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Titel des Beitrags: Histopathological comparison of biodegradable polymer and permanent polymer based sirolimus eluting stents in a porcine model of coronary stent implantation

Abstract: Biodegradable stent coatings were recently introduced as a potential solution to overcome sustained inflammatory responses observed with permanent polymer-based drug-eluting stents. In a preliminary study, selected biodegradable or permanent polymer-based sirolimus-eluting stent (SES) formulations were screened for effectiveness in comparison to bare metal stents (BMS) at 28 days. Subsequently, the most favourable SES formulation was compared to commercially available SES (Cypher (TM)) at 28, 90 and 180 days to investigate the histopathologic response as well as tissue, blood and organ pharmacokinetics. Overlapping SES implantation was conducted to evaluate vascular healing at 28 days in this particular setting. SES with biodegradable poly (L-lactide) polymer (PLLA) or poly(lactide-co-glycolide) showed the most favourable outcome with regards to reductions in neointimal area in comparison to BMS at 28 days. The PLLA SES showed a similar reduction in neointimal area compared to Cypher (TM) at 28 days, with significant greater reductions at 90 and 180 days (1.7 +/- 0.7 mm(2) vs. 3.1 +/- 1.5 mm(2), p=0.03 and 1.8 +/- 1.2 mm(2) vs. 3.0 +/- 1.5 mm(2), p=0.01, respectively). Sirolimus vascular tissue concentrations were detectable up to 90 days following implantation. Overlapping stented
segments showed favourable histopathologic results with respect to fibrin deposition and endothelialisation at 28 days. In conclusion, the use of PLLA as drug-eluting matrix resulted in mild inflammatory responses in the presence of effective sirolimus tissue concentrations. The greater efficacy observed at long-term follow-up in PLLA SES compared to Cypher (TM) may be a multifactorial result of stent design, polymer biocompatibility and improved release kinetics.