



# Endeavor<sup>®</sup> Sprint

ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM

**ENDEAVOR III and ENDEAVOR Pooled Analysis at 5  
Years – ACC 2010**

Healing First, Results That Last



# ENDEAVOR III – Significant Differences At 5 Years

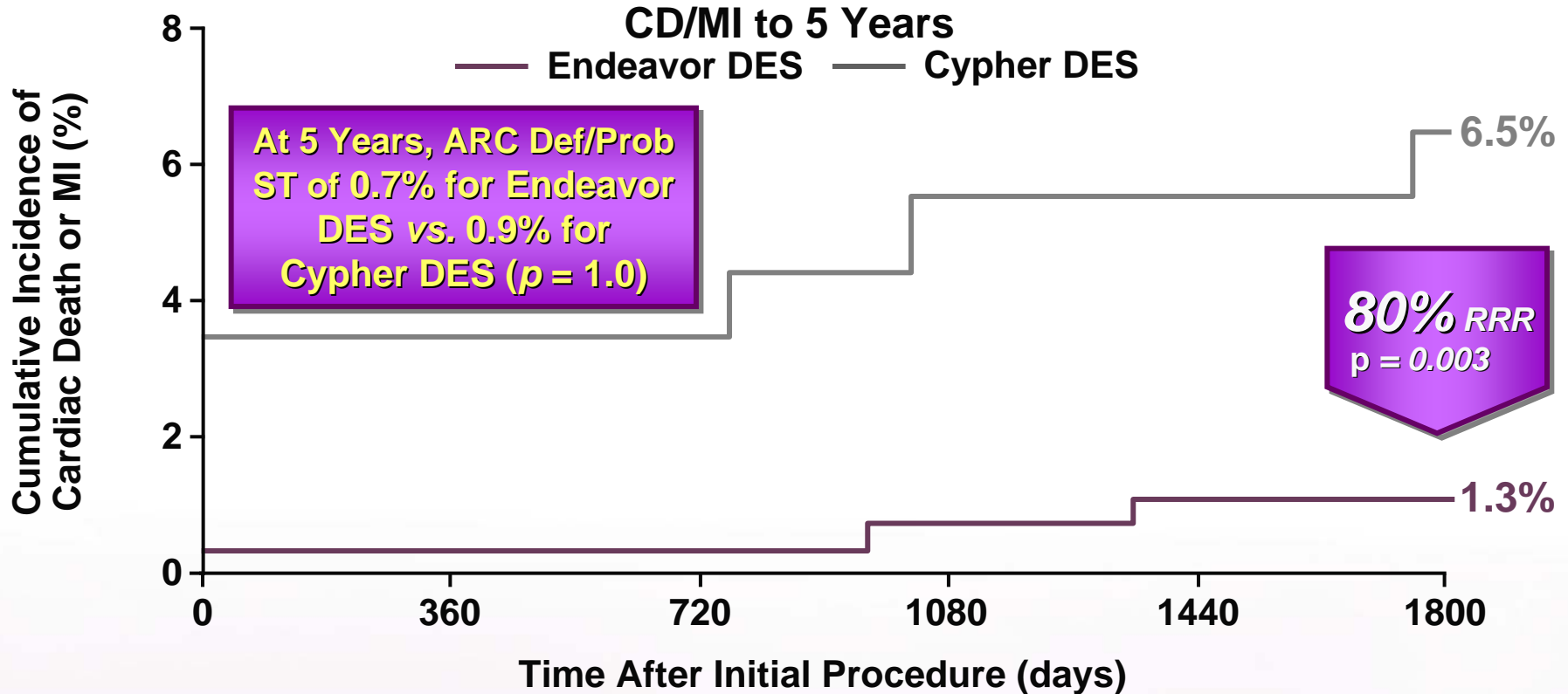
- **Significant differences in safety and composite endpoints:**
  - **80% relative risk reduction in CD/MI (Endeavor DES 1.3% vs. Cypher DES 6.5%,  $p = 0.003^1$ )**
  - **37% relative risk reduction in MACE (Endeavor DES 14.0% vs. Cypher DES 22.2%,  $p = 0.0495^2$ )**
- **Confirmation of late TLR catch up with Cypher DES**
  - **86% increase in TLR with Cypher DES vs. 21% increase with Endeavor DES from years 1–5 drives similar TLR rate at 5 years (Endeavor DES 8.0% vs. Cypher DES 6.5%,  $p = 0.547^1$ )**
- **Primary endpoint: In-segment late lumen loss by QCA at 8 months, 0.36 for Endeavor vs. 0.13 for Cypher ( $p < 0.001$ )**

<sup>1</sup>  $p$ -Value was calculated by logrank test.  $p$ -Values are unadjusted for multiple comparisons.

<sup>2</sup>  $p$ -Value was calculated by Fisher Exact test.

ENDEAVOR III was not specifically designed or powered to individually compare CD/MI, MACE, or TLR. MACE is composed of Death, MI, Emergent CABG, TLR.

