

# **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**



- 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



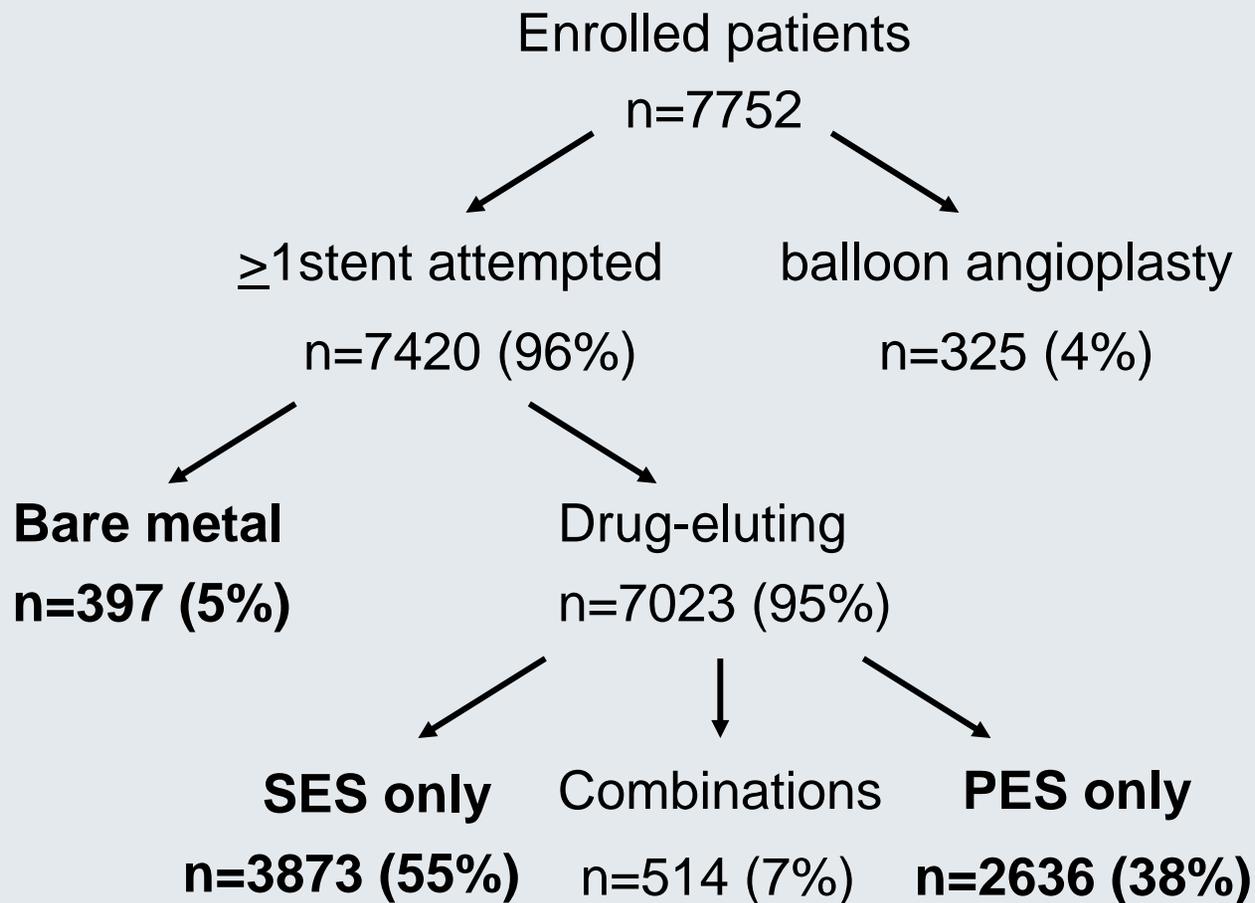
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# Data Collection and Management

- 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





	<b>BMS Group (n=397)</b>	<b>SES Group (n=3873)</b>	<b>PES Group (n=2636)</b>	<b>P BMS vs. DES</b>	<b>P SES vs. PES</b>
Age, mean, SD (years)	66.0, 11.9	63.6, 12.0	64.7, 11.6	<b>0.001</b>	<b>0.0009</b>
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	<b>0.0002</b>	0.09
Prior angioplasty, %	29.5	36.9	38.1	<b>0.0017</b>	0.33

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

Missing cases exist for some variables.



	<b>BMS Group (n=397)</b>	<b>SES Group (n=3873)</b>	<b>PES Group (n=2636)</b>	<b>P BMS vs. DES</b>	<b>P SES vs. PES</b>
Vessel Disease				<b>0.03</b>	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, %				<b>&lt;.0001</b>	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	<b>&lt;.0001</b>	0.72
Ejection fraction <40%, %	20.0	13.2	13.5	<b>0.001</b>	0.73



	<b>BMS Group (n=397)</b>	<b>SES Group (n=3873)</b>	<b>PES Group (n=2636)</b>	<b>P BMS vs. DES</b>	<b>P SES vs. PES</b>
Attempted lesions, mean, SD	1.3, 0.5	1.5, 0.7	1.4, 0.7	<b>&lt;.0001</b>	<b>0.003</b>
Multi-lesion intervention, %	25.5	34.7	32.3	<b>0.0005</b>	<b>&lt;0.05</b>
Stents used, mean, SD	1.2, 0.5	1.4, 0.7	1.3, 0.6	<b>&lt;0.0001</b>	<b>0.004</b>
Multiple DES used, %	--	29.1	26.9	--	<b>0.05</b>
Stent overlap, %	13.2	17.5	15.1	<b>0.06</b>	<b>0.004</b>
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	<b>0.02</b>
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	<b>0.01</b>
Calcified	29.8	24.1	29.5	0.15	<b>&lt;.0001</b>
Total occlusion	19.1	11.2	9.9	<b>&lt;.0001</b>	0.11
De novo lesion treated	96.5	93.7	94.1	<b>0.01</b>	0.37



# Procedural Characteristics

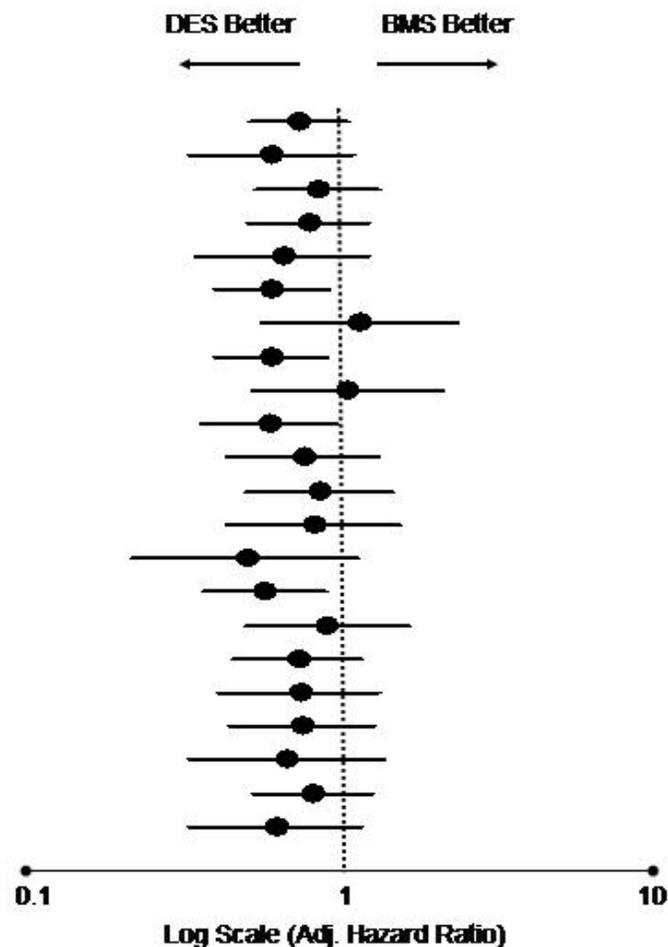
	<b>BMS Group (n=397)</b>	<b>SES Group (n=3873)</b>	<b>PES Group (n=2636)</b>	<b>P BMS vs. DES</b>	<b>P SES vs. PES</b>
Maximum diameter of stent used, mean, SD	3.3, 0.9	3.0, 0.4	2.9, 0.4	<b>&lt;.0001</b>	<b>&lt;.0001</b>
Maximum length of stent used, mean, SD	18.3, 6.8	20.2, 7.2	18.6, 7.0	<b>0.0002</b>	<b>&lt;.0001</b>
Lesion Complication, %					
Abrupt closure	0.5	0.2	0.6	0.70	<b>0.02</b>
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	<b>&lt;.0001</b>	<b>0.03</b>
Procedural Success, %				<b>0.005</b>	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



<b>Clinical Event</b>	<b>BMS (n=397)</b>	<b><u>1-Year</u> DES (n=6509)</b>	<b>p- value</b>
Death	5.9%	3.1%	<b>0.005</b>
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%	<b>0.0007</b>
TVR (via PCI/CABG)	9.5%	6.0%	<b>0.007</b>
Death/MI	9.0%	5.2%	<b>0.002</b>

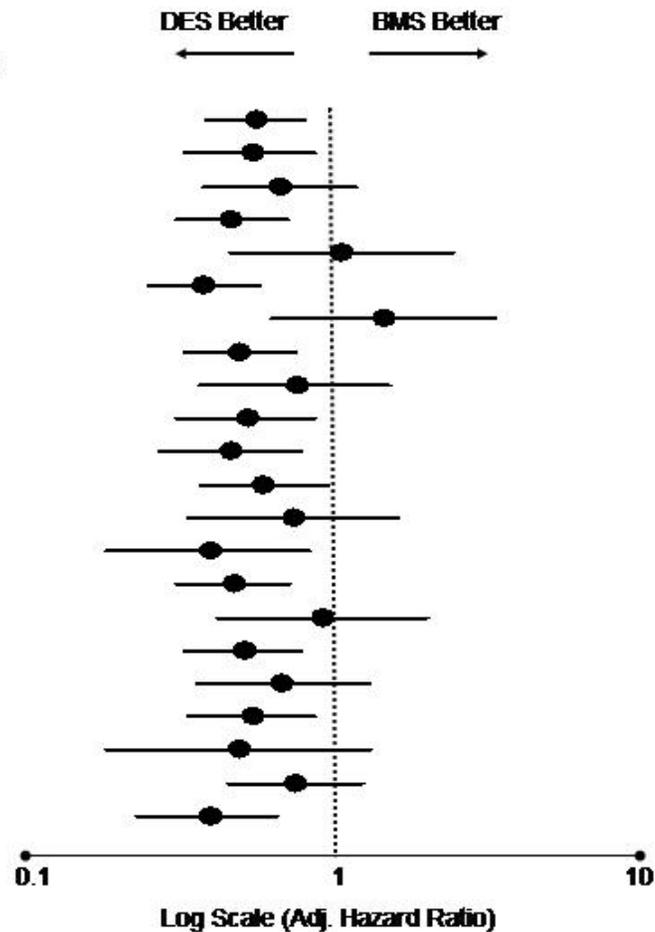


	<b>N</b>	<b>HR</b>	<b>95% C.I.</b>
<b>All Patients</b>	<b>6906</b>	<b>0.74</b>	<b>0.52-1.07</b>
<b>Age &lt; 65 years</b>	<b>3527</b>	<b>0.61</b>	<b>0.33-1.11</b>
<b>Age ≥ 65 years</b>	<b>3241</b>	<b>0.85</b>	<b>0.54-1.35</b>
<b>Male</b>	<b>4692</b>	<b>0.80</b>	<b>0.51-1.25</b>
<b>Female</b>	<b>2214</b>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





	<b>N</b>	<b>HR</b>	<b>95% C.I.</b>
<b>All Patients</b>	6906	0.58	0.40-0.83
<b>Age &lt; 65 years</b>	3527	0.56	0.34-0.90
<b>Age ≥ 65 years</b>	3241	0.69	0.39-1.21
<b>Male</b>	4692	0.48	0.32-0.73
<b>Female</b>	2214	1.09	0.48-2.50
<b>No hx PCI</b>	4288	0.39	0.26-0.60
<b>Hx PCI</b>	2511	1.49	0.65-3.41
<b>No hx CABG</b>	5502	0.51	0.34-0.78
<b>Hx CABG</b>	1324	0.78	0.38-1.56
<b>Single vessel dx</b>	3718	0.54	0.32-0.90
<b>Multi-vessel dx</b>	2734	0.48	0.28-0.81
<b>Elective</b>	4521	0.61	0.38-1.00
<b>Urgent</b>	1691	0.76	0.35-1.66
<b>Emergent</b>	694	0.41	0.19-0.87
<b>No hx MI</b>	4872	0.49	0.32-0.74
<b>Hx MI</b>	1816	0.94	0.43-2.07
<b>No diabetes</b>	4615	0.53	0.34-0.81
<b>Diabetes</b>	2153	0.70	0.37-1.35
<b>LVEF &gt; 40</b>	4345	0.56	0.35-0.90
<b>LVEF ≤ 40</b>	690	0.51	0.19-1.37
<b>Single lesion PCI</b>	4611	0.77	0.47-1.28
<b>Multi-lesion PCI</b>	2293	0.41	0.24-0.68





