	26.6	18.3	20.0	0.0002	0.09
Prior angioplasty, %	29.5	36.9	38.1	0.0017	0.33

DES- drug eluting stent (includes sirolimus- and paclitaxel- eluting stents)

Missing cases exist for some variables.



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Baseline Characteristics

	BMS Group (n=397)	SES Group (n=3873)	PES Group (n=2636)	P BMS vs. DES	P SES vs. PES
Vessel Disease				0.03	0.65
Single	59.2	57.6	57.5		
Double	21.5	26.6	27.4		
Triple	19.3	15.9	15.1		
Indication for procedure, %				<.0001	0.13
Acute MI	31.8	21.0	20.8		
Unstable angina	26.3	31.6	34.2		
Stable Angina	9.6	14.4	14.5		
Objective evidence of Ischemia	23.7	25.0	23.3		
Other/undetermined	8.6	8.0	7.1		
Ejection fraction, mean, SD	49.5, 13.9	52.7, 12.5	52.8, 13.0	<.0001	0.72
Ejection fraction <40%, %	20.0	13.2	13.5	0.001	0.73



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Procedural Characteristics

	BMS Group (n=397)	SES Group (n=3873)	PES Group (n=2636)	P BMS vs. DES	P SES vs. PES
Attempted lesions, mean, SD	1.3, 0.5	1.5, 0.7	1.4, 0.7	<.0001	0.003
Multi-lesion intervention, %	25.5	34.7	32.3	0.0005	<0.05
Stents used, mean, SD	1.2, 0.5	1.4, 0.7	1.3, 0.6	<0.0001	0.004
Multiple DES used, %	--	29.1	26.9	--	0.05
Stent overlap, %	13.2	17.5	15.1	0.06	0.004
Procedural glycoprotein IIb/IIIa inhibitor, %					
Planned	44.5	45.7	45.2	0.69	0.70
Bail-out	2.8	1.8	2.7	0.40	0.02
Lesion types, %					
Ostial	12.4	13.8	15.1	0.30	0.13
Bifurcation main branch	6.8	8.2	8.3	0.31	0.93
Bifurcation side branch	3.5	6.2	4.7	0.08	0.01
Calcified	29.8	24.1	29.5	0.15	<.0001
Total occlusion	19.1	11.2	9.9	<.0001	0.11
De novo lesion treated	96.5	93.7	94.1	0.01	0.37



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Procedural Characteristics

	BMS Group (n=397)	SES Group (n=3873)	PES Group (n=2636)	P BMS vs. DES	P SES vs. PES
Maximum diameter of stent used, mean, SD	3.3, 0.9	3.0, 0.4	2.9, 0.4	<.0001	<.0001
Maximum length of stent used, mean, SD	18.3, 6.8	20.2, 7.2	18.6, 7.0	0.0002	<.0001
Lesion Complication, %					
Abrupt closure	0.5	0.2	0.6	0.70	0.02
Dissection	4.1	2.5	3.2	0.14	0.07
Side branch occlusion	0.3	1.0	1.5	0.08	0.06
Persistent flow reduction	2.3	0.3	0.7	<.0001	0.03
Procedural Success, %				0.005	0.31
Complete	96.7	98.7	98.3		
Partial	2.8	1.3	1.5		
Failure	0.5	0.1	0.2		
Angiographic success of all lesions, %	97.7	98.6	98.2	0.17	0.21



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BMS vs. DES Adverse Events

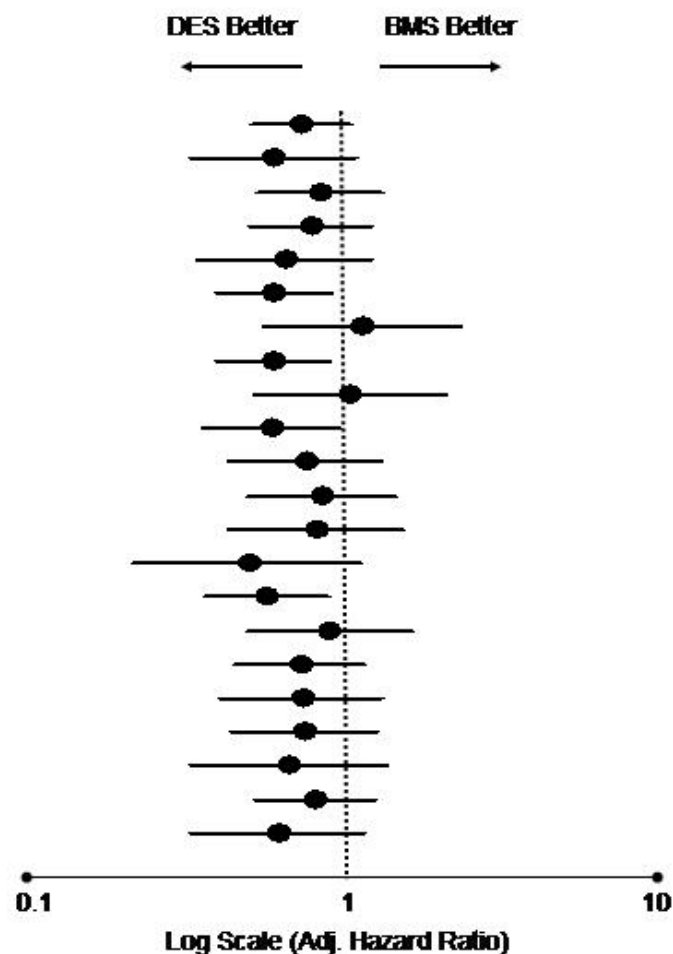
Clinical Event	BMS (n=397)	<u>1-Year</u> DES (n=6509)	p- value
Death	5.9%	3.1%	0.005
Myocardial infarction	3.5%	2.4%	0.19
Stent thrombosis	0.8%	0.6%	0.67
Repeat PCI: Any	9.3%	8.4%	0.62
CABG	3.5%	1.4%	0.0007
TVR (via PCI/CABG)	9.5%	6.0%	0.007
Death/MI	9.0%	5.2%	0.002



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DES vs. BMS 1-year Death/MI

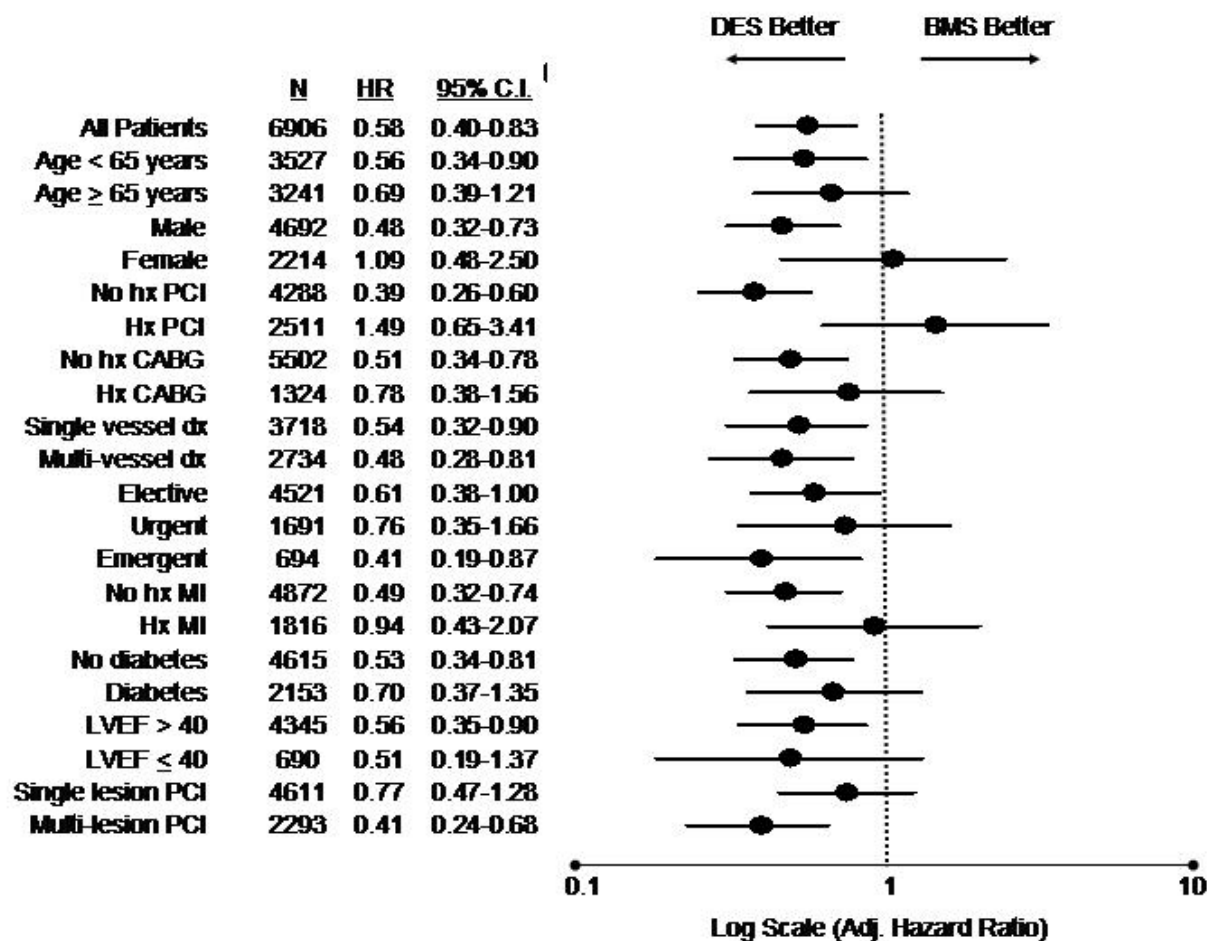
	N	HR	95% C.I.
All Patients	6906	0.74	0.52-1.07
Age < 65 years	3527	0.61	0.33-1.11
Age ≥ 65 years	3241	0.85	0.54-1.35
Male	4692	0.80	0.51-1.25
Female	2214	0.66	0.35-1.24
No hx PCI	4288	0.61	0.40-0.93
Hx PCI	2511	1.16	0.56-2.40
No hx CABG	5502	0.61	0.40-0.92
Hx CABG	1324	1.06	0.53-2.15
Single vessel dx	3718	0.60	0.36-0.99
Multi-vessel dx	2734	0.77	0.44-1.35
Elective	4521	0.86	0.50-1.48
Urgent	1691	0.83	0.44-1.56
Emergent	694	0.51	0.22-1.15
No hx MI	4872	0.58	0.37-0.91
Hx MI	1816	0.91	0.50-1.67
No diabetes	4615	0.74	0.46-1.18
Diabetes	2153	0.75	0.41-1.34
LVEF > 40	4345	0.76	0.45-1.30
LVEF ≤ 40	690	0.68	0.33-1.39
Single lesion PCI	4611	0.82	0.53-1.28
Multi-lesion PCI	2293	0.63	0.33-1.18





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DES vs. BMS 1-year TVR





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SES vs. PES Adverse Events

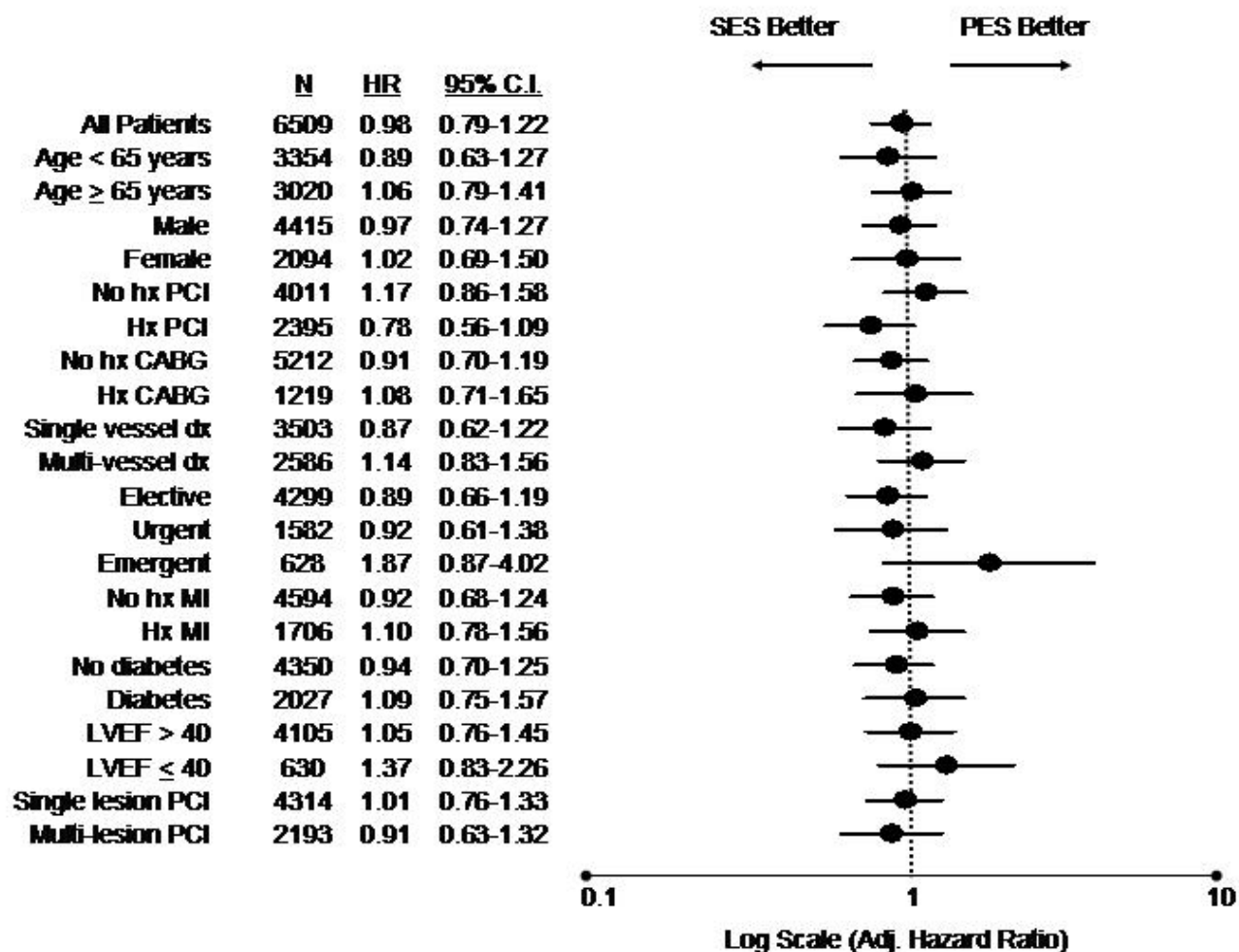
Clinical Event	<u>In-Hospital</u>			<u>1-Year</u>		
	SES (n=3873)	PES (n=2636)	p-value	SES (n=3873)	PES (n=2636)	p-value
Death	0.2%	0.08%	0.22	3.3%	2.8%	0.45
Myocardial infarction	0.6%	0.5%	0.40	2.2%	2.6%	0.20
Stent thrombosis	0.03%	0.1%	0.31	0.5%	0.8%	0.06
Repeat PCI: Any	0.4%	0.3%	0.67	8.7%	7.9%	0.37
CABG	0.1%	0.04%	0.41	1.3%	1.5%	0.53
TVR (via PCI/CABG)	0.3%	0.2%	0.49	6.3%	5.5%	0.20
Death/MI	0.8%	0.5%	0.18	5.2%	5.3%	0.64

