HORIZONSAMI

A Prospective, Randomized Comparison of Paclitaxel-eluting TAXUS Stents vs. Bare Metal Stents During Primary Angioplasty in Acute Myocardial Infarction

One Year Results —

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For the HORIZONS-AMI Investigators

Harmonizing Outcomes with Revascularization and Stents in AMI

3602 pts with STEMI with symptom onset ≤12 hours

Aspirin, thienopyridine **UFH + GP IIb/IIIa inhibitor Bivalirudin monotherapy** (± provisional GP llb/llla) (abciximab or eptifibatide) Emergent angiography, followed by triage to... **CABG – Primary PCI – Medical Rx**

3000 pts eligible for stent randomization

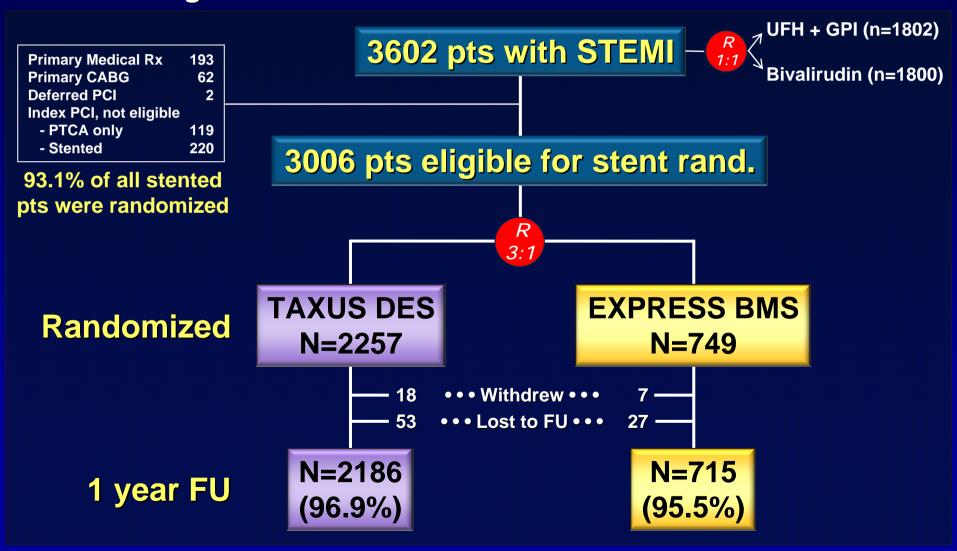
Paclitaxel-eluting TAXUS stent

Bare metal EXPRESS stent

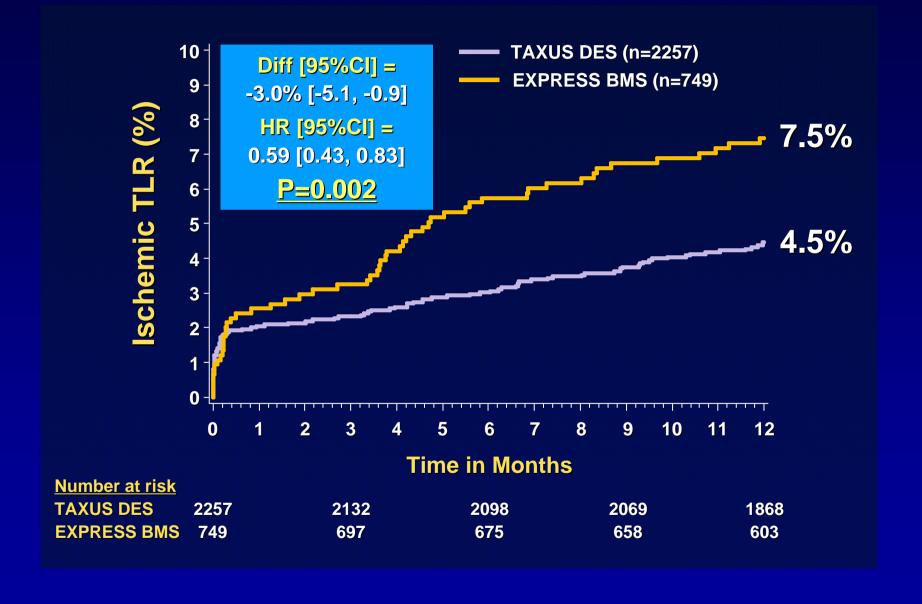
Clinical FU at 30 days, 6 months, 1 year, and then yearly through 5 years; angio FU at 13 months

