

Longitudinal Outcomes Following Drug Eluting Stent Implantation

David Magid, MD, MPH

Ralph Brindis, MD

Alan S. Go, MD

Kaiser Permanente of Colorado

Kaiser Permanente of Northern California

FDA Advisory Committee Meeting

December 8, 2006

Overview

- Pattern of DES use
- Rate and Timing of Adverse Events (MI and death) in all DES Patients
 - Chart review of AMI events in Colorado
- Predictors of Adverse Outcomes
- Relationship between post-DES clopidogrel use and adverse outcomes

Longitudinal Kaiser Cohort

- PCI: > 95% received stents
 - >95% were DES
- 4195 patients with ≥ 1 DES
 - 2004: 1698 patients
 - 2005: 1697 patients
 - 2006: 800 patients
- Outcomes through Oct. 31, 2006
 - Myocardial infarction
 - All-cause mortality

Data Sources

- ACC-NCDR Cath-PCI Registry
- Pharmacy Dispensing Records
- Hospital Claims – primary discharge diagnosis of AMI (ICD-9 410.XX)
- Kaiser & State Death Registry Files

Patient Characteristics

Age (mean) 64.9 years

Women 30.1%

Race/Ethnicity

White 75.0%

Black 5.2%

Asian 10.8%

Hispanic 6.3%

Medical History

	Percent
Diabetes	30.2
Smoking	53.1
Hypertension	78.1
Hyperlipidemia	86.6

Medical History

	Percent
Prior MI	28.9
Prior PCI	29.2
Prior CABG	17.7
Prior CHF	10.8

Clinical Setting

	Percent
Non-ACS	28.2
ACS	71.8
USA (29.8%)	
NSTEMI (29.2%)	
STEMI (12.8%)	

Lesion Characteristics

Percent

Lesion Risk

High Risk(C)

36.6

Low(A)/Medium(B)