For in-hospital comparisons, Fisher's Exact test was used for cells with expected counts less than five



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SES vs. PES 1-year Death/MI

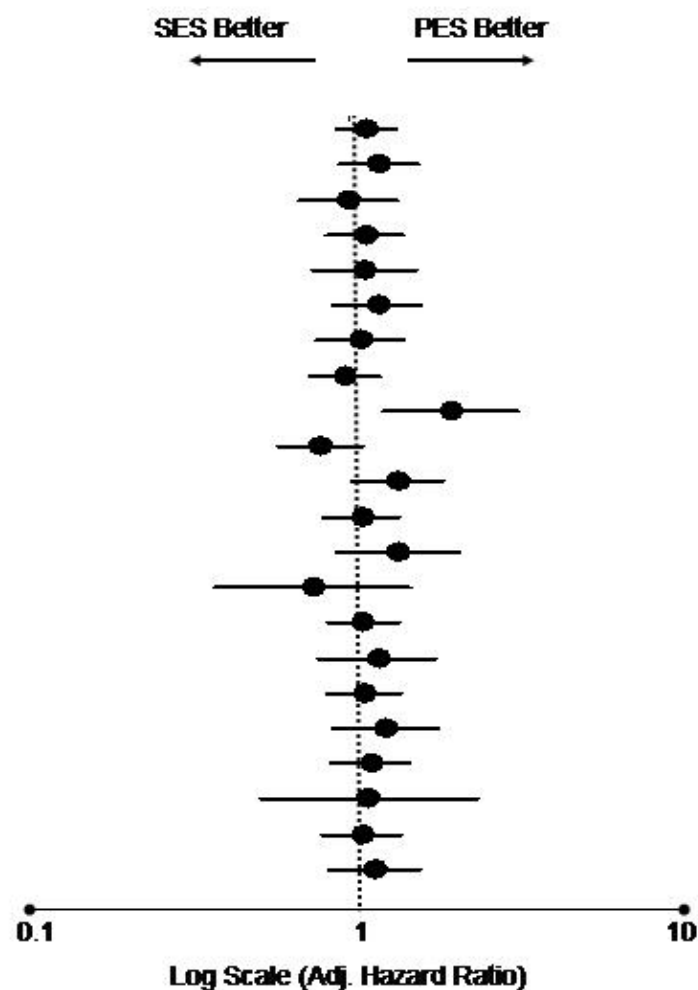




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SES vs. PES 1-year TVR

	N	HR	95% C.I.
All Patients	6509	1.11	0.90-1.38
Age < 65 years	3354	1.22	0.92-1.63
Age ≥ 65 years	3020	0.98	0.69-1.39
Male	4415	1.11	0.84-1.45
Female	2094	1.10	0.76-1.60
No hx PCI	4011	1.21	0.88-1.65
Hx PCI	2395	1.07	0.78-1.47
No hx CABG	5212	0.96	0.74-1.23
Hx CABG	1219	2.04	1.26-3.30
Single vessel dx	3503	0.80	0.59-1.10
Multi-vessel dx	2586	1.40	1.01-1.95
Elective	4299	1.08	0.82-1.41
Urgent	1582	1.40	0.90-2.18
Emergent	628	0.76	0.38-1.53
No hx MI	4594	1.09	0.84-1.42
Hx MI	1706	1.21	0.79-1.84
No diabetes	4350	1.10	0.84-1.44
Diabetes	2027	1.28	0.88-1.87
LVEF > 40	4105	1.15	0.87-1.53
LVEF ≤ 40	630	1.13	0.53-2.45
Single lesion PCI	4314	1.08	0.81-1.44
Multi-lesion PCI	2193	1.18	0.85-1.64





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Unique Features

- Conducted in the United States
- Included all PCI procedures, not just DES
 - Stents used in 96%
 - 95% of stented patients received a DES
 - During 2005, physicians attempted to implant a stent, preferable a DES, whenever possible



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BMS vs. DES

- Patient selection
 - BMS preferred for AMI, CABG
 - DES preferred for prior stent procedures
- Clinical outcomes
 - Unadjusted data for death favored DES (3.1%% vs. 5.9%, $p=0.005$) and Death/MI (5.2% vs. 9.0%, 0.002) but no difference following adjustment (HR 0.74, 95% CI 0.52-1.07)
 - Unadjusted data favored DES for TVR (6.0% vs. 9.5%, 0.007) as well as adjusted results (HR 0.58, 95% CI 0.40-0.83).
 - Benefit for reducing need for repeat revascularization without excess of adverse clinical events confirmed in a broad population of patients



- Patient selection
 - Baseline clinical and angiographic features nearly identical
- Clinical outcomes
 - Early, intermediate and one-year clinical outcomes similar (p=ns) with rates of major adverse events low.
 - Death 3.3%, 2.8%
 - MI 2.2%, 2.6%
 - Death/MI 5.2%, 5.3%
 - Stent thrombosis 0.5%, 0.8%
 - No significant differences in rates of any repeat PCI, CABG or TVR (6.3%, 5.5%)



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Limitations

- Number of BMS patients relatively small in comparison to DES group
- Selection bias between BMS and DES patients
- Adjustment may not compensate for baseline differences
- No information regarding antiplatelet therapy usage during follow-up
- Follow-up beyond one-year desirable



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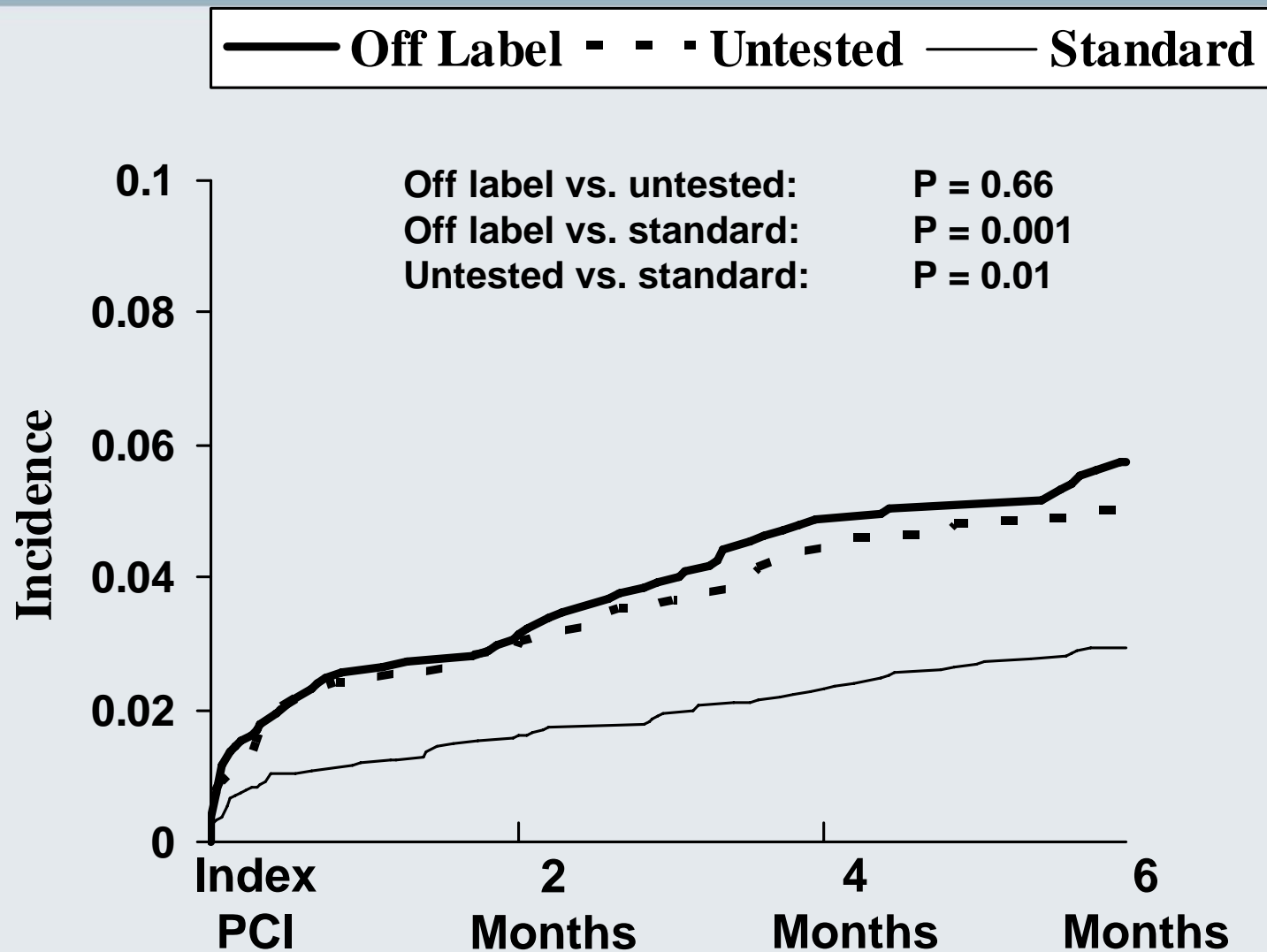
Conclusions

- DEScover was successful in enrolling, collecting and analyzing data for over 7700 patients from 140 US centers representing a large, cross-sectional experience of PCI in the United States
- Usage patterns and outcomes of patients treated with DES described
- Findings support the use of DES
- 1-year DEScover results available electronically
<http://circ.ahajournals.org/rapidaccess.shtml>



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Off-Label Use of DES Death/MI at Six-Months

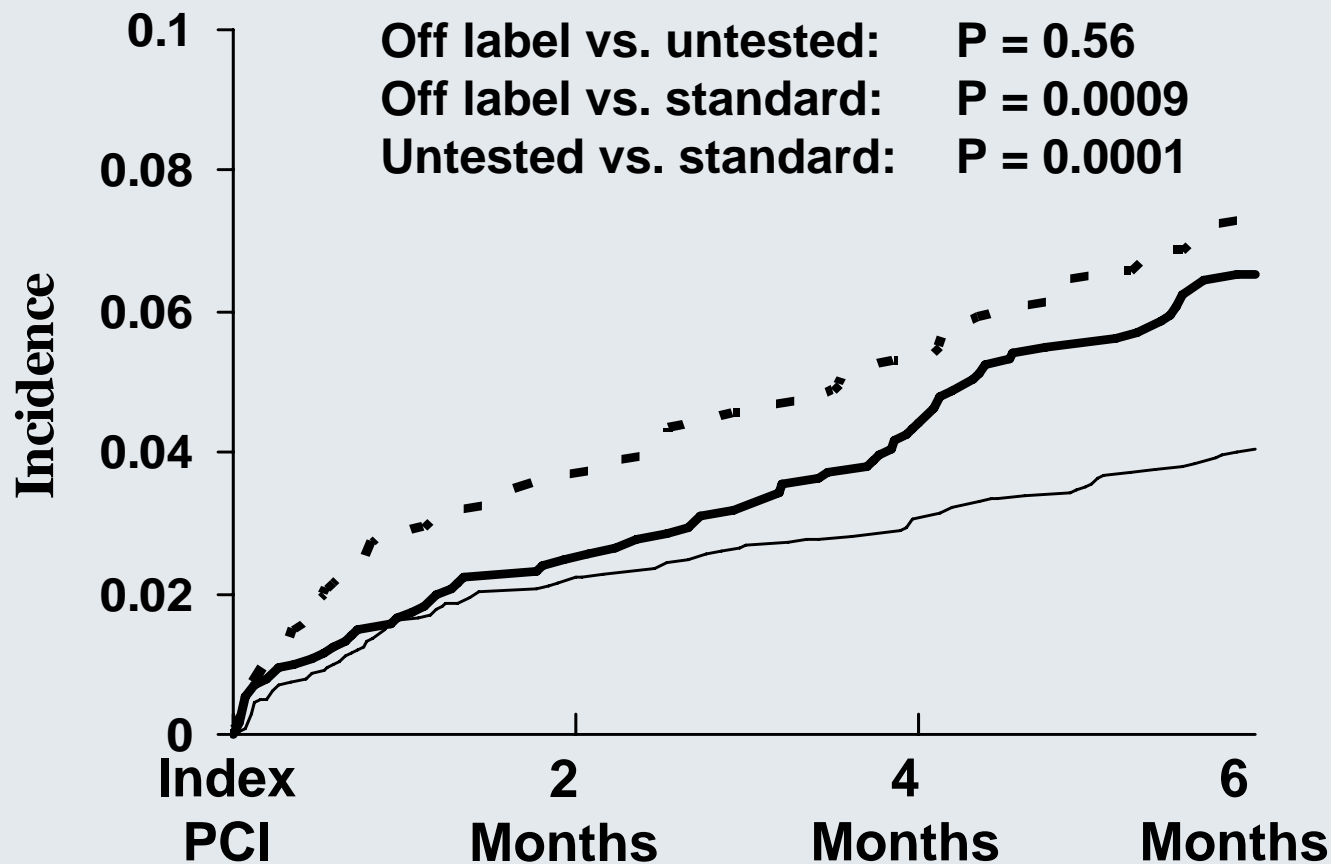




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Off-Label DES CABG or Repeat PCI at 6-Months