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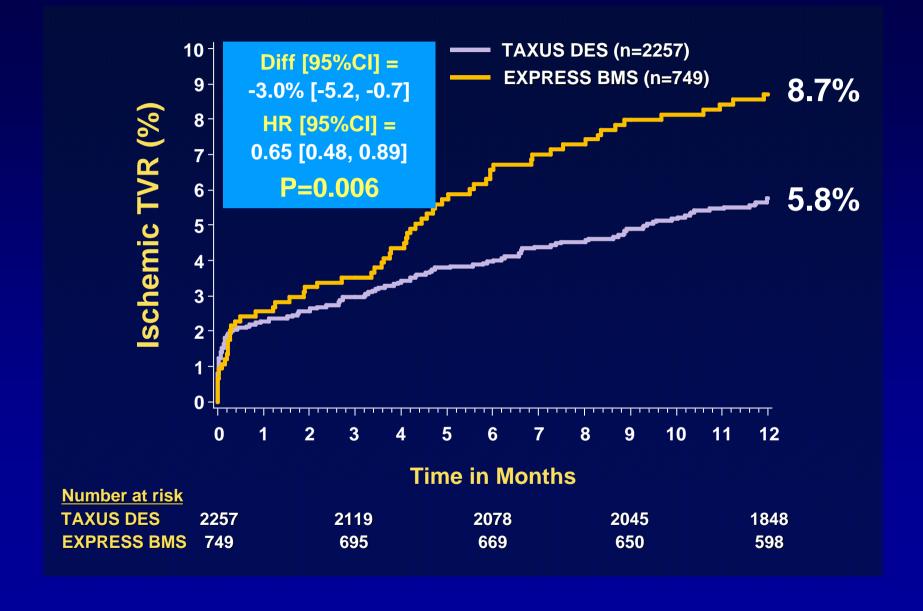
Harmonizing Outcomes with Revascularization and Stents in AMI



