Late Breaking Science: Linking Genes to Function in the Heart and Vasculature

β-Radiation to INHIBIT Recurrence of In-Stent Restenosis: Clinical and Angiographic Results of the Multicenter, Randomized, Double-Blind Study

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Background: Clinical trials utilizing gamma radiation therapy have demonstrated a reduction in the recurrence of restenosis for patients with in-stent restenosis (ISR). INHIBIT (Intimal Hyperplasia Inhibition with Beta In-stent Trial) is a multicenter randomized double blind study designed to evaluate the safety and efficacy of ^{32}P (a pure beta emitter) delivered into a centering balloon catheter via an automatic afterloader for the prevention of recurrent ISR. **Methods:** Three hundred and thirty two patients with in-stent restenosis in native coronaries with lesion $<$47 mm in length underwent intervention with balloon, atherectomy, or stent placement (new stenting was placed in 25% of lesions). Following intervention, a helical centering balloon catheter 2.5–3.5 mm positioned at the treated segment and automatically loaded with a ^{32}P source 0.018 wire, 27 mm in length to deliver a randomized dose of either 0 or 20 Gy prescribed at 1.0 mm from the lumen diameter. Manual stepping of the radiation catheter was performed in 42% of lesions (those $>$22 mm in length) with an overlap of up to 2 mm at the stented segment. **Results:** There was a 56% reduction in the safety endpoint (composite of death, Q MI, TSR). The event rate was 14% radiated vs. 31% control, $p=0.0002$. There was a 50% reduction in the efficacy endpoint (angiographic binary restenosis rate). The restenosis rate was 26% radiated vs. 52% control, $p=0.0003$. There were no adverse effects related to the radiation. **Conclusion:** The INHIBIT Trial results have supported the hypotheses for reduction in MACE and binary angiographic restenosis.

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