# 80% Significant Risk Reduction in Cardiac Death/MI



Endeavor	323	321	314	306	298	290
CI (%)	0.62	0.62	0.62	0.95	1.29	1.29
Cypher	113	109	107	103	98	94
CI (%)	3.54	3.54	3.54	5.45	5.45	6.50

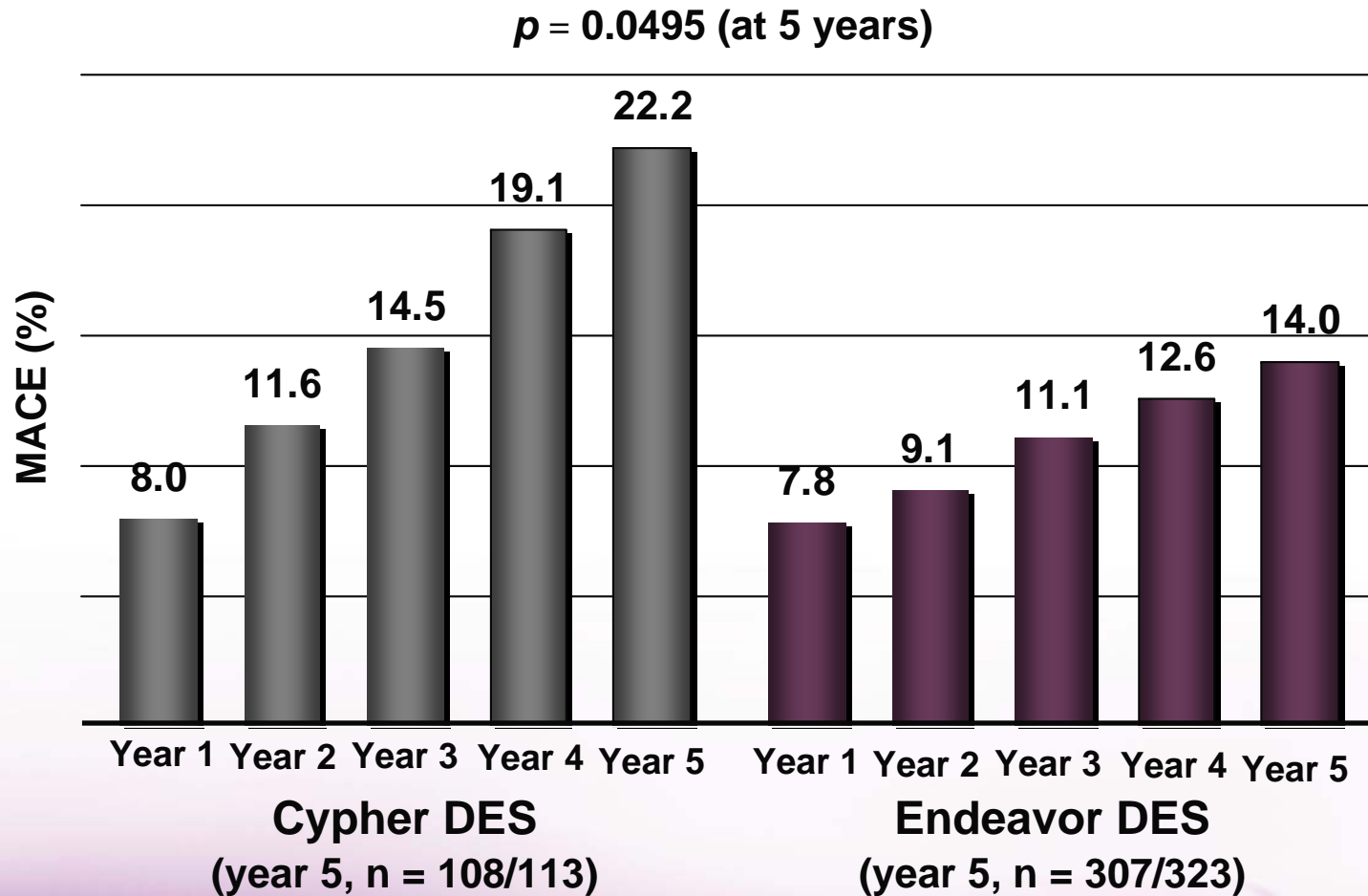
$p$ -Values are unadjusted for multiple comparisons.  $p$ -Values were calculated by logrank test.

ENDEAVOR III was not specifically designed or powered to individually compare CD/MI or ST. RRR = relative risk reduction.

ENDEAVOR III primary endpoint: In-segment late lumen loss by QCA at 8 months. 0.36 for Endeavor vs 0.13 for Cypher ( $p < 0.001$ ).