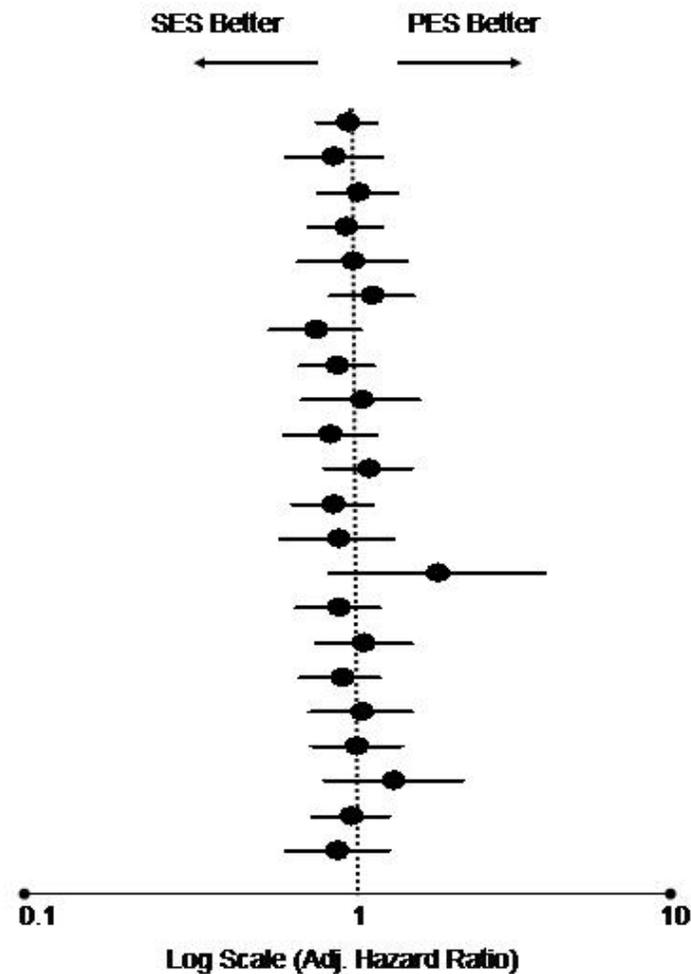
Clinical Event	<u>In-Hospital</u>			<u>1-Year</u>		
	SES (n=3873)	PES (n=2636)	p- value	SES (n=3873)	PES (n=2636)	p- value
Death	0.2%	0.08%	0.22	3.3%	2.8%	0.45
Myocardial infarction	0.6%	0.5%	0.40	2.2%	2.6%	0.20
Stent thrombosis	0.03%	0.1%	0.31	0.5%	0.8%	0.06
Repeat PCI: Any	0.4%	0.3%	0.67	8.7%	7.9%	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



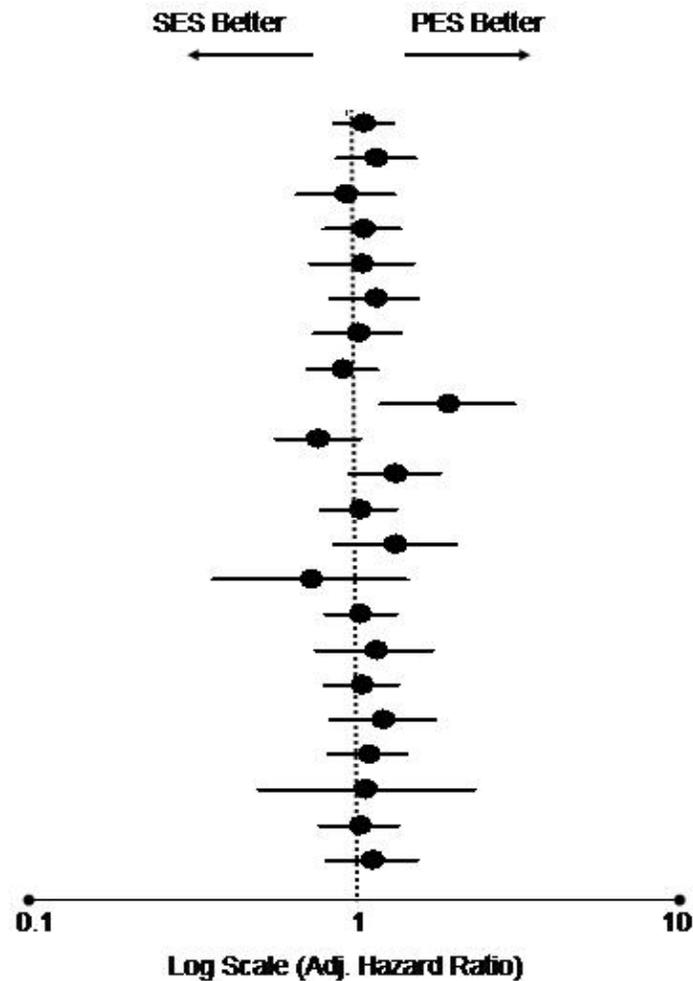
# SES vs. PES 1-year Death/MI

	<b>N</b>	<b>HR</b>	<b>95% C.I.</b>
<b>All Patients</b>	6509	0.98	0.79-1.22
<b>Age &lt; 65 years</b>	3354	0.89	0.63-1.27
<b>Age ≥ 65 years</b>	3020	1.06	0.79-1.41
<b>Male</b>	4415	0.97	0.74-1.27
<b>Female</b>	2094	1.02	0.69-1.50
<b>No hx PCI</b>	4011	1.17	0.86-1.58
<b>Hx PCI</b>	2395	0.78	0.56-1.09
<b>No hx CABG</b>	5212	0.91	0.70-1.19
<b>Hx CABG</b>	1219	1.08	0.71-1.65
<b>Single vessel dx</b>	3503	0.87	0.62-1.22
<b>Multi-vessel dx</b>	2586	1.14	0.83-1.56
<b>Elective</b>	4299	0.89	0.66-1.19
<b>Urgent</b>	1582	0.92	0.61-1.38
<b>Emergent</b>	628	1.87	0.87-4.02
<b>No hx MI</b>	4594	0.92	0.68-1.24
<b>Hx MI</b>	1706	1.10	0.78-1.56
<b>No diabetes</b>	4350	0.94	0.70-1.25
<b>Diabetes</b>	2027	1.09	0.75-1.57
<b>LVEF &gt; 40</b>	4105	1.05	0.76-1.45
<b>LVEF ≤ 40</b>	630	1.37	0.83-2.26
<b>Single lesion PCI</b>	4314	1.01	0.76-1.33
<b>Multi-lesion PCI</b>	2193	0.91	0.63-1.32





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





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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



- 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%)



- 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



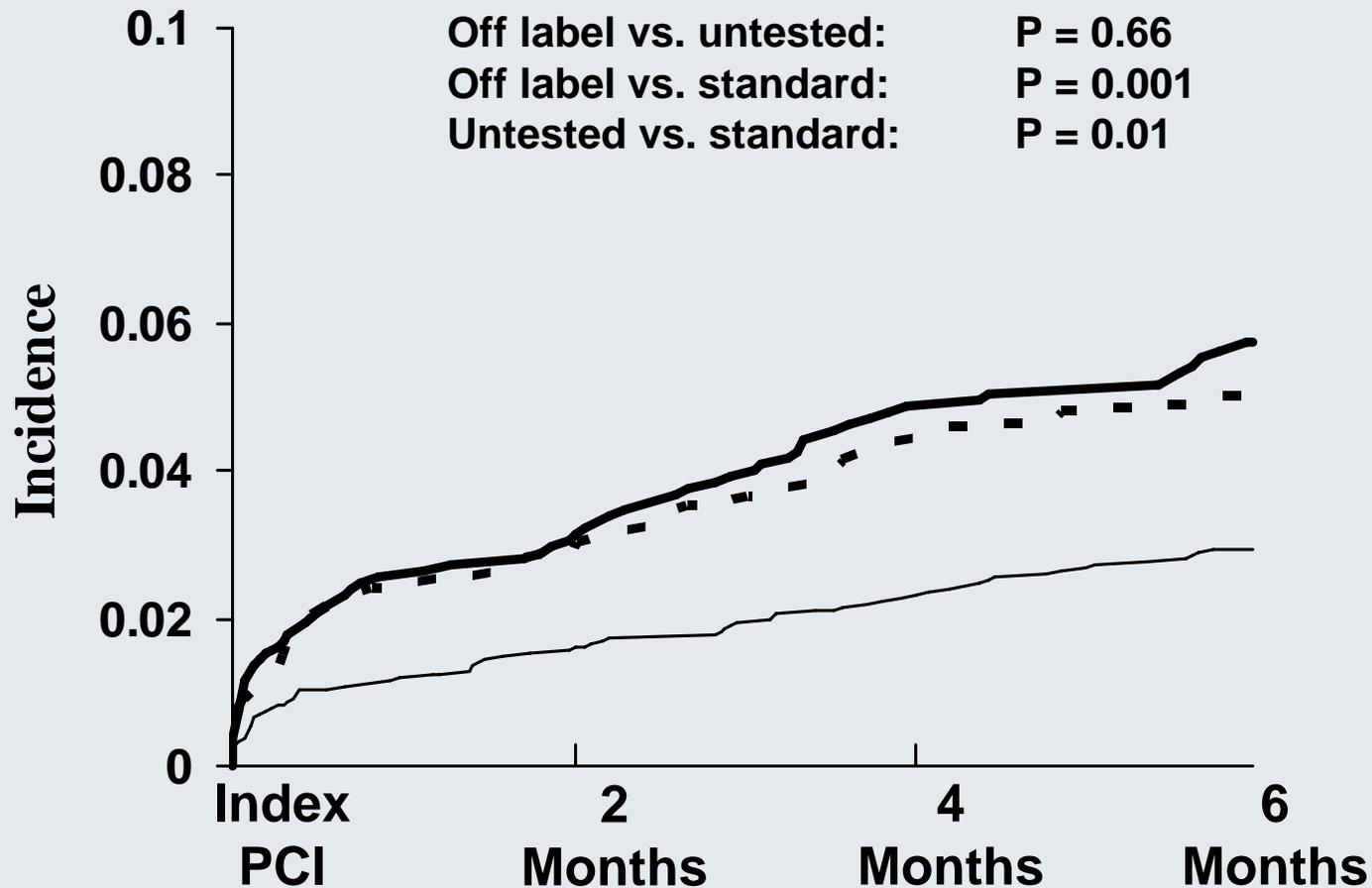
- DEScover was successful in enrolling, collecting and analyzing data for over 7700 patients from 140 US centers representing a large, cross-sectional experience of PCI in the United States
- Usage patterns and outcomes of patients treated with DES described
- Findings support the use of DES
- 1-year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



