No country for old stents? Improving long-term patient outcomes with biodegradable polymer drug-eluting stents.

Abstract: Biodegradable polymer-coated drug-eluting stents (DESs) represent an attractive approach to improve vascular healing after coronary intervention. The proof-of-concept chain of investigation includes preclinical safety assessment, surrogate end point clinical efficacy studies and large-scale clinical outcome studies, in which noninferiority against benchmark devices is assessed at 12 months, with adjudication of hypothesized clinical advantage at long-term follow-up. The 4-year outcome data from large-scale trials such as the LEADERS study represents a final link in this process. Data from this trial show maintenance of noninferiority and an overall improvement in the composite of death, myocardial infarction and revascularization with biodegradable polymer DESs versus durable polymer sirolimus-eluting stents that is statistically significant and perhaps also clinically important (risk ratio: 0.81; 95% CI: 0.66-1.00; p-value for superiority = 0.05). Furthermore, although reductions in the incidence of stent thrombosis with biodegradable polymer stents at 4 years did not reach statistical significance, in keeping with the hypothesized mechanism of benefit, the observed risk differences seemed to be driven by a reduction in very late events beyond 1 year after intervention. These findings are backed up by those from a pooled analysis of the three largest biodegradable polymer DES
randomized trials. With the availability of high-quality biodegradable polymer devices and the phasing out of earlier generation devices, the next 5 years will see increasing uptake of this therapy in routine practice. Whether improvements in outcomes with biodegradable polymer DESs can also be demonstrated against second-generation durable polymer stents is the subject of a number of ongoing clinical trials.