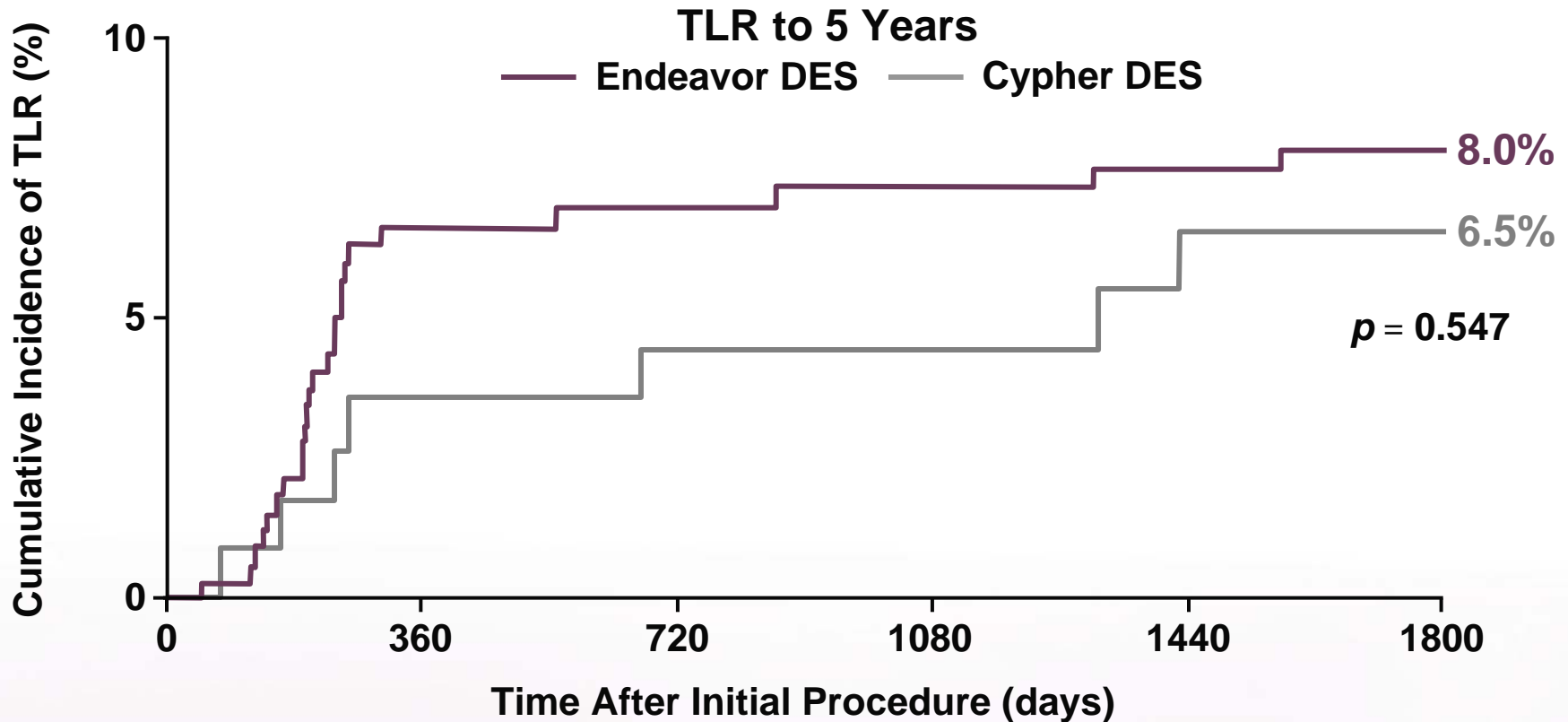
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# 37% Significant Risk Reduction in MACE



$p$ -Value was calculated by Fisher Exact test.  $p$ -Values for outcome differences are unadjusted for multiple comparisons. ENDEAVOR III was not specifically designed or powered to individually compare MACE. MACE is composed of Death, MI, Emergent CABG, TLR. ENDEAVOR III primary endpoint: In-segment late lumen loss by QCA at 8 months. 0.36 for Endeavor vs 0.13 for Cypher ( $p < 0.001$ ).

# Endeavor DES Displayed Low And Sustained TLR Rates



Endeavor	323	323	280	272	263	257
CI (%)	0.0	6.6	6.9	7.3	7.7	8.0
Cypher	113	113	107	101	97	91
CI (%)	0.0	3.5	4.5	4.5	6.5	6.5

*p*-Values are unadjusted for multiple comparisons.

*p*-Values were calculated by logrank test.

ENDEAVOR III was not specifically designed or powered to individually compare TLR.

ENDEAVOR III primary endpoint: In-segment late lumen loss by QCA at 8 months. 0.36 for Endeavor vs 0.13 for Cypher ( $p < 0.001$ ).

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# ENDEAVOR III – Significant Differences At 5 Years

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  - **37% relative risk reduction in MACE (Endeavor DES 14.0% vs. Cypher DES 22.2%,  $p = 0.0495^2$ )**
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## ENDEAVOR III Consistent With ENDEAVOR Pooled Analysis



# ENDEAVOR III: Results Consistent with The Pooled Analysis

- Endeavor has robust, long-term clinical proof:
  - More than 2100 patients studied with over 1100 patients now out to 5 years in pooled analysis
- Low 7% TLR at 5 years in more than 1100 patients in ENDEAVOR Pooled Analysis
- Despite only 39% of patients on DAPT at 1 year in ENDEAVOR Pooled Analysis:<sup>1</sup>
  - Observed reduction in ST<sup>2</sup> to 5 years: Endeavor 0.8% vs. BMS 1.7%,  $p = 0.051$ )
  - Extremely low 0.2% VLST<sup>2</sup> for Endeavor DES after 1 year through 5 years
  - Significant reduction in CD/MI vs. BMS at 5 years (Endeavor 5.2% vs. BMS 8.4%,  $p = 0.003$ )