— Off Label - - - Untested — Standard



Drug-eluting vs. Bare Metal Stents: Background

- **Stents are utilized almost uniformly in patients undergoing percutaneous coronary intervention**
- **Until recently, drug-eluting stents have been the preferred treatment**
- **Some have raised concerns that drug-eluting stents may be associated with more frequent stent thrombosis leading to excess death and MI**
- **Robust comparisons of drug-eluting and bare metal stents have been limited to highly selected, simple patient subgroups.**
- **Comparisons between DES and BMS for non-protocol usage have been limited**

Drug-eluting vs. Bare Metal Stents: Purpose of Investigation

In the setting of routine clinical practice to:

- **Determine and compare the baseline clinical and angiographic features, procedural strategies and clinical outcomes of patients treated with a bare metal and drug-eluting stent**
- **Compare outcomes following adjustments for baseline imbalances**

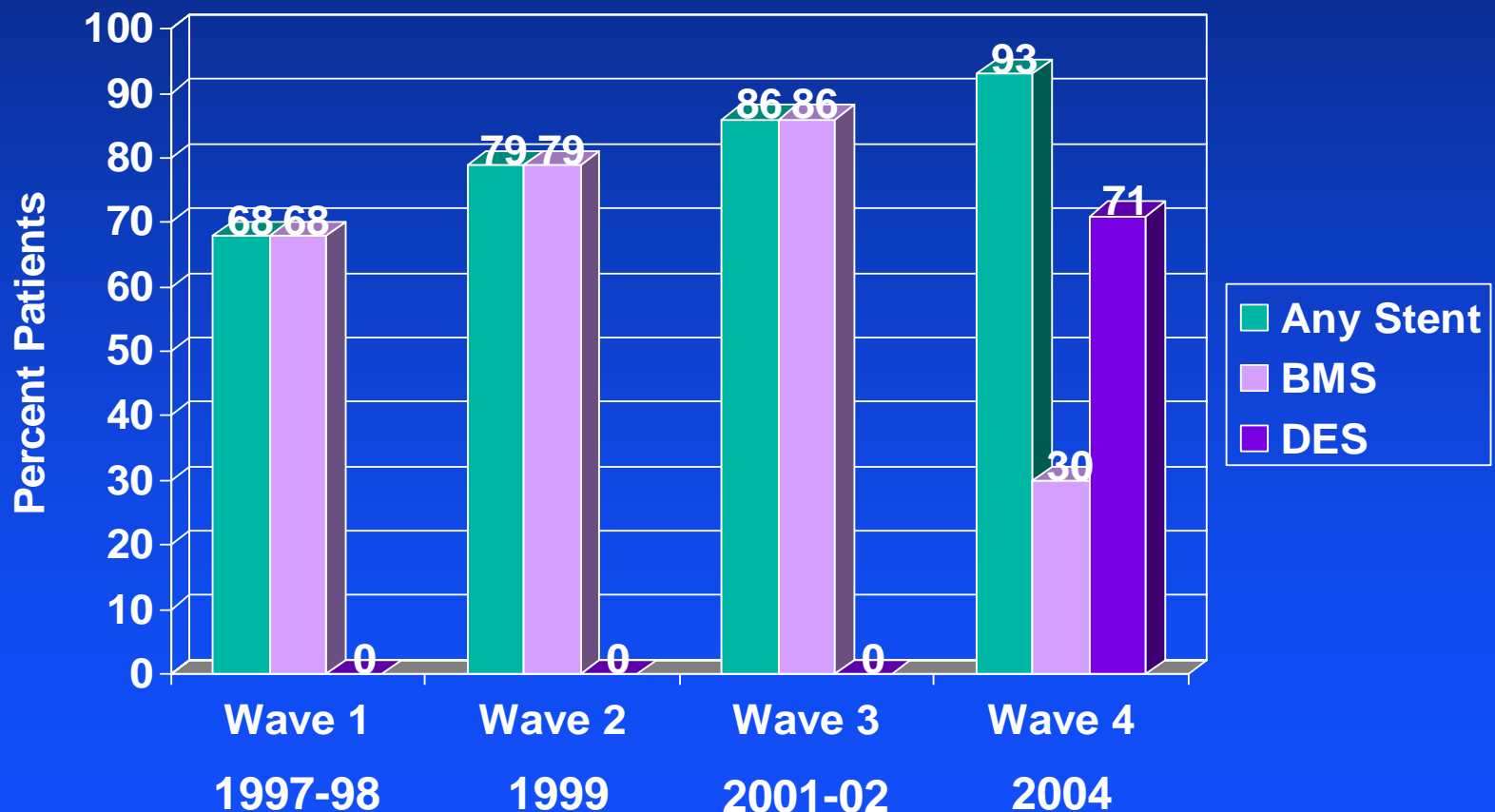
Dynamic Registry

- Prospective observational investigation
- Enrollment of sequential “waves” of patients having coronary intervention
- 2000 patients per wave separated by 18 months
- Specially trained research coordinators
- Consecutive cases
- Extended enrollment for women and minorities

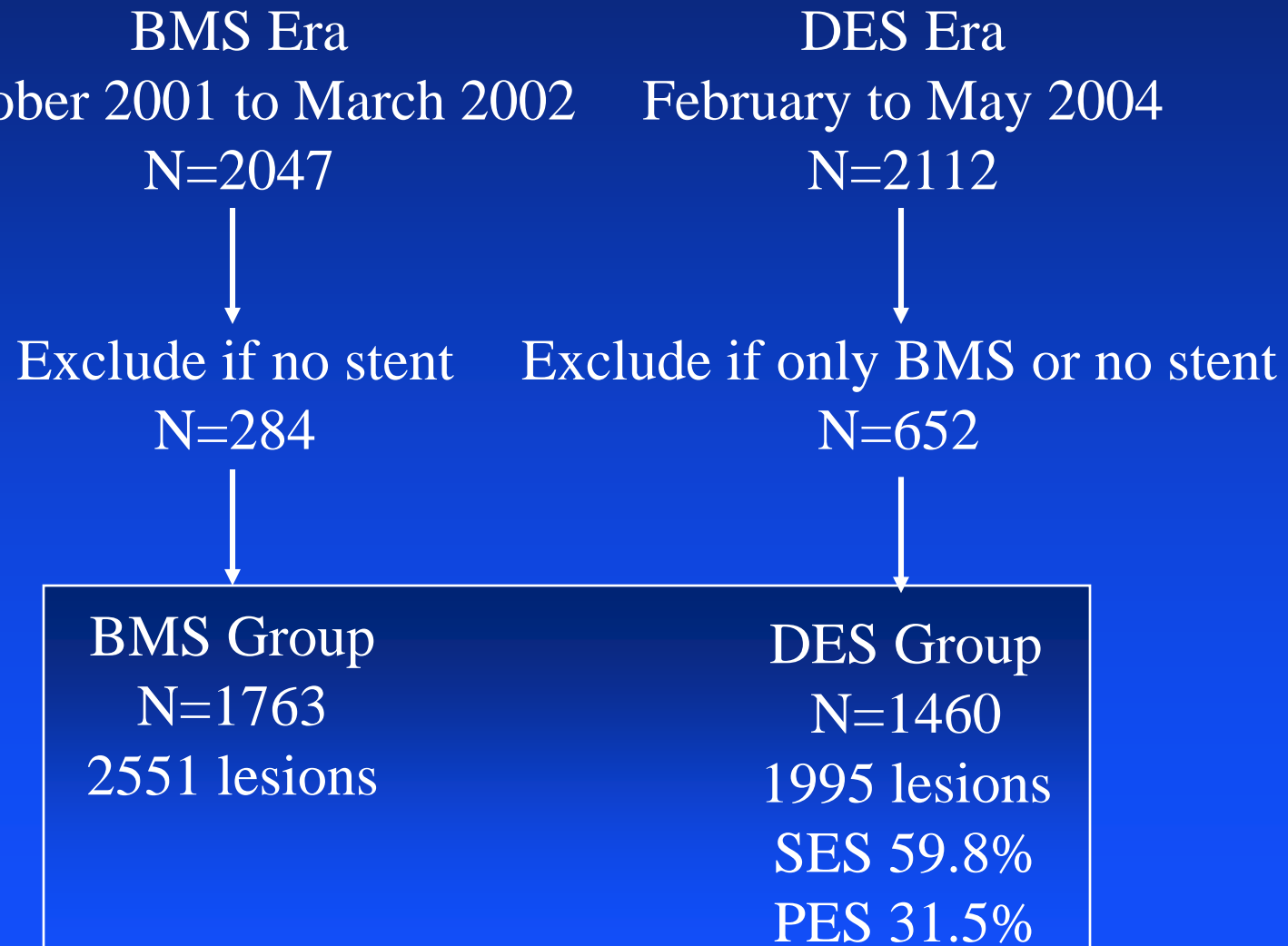
NHLBI Dynamic Registry: Enrollment Waves

	Year	Technology
Wave 1	1997-98	Initial wave: BMS
Wave 2	1999	BMS: 5-year Follow-up
Wave 3	2001-02	Brachytherapy
Wave 4	2004	DES: <1 year
Wave 5	2006	DES: mature

NHLBI Dynamic Registry: Stent Usage According to Wave



DES vs. BMS: Study Population



Study Design

- Identified patient treated with DES in Wave 4 (2004) and compared them to BMS patients treated with a BMS in Wave 3 (2002)
- Intent was to eliminate selection bias seen in Wave 4
- Patients treated with BMS in Wave 3 would likely have been treated with DES had one been available
- Each patient was followed for at least one-year.
- Exclusion: Refusal or inability to provide written informed consent

Statistical Analysis

- **Univariate differences between BMS and DES**
 - ◆ **Categorical variables: chi-square test**
 - ◆ **Continuous data: Wilcoxon rank-sum test**
- **Cumulative one-year event rates**
 - ◆ **Kaplan-Meier approach and compared by log-rank statistic**
- **Multivariable analysis**
 - ◆ **Cox proportional hazards regression used to estimate unadjusted and adjusted hazard ratios of adverse clinical outcomes**
- **Probability values <0.05 were considered significant**
- **Follow-up at one-year complete in 92.0% of BMS group and 94.5% of DES group**

DES vs. BMS:

Baseline Characteristics

Variable	BMS n=1763	DES n=1460	p-value
Mean Age (years)	64.4	63.7	0.07
% Female	35.8	33.3	0.14
Diabetes, %	29.1	34.3	0.001
Hypertension, %	74.1	79.1	0.001
Hypercholesterolemia, %	69.8	77.5	<0.0001
Current smoking, %	24.4	21.4	0.05
Prior myocardial infarction, %	26.2	26.4	0.90
Prior coronary bypass, %	17.4	19.1	0.21
Prior angioplasty, %	36.8	42.3	0.002
Prior CHF	12.7	9.3	0.003

DES vs. BMS:

Baseline Characteristics

Variable	BMS n=1763	DES n=1460	p-value
Vessel Disease			0.098
Single	37.6	33.8	
Double	32.0	32.5	
Triple	30.1	33.5	
Indication for procedure, %			<0.0001
Acute MI	29.8	23.8	
Unstable Angina	39.9	35.9	
Stable Angina	19.7	25	
Other	10.6	15.3	
Ejection Fraction, mean	51.5	52.3	0.09
Cardiogenic Shock	2.1	0.5	<0.0001

DES vs. BMS: Attempted Lesion Characteristics

Variable	BMS n=2551	DES n=1995	p-value
Mean Reference Vessel Diameter	3.1	3.0	0.07
Mean Lesion Length	13.4	15.9	<0.0001
Lesion Types, %			
Total Occlusion	9.2	7.4	0.03
Thrombus	15.4	11.0	<0.0001
Calcified	22.3	26.5	0.001
Bifurcation	13.2	10.2	0.002
Ostial	6.9	8.8	0.02
Lesion Tortuosity, %			
None/Mild	75.0	73.2	0.19
Moderate/Severe Tortuosity	25	26.8	

DES vs. BMS: Procedural Characteristics

	BMS n= 2551	DES n=1995	p-value
Lesion Complication, %			
Abrupt Closure	0.2	0.0	0.03
Dissection	1.9	2.1	0.80
Side Branch Occlusion	2.1	2.2	0.85
Persistent flow reduction	0.7	0.9	0.68
Procedural Success, %			0.16
Complete	96.5	97.3	
Partial	3.2	2.2	
Failure	0.3	0.5	
Angiographic success, %	97.5	98.0	0.33

DES vs. BMS: In-hospital Unadjusted Event Rates

Variable	BMS n=1763	DES n=1460	p- value
Death	1.1	0.5	0.06
MI	1.9	2.2	0.60
CABG	0.3	0.1	0.10
MACE (Death, Any MI, Any CABG)	3.2	2.6	0.29
Bleeding Requiring Transfusion	1.6	1.3	0.50

