Percutaneous Myocardial Revascularization

Presented to the

Medicare Coverage Advisory Committee

July 14, 2004

Richard L. Popp, MD
Past President, American College of Cardiology
Professor, Cardiovascular Medicine
Director of Ethics and Policy, Program of Biodesign
Stanford University, Stanford, CA

Disclosure

- Past President, ACC
- Consultant to CardioGenesis Corporation
  - Co-chair, Medical Review Board
    - Expert Review of Clinical Findings, Axcis PMR System
    - Integrally involved in FDA review process

PMR Methods and Devices

Sole Therapy Randomized Trials with 1 Year Follow-up

- CardioGenesis Axcis PMR System
  - Oesterle 2000; Gray 2003
  - Salem 2004: double blind, sham-controlled trial
- Different Methods/Devices
  - Eclipse PMR System: Whitlow 2003
  - Biosense DMR System: No peer-reviewed article

CardioGenesis Axcis PMR System

Significant Improvement at 1 Year in Pivotal RCTs

- ≥2-Class Angina Improvement
  - Oesterle: 46% vs. 11% ($p<0.01$)
  - Gray: 36% vs. 0% ($p<0.01$)
  - Salem sham trial: 35% vs. 14% ($p=0.04$)
- Other outcomes

CardioGenesis Axcis PMR System

Operative Mortality and 1 Year Survival

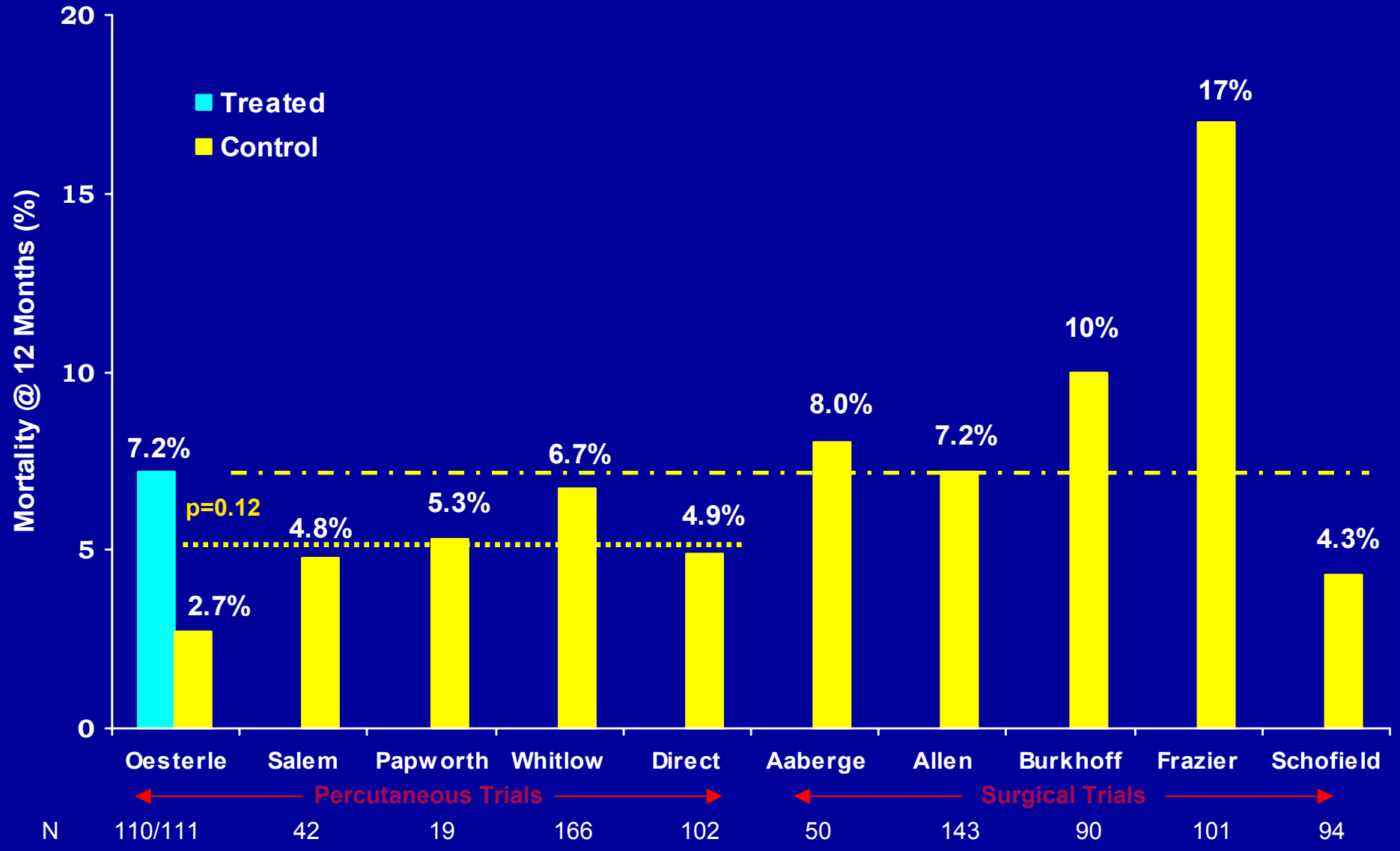
		30-Day Mortality		1-Year Survival		
Trial	**N**	**PMR**	**Control**	**PMR**	**Control**	**p**
Oesterle [*Lancet 2000*]	221	0.9%	0.0%	93%	97%	0.12
Gray [*Am J Cardiol 2003*]	73	0.0%	2.7%	97%	97%	ns
Salem [*Am J Cardiol 2004*]	82	0.0%	2.5%	100%	95%	0.17

Control (Oesterle and Gray) = optimal medical management

Control (Salem) = sham procedure + optimal medical management

Supplemental Information

12-Month Mortality in RCTs – 'No Option' Control Groups



CardioGenesis Axcis PMR System

- Clinically important net health benefit
- Applicable to Medicare pts and physicians

CardioGenesis Axcis PMR System

Medical Review Board Consensus Opinion

- Product is for selected No Option patients
- Prospectively defined primary endpoints met with high degree of significance
  - Sham controlled trial validates angina improvement
- Should not ignore ancillary information
- Background/attitude conditions interpretation of scientific data
- Protection versus over-protection
- The clinical need is compelling