Stent Use in STEMI - Registries and Randomized Trials

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Presenter Disclosure Information

The following relationships exist related to this presentation:

Salary support from and consultant to Harvard Clinical Research Institute

Executive Committee DAPT study (unpaid)

PI Medtronic DAPT (fees paid to Beth Israel Deaconess Medical Center)

Stent Use in STEMI

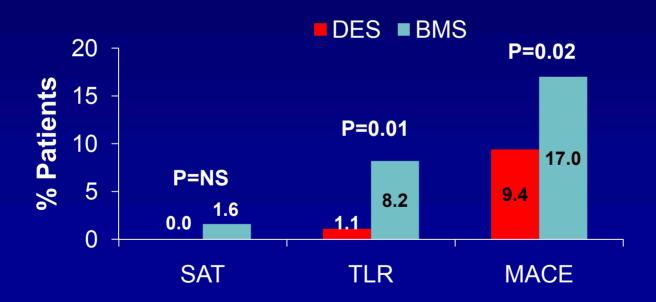
Compared with PTCA, BMS improve acute procedural outcomes and reduce risk for TLR -

- DES versus BMS
 - Are there differences in safety?
 - Early and late stent thrombosis
 - Death and MI
 - Are there significant differences in TLR or TVR?
- RCT versus Registries
 - Generalizability versus validity
 - Power for assessing infrequent events

Before ESC 2006

Rotterdam Registry

186 consecutive DES patients (2002-2003) versus 183 BMS patients in preceding time interval