63.4

Previous Treated Lesion

9.9

Graft PCI

7.0

Bifurcation

9.9

Lesion Length > 30mm

17.6

Stent Characteristics

Stents Implanted	Percent
------------------	---------

1	57.8
---	------

2	33.5
---	------

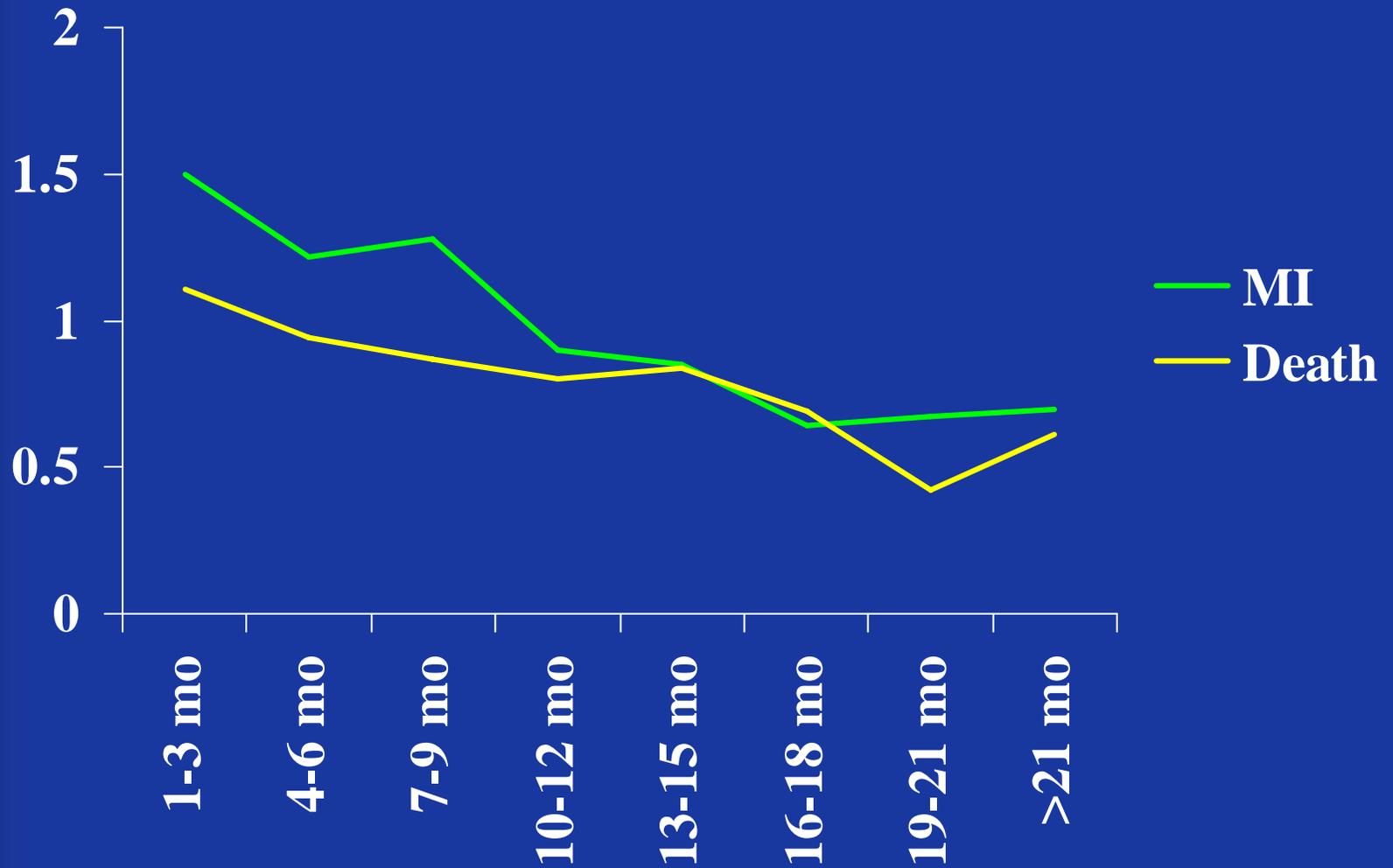
≥ 3	8.7
----------	-----

Stent Type	
------------	--

Cypher	65.8
--------	------

Taxus	34.2
-------	------

Timing of Events After DES Implantation



Predictors of MI Post-DES Placement (2004-2006)

Hazard Ratio

Diabetes	3.2
Graft PCI	2.6
Les. Length > 30mm	1.9
CHF	1.8
Lesion Risk	1.4

Predictors of Death Post-stent Placement

	Hazard Ratio
CHF	3.8
Bifurcation	1.8
Age (decades)	1.7
Diabetes	1.6
ACS	1.4
Current smoker	1.3

Relationship Between Extended Clopidogrel Use and Subsequent AMI

	RR	CI
1-3 mo	0.49	0.37-0.65
4-6 mo	0.73	0.51-1.05
7-9 mo	0.87	0.55-1.38
10-12 mo	0.99	0.57-1.71

Extended : > 3months post Cypher
and > 6 months post Taxus

Relationship Between Extended Clopidogrel Use and Subsequent Death

	RR	CI
1-3 mo	0.35	0.24-0.51
4-6 mo	0.56	0.35-0.90
7-9 mo	0.69	0.39-1.24
10-12 mo	0.85	0.43-1.70

Extended : > 3months post Cypher
and > 6 months post Taxus

Colorado AMI Review (n = 24)

- 15/24 (62%) Probable/Definite Stent Thrombosis*
- 12 of the 15 (80%) cases of Stent Thrombosis occurred in the first year after stent implantation
- 7 of the 12 cases in the first year occurred in months 6-12 after DES

* Study Endpoints - ARC Clinical Trials Consortium

Limitations

- Limited long-term follow-up
- Difficult to draw definitive conclusions of the efficacy of DES in subgroups
- Potential protective effects of clopidogrel may be due to confounding factors

Summary

- A high proportion of DES are implanted in the setting of ACS.
- DES implanted in lesions outside current FDA indications are associated with an increased risk of adverse events.
- Clopidogrel may be associated with a reduction in adverse outcomes in the 1-6 months past current recommended therapy with no significant protective effect thereafter.

Thank You