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

— Off Label - - - Untested — Standard

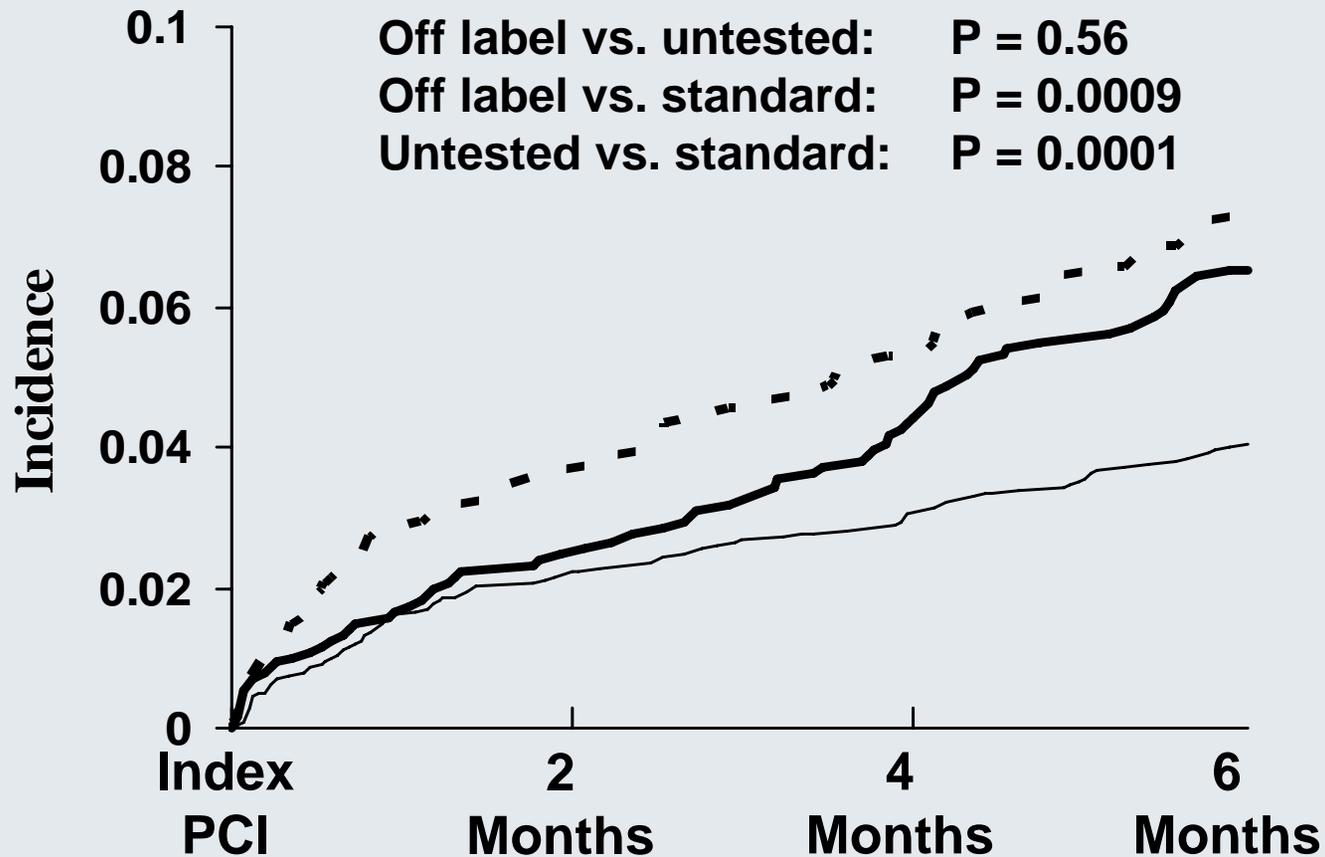




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## Off-Label DES CABG or Repeat PCI at 6-Months

— 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**

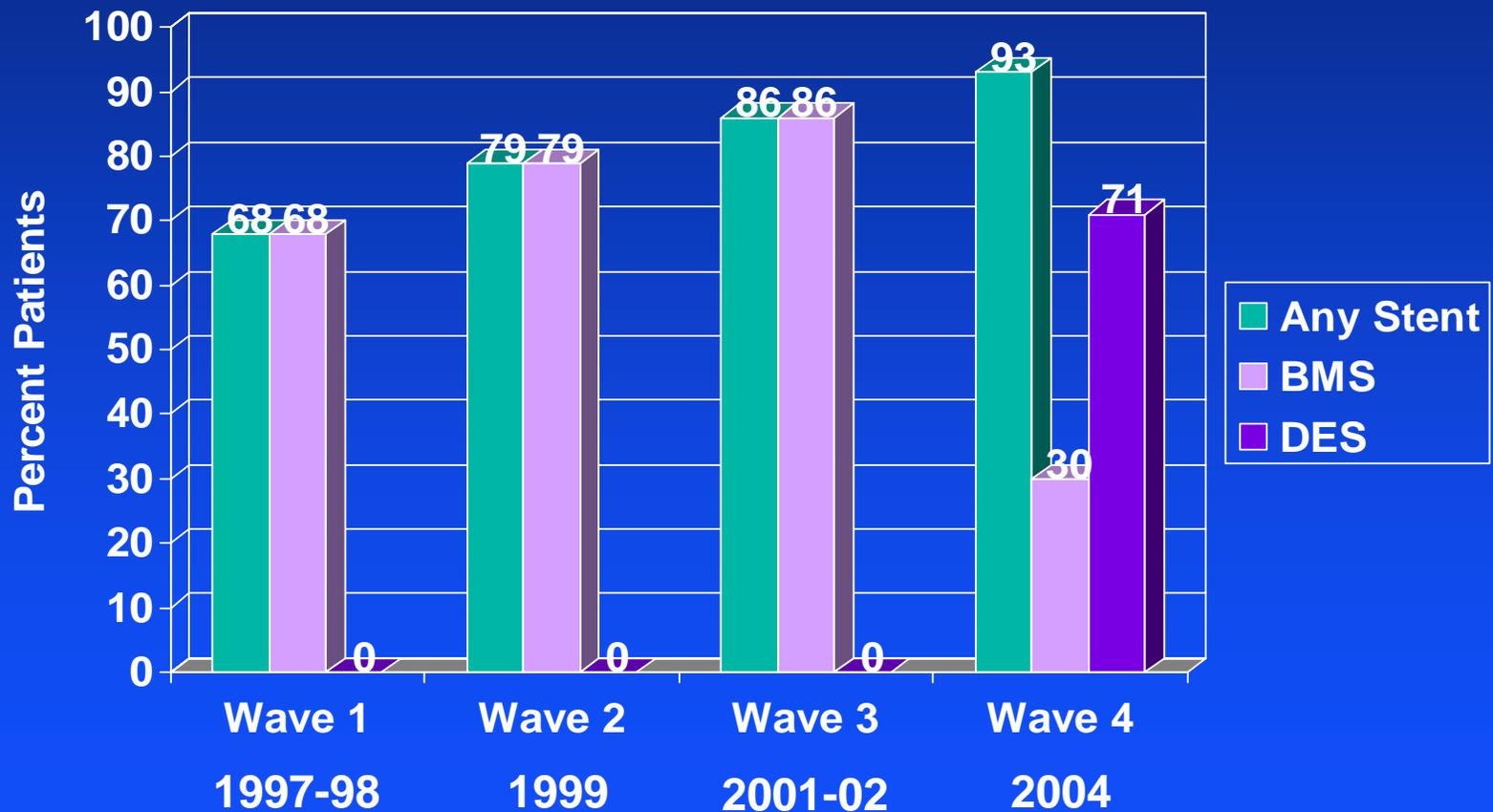
# Dynamic Registry

- **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**

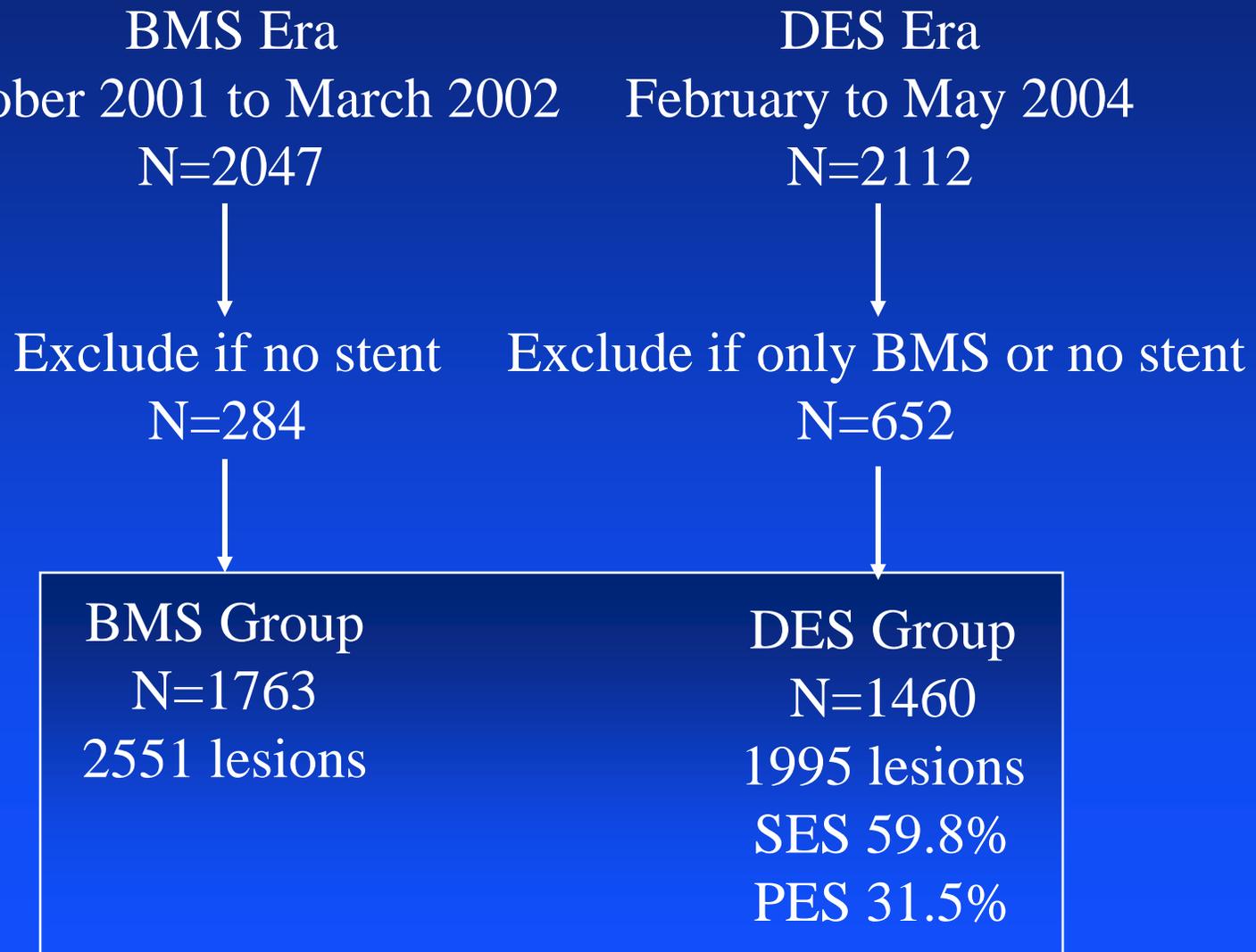
# **NHLBI Dynamic Registry: Enrollment Waves**

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

# 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	<b>0.001</b>
Hypertension, %	74.1	79.1	<b>0.001</b>
Hypercholesterolemia, %	69.8	77.5	<b>&lt;0.0001</b>
Current smoking, %	24.4	21.4	<b>0.05</b>
Prior myocardial infarction, %	26.2	26.4	0.90
Prior coronary bypass, %	17.4	19.1	0.21
Prior angioplasty, %	36.8	42.3	<b>0.002</b>
Prior CHF	12.7	9.3	<b>0.003</b>

# 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, %			<b>&lt;0.0001</b>
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	<b>&lt;0.0001</b>

# 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	<b>&lt;0.0001</b>
Lesion Types, %			
Total Occlusion	9.2	7.4	<b>0.03</b>
Thrombus	15.4	11.0	<b>&lt;0.0001</b>
Calcified	22.3	26.5	<b>0.001</b>
Bifurcation	13.2	10.2	<b>0.002</b>
Ostial	6.9	8.8	<b>0.02</b>
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	<b>0.03</b>
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	<b>&lt;0.001</b>
Target Vessel Revascularization	9.2	4.9	<b>&lt;0.001</b>
Repeat Revascularization	15.0	10.0	<b>&lt;0.001</b>
MACE (Death, MI, Repeat Revascularization)	20.9	15.5	<b>&lt;0.001</b>

