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Title **Safety and efficacy of drug-eluting balloon angioplasty for coronary artery stenosis: in-stent restenosis and de novo lesions**

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Aim

To evaluate safety and effectiveness of the drug-coated balloon (DCB) in PTCA in patients with ischemic disease due to coronary stenosis, either in-stent reestenosis or de novo lesions.

Conclusions and results

Paclitaxel-eluting balloons appear to be more effective in treating in-stent restenosis than conventional balloon angioplasty whereas they did not show superiority when compared with paclitaxel-coated stents. There is not enough evidence over safety and effectiveness of the use of drug-coated balloons in PTCA in de novo lesions.

Attending to selection criteria, 20 studies were included in the systematic review (12 studies RCTs and 8 prospective multicentric registries). The safety and effectiveness of DCBs in in-stent restenosis were evaluated in 8 RCTs and 2 registries. The safety and effectiveness of DCBs in de novo lesions were evaluated in 4 RCTs and 4 registries. In in-stent restenosis, patients treated with paclitaxel-eluting balloon had lower late lumen loss, binary restenosis rate and target lesion revascularization compared to patients in the conventional balloon angioplasty was used. No significant differences in the rate of myocardial infarction, stent thrombosis, all-causes death and cardiac-related death were found. Comparing the drug-eluting balloon with paclitaxel-coated stents (Taxus) only significant difference in late lumen loss in favor of the balloons was found. In de novo lesions there were not significant differences between DCB and first generation drug-eluting stents (paclitaxel) in clinical variables, in small vessels and diabetics. When the second generation drug-eluting stent was the comparator, in bifurcations or patients with ST-segment elevation myocardial infarction (STEMI) the results were in general unfavorable to DCB treatment.

Methods

A systematic review of the scientific literatures was made in the main biomedical databases. The search was conducted in May 2014 with monthly updates to retrieve recent articles. Two independent reviewers selected the papers in accordance with a series of pre-established inclusion/exclusion criteria. The data were summarized in evidence tables, and the methodological quality of the studies was assessed using the system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group. A meta-analysis, if appropriate, was performed in the case of randomized clinical trials (RCTs). We used the Review Manager programme version 5.2 and we obtained a pooled measure of the variables of interest. In the case series, the means and SDs weighted by sample size were calculated with the SPSS statistics programme version 19.

Further research/reviews required

Further larger and well-designed studies with standard and latest comparators as second generation drug-eluting stents are needed to stablish an application in this setting.

Written by

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