DES vs. BMS: Cumulative Unadjusted One-Year Event Rates

Variable	BMS n=1763	DES n=1460	p-value
Death	4.3	3.6	0.33
MI	4.7	4.5	0.87
CABG	3.1	1.2	<0.001
Target Vessel Revascularization	9.2	4.9	<0.001
Repeat Revascularization	15.0	10.0	<0.001
MACE (Death, MI, Repeat Revascularization)	20.9	15.5	<0.001

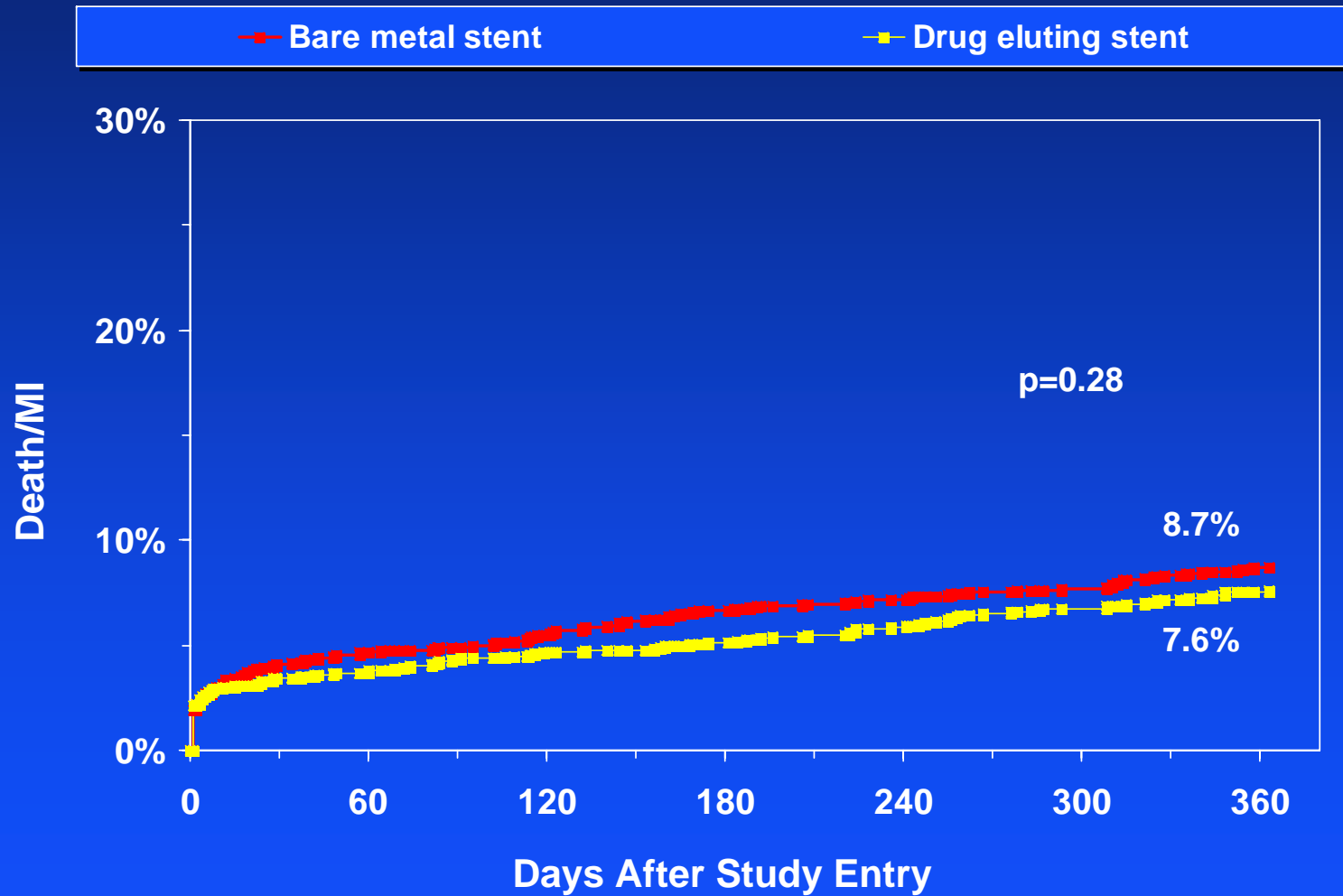
DES vs. BMS: Adjusted and Unadjusted Events at One-Year

Adverse Outcome	HR	95% CI	p-value
Death			
Unadjusted	0.84	0.58-1.21	0.35
Adjusted	0.98	0.66-1.44	0.91
Myocardial infarction			
Unadjusted	0.96	0.69-1.34	0.81
Adjusted	0.98	0.70-1.38	0.92
Coronary artery bypass graft			
Unadjusted	0.39	0.22-0.68	0.001
Adjusted	0.34	0.20-0.61	<0.001
Death/MI			
Unadjusted	0.87	0.67-1.12	0.23
Adjusted	0.86	0.66-1.12	0.27
Death/MI/CABG			
Unadjusted	0.76	0.60-0.95	0.02
Adjusted	0.73	0.57-0.93	0.01
Repeat PCI			
Unadjusted	0.69	0.55-0.86	0.001
Adjusted	0.65	0.51-0.82	<0.001
Repeat Revascularization			
Unadjusted	0.64	0.52-0.79	<0.001
Adjusted	0.57	0.45-0.71	<0.001
MACE			
Unadjusted	0.72	0.61-0.86	<0.001
Adjusted	0.68	0.56-0.81	<0.001

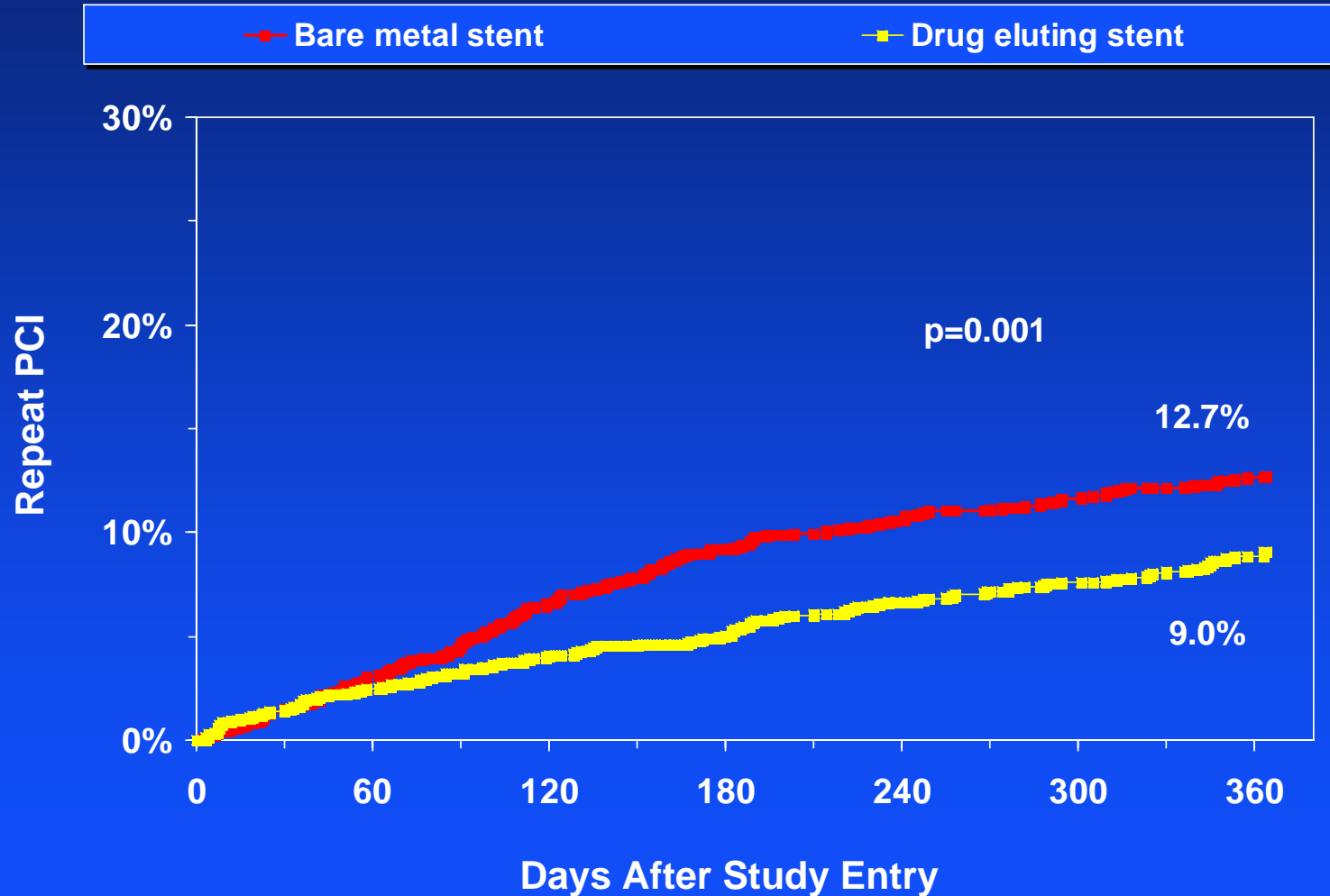
DES vs. BMS: Events at One-Year in Discharged Patients Following an Uncomplicated Hospital Stay

Adverse Outcome (%)	BMS (n=1706)	DES (n=1422)	p-value
Death	3.0	3.1	0.93
MI	2.8	2.3	0.42
CABG	2.7	1.2	0.004
Death/MI	5.8	5.1	0.45
Death/MI/CABG	8.0	6.1	0.04
Repeat PCI	12.6	8.8	<0.001
Repeat Revascularization	14.7	9.9	<0.001
MACE†	18.1	13.4	<0.001

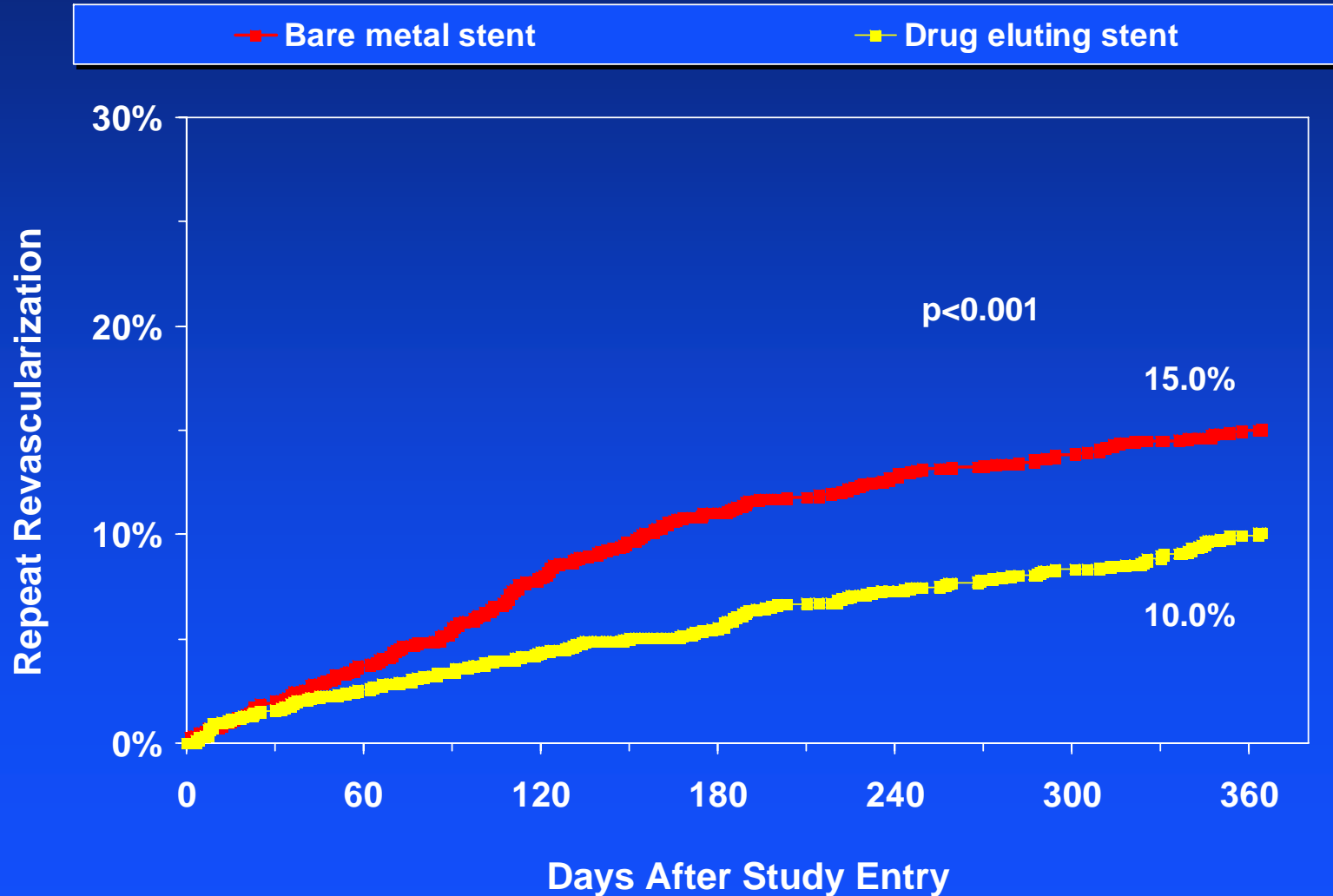
DES vs. BMS: Death and MI



DES vs. BMS: Repeat PCI



DES vs. BMS: Repeat PCI or CABG



DES vs. BMS: Conclusions

- DES as used in routine clinical practice and in pts with more complex lesions was associated with similar high rates of procedural success and low rates of in-hospital adverse events compared to BMS.
- At one-year, DES pts experienced less subsequent CABG and repeat PCI without any excess in adverse clinical events including death or MI.
- These findings support the use of DES in routine clinical practice.