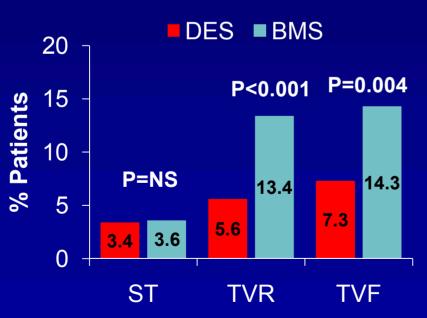


P Lemos et al. JACC 2004;43;704-08

Before ESC 2006 - RCTS

TYPHOON

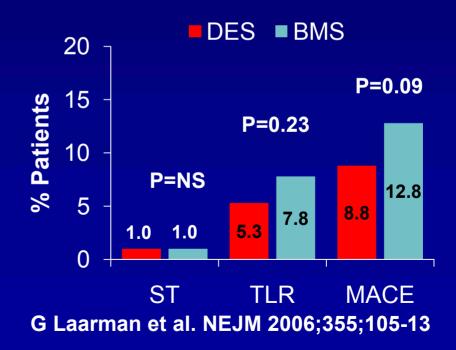
SES vs BMS N=712 1-Year Outcomes



C Spaulding et al. NEJM 2006;355;1093-1104

PASSION

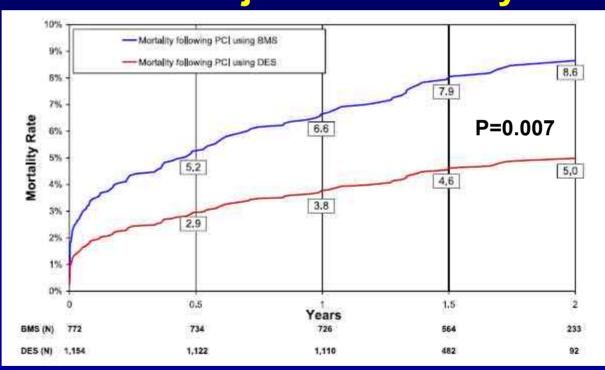
PES vs BMS N=619 1-Year Outcomes



New York State Registry

N = 1926 : 1154 DES vs 772 BMS October 2003 – December 2004

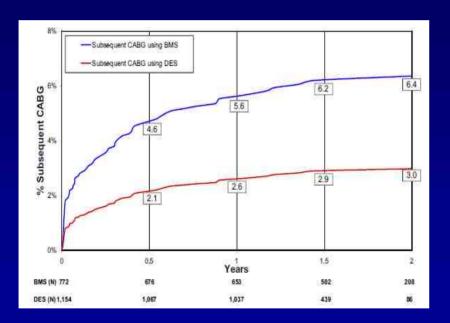
Risk Adjusted Mortality



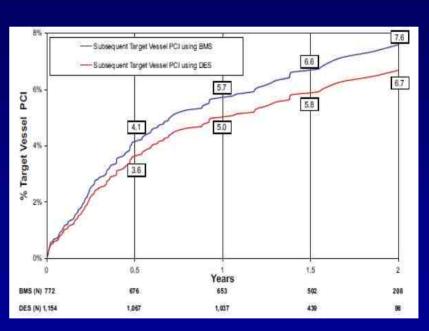
E Hannan et al. JACC Int 2008;1;129-35

New York State Registry

Subsequent CABG



TVR PCI



Massachusetts PCI Registry

N = 2596 (propensity matched) April 2003 – September 2004

3.7% vs 5.8% at 30 days

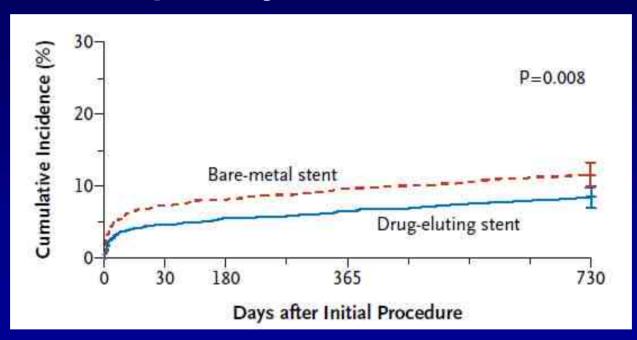
P=0.008

P=NS

P=0.003

Massachusetts PCI Registry

Two-Year Mortality Propensity Matched Pairs



Other Registries

Two Year Outcomes

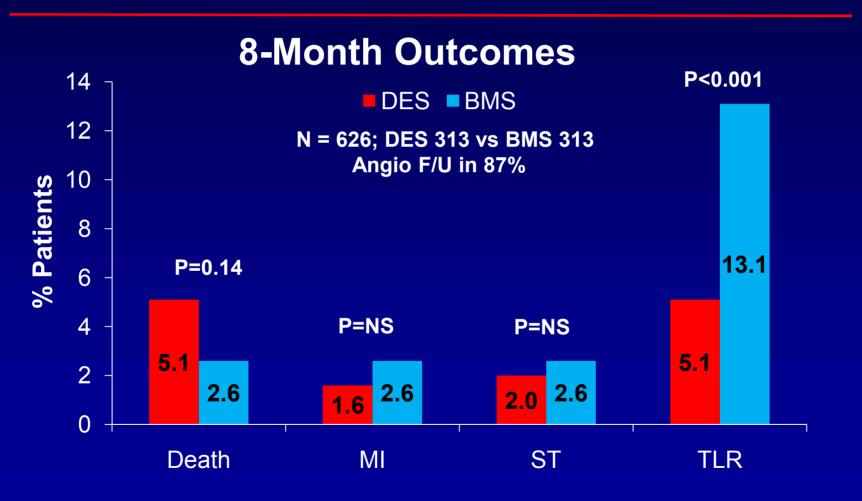
Study/Year	N % DES	Death DES vs BMS	MI DES vs BMS	TLR DES vs BMS
Shishehbor/2008	480	9% vs. 9%		9% vs 14%
(propensity match)	(50)	970 VS. 970		(p=0.04)
Brodie/2008*	1840 (70)	8.0% vs 13.7% (p=0.004) adj. p =0.34	5.0% vs 6.9% p= NS	8.0% vs 11.3% (adj. p = 0.02)
Jensen/2008	3756	7.8% vs 11.4% (p=0.004) (adj. p = 0.09)	5.2% vs 6.3% p=NS	7.2% vs. 8.7% (adj. p = 0.012)

Other Registries

Stent Thrombosis

Study/Year	N	ST (1 year)	ST (1-2 years)	ST (2 years)
	% DES	DES vs BMS	DES vs BMS	DES vs BMS
Brodie/2008*	1840	0.8% vs 3.6%	1.1% vs. 0.3%	1.8% vs 3.9%
	(70)	(p<0.001)	(adj. p = 0.28)	(adj. p = 0.11)
Jensen/2008	3756	1.5% vs 1.0%	0.4% vs. 0.1% (adj. p = 0.03)	1.9% vs 1.1% (adj. p = 0.17)

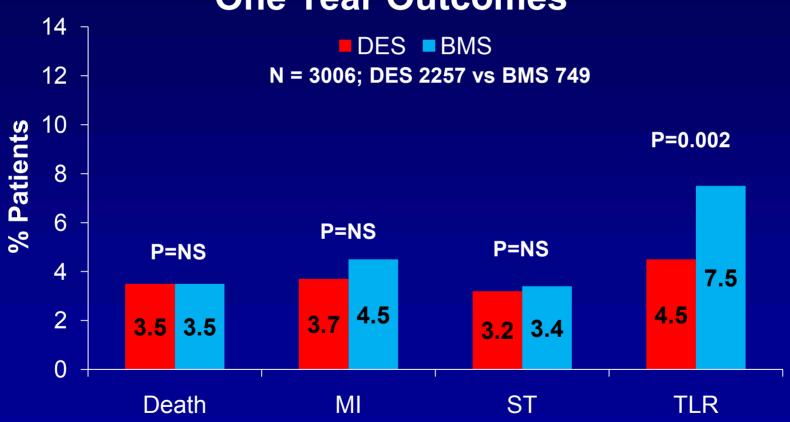
Randomized Trials DEDICATION Trial



G Stone et al. NEJM 2009;360;1946-59

Randomized Trials HORIZONS-AMI Trial





G Stone et al. NEJM 2009;360;1946-59

Conclusions

- Both Registries and RCTs show significant reduction in TLR for DES – the absolute benefit may vary by case selection and routine angiographic follow-up.
- The mortality benefit (especially early) observed for DES vs BMS in some registries is likely related to unmeasured confounding and case selection.
- The absence of a difference in mortality or ST observed in RCTs requires confirmation in larger numbers and longer term follow-up.
- DES vs BMS selection based on restenosis risk and absence of contraindications for DES and DAPT