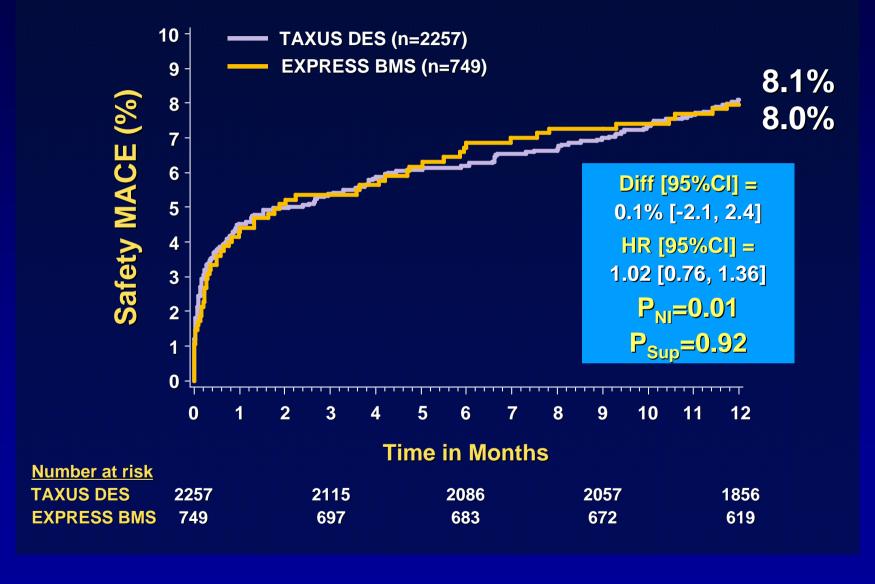
Primary Efficacy Endpoint: Ischemic TLR



Secondary Efficacy Endpoint: Ischemic TVR

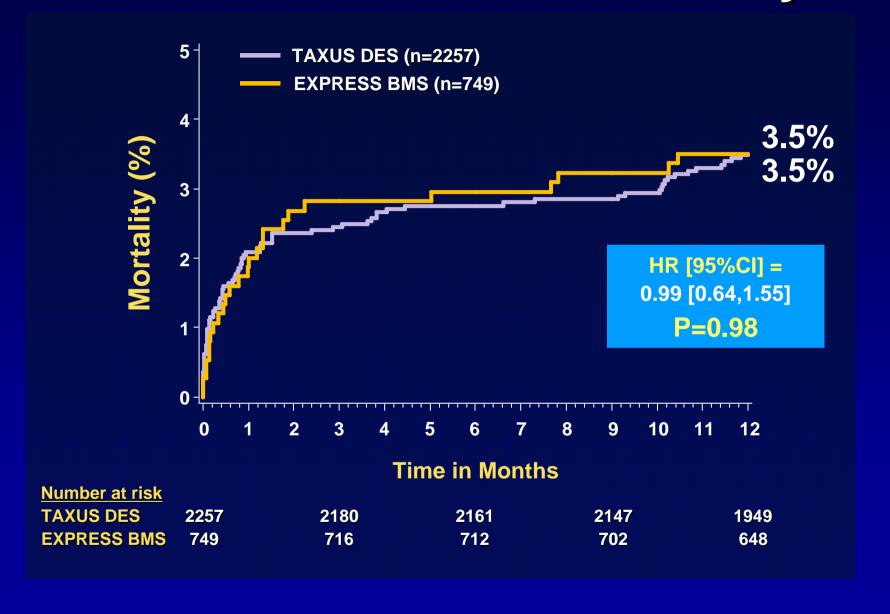


Primary Safety Endpoint: Safety MACE*

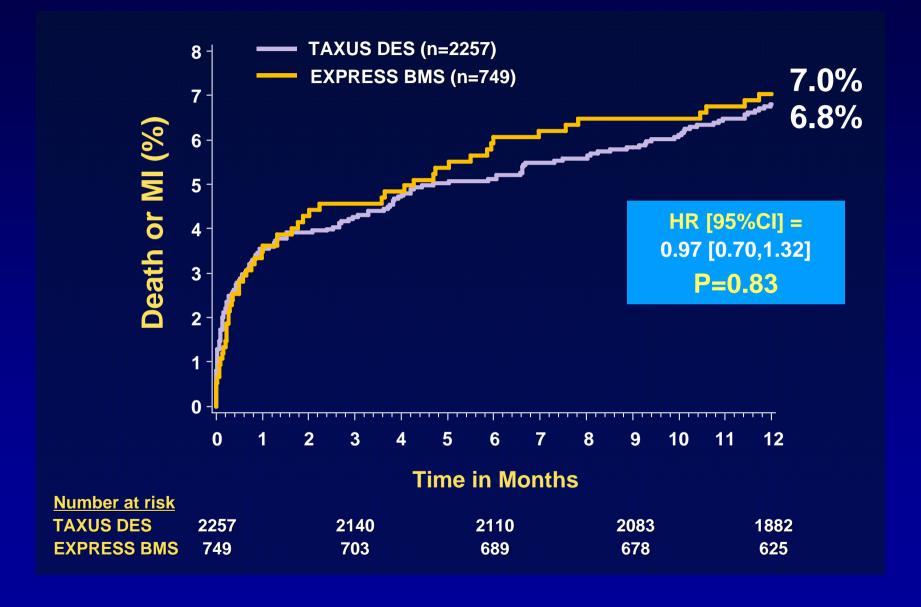