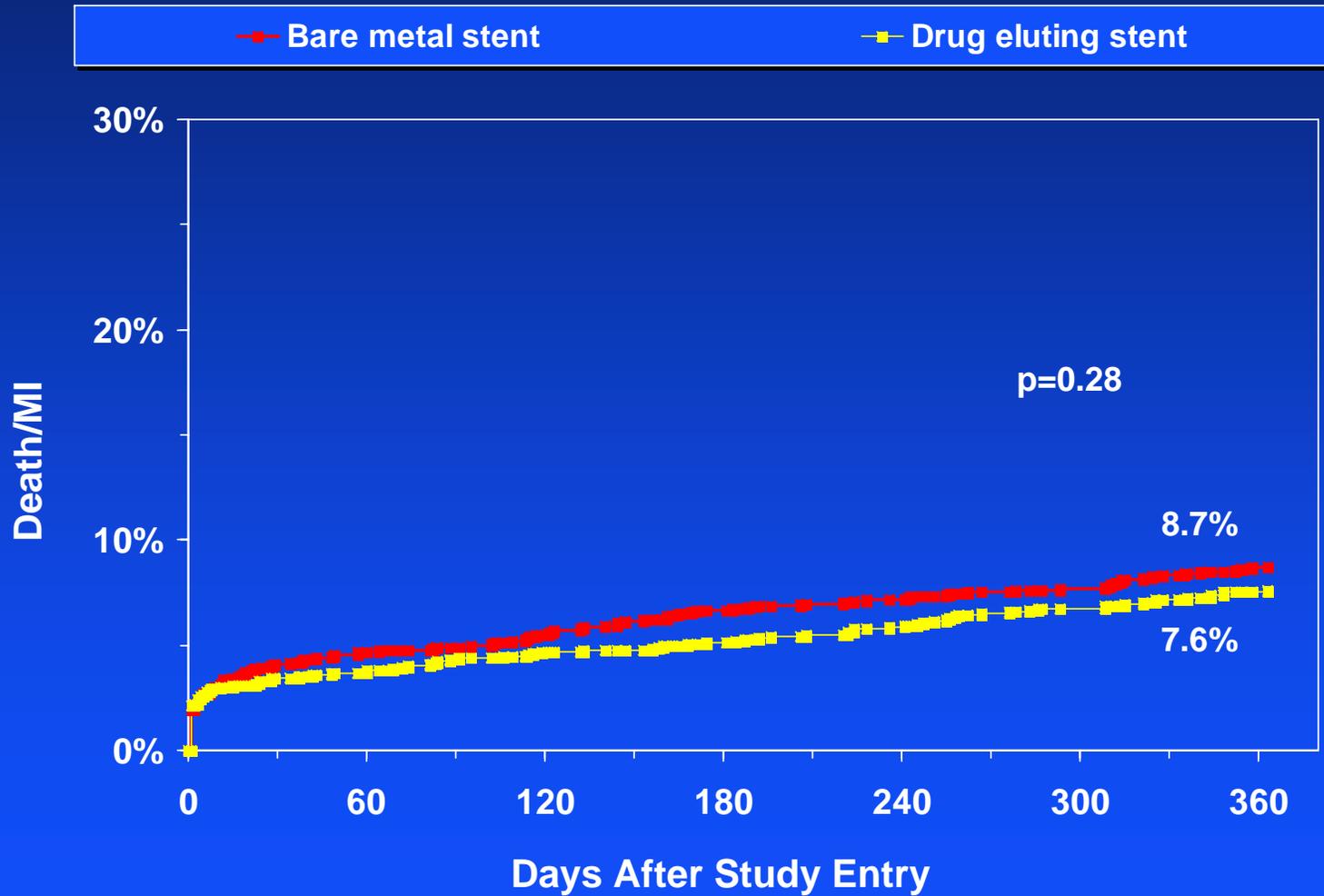
# DES vs. BMS: Adjusted and Unadjusted Events at One-Year

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

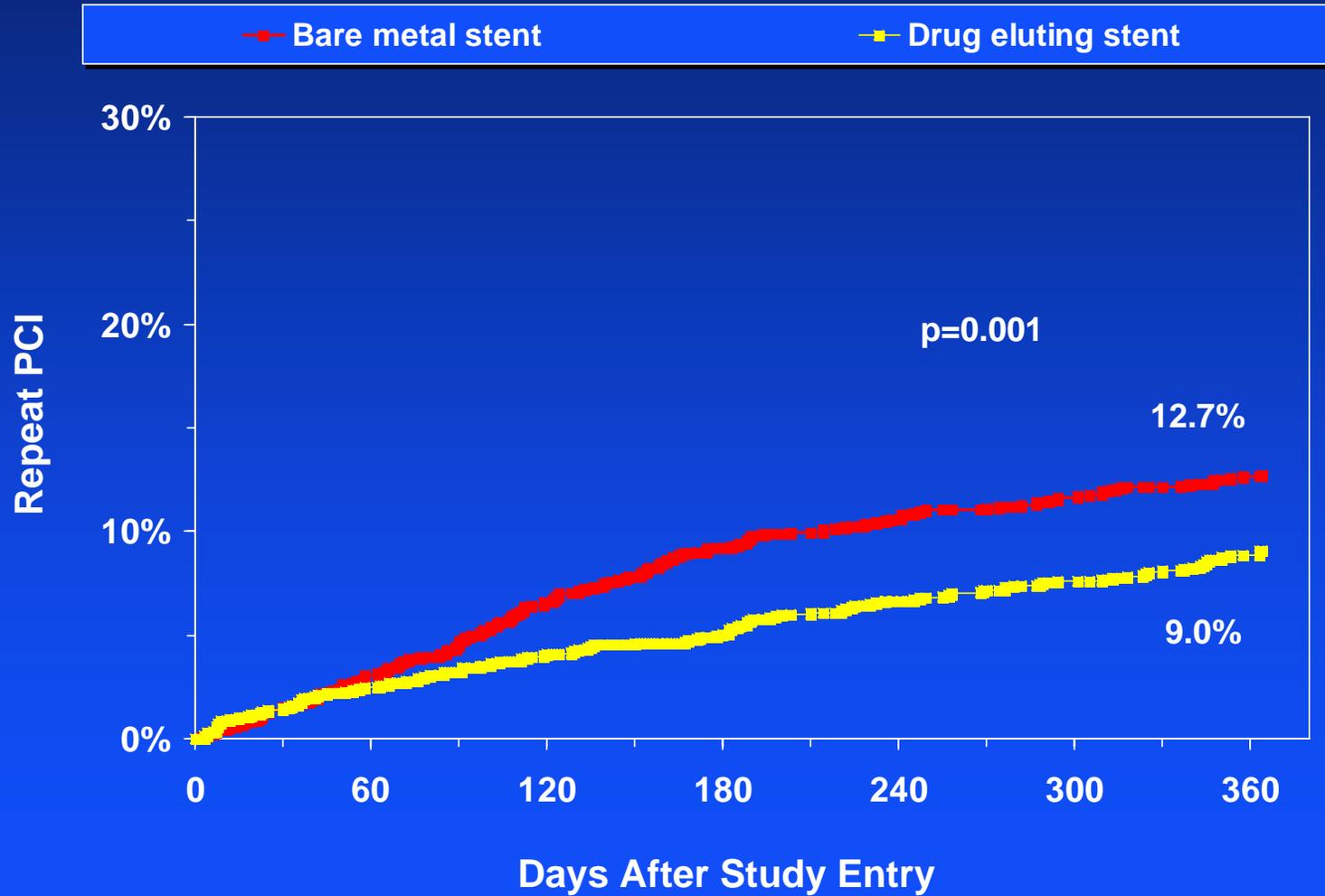
# DES vs. BMS: Events at One-Year in Discharged Patients Following an Uncomplicated Hospital Stay