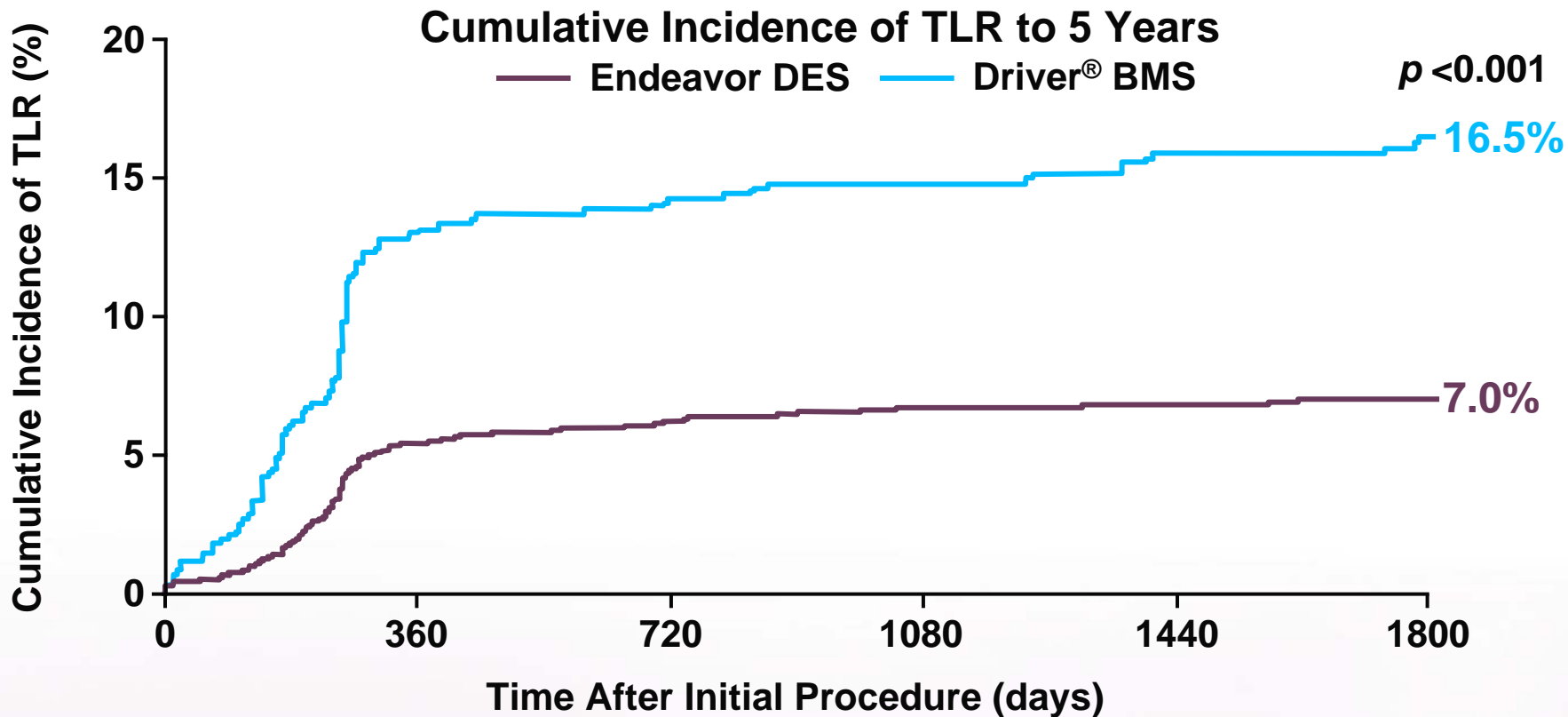
<sup>1</sup>ENDEAVOR Pooled Analysis: E I 5-year, E II 5-year, E III CA 5-year, E IV 3-year, E pK 3-year.

<sup>2</sup>ARC definite/probable stent thrombosis definition used. p-Values are unadjusted for multiple comparisons.

Dual antiplatelet therapy usage based on case report forms. The optimal duration of DAPT, specifically clopidogrel, is unknown and DES thrombosis may still occur despite continued therapy.



# Endeavor DES Demonstrated a Significant TLR Reduction in Pooled Analysis



Endeavor	2132	2130	1908	1842	1552	1100
CI (%)	0.09	5.43	6.23	6.75	6.83	7.00
Driver	596	595	489	474	456	445
CI (%)	0.17	13.16	14.23	14.78	15.91	16.49

