ACC.13
62nd Annual Scientific Session & Expo
TCT@ACC-i2

E1921
JACC March 12, 2013
Volume 61, Issue 10

TCT@ACC-i2: Invasive and Interventional Cardiology

COMPARISON BETWEEN ORAL RAPAMYCIN PLUS BARE METAL STENT VERSUS DRUG ELUTING STENT FOR THE PREVENTION OF RESTENOSIS IN THE TREATMENT OF CORONARY DISEASE WITH PCI: FIVE-YEARS FINAL RESULTS FROM THE ORAR III TRIAL

Poster Contributions
Poster Sessions, Expo North
Monday, March 11, 2013, 9:45 a.m.-10:30 a.m.

Session Title: Adjunct Pharmacology
Abstract Category: 39. TCT@ACC-i2: Adjunct Pharmacology
Presentation Number: 2115-223

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Background: One and three years results of ORAR III trial previously published showed a significant reduction in costs with oral rapamycin plus bare metal stent (OR) compared with drug eluting stents (DES) without significant differences in death, myocardial infarction (MI) and stroke for the prevention of restenosis. (NCT00552669)

Methods: From January 2006 to September 2007 in 3 hospitals in Buenos Aires, Argentina, 200 patients (pts) were randomized either to OR (n=100) or DES (n=100). Primary endpoints were to compare costs of initial strategy and clinical efficacy and safety of OR vs DES treatment for denovo coronary lesions evaluated by the composite of death, MI (myocardial Infarction) and stroke (D,MI,S) and Target Vessel Failure (TVF) defined as cardiac death, MI and Target Vessel Revascularization (TVR), and TVR alone at 5 years of follow up. A sub-analysis of pts over and under 65 years old was also done (≥65 years: 40 pts in OR and 48 pts in DES). OR was given as a bolus of 10 mg the day before PCI followed by 3 mg/daily during the following 13 days. DES group received clopidogrel for at least one year and OR group for a month.

Results: Baseline demographic, clinical and angiographic characteristics were similar. Multiple vessel disease was 48% of OR and 51% of DES (p=0.9) and 171 stents in OR vs 176 in DES groups were deployed (p=0.9). Stents used in DES group were Taxus, Boston Scientific (60%), Endeavor, Medtronic (34%) and Cypher, Johnson & Johnson (6%).5 years clinical follow up was accomplished in 99% of pts. Costs were significantly higher in DES group (p<0.001). The composite of D,MI,S was 12.0% in OR group vs. 25.0% in DES, p=0.01 and TVR was 14.5 % in OR group vs 21.1% in DES group, p=0.1. When analyzing pts ≥ 65 years dyslipemia was the only significantly different baseline characteristic. Pts ≥ 65 years had significantly lower incidence of TVF in OR group (p=0.04), this difference disappeared in patients under 65 years (p=0.8).

Conclusions: Final five years results of the ORAR III trial showed that first generation DES design was associated with significant higher incidence of D, MI and stroke than OR plus BMS. Cumulative costs were significantly higher with DES therapy.