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

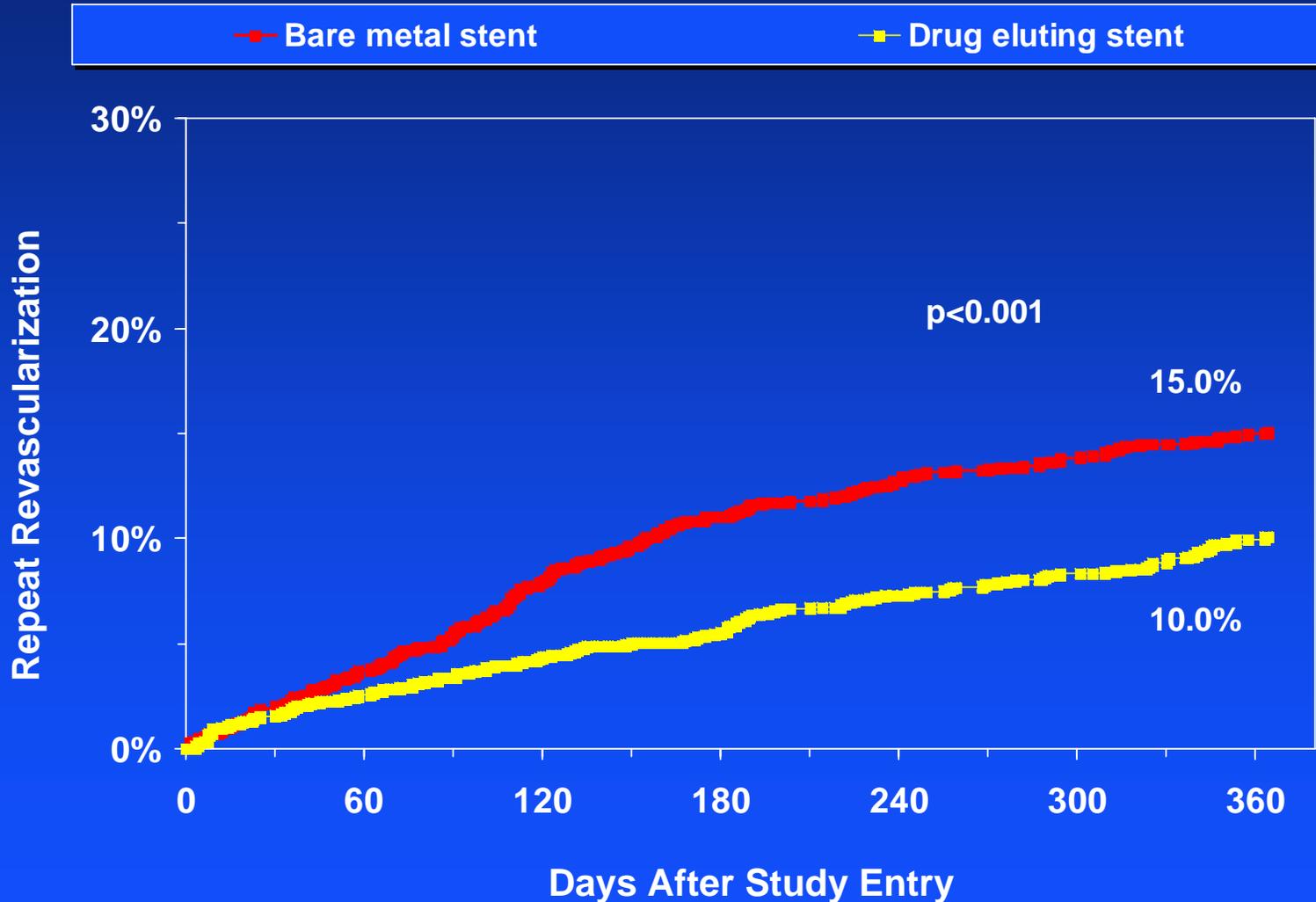
# DES vs. BMS: Death and MI



# 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

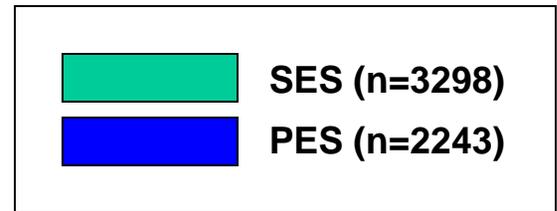
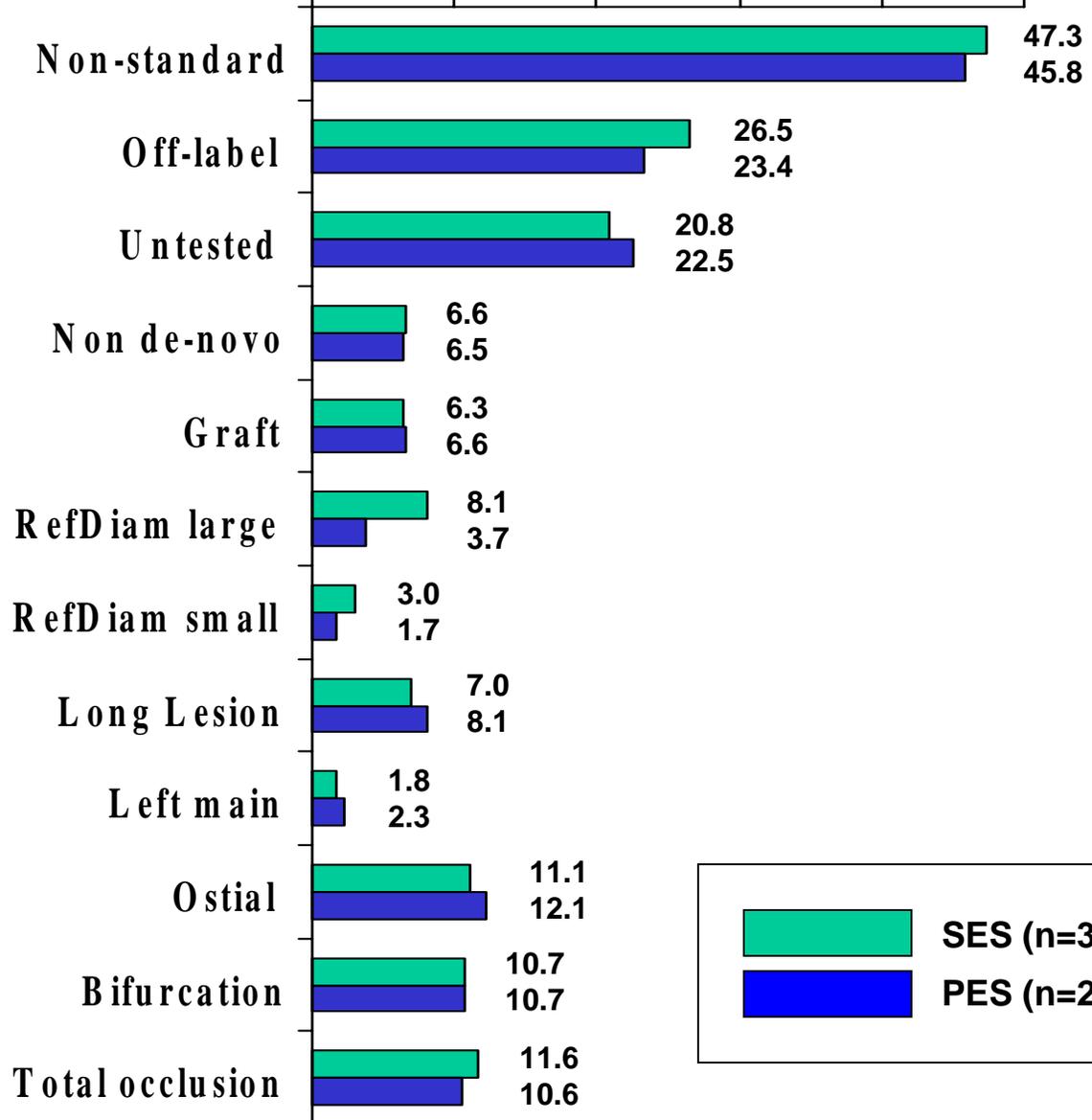
Percentage of patients

0 10 20 30 40 50

**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 N=398
	SES	PES	SES	PES	
	N=1738	N=1212	N=1560	N=1027	
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