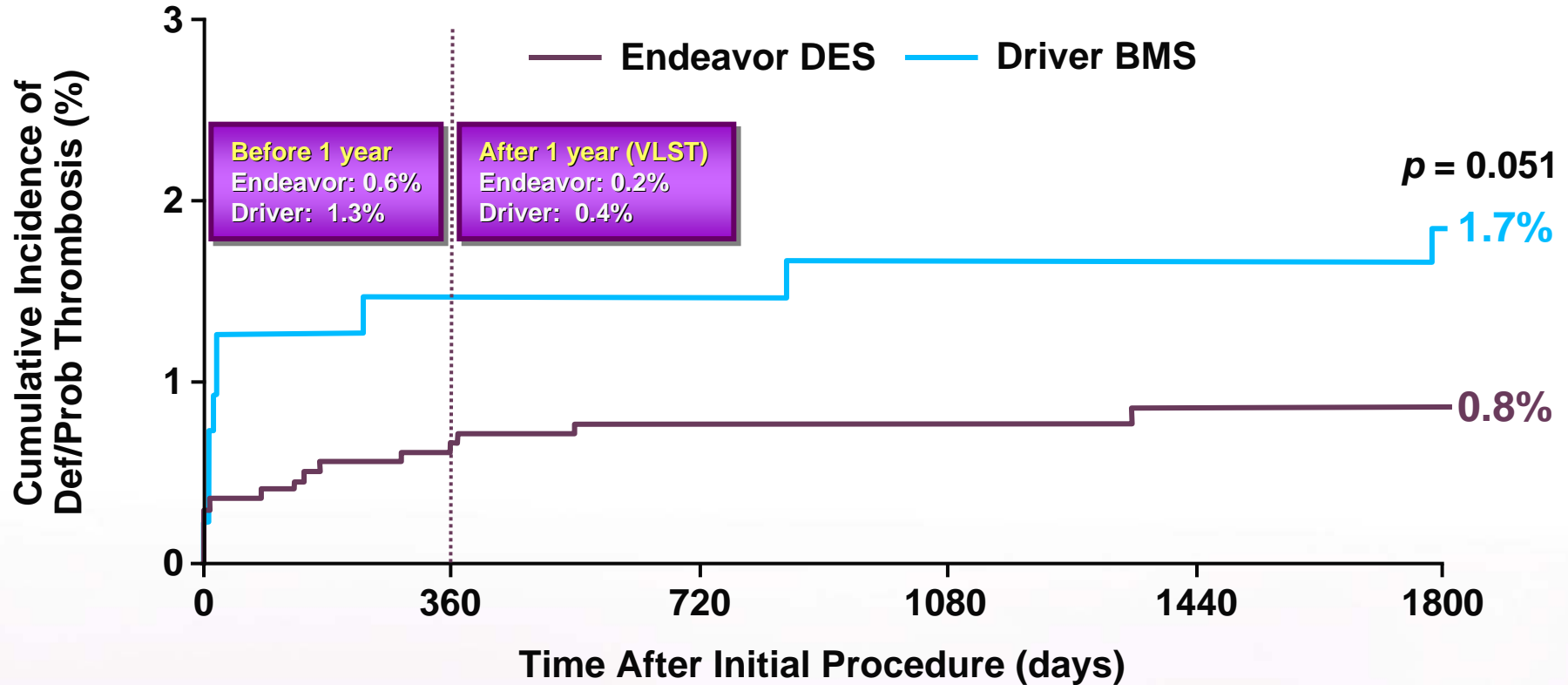
*p*-Values are unadjusted for multiple comparisons.

*p*-Values were calculated by logrank test.

ENDEAVOR Pooled Analysis: E I 5-year, E II 5-year, E II CA 5-year, E III 5-year, E IV 3-year, E pK 3-year.

# Observed Reduction in ST vs. BMS at 5 Years in Pooled Analysis

0.2% ARC definite/probable VLST in more than 1100 patients to 5 years



Endeavor	2132	2131	2044	1989	1687	1199
CI (%)	0.05	0.62	0.71	0.71	0.80	0.80
Driver	596	595	570	559	543	538
CI (%)	0.17	1.35	1.35	1.52	1.52	1.71