On-Label vs. Off-Label Indication

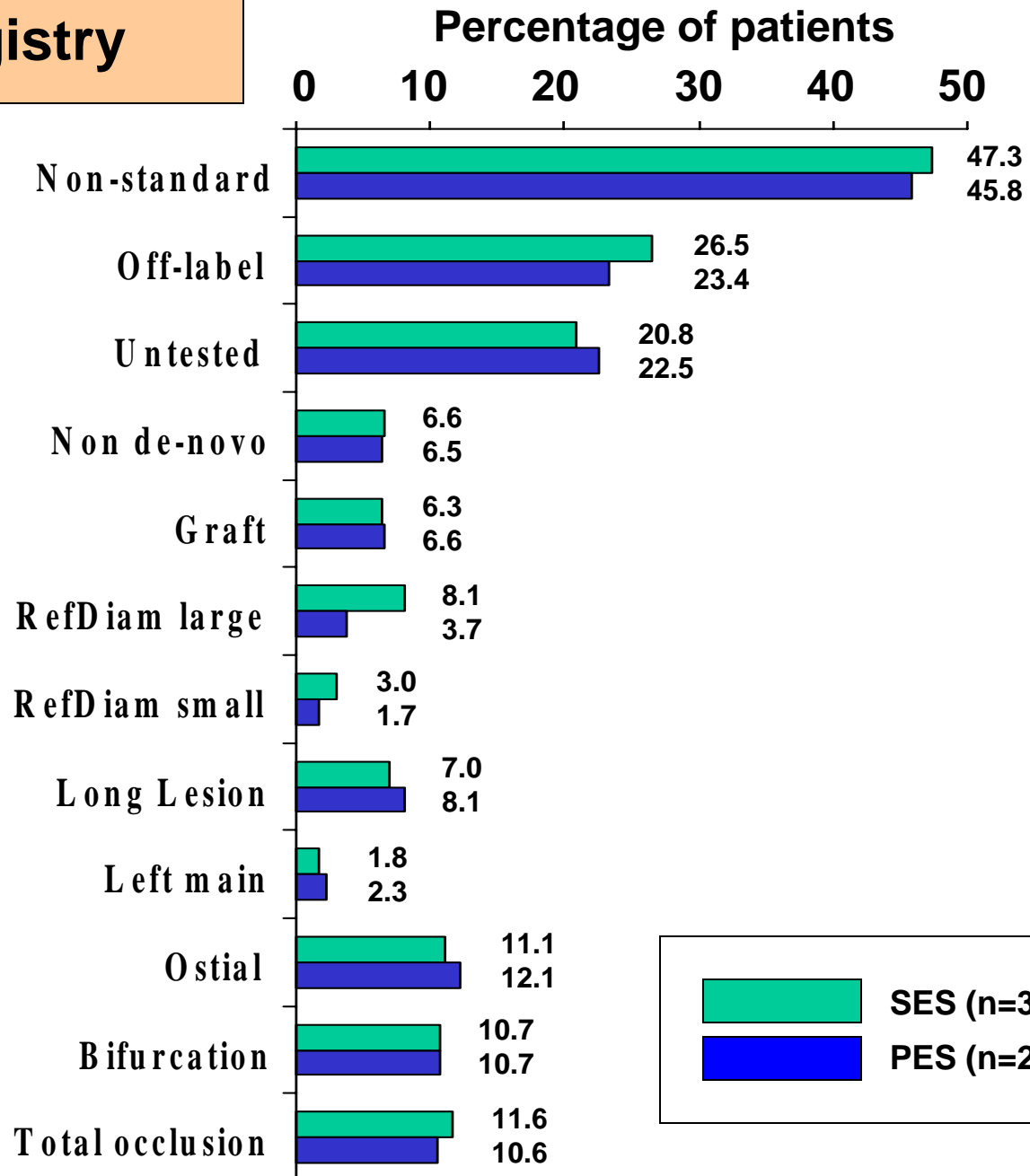
- Standard (On-label)
- Off-label (lesion-based)
 - Non-de novo
 - Vein graft
 - Reference diameter large
 - Reference diameter small
 - Long lesion
 - Left main lesion site
 - Ostial location
 - Bifurcation lesion
 - Total occlusion

DESCover Registry

DES Use

Off-Label DES Use

Untested DES Use



DESCover Registry

One-Year Cumulative Incidence Rates by Stent Use

1-year event rate (%)	<u>Standard Use</u>		<u>Non-standard use</u>		BMS
	SES	PES	SES	PES	
	N=1738	N=1212	N=1560	N=1027	N=398
Death	2.9	2.2	3.6	3.3	5.8
Myocardial infarction	1.7	2.0	1.8	3.0	2.6
Stent thrombosis (ST)	0.2	0.4	0.7	1.0	0.5
Death/MI	4.3	4.2	5.2	6.2	8.1
Death/MI/ST	4.3	4.3	5.4	6.4	8.1
Repeat PCI	6.5	6.8	10.3	8.6	9.5
Repeat revasc.	7.0	8.0	11.3	9.9	12.4

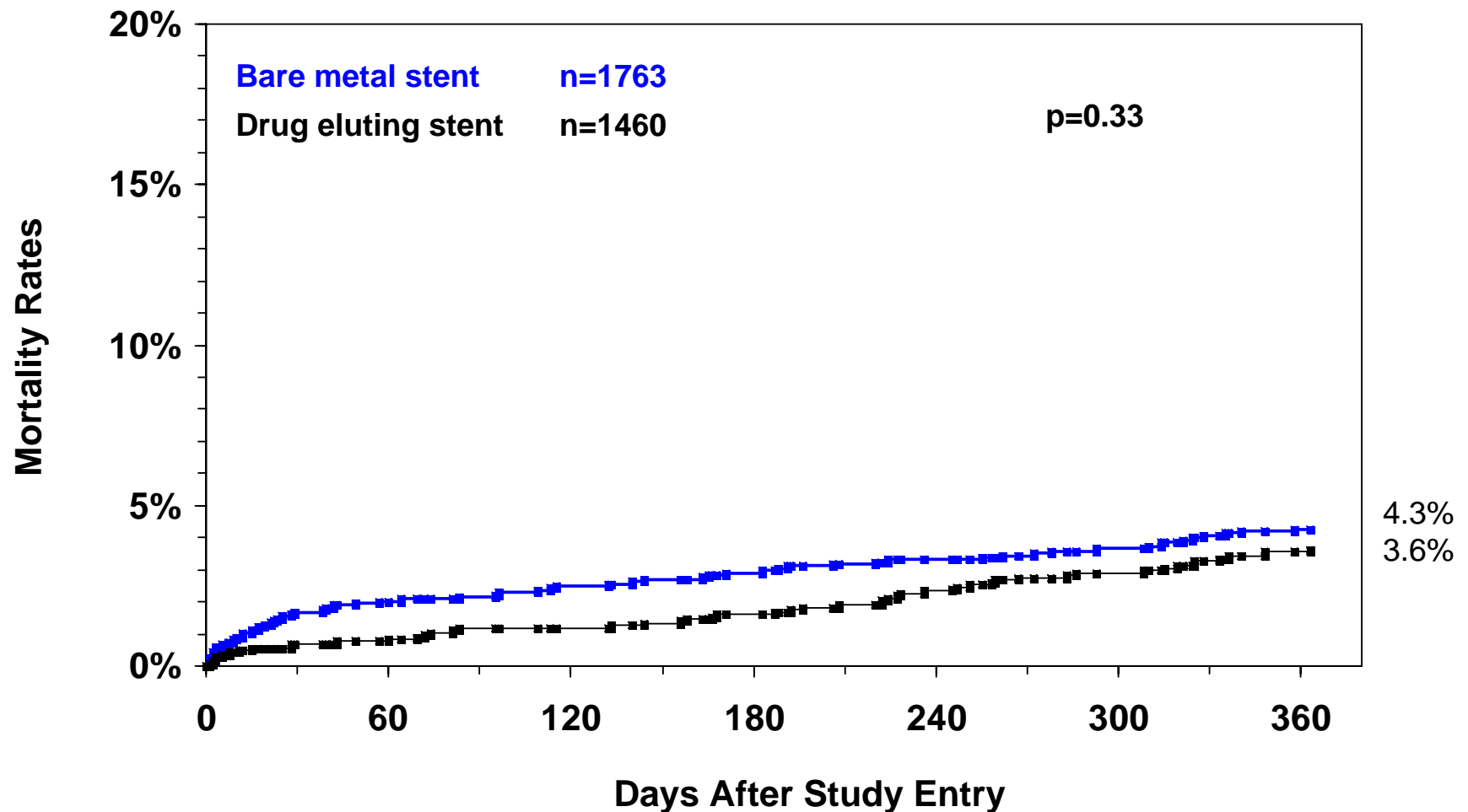
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One-year cumulative mortality rates by stent type

BMS patients from wave 3 and DES patients from wave 4

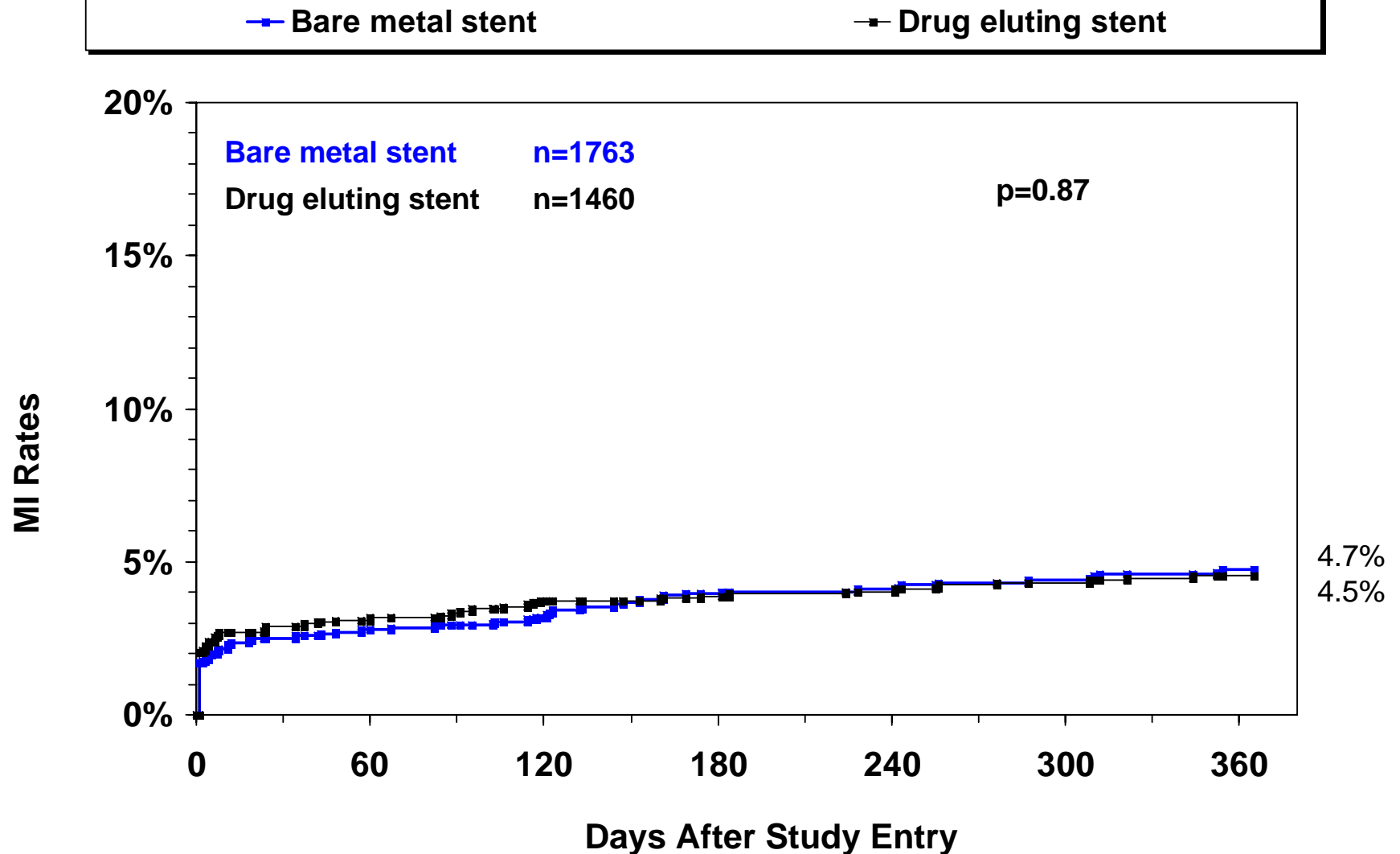
—■ Bare metal stent

—■ Drug eluting stent



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One-year cumulative MI rates by stent type
BMS patients from wave 3 and DES patients from wave 4