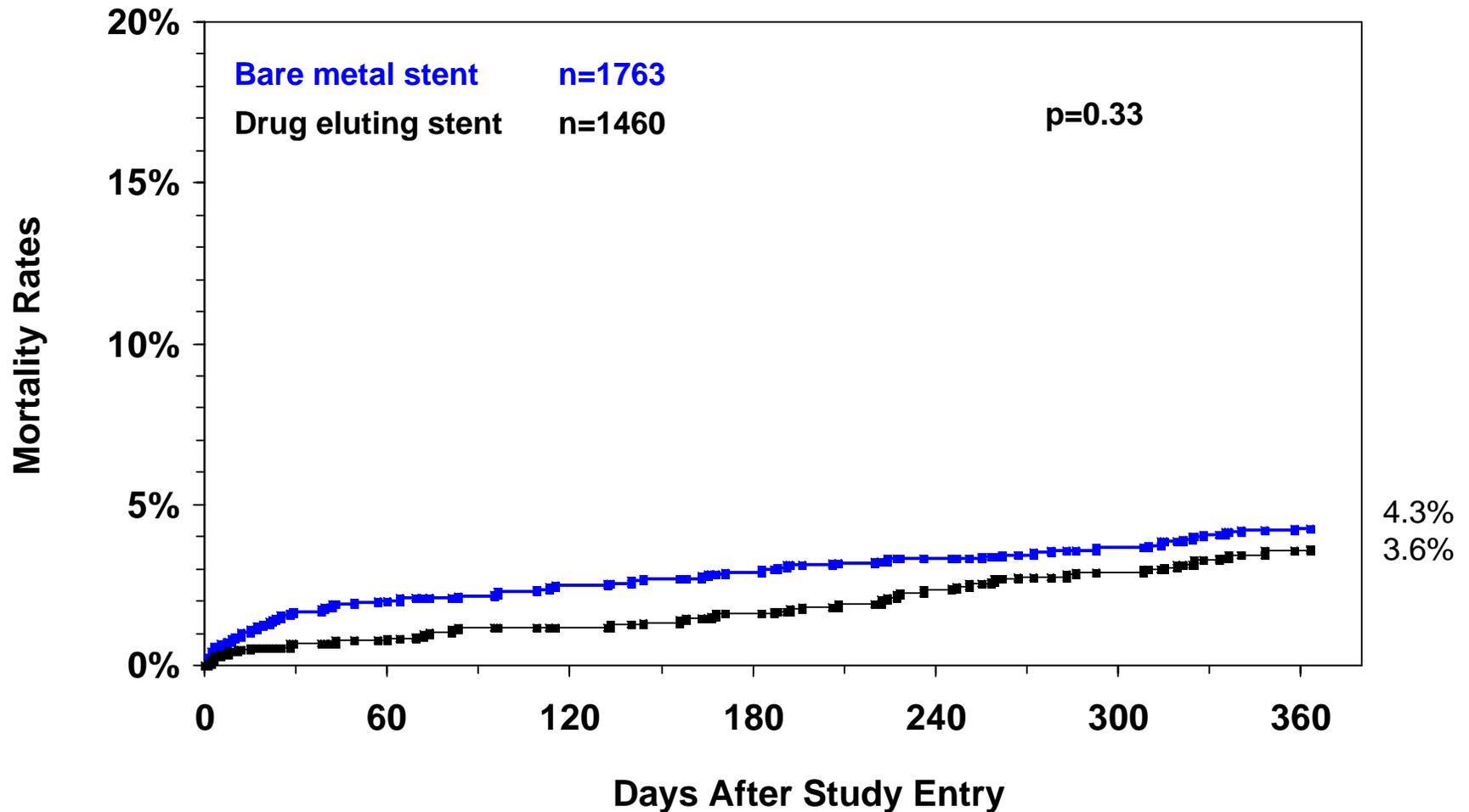
# NHLBI Dynamic Registry

## 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

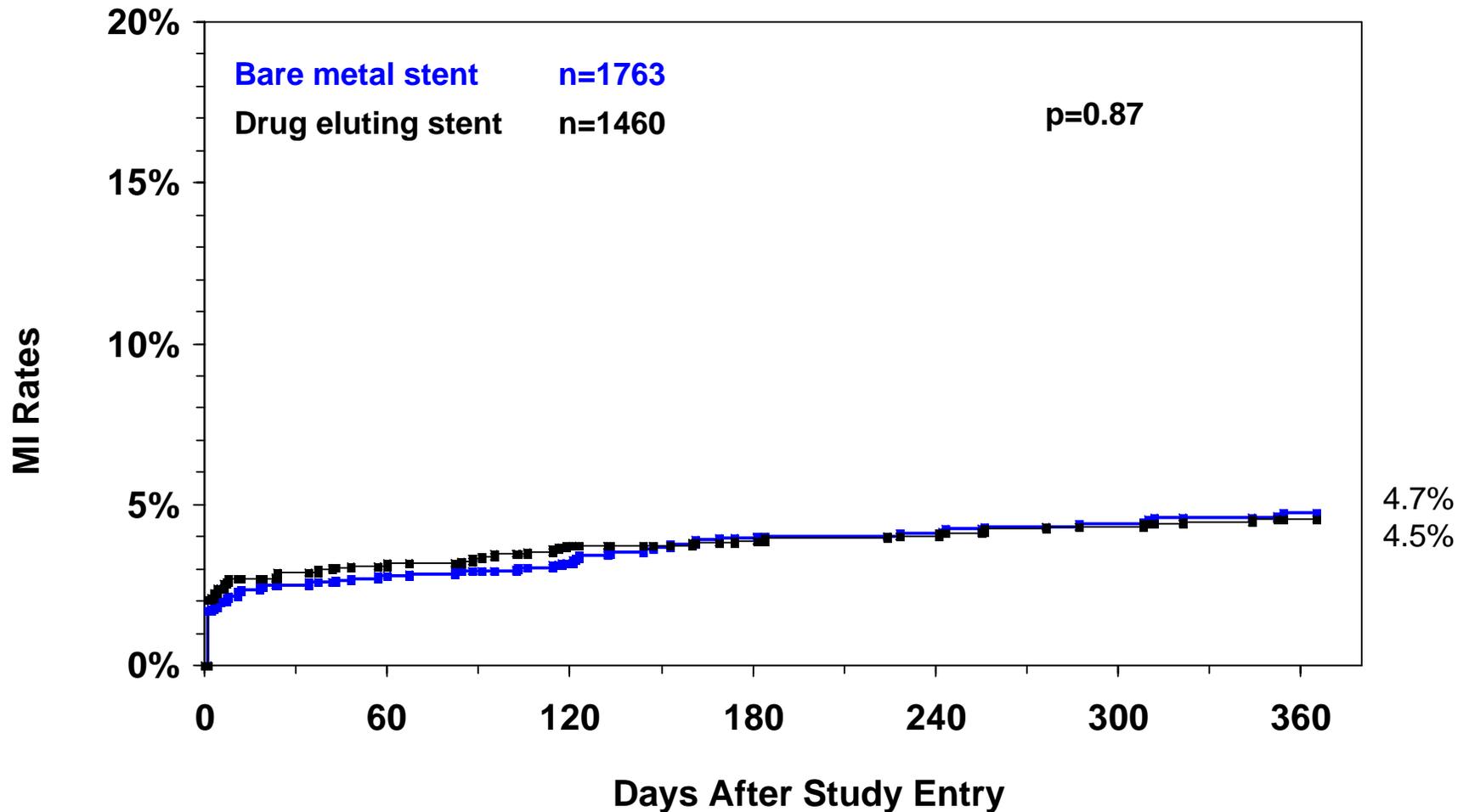


# NHLBI Dynamic Registry

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

—■ Bare metal stent

—■ Drug eluting stent

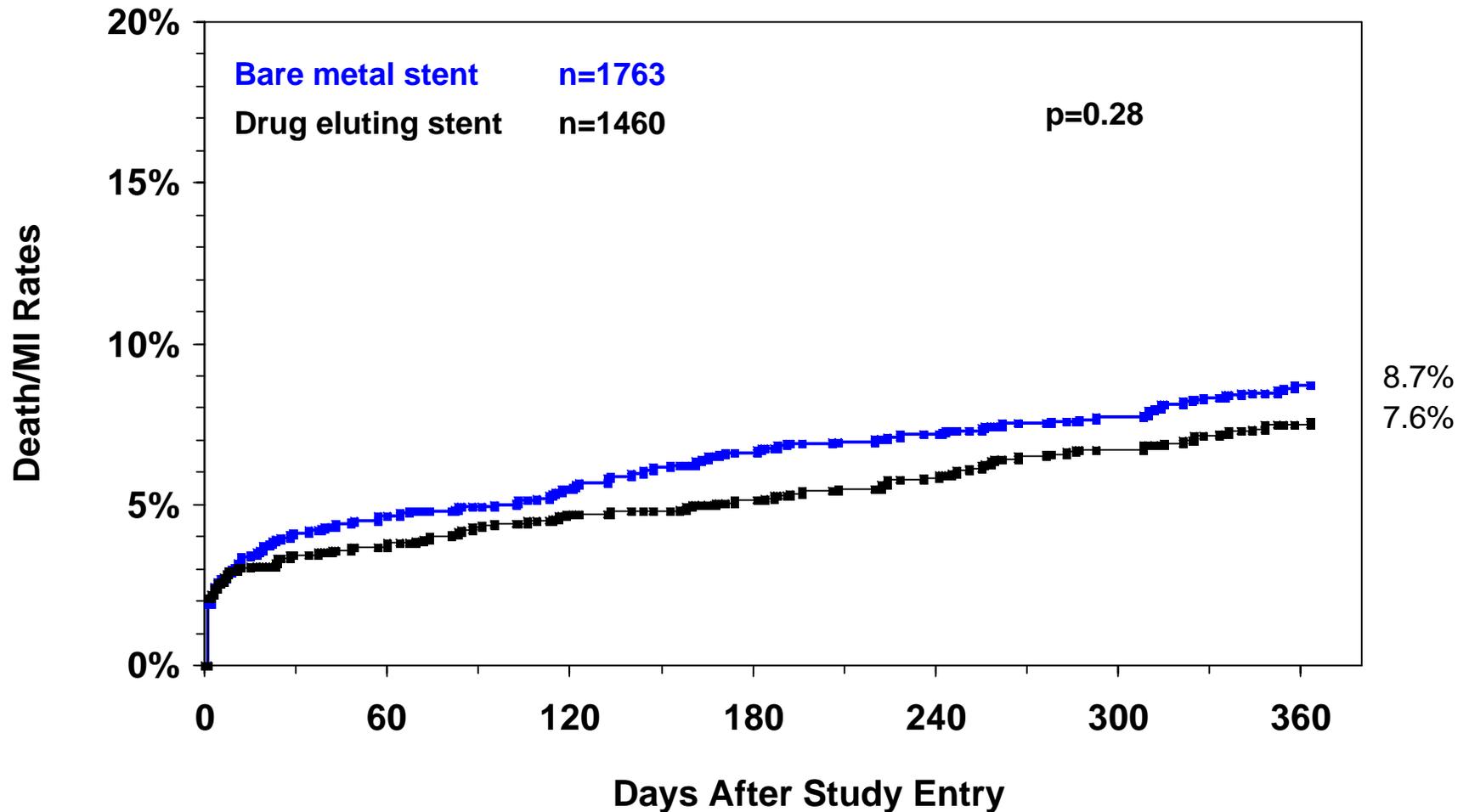


# NHLBI Dynamic Registry

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



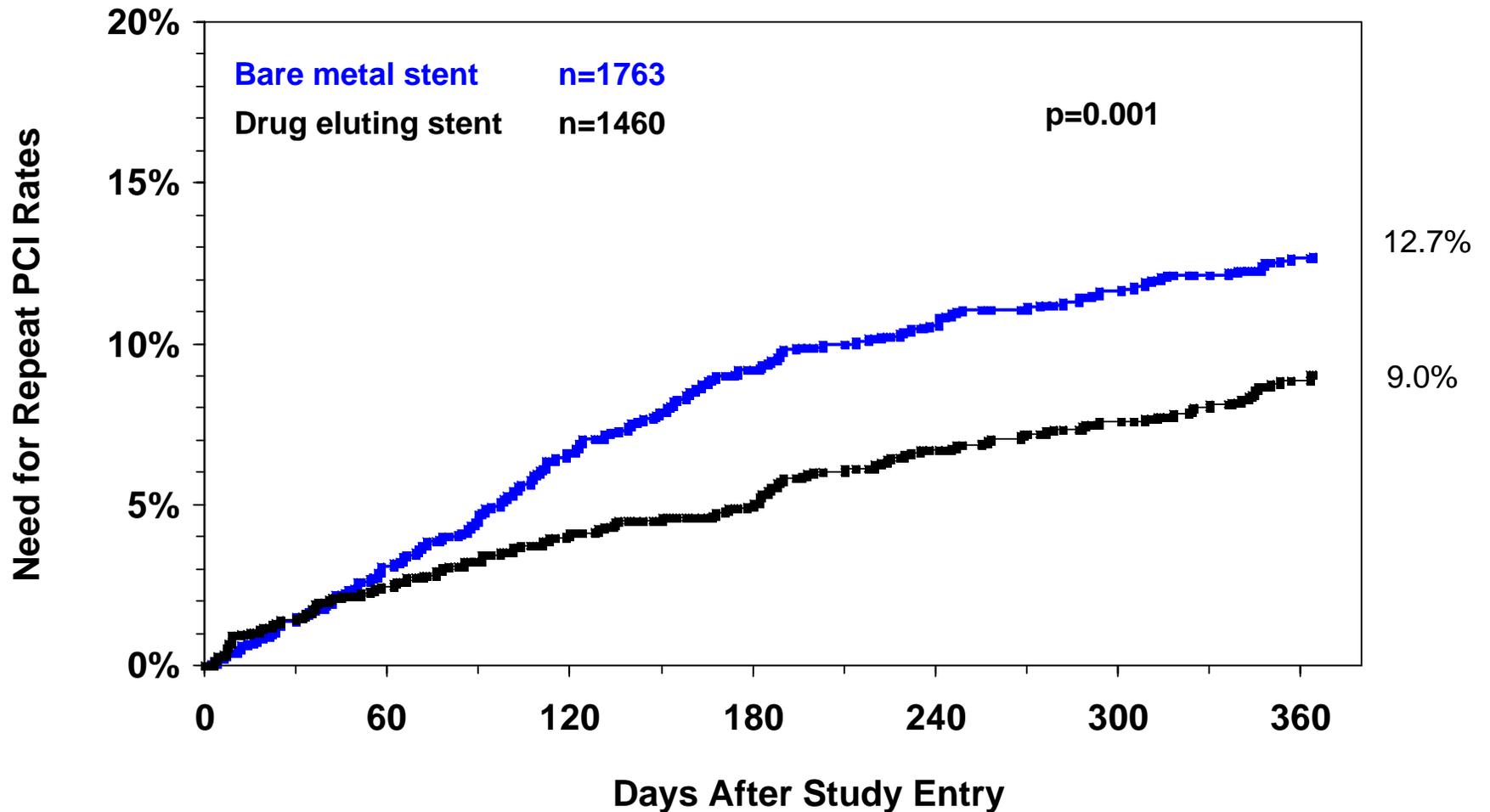
# NHLBI Dynamic Registry

## 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

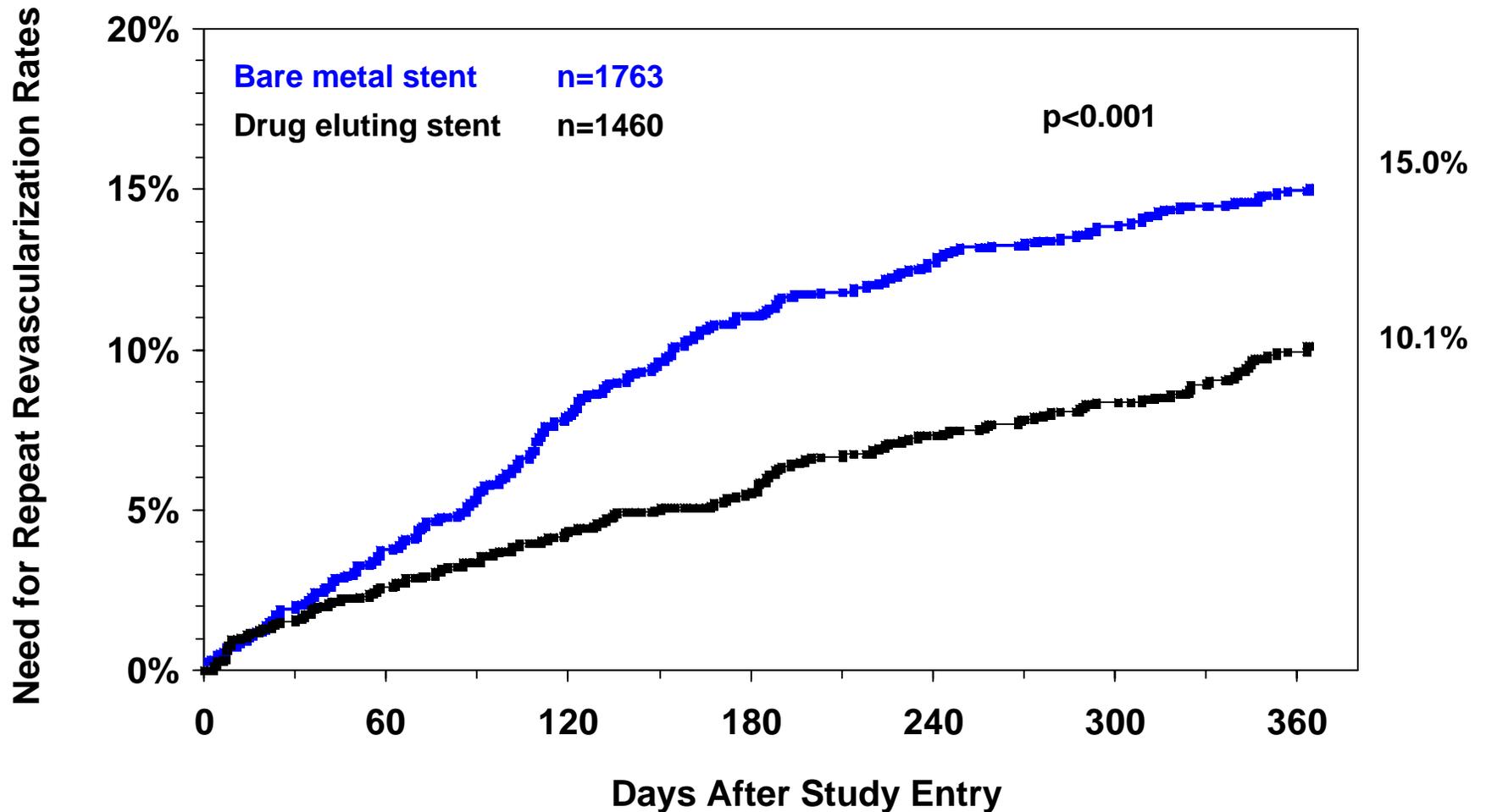


# NHLBI Dynamic Registry

One-year need for repeat revascularization rates by stent type  
BMS patients from wave 3 and DES patients from wave 4

