References


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Guidelines for percutaneous coronary interventions

The recently published guidelines for PCI by the European task force were set out to mark a timely milestone, but missed this goal unfortunately as a result of unbalanced statements. Various peculiarities make it difficult to follow those guidelines for various reasons.

First, statements and findings from the Taxus VI trial were utilized for the paper; although the stent utilized in Taxus VI has never been marketed and is not available while results from other trials are neglected. Secondly, results from RCTs on various interesting subsets of patients with focus on in-stent restenosis, diabetes, and small vessels have not been taken into consideration; nevertheless, the authors of the guidelines are demanding such RCTs even at a time when ARTS II and TROPICAL could not use bare metal controls, but rather had to compare with historical controls for ethical reason.

Thirdly, the authors’ conclusion of equipotential effects of sirolimus and paclitaxel coated stents only on the basis of the small TAXI trial is likely to be oversimplified and more than courageous; justified is only that the hypothesis of 6% MACE with sirolimus and 14% with paclitaxel were not met. Finally, although the preamble to those guidelines claims both to present all relevant evidence on a particular issue and to be developed by an unquestionable decision-making process, none of those standards have been met. It is already late for an update.

References


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Guidelines for percutaneous coronary interventions: reply

The members of the ESC PCI guidelines task force appreciate the comments made by Dr Nienaber regarding our analysis and recommendations for drug-eluting stents (DES).

(1) Dr Nienaber states that our recommendations for DES should not have been based on the TAXUS-VI trial, because this trial investigated the moderate-release form of the Taxus stent which has not been marketed. First, in the TAXUS-II trial, there were no clinically or angiographically relevant differences between the marketed slow-release and the not marketed moderate-release forms in equivalent lesions. Furthermore, comparing the TAXUS-VI results with TAXUS-V also did not reveal clinically relevant differences between the slow-release and the moderate-release forms. From Dr Nienaber’s point of view, we should also not have recommended the Cypher stent—at least for Germany: the currently marketed Cypher Select stent was not the one that was investigated in the SIRIUS trial (Cypher Bx Velocity). As another example, in most European countries, clopidogrel is not labelled for use after coronary stent implantation. Should the ESC PCI guidelines therefore not recommend clopidogrel after stent implantation?

(2) Regarding the use of DES for in-stent restenosis, Dr Nienaber criticizes that we demanded randomized, controlled studies before making definitive recommendations, ‘even at a time when ARTS II and TROPICAL could not use bare metal controls, but rather had to compare with historical controls for ethical reason’. The ESC PCI guidelines committee strongly believes that for