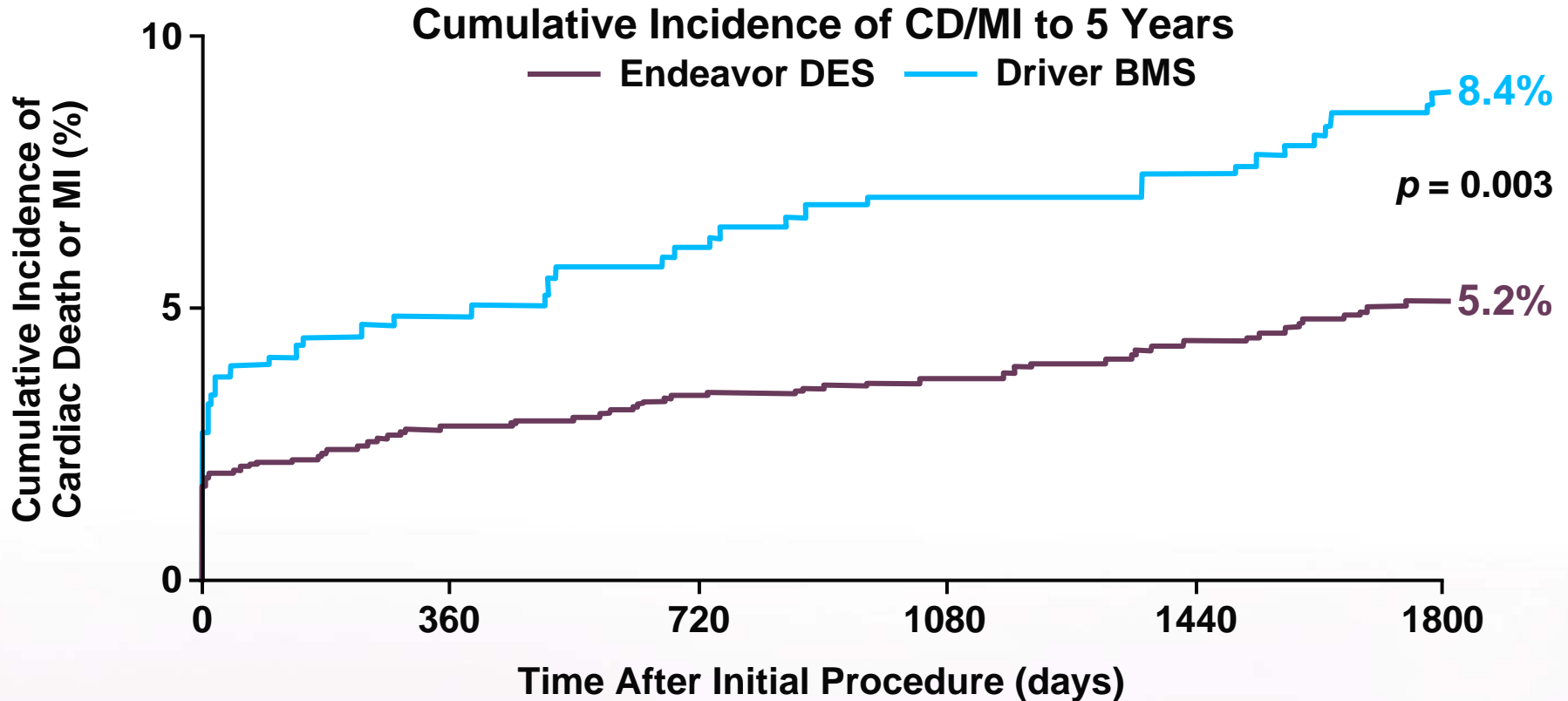
ENDEAVOR Pooled Analysis: E I 5-year, E II 5-year, E II CA 5-year, E III 5-year, E IV 3-year, E pK 3-year.

By intention to treat (ITT), an Endeavor patient in E III had an ST at 1349 days. Per ARC definition, this uncensored event is included in the primary ITT analysis, although the event may not have been related to the Endeavor stent.

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p-Values are unadjusted for multiple comparisons.  
p-Values were calculated by logrank test.

# Significant Reduction in CD/MI vs. BMS at 5 Years in Pooled Analysis



Endeavor	2132	2102	2009	1951	1649	1168
CI (%)	1.41	2.83	3.42	3.77	4.42	5.17
Driver	596	581	555	544	529	523
CI (%)	2.52	4.54	5.75	6.62	6.98	8.42

p-Values are unadjusted for multiple comparisons.

p-Values were calculated by logrank test.

ENDEAVOR Pooled Analysis: E I 5-year, E II 5-year, E II CA 5-year, E III 5-year, E IV 3-year, E pK 3-year.



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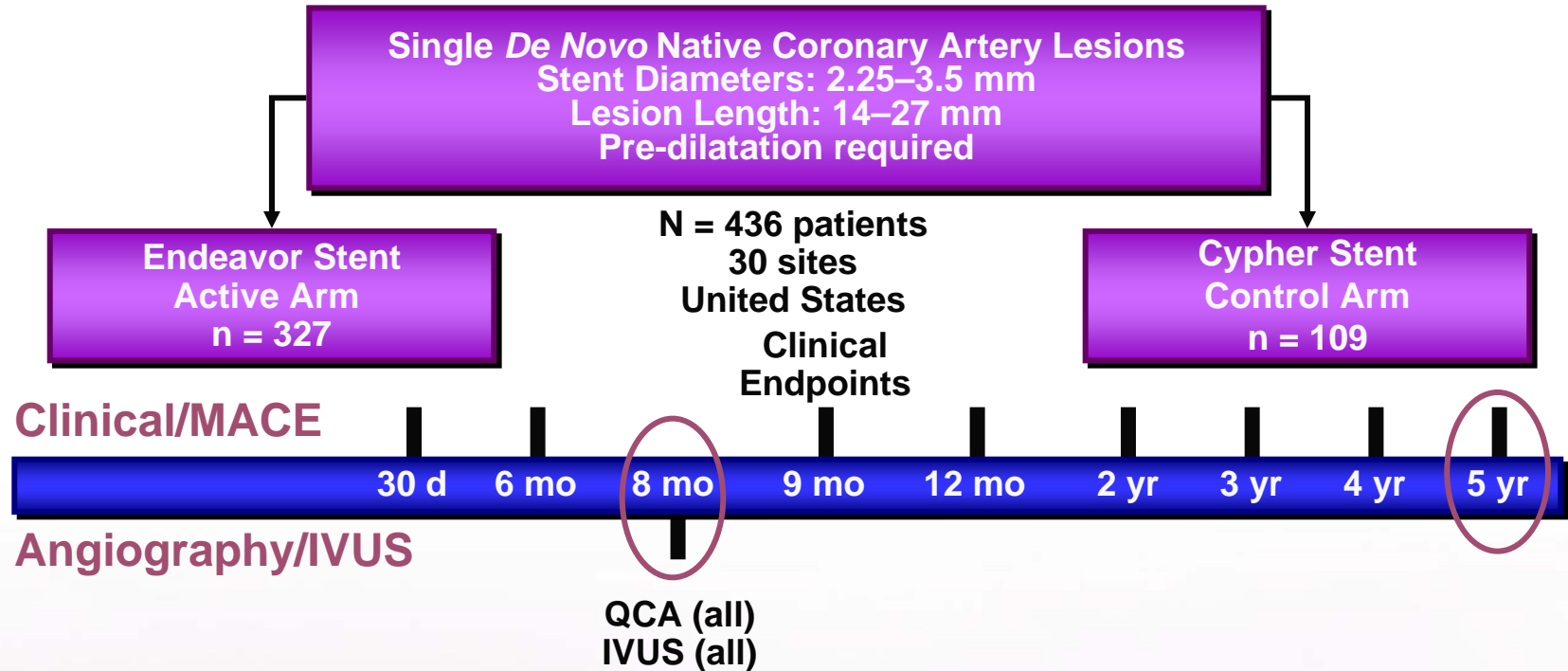
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## Appendix



