
Abstract:
Drug-eluting stent (DES) therapy has represented a very significant milestone in the evolution of percutaneous coronary intervention (PCI) therapy. This review attempts to provide a balanced overview of the unprecedented wealth of data generated on this new technology, by examining the evidence bases for anti-restenotic efficacy, safety and cost effectiveness. The performance of a DES may be related to each of its three components: stent backbone; carrier polymer (to control drug-release kinetics); and active drug. In terms of anti-restenotic efficacy, the most appropriate parameters to examine are target lesion revascularization, angiographic restenosis and late luminal loss. The principal safety parameters are overall mortality, myocardial infarction (MI) and stent thrombosis. Anti-restenotic superiority of DES over bare metal stents (BMS) has been demonstrated across a spectrum of disease from straightforward 'vanilla lesions' through higher disease complexity in pivotal clinical trials to phase IV studies of efficacy in 'off-label' populations. The treatment effect of DES versus BMS is consistent in terms of a reduction in the need for repeat intervention of the order of 35-70%. Regarding differential efficacy of first-generation DES, a benefit may exist in favour of the Cypher (sirolimus-eluting) stent over Taxus (paclitaxel-eluting), particularly in high-risk lesion subsets. The second-generation approved devices are the Endeavor...
(zotarolimus-eluting) and Xience (everolimus-eluting) DES. While all four of these stents are permanent polymer-based, the current focus of development is towards DES platforms that are devoid of durable polymer, the presence of which has been implicated in late adverse events. In terms of safety concerns raised in relation to DES therapy, it is reasonable to conclude the following at 4- to 5-year post-stent implantation: (i) that there is no increased risk of death or MI with DES (neither is there a general signal of mortality reduction with DES) compared with BMS; and (ii) there is very little, if any, overall increased risk of stent thrombosis with DES compared with BMS, although a difference in the time distribution of thrombotic events after PCI may exist, i.e. a slight excess of events with BMS in the first 6 months and with DES beyond 12 months. Duration of dual anti-platelet therapy after stenting is a central issue and is also, at present, a matter of clinical equipoise. A threshold for cost effectiveness likely exists where the price premium associated with DES is approximately euro 450. On the balance of benefit and risk data available, DES implantation should be the preferred approach across the spectrum of patients with obstructive coronary disease who require PCI therapy.