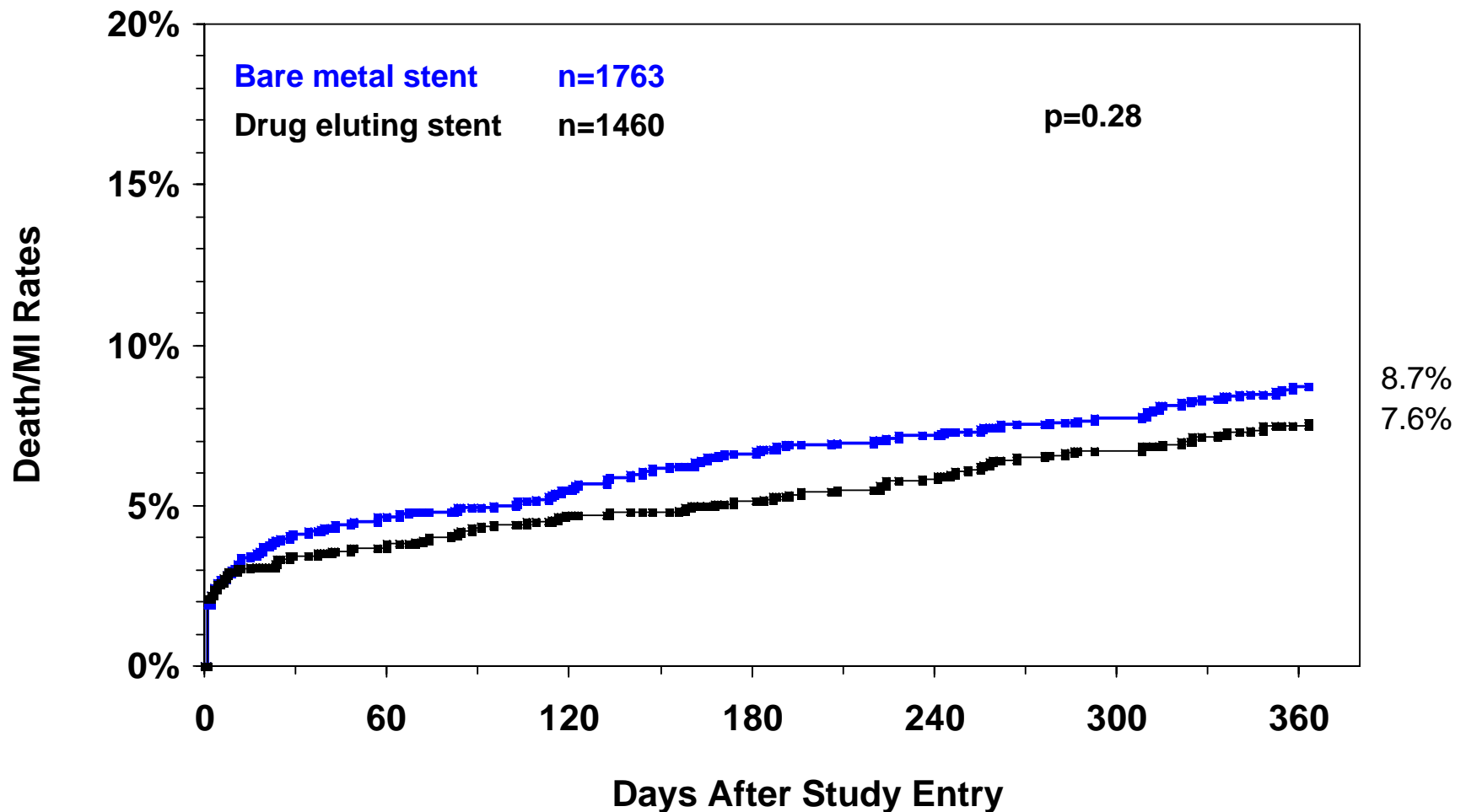
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One-year composite death and MI rates by stent type

BMS patients from wave 3 and DES patients from wave 4

— Bare metal stent

— Drug eluting stent



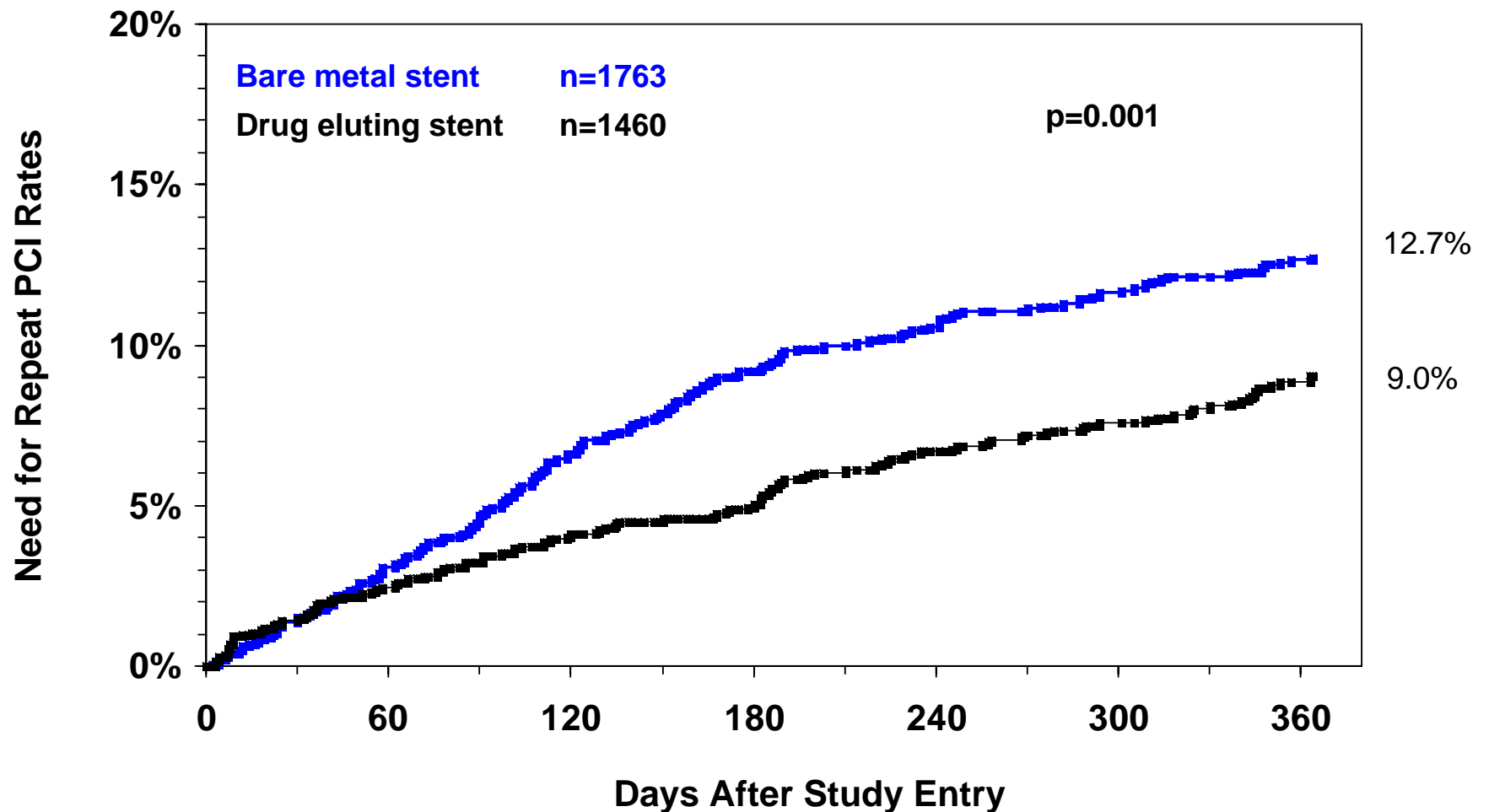
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One-year need for repeat PCI rates by stent type

BMS patients from wave 3 and DES patients from wave 4

— Bare metal stent

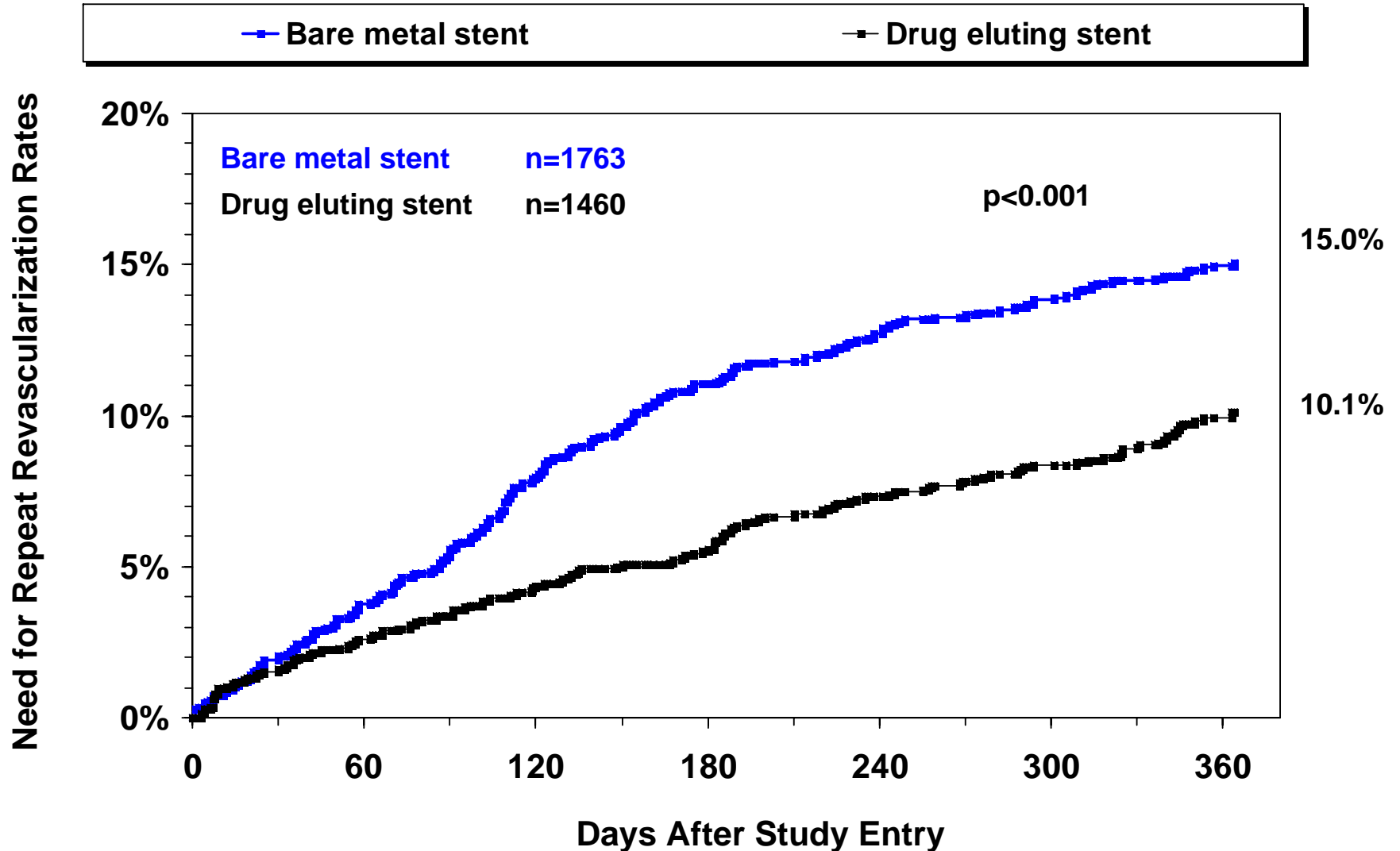
— Drug eluting stent



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One-year need for repeat revascularization rates by stent type

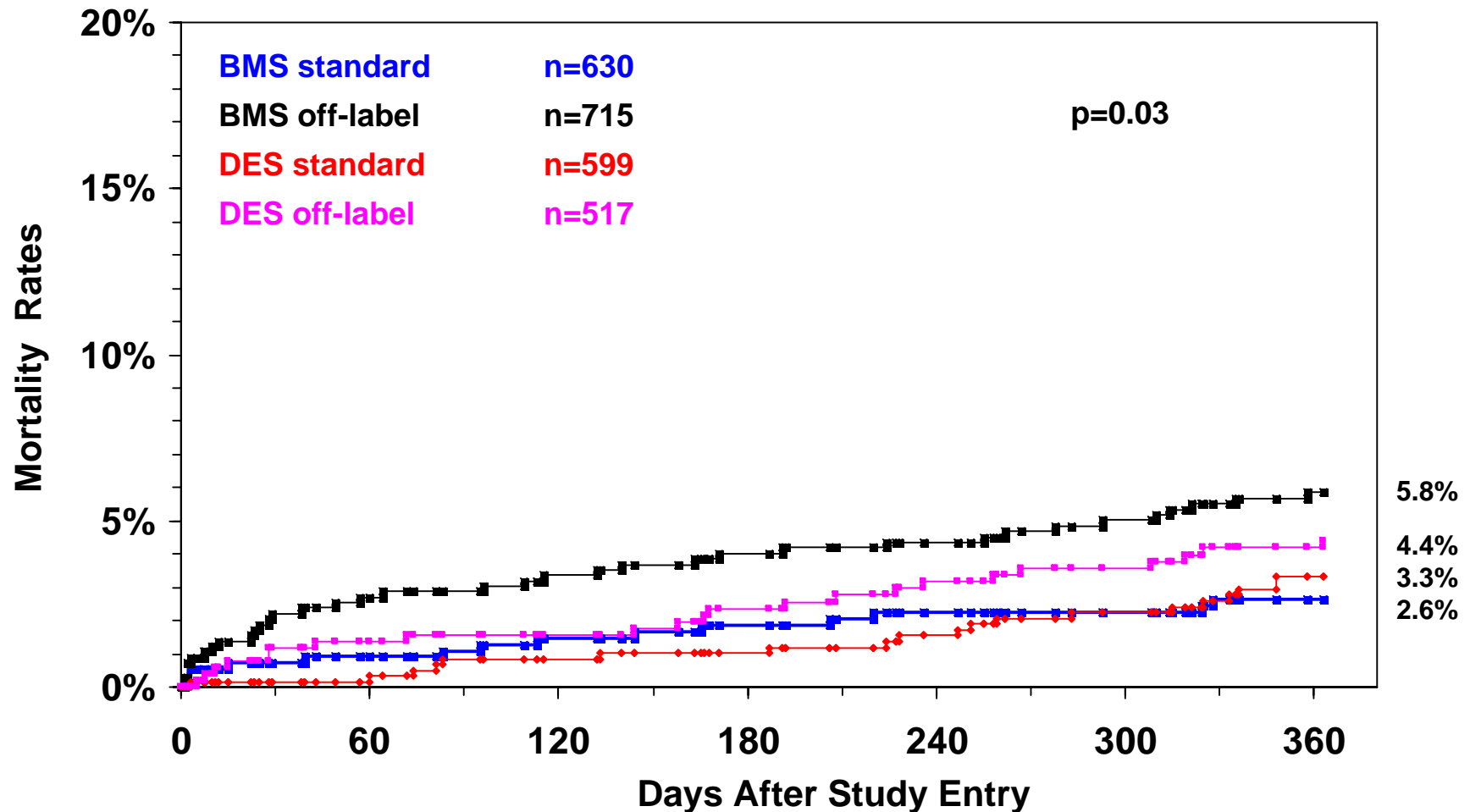
BMS patients from wave 3 and DES patients from wave 4



