From bench to bedside: initial experience with the Primus drug-coated balloon catheter.

Abstract:
Drug-coated balloon (DCB) technology has emerged as a promising therapy particularly in the treatment of coronary in-stent restenosis. Although a variety of devices are available for clinical use, clinical outcomes have been variable and scope for significant improvement exists. In a preclinical study, a total of 10 juvenile healthy farm pigs underwent catheter-based DCB deployment in coronary arteries with angiographic and pathological follow-up at 7 or 28 days. Animals were randomly allocated to the PRIMUS or Dior® DCB (N.=10 per group) and evaluated by histopathology and morphometric analysis. In a first-in-man clinical study a total of 19 consecutive patients presenting with restenosis within drug-eluting stents were treated with the PRIMUS DCB. Clinical follow-up was performed out to 6 months. Neointimal thickness was similar between the PRIMUS and Dior® DCB groups, while fibrin deposition and inflammation were more sustained in the PRIMUS group at 28 days. In 19 consecutive patients presenting with in-stent restenosis of drug-eluting stents, treatment with the PRIMUS DCB catheter resulted in high procedural efficacy. There were no adverse clinical events observed out to 6 months. The PRIMUS DCB demonstrates high preclinical safety and excellent acute performance and safety. Further studies are needed to delineate the relative merits of this
novel DCB compared to other devices.

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