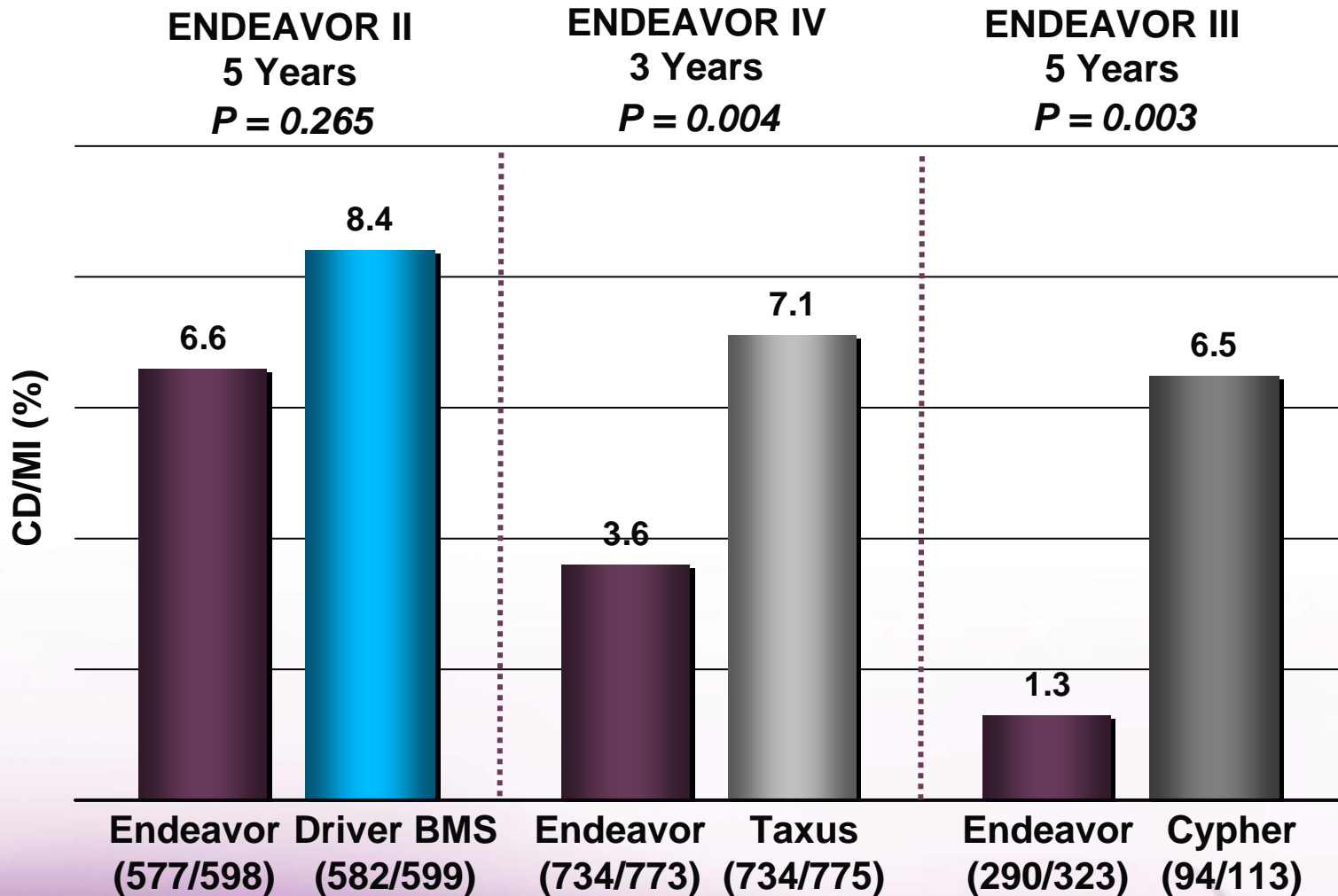
# ENDEAVOR III

*Randomized, controlled trial design; PI Dr. M. Leon*



**Primary Endpoint: In-segment late lumen loss by QCA at 8 months**  
**Secondary Endpoints: TLR, TVR, TVF at 9 months and ABR at 8 months**  
**Drug Therapy: ASA and Clopidogrel/Ticlid  $\geq$  3 months**  
**100% angiographic follow-up**

