

Efficacy and Safety of Percutaneous Coronary Interventions Using Titanium-Nitride-Oxide Coated Bioactive Stents versus Drug-Eluting Stents in Coronary Artery Disease. A Systematic Literature Review and Meta-Analysis.

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Introduction: Drug-eluting stents (DES) have mostly replaced bare-metal stents in percutaneous coronary interventions (PCI). Platforms and Eluted drugs have evolved to improve efficacy and reduce adverse events but durable efficacious doses of eluted drugs still convey risks of complications. Titanium-nitride-oxide (TNO) coated stents ('Bioactive stents' BAS) have been tested versus DES in randomized clinical trials (RCTs) as a non-drug-eluting alternative.

Hypothesis: Independent systematic review of the efficacy and safety of TNO BAS vs. DES in PCI for Coronary artery disease (CAD) including stable coronary artery disease and acute Coronary Syndrome (ACS).

Methods: Independent review and meta-analysis of RCT comparing clinical outcomes in BAS versus DES, in accordance with PRISMA, from a search in Pubmed, Embase, Web of Science and the Cochrane Library (8 March 2018). Publications and presentations were manually searched by 2 reviewers. All RCT were selected. Any disagreements were resolved by a third reviewer. Study management conformed to the Cochrane manual, and data were analyzed in RevMan 5.3. Outcomes of BAS and DES were quantitatively compiled. Sensitivity analysis was systematically performed for each endpoint.

Results: Five RCT were identified and included, with 1855 BAS vs. 1363 DES pts at 1 year and 783 BAS vs. 771 DES at 5 years. No publication bias was detected. Risk of bias within studies was present mainly due to the inability to blind operators. ORs presented no significant heterogeneity. Outcomes, all indications pooled (at 1 year / 5 years): Stent-oriented Major Adverse Cardiac Events (TLR-MACE) RR 1.05, 95%CI [0.84, 1.31] / 0.82 [0.66, 1.02]; probable or definite stent thromboses (STH per ARC) 0.39 [0.22, 0.69] / 0.25 [0.11, 0.56]; Myocardial infarction: 0.39 [0.27, 0.57] / 0.54 [0.38, 0.76]. In ACS: TLR-MACE: 0.93 [0.72, 1.20] / 0.74 [0.58, 0.95]; STH: 0.35 [0.20, 0.64] / 0.20 [0.09, 0.49]; MI: 0.42 [0.28, 0.63] / 0.51 [0.35, 0.74]. Total deaths: no significant difference. Results were robust to sensitivity analysis. Results were driven to a large extent by results in ACS.

Conclusions: Evidence from RCTs shows a similar incidence of MACE in BAS and DES but a lower incidence of stent thrombosis and a lower incidence in MI with BAS at 1 year and 5 years, in all patients but particularly in ACS. BAS appears to offer a better efficacy/risk than DES.