Long-term Outcome of Biodegradable Compared to Durable Polymer Drug-eluting Stents and Bare Metal Stents - Main Results of a Prospective Randomized Trial

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Background: Biodegradable-polymer drug-eluting stents (BP-DES) were developed to be as effective as second-generation durable-polymer drug-eluting stents (DP-DES) and as safe >1 year as bare-metal stents (BMS). Thus, late stent thrombosis attributed to the durable polymer should no longer appear. A comprehensive evaluation of these aspects of BP-DES within one long-term trial is lacking, however.

Methods: Between April 2010 and May 2014, 2291 patients presenting with acute or stable coronary disease needing stents >3.0mm in diameter were randomly assigned to biolimus-A9-eluting BP-DES, second-generation everolimus-eluting DP -DES or thin-strut silicon-carbide-coated BMS in eight European centers. All patients were treated with aspirin and risk-adjusted doses of prasugrel. The primary endpoint was combined cardiac death, myocardial infarction and clinically indicated target -vessel revascularization within two years. The combined secondary safety endpoint was stent thrombosis with related myocardial infarction or death.

Findings: The cumulative incidence of the primary endpoint was 7.6% with BP-DES, 6.8% with DP -DES and 12.7% with BMS. By intention-to-treat BP-DES were non-inferior compared to DP -DES (absolute risk difference 0.78%, [-1.93%,3.50%], p for non-inferiority 0.042) and superior to BMS (absolute risk difference -5.16,[-8.32,-2.01], p=0.0011)). The three stent groups did not differ in the combined safety endpoint, with no decrease in these events, particularly stent thrombosis , >1 year with BP-DES.

Interpretation: BP-DES proofed non-inferior to DP -DES and more effective than thin-strut BMS, but there was no evidence for a reduced rate of late stent thrombosis and related clinical events with BP-DES. Findings challenge the concept that durable polymers are key in late stent thrombosis formation.

Disclosure:

C.A. Kaiser: Research Grant; Modest; Stentys, Biotronik Switzerland. Research Grant; Significant; Basel Cardiovascular Research Fundation. Speakers Bureau; Modest; Eli Lilly Switzerland, Daiichy Sankyo Switzerland, Abbott Vacular Switzerland, Astra Zeneca Switzerland. Consultant/Advisory Board; Modest; Abbott Vascular Switzerland, Eli Lilly Switzerland, Daiichy Sankyo Switzerland, Astra Zeneca Switzerland, GE Healthcare Switzerland, Bayer Switzerland. S. Galatius: Other Research Support; Modest; Pfizer (SPIRE-1-trial), Servier (MODIFY -trial), GSK (SOLID -trial), Novartis
(Atmosphere-trial), Stentys (SIZING-trial), Terumo (E-NOBORI-trial), Eli Lilly (EF JE-trial). Consultant/Advisory Board; Modest; Eli Lilly, Servier. M. Pfisterer: None.