# Significant Reductions in CD/MI vs. Taxus<sup>®</sup> and Cypher DES

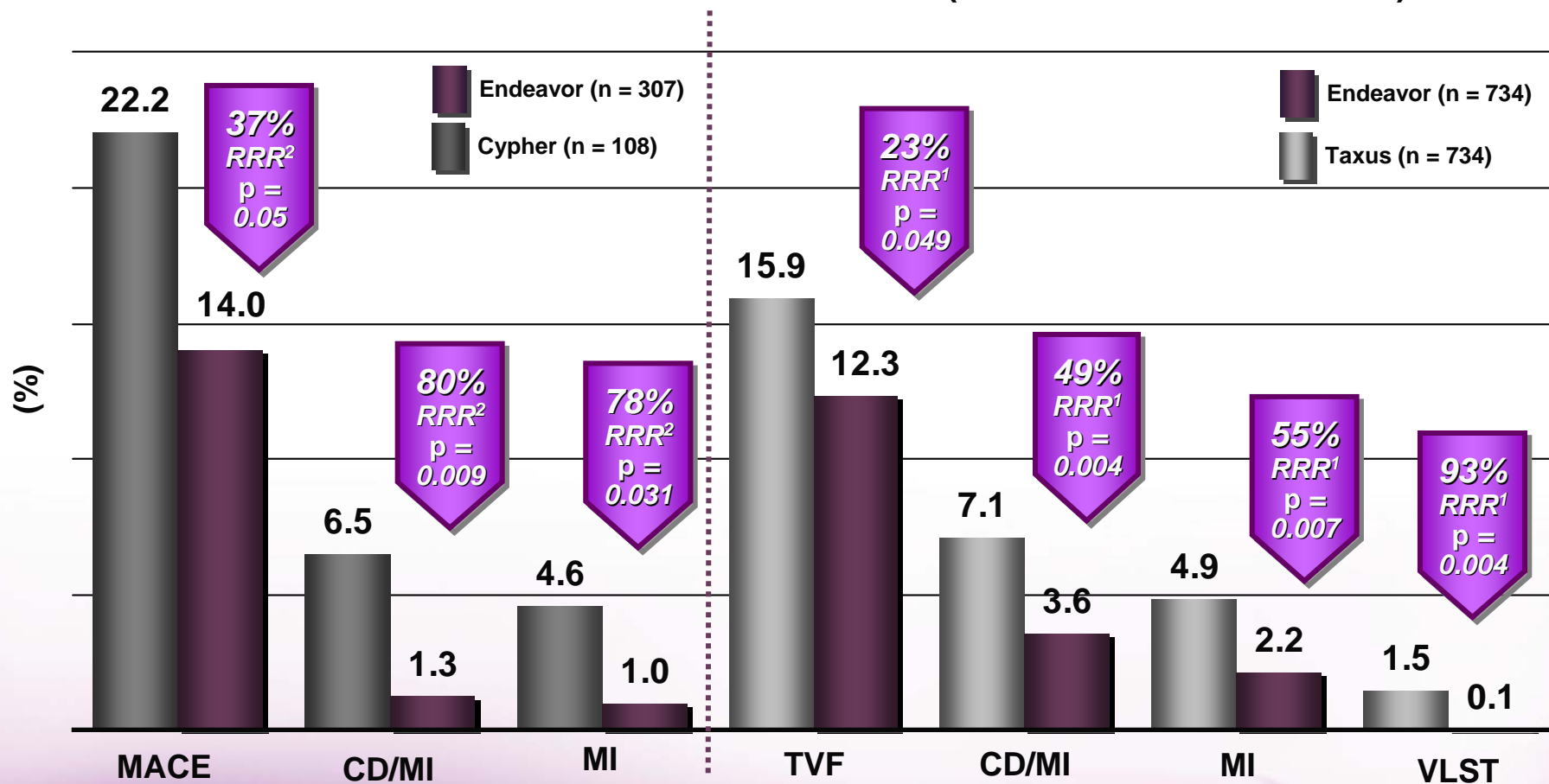


ENDEAVOR II,III, IV *p*-value were calculated by logrank test.  
*p*-values for outcome differences are unadjusted for multiple comparisons.  
 ENDEAVOR II, III, IV were not specifically designed or powered to individually compare CD/MI.

# Endeavor DES Showed Statistically Significant Reductions in Event Rates vs. Cypher AND Taxus DES

Vs. Cypher DES  
(ENDEAVOR III at 5 years)

Vs. Taxus DES  
(ENDEAVOR IV at 3 Years)



p-Values for outcome differences are unadjusted for multiple comparisons.

<sup>1</sup>p-Values were calculated by logrank test.

<sup>2</sup>p-Values were calculated by Fisher's exact test.

ENDEAVOR III was not specifically designed or powered to individually compare MACE, CD/MI or MI.

ENDEAVOR IV was not specifically designed or powered to individually compare TLR, MI, CD/MI or VLST.

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