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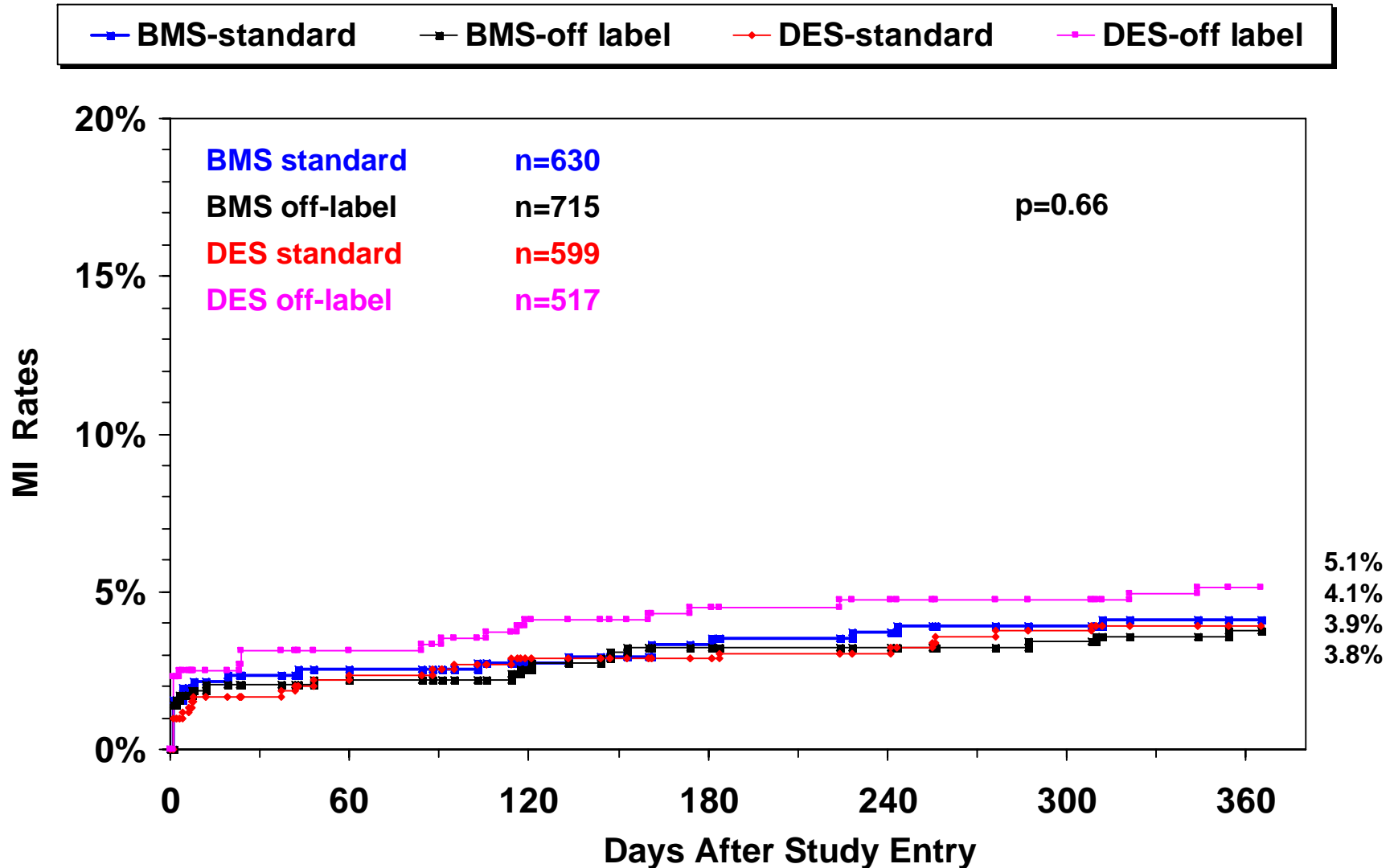
One-year cumulative mortality rates by stent type & label indications
BMS patients from wave 3 and DES patients from wave 4

—■— BMS-standard —■— BMS-off label —◆— DES-standard —◆— DES-off label



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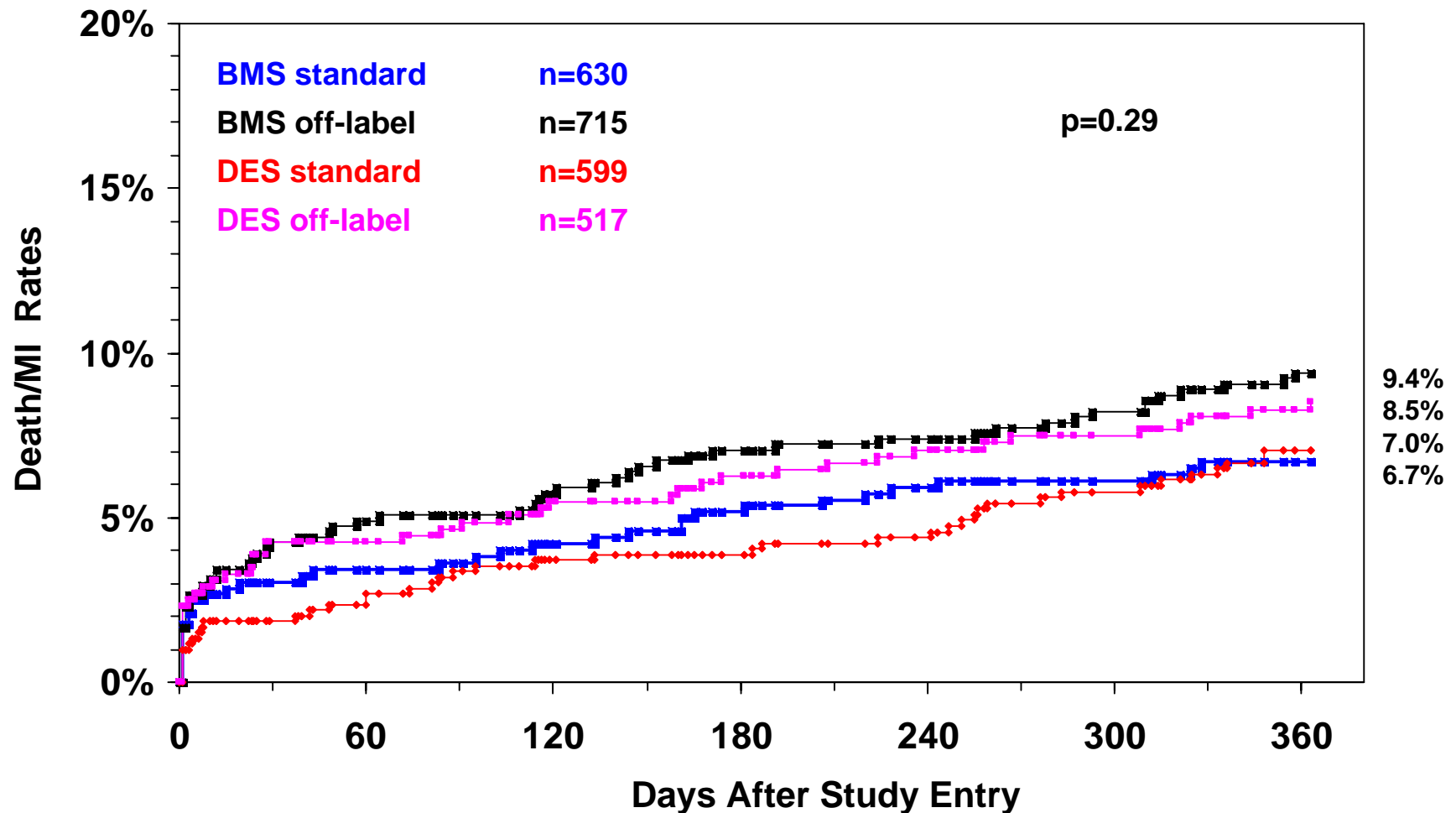
One-year cumulative myocardial infarction rates by stent type & label indications
BMS patients from wave 3 and DES patients from wave 4



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One-year composite death and MI rates by stent type & label indications
BMS patients from wave 3 and DES patients from wave 4

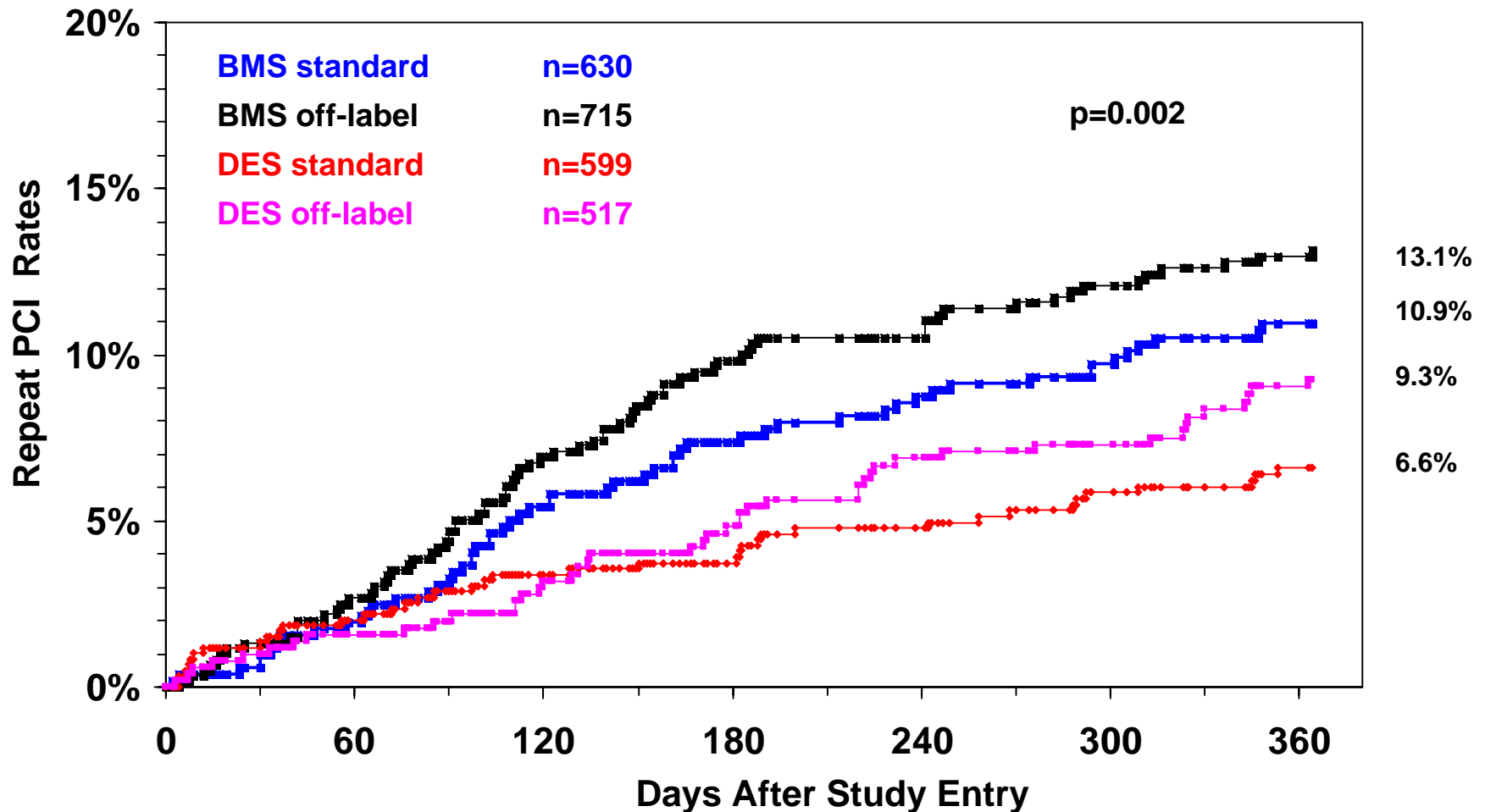
—■— BMS-standard —■— BMS-off label —●— DES-standard —■— DES-off label