— Bare metal stent

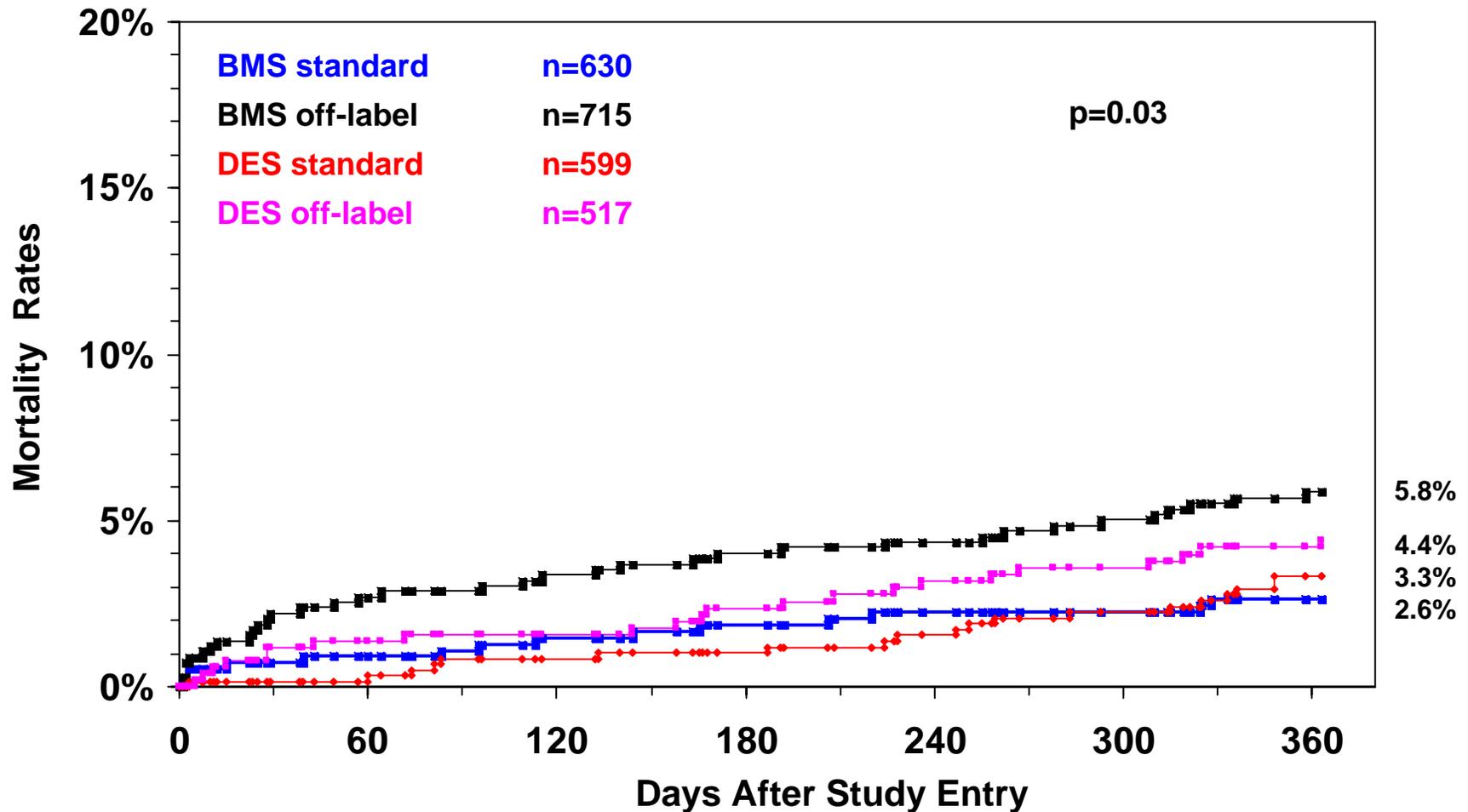
— Drug eluting stent



# NHLBI Dynamic Registry

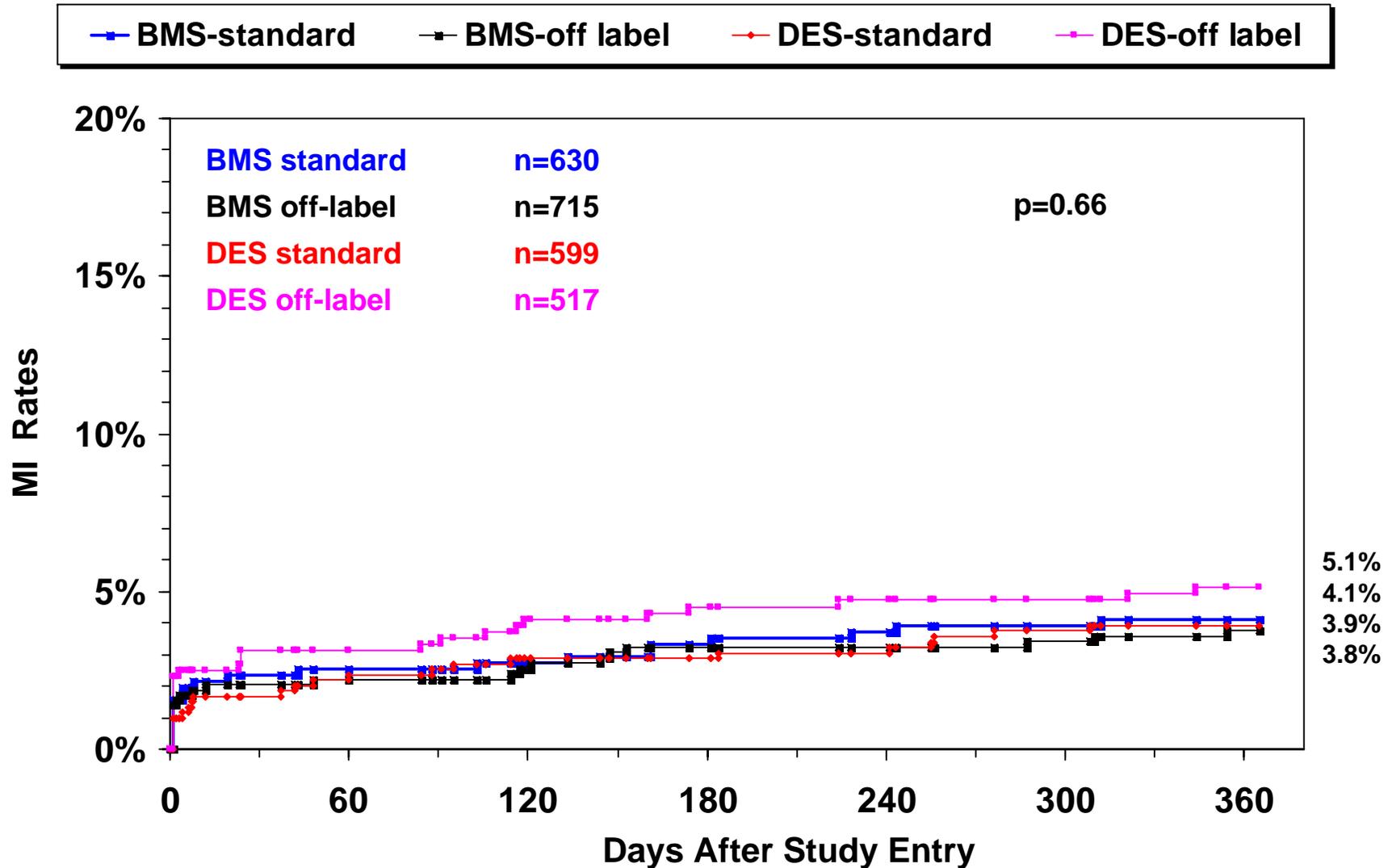
One-year cumulative mortality rates by stent type & label indications  
BMS patients from wave 3 and DES patients from wave 4

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



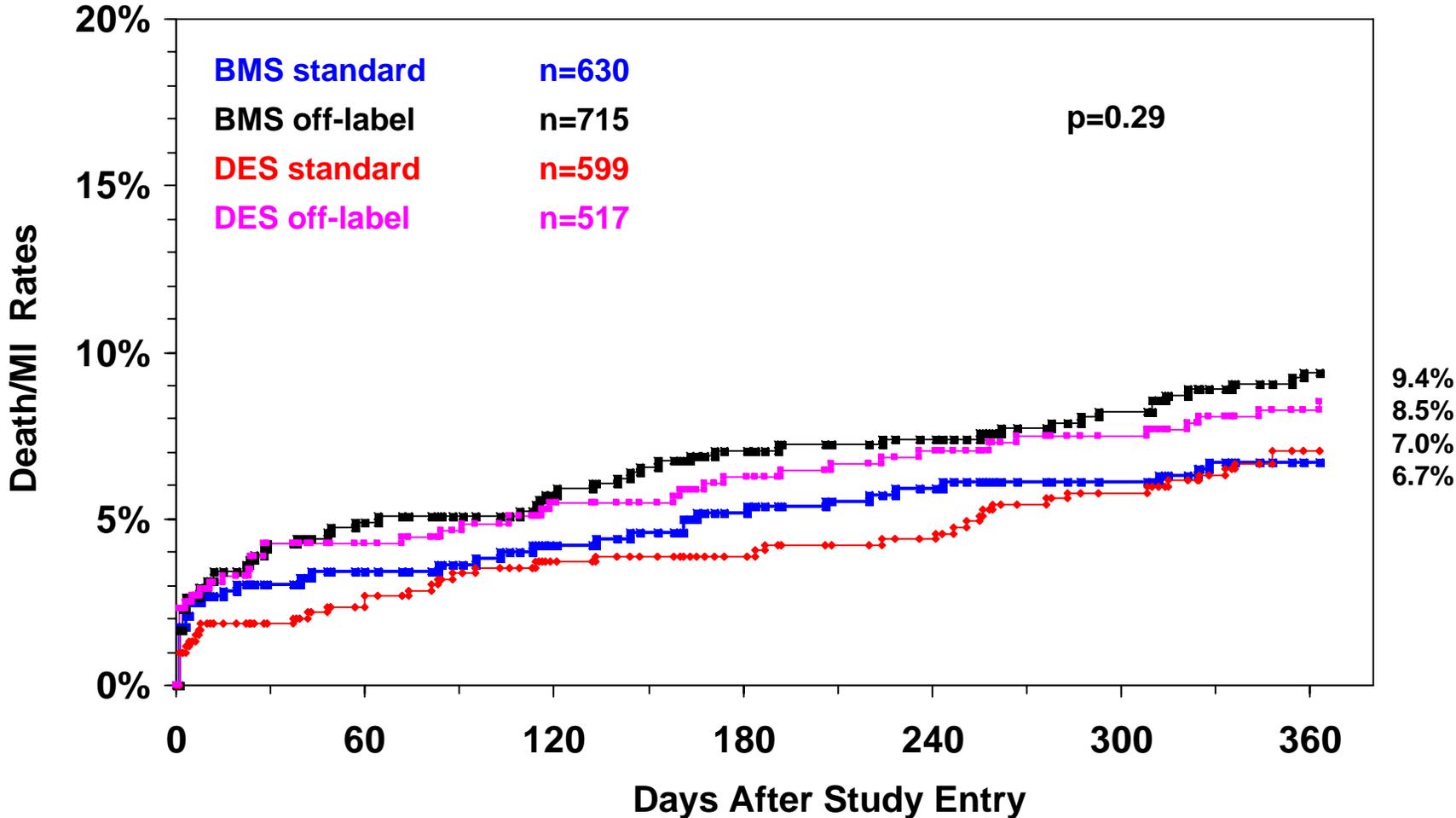
# NHLBI Dynamic Registry

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



# NHLBI Dynamic Registry

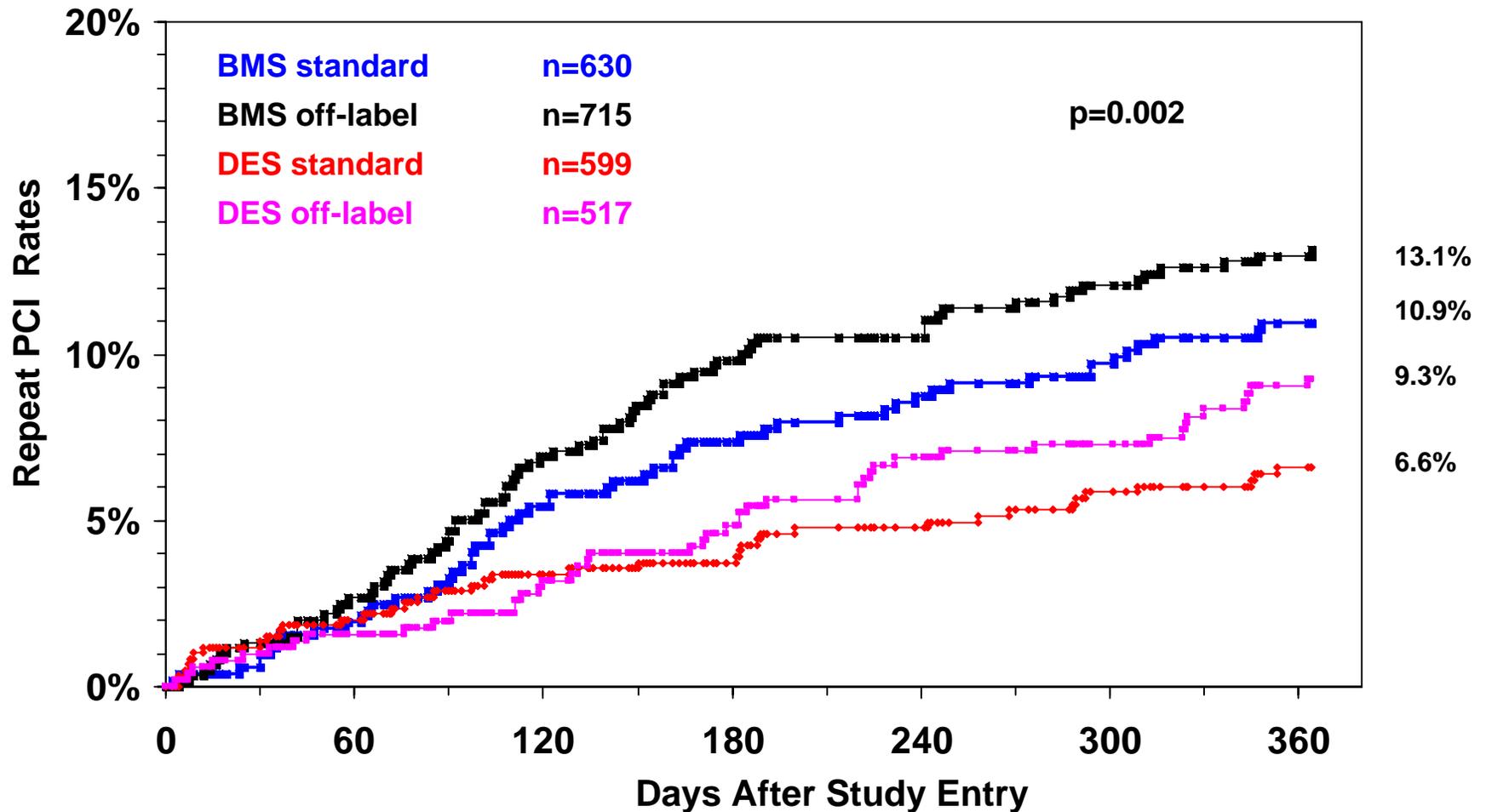
One-year composite death and MI rates by stent type & label indications  
BMS patients from wave 3 and DES patients from wave 4



