

Percutaneous Myocardial Revascularization

Presented to the
Medicare Coverage Advisory Committee

July 14, 2004

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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

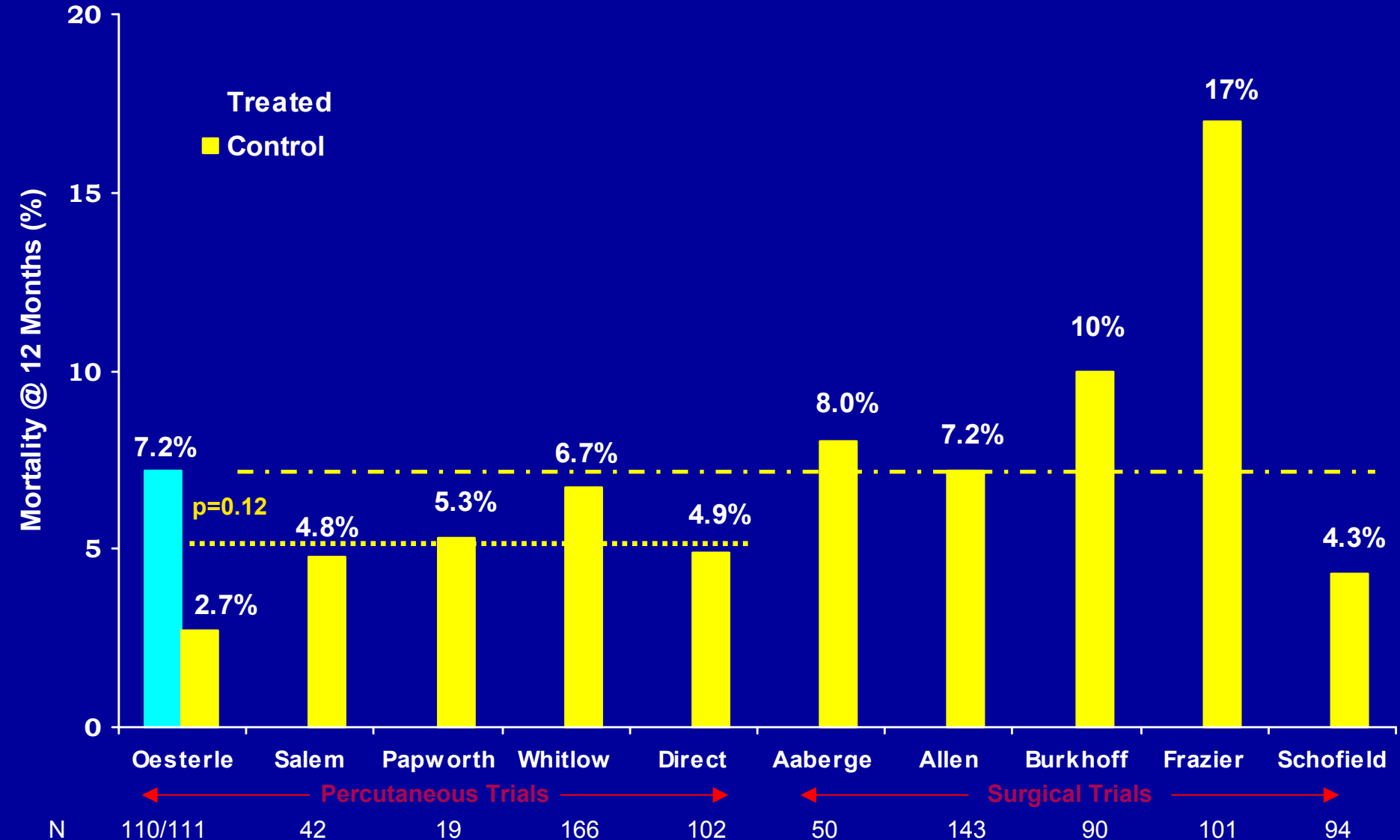
| Trial | N | 30-Day Mortality | | 1-Year Survival | | p |
|--------------------------------------|-----|------------------|---------|-----------------|---------|------|
| | | PMR | Control | PMR | Control | |
| Oesterle [<i>Lancet</i> 2000] | 221 | 0.9% | 0.0% | 93% | 97% | 0.12 |
| Gray [<i>Am J Cardiol</i> 2003] | 73 | 0.0% | 2.7% | 97% | 97% | ns |
| Salem [<i>Am J Cardiol</i> 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