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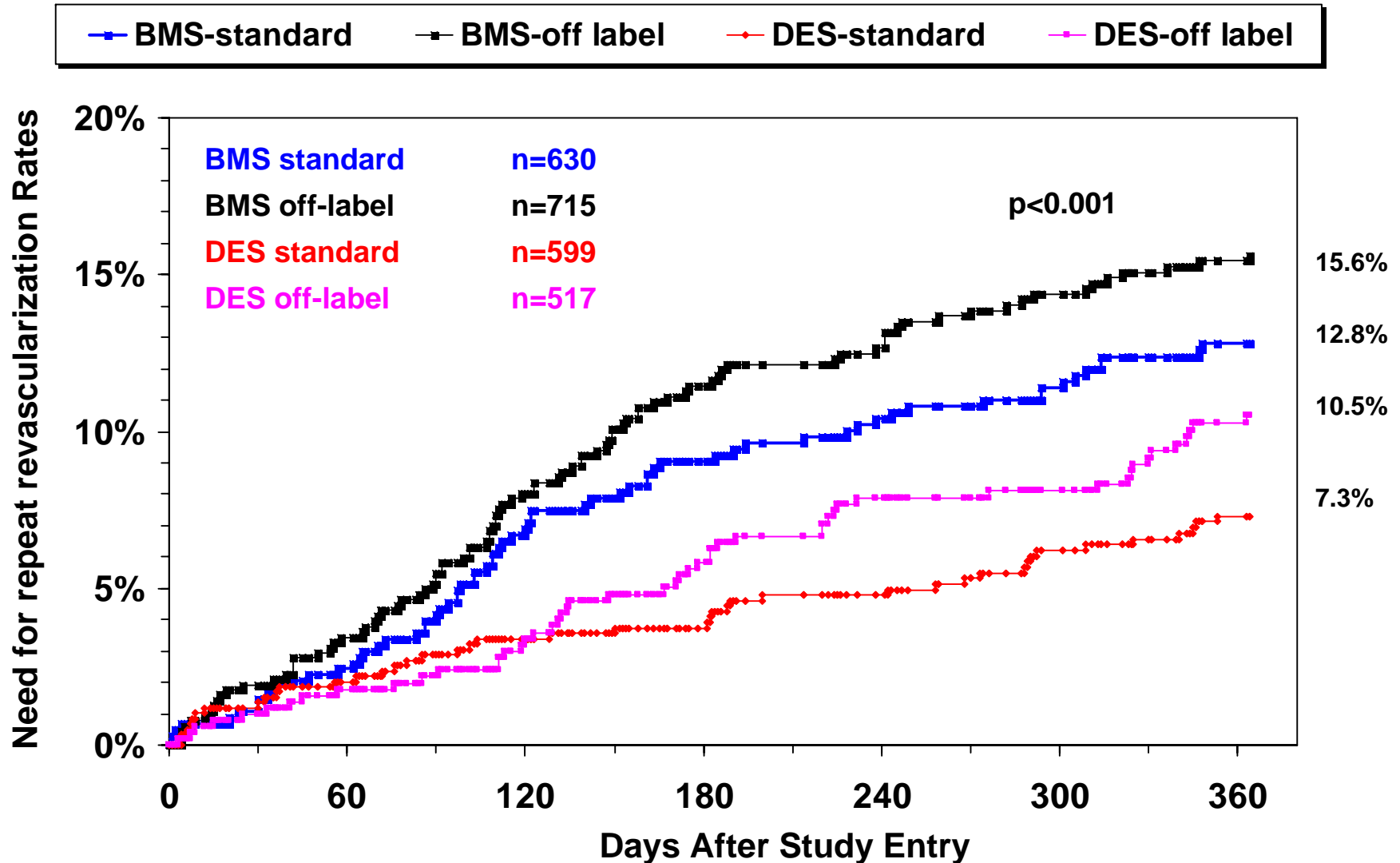
One-year repeat PCI rates by stent type & label indications
BMS patients from wave 3 and DES patients from wave 4

— BMS-standard — BMS-off label — DES-standard — DES-off label



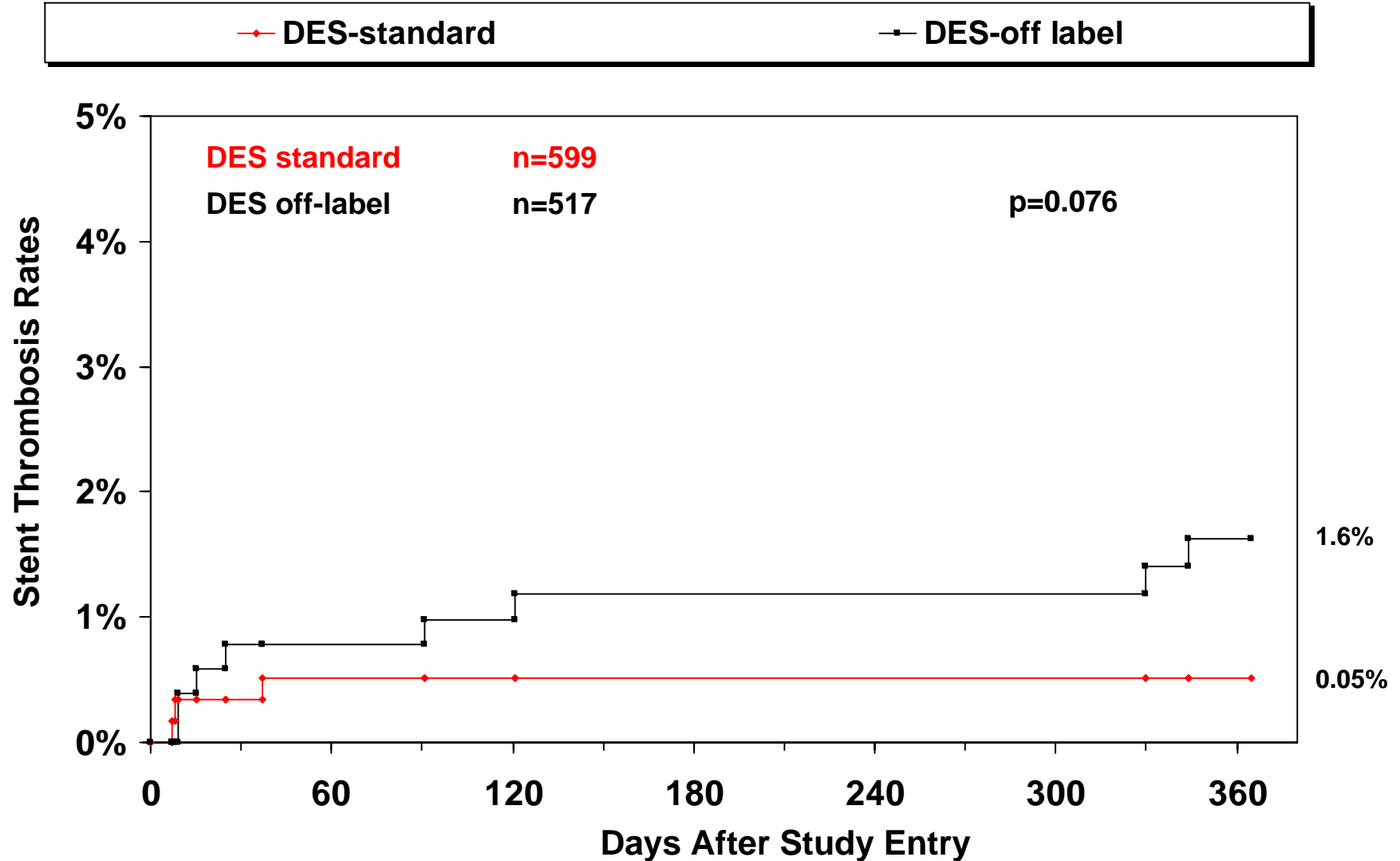
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One-year repeat revascularization rates by stent type & label indications
BMS patients from wave 3 and DES patients from wave 4



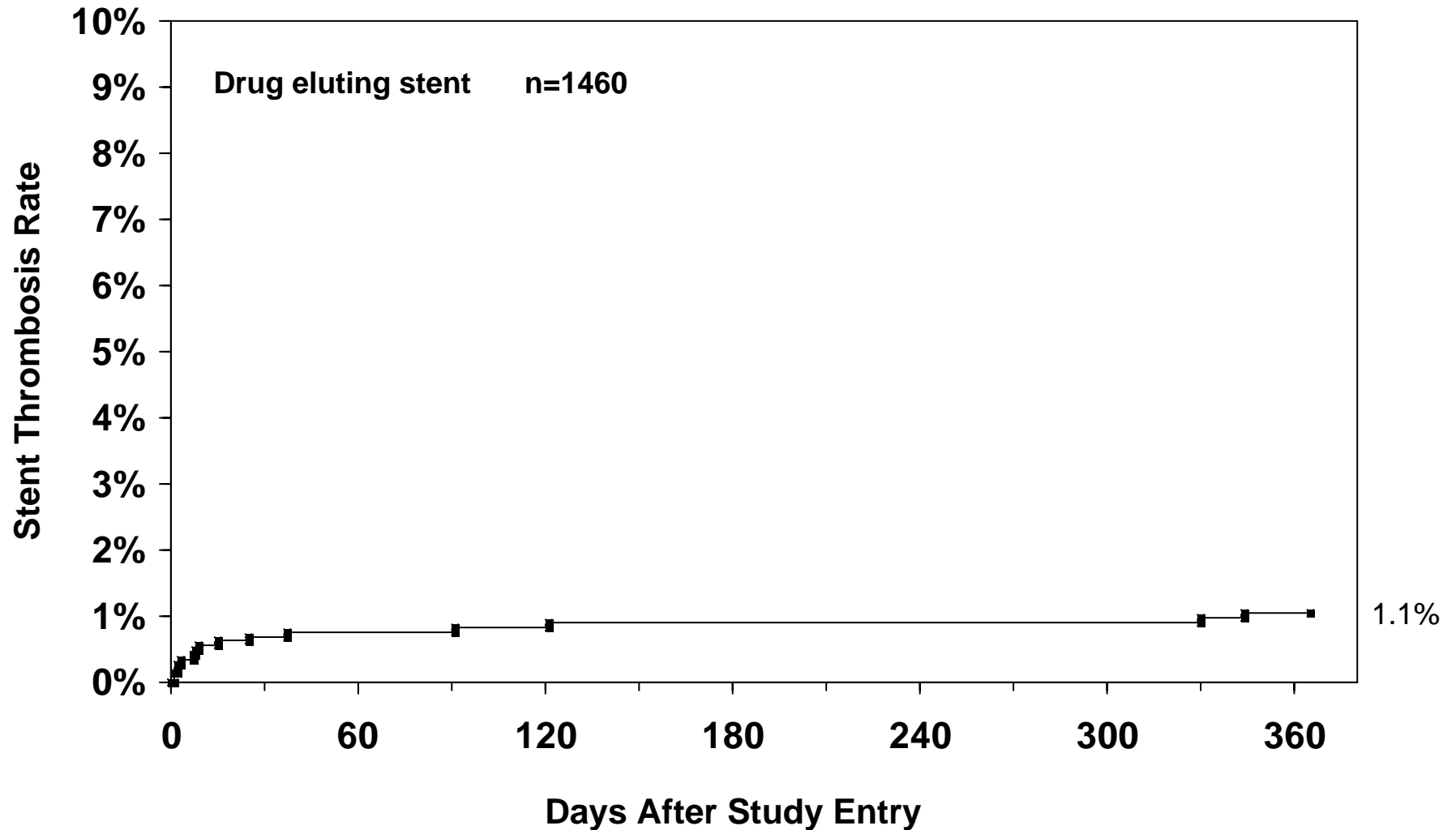
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One-year stent thrombosis rates by label indications in DES patients



NHLBI Dynamic Registry

One-year Stent Thrombosis rate in wave 4 DES patients



Conclusions

- Findings were similar in the two independent “real-world” US registries
- There was no signal of excess death or MI among DES patients
- Substantial reduction in the rates of TVR by either CABG or PCI were observed
- Off-label patient outcomes were worse than on-label ones
- BMS off-label had the worst results, DES on-label the best

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Newer Stents Pose Dangers, 2 Doctors Say

By BARNABY J. FEDER
Published: October 12, 2006

More than 2,000 patients are dying needlessly each year from the use of [stents](#), the tiny metal devices that prop open heart arteries, according to an editorial published yesterday by a leading medical society.

The editorial is the latest salvo in a growing debate among doctors about the risks of fatal blood clotting and serious heart attacks associated with the latest generation of stents, which are drug-coated. The devices are sold by Boston Scientific and Johnson & Johnson. The drug coating is meant to reduce inflammation at the site of the stent, in hopes of preventing a recurrence of the arterial blockage that led to the insertion of the device.

The article, published as [a guest editorial on the Web site of the American College of Cardiology](#), said patients faced a lower risk if treated with older, bare-metal stents that might work just as well in many cases.

Stents have become the preferred therapy for millions of Americans a year. And all stents

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From the desk of the Cardiosource Editor-in-Chief and guest editors. Editorial comments reflect the personal opinion of the editor and do not necessarily reflect the official opinion of the American College of Cardiology.

Write the Editor

Editorial

Article References

Title: Drug-Eluting Stents: An Ounce of Prevention for a Pound of Flesh?

Author: [Sanjay Kaul, M.D.](#)

Author Disclosure: This author has nothing to disclose.

Author: [George A. Diamond, M.D., F.A.C.C.](#)

Author Disclosure:

Date Posted: 10/11/2006

September 14, 2006

FDA is issuing an alert to consumers about an outbreak of *E. coli* O157:H7.... To date, preliminary epidemiological evidence suggests that bagged fresh spinach may be a possible cause of the [50 cases of illness and one death among millions of potential consumers].... Based on the current information, FDA advises that consumers not eat bagged fresh spinach at this time.

September 14, 2006

FDA [is] aware of recent data suggesting a small but significant increase in the rate of death and myocardial infarction (heart attack) possibly due to stent thrombosis (a blood clot in the stent) in patients treated with DES.... [T]he data we currently have do not allow us to fully characterize the mechanism, risks, and incidence of DES thrombosis.... At this time, FDA believes that coronary DES remain safe and effective....

"Drug-eluting stents (DES) have dramatically transformed the landscape of interventional cardiology largely on the basis of empirical evidence showing profound reduction in angiographic and clinical restenosis without any significant increase in adverse events. The justification for the enormous surfeit of DES use (totaling nearly 6 million patients globally to date at a cost of \$4-5 billion annually) is founded on the notion that restenosis-although not a major impediment on survival-impacts importantly on quality-of-life, and the need for repeat revascularization. To some extent, our preoccupation with cosmetic angiographic improvement as a surrogate for meaningful clinical benefit has fueled the unbridled enthusiasm for DES, typified by proclamations to the effect that "the Achilles' heel of stenting (restenosis) has finally been put to

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