# NHLBI Dynamic Registry

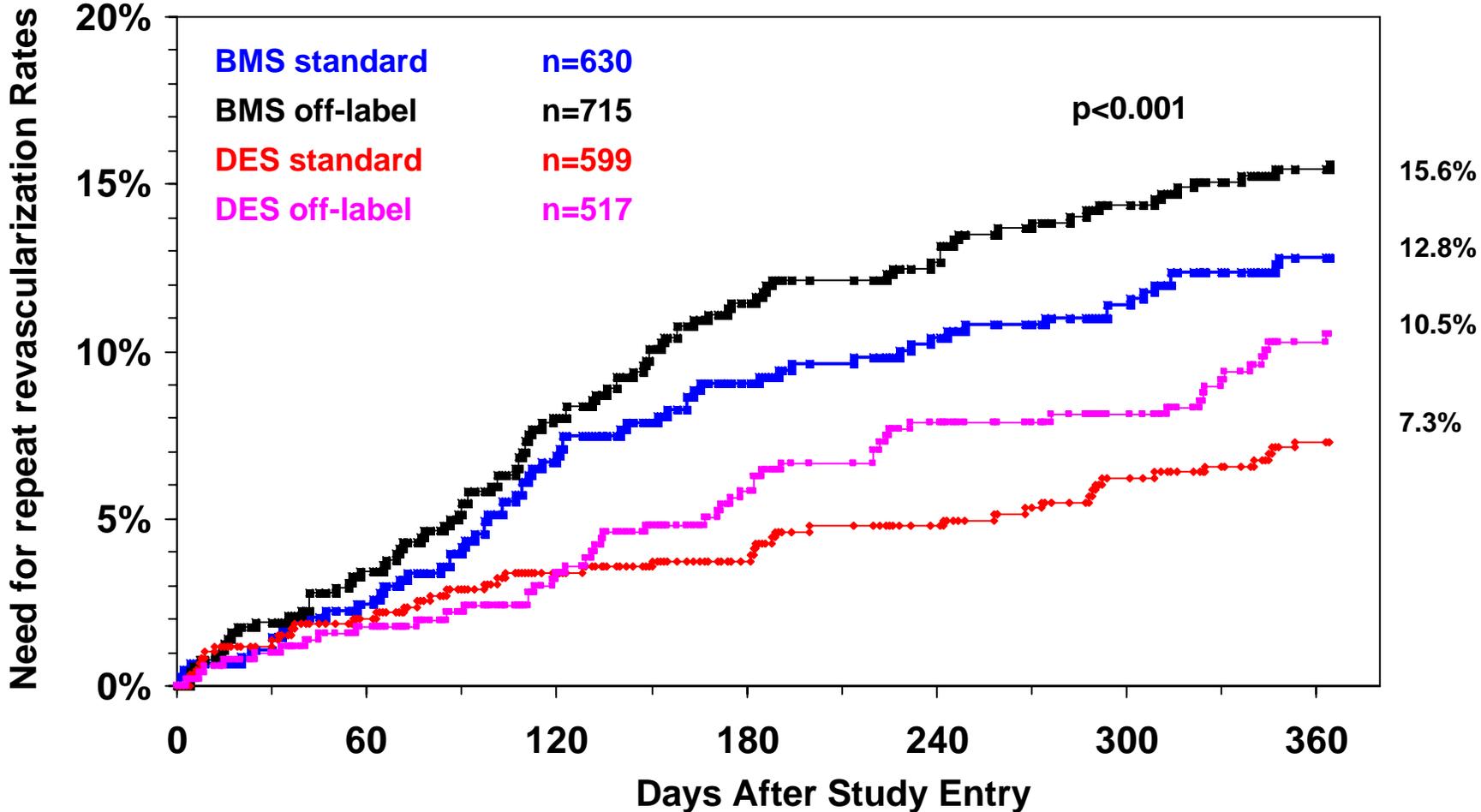
One-year repeat PCI rates by stent type & label indications  
BMS patients from wave 3 and DES patients from wave 4

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



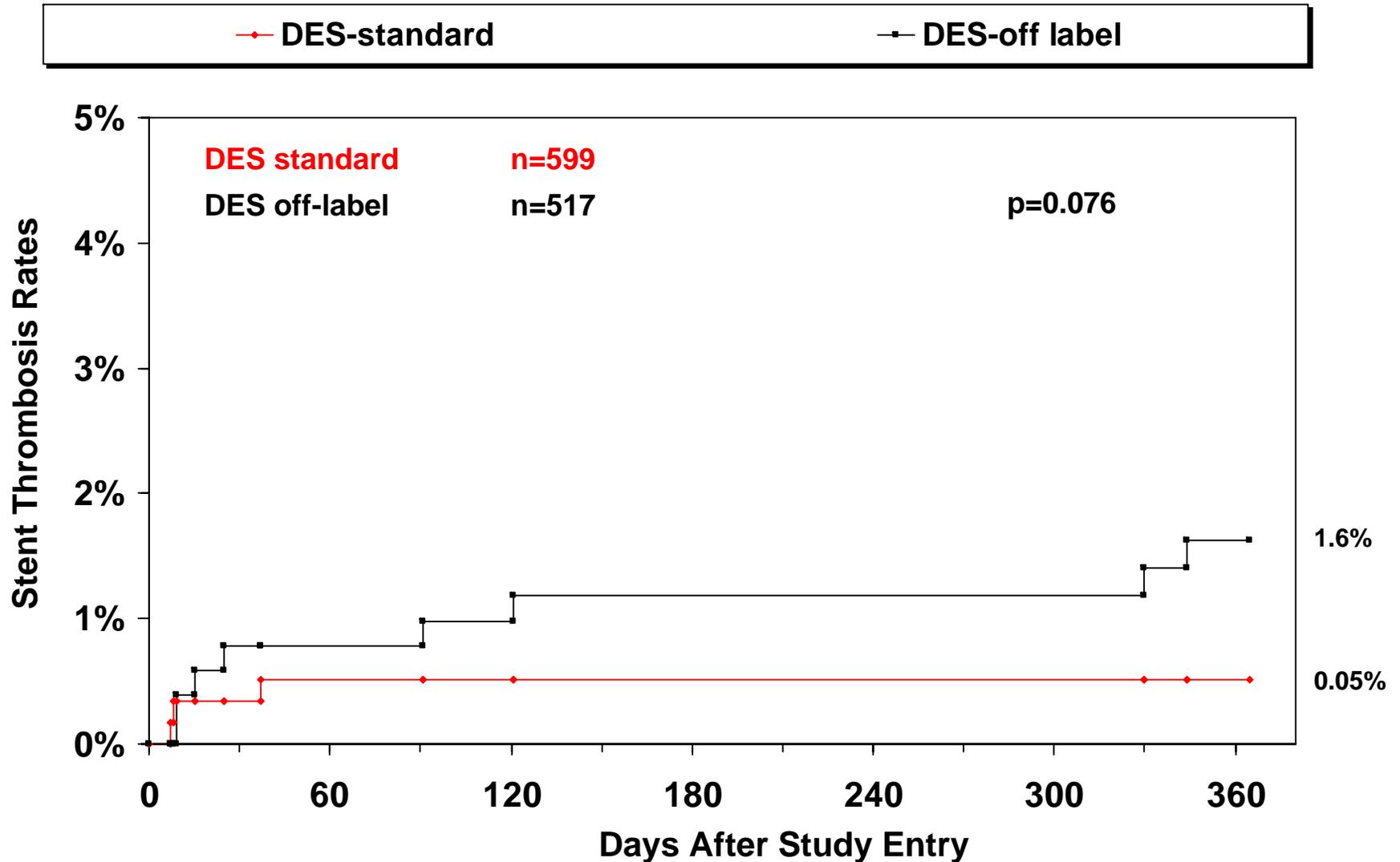
# NHLBI Dynamic Registry

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



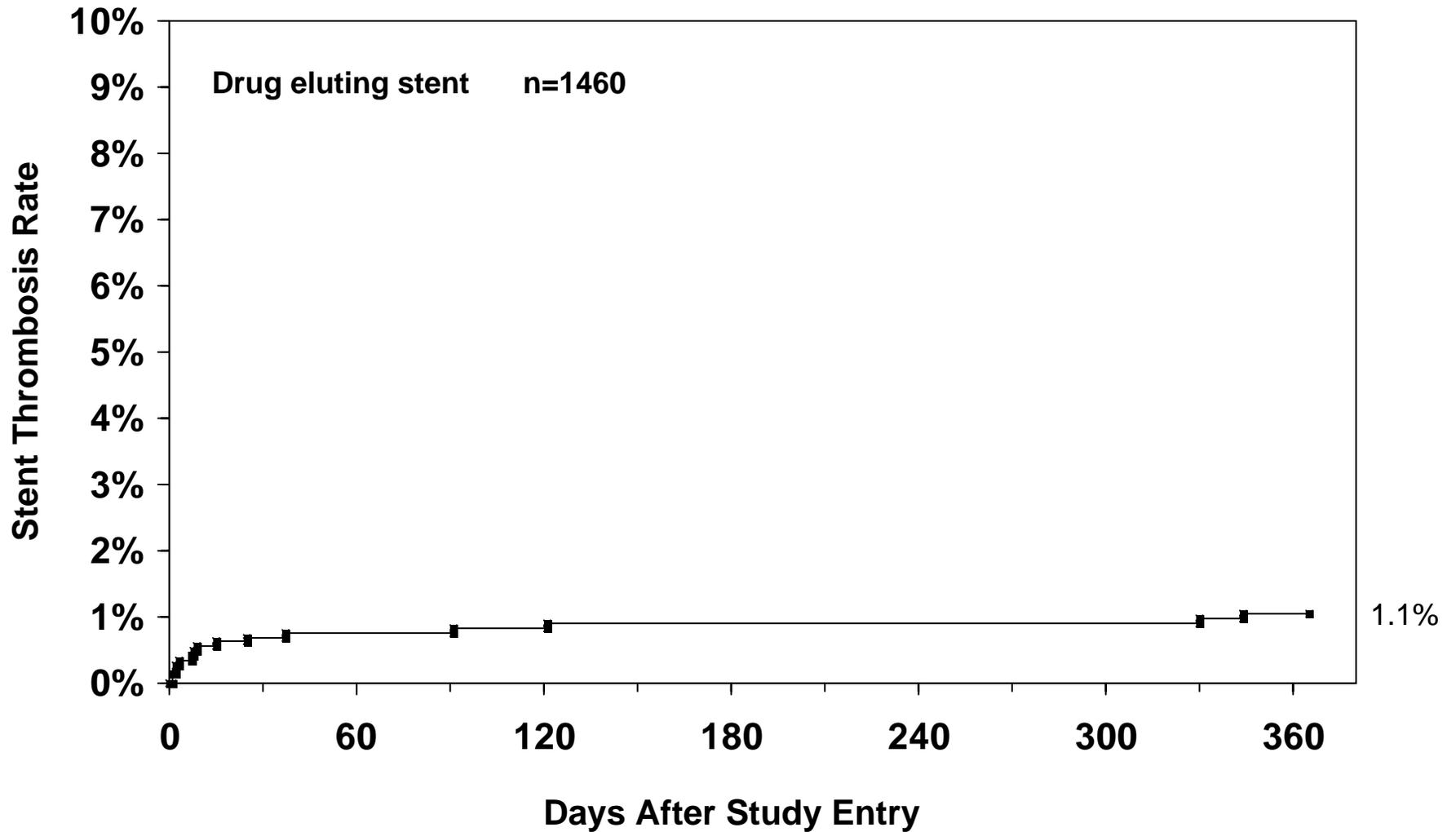
# NHLBI Dynamic Registry

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



# 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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**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 rest."

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