

2015 - SAFETY AND EFFICACY OF DRUG-ELUTING BALLOON ANGIOPLASTY FOR CORONARY ARTERY STENOSIS: IN-STENT RESTENOSIS AND DE NOVO LESIONS.

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Summary

Introduction: ischemic heart disease (IHD) is one of the five leading death causes in Spain. The mortality rate is about 75 deaths for 100.000 population. When myocardial revascularization is needed, the principal treatment is the percutaneous transluminal coronary angioplasty (PTCA), using bare metal stents or drug eluting stents. In 2012 the mean of PTCA performed in Spain was 1434/106 population. Recently a new device has emerged as a complement or alternative to stents in PTCA. The drug-coated balloon that releases an antiproliferative drug, paclitaxel, to the vessel, leaves no permanent structure and has been evaluated in lesions of in-stent restenosis of a previous stent, where the multiple layers can be avoided, and in de novo lesions like small vessels and bifurcations, where the stents can show a difficult in its performance.

Objectives: 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 restenosis or de novo lesions.

Methods: a systematic review of the scientific literatures was made in the following databases: Centre for Reviews and Dissemination (CRD Databases), Medline (PubMed), EMBASE (Ovid SP), ISI Web of Science (Web of Knowledge, WoK) and ClinicalTrial.gov. 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.

Results: attending to selection criteria, 20 studies were included in the systematic review. According to design, 12 studies were RCTs and 8 were observational studies (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. Two observational studies included the two types of patients. According to GRADE system the case series had very low quality for all variables because its lack of control group. In RCTs the quality was very variable, ranging from low to high depending on different scenarios and interventions. 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

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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.

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