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MYOCARDIAL ISCHEMIA AND INFARCTION

PATIENT CHARACTERISTICS AND OPERATIVE RISK WITH STAND-ALONE TRANSMYOCARDIAL REVASCULARIZATION

ACC Poster Contributions

Ernest N. Morial Convention Center, Hall F

Tuesday, April 05, 2011, 9:30 a.m.-10:45 a.m.

Session Title: Coronary Surgery, PCI and Laser

Abstract Category: 7. Coronary Artery Bypass Surgery/Innovative Techniques

Session-Poster Board Number: 1143-362

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Background: Transmyocardial revascularization (TMR) provides symptomatic relief of angina, decreased rehospitalizations and improved exercise treadmill times in refractory angina pts not amenable to revascularization. Following initial approval, a phase IV, post approval study (PAS) for stand-alone TMR was required to characterize the pts treated and to identify any unanticipated safety issues in clinical application.

Methods: 358 patients with class IV RA at 19 centers were enrolled from 2000-2010 to be treated with stand-alone TMR with a Ho:YAG laser. Baseline patient characteristics, operative details and major adverse cardiac events at 30-days were obtained. Mortality data was available in 100%.

Results: Compared to the original pivotal trial of TMR versus medical management, patients in the PAS were older (62.1 vs 60.0 years, $p=0.04$); had a higher incidence of hypertension (89% vs 70%, $p<0.001$); and a higher incidence of previous PCI (59% vs 48%, $p=.02$). Despite these differences, the operative mortality in the PAS was significantly lower than the TMR treated group from the pivotal trial (2.2% (8/358) vs 5.3% (7/132); $p=0.003$). Patients with LVEF $\leq 30\%$ had higher operative mortality than patients $>30\%$ (11.1% (3/27) vs 1.5% (5/331), $p=0.017$). Of the 358 patients enrolled in the PAS, 9.2% experienced MACE events (cardiac death, arrhythmias, CVA, CHF and MI). Arrhythmias were the most prevalent. The number of TMR channels created was the only statistically significant predictor of MACE in the PAS. Patients with ≥ 40 TMR channels had a statistically higher MACE rate compared to those with < 40 channels 18.67% vs.6.96%, $p = 0.0095$).

Conclusions: These results suggest stand-alone TMR had been implemented safely into clinical practice with lower 30-day mortality than the pivotal trial. The results also suggest further opportunity to reduce the operative risk by avoiding patients with LVEF $\leq 30\%$ and reducing operative MACE by limiting the number of channels to <40 . These results will be used to update the product instructions for use to highlight patient safety considerations.