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A NOVEL POLYMER COATING FOR DRUG ELUTING STENT APPLICATIONS

i2 Oral Contributions
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Session Title: Pre-clinical DES
Abstract Category: 15. PCI - DES (pre-clinical development)
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Background: Although polymer coatings are widely used in drug eluting stents (DES), a lack of biocompatibility could have a profound influence on chronic inflammation and long-term stent healing. The biocompatibility and efficacy of a novel non-erodible polymer (Baymedix™ CD 500, Bayer, Germany) on a CoCr stent platform loaded with sirolimus (SRL) was examined.

Methods: Male New Zealand White rabbits (n=10) were implanted with CD 500 SRL-eluting stents (n=8); a bare-metal stent (BMS) without polymer or drug or 2nd generation DES, (Xience V, Abbott Vascular, Santa Clara, CA) served as controls (n=6 each). Bilateral stents were implanted into ilio-femoral arteries for 28 days and processed for light microscopy.

Results: All stents remained widely patent with no evidence of luminal thrombosis. Neointimal thickness was significantly reduced in CD 500 SRL stents compared to BMS with equivalency to Xience V (Figure). The percentage of peri-strut fibrin was comparable between DES (CD 500 SRL=14.21±8.68% vs. Xience V=17.18±6.15%, p=0.49). Inflammation was mild for all stent groups (inflammation score: BMS = 0.11±0.17 vs. CD 500 SRL = 0.50±0.47 vs. Xience V =0.67±0.56, p=0.11). No delamination of the Baymedix™ CD 500 polymer coating was observed.

Conclusion: SRL-eluting stents with Baymedix™ CD 500 coating demonstrated a significant reduction in neointimal growth with equivalency to Xience V. These results show promise of a new non-erodible polymer for therapeutic drug delivery of coronary stents.