^{*} Safety MACE = death, reinfarction, stroke, or stent thrombosis

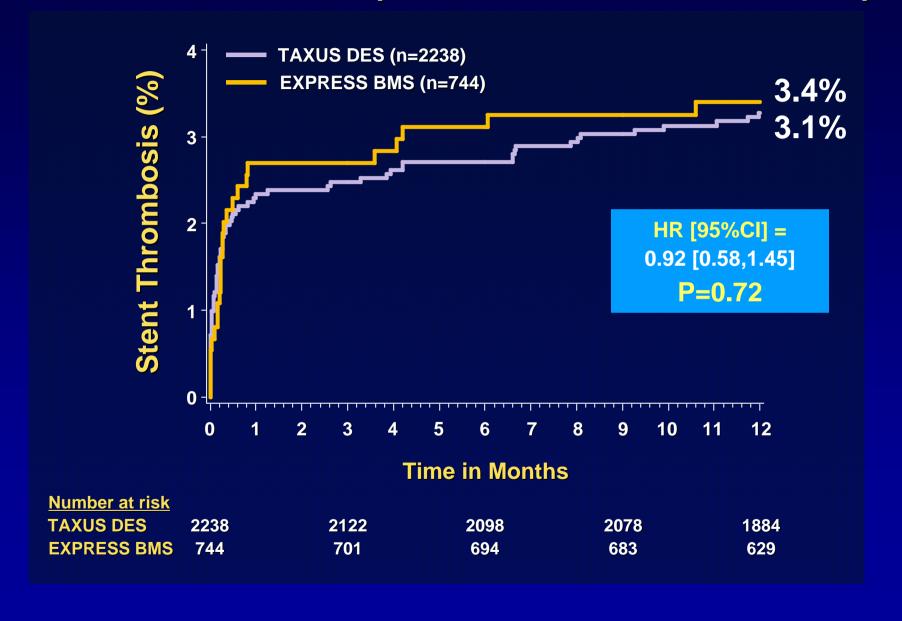
One-Year All-Cause Mortality



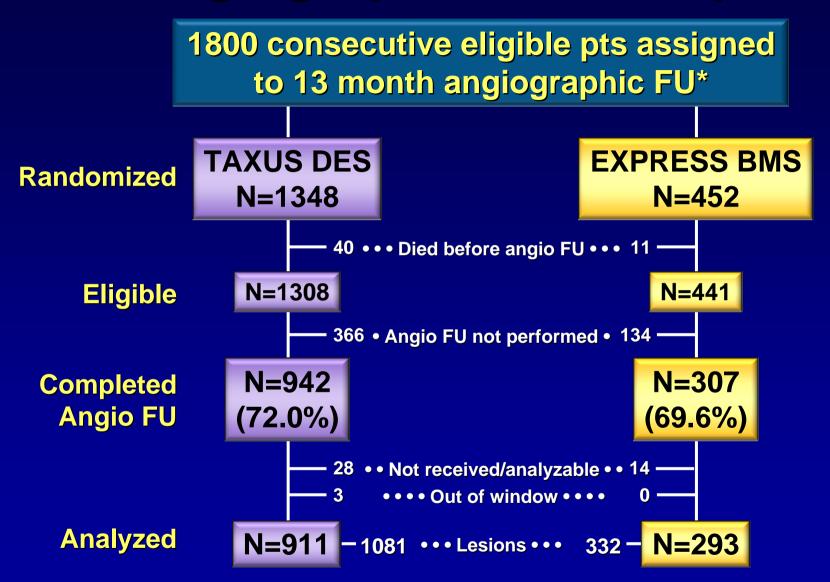
One-Year Death or Reinfarction



Stent Thrombosis (ARC Definite or Probable)

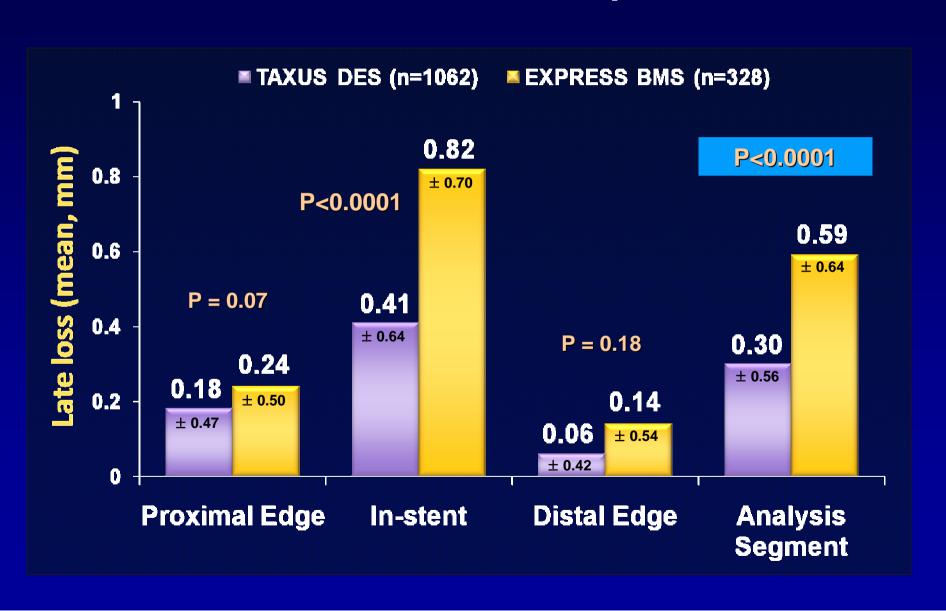


Angiographic Follow-up

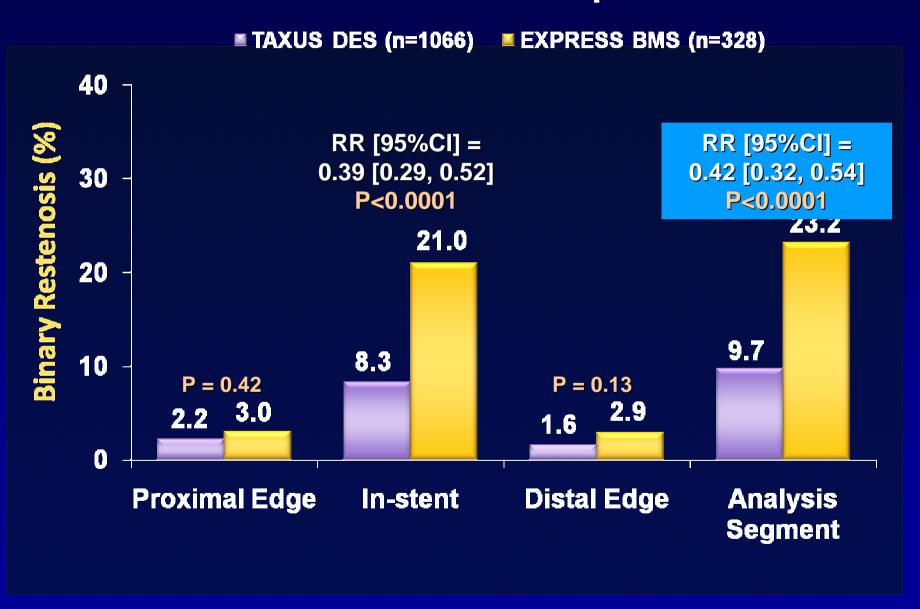


^{*} Randomized in stent arm; stent procedure successful (DS <10%, TIMI-3 flow, ≤NHLBI type A peristent dissection); no stent thrombosis or CABG w/i 30 days

Angiographic Late Loss at 13 Month Lesions with Stents Implanted



Binary Angiographic Restenosis at 13 Months Lesions with Stents Implanted



Conclusions

- In this large-scale, prospective, randomized trial of pts with <u>STEMI undergoing primary stenting</u>, the implantation of paclitaxel-eluting <u>TAXUS</u> stents compared to bare metal EXPRESS stents resulted in:
 - A significant 41% reduction in the 1-year primary efficacy endpoint of ischemia-driven TLR, and a significant 56% reduction in the 13 month major secondary efficacy endpoint of binary restenosis
 - Non inferior rates of the primary composite safety endpoint of all cause death, reinfarction, stent thrombosis or stroke at 1-year

Conclusions

 The long-term safety and efficacy profile of paclitaxel-eluting TAXUS stents compared to bare metal EXPRESS stents in STEMI will be determined by the ongoing 5 year follow-up of patients randomized in the HORIZONS-AMI trial