SAFETY AND EFFECTIVENESS OF BIORESORVABLE VASCULAR SCAFFOLD (BVS) FOR THE TREATMENT OF DE NOVO CORONARY ARTERY DISEASE

Spanish full text

ABSTRACT

Introduction: Ischaemic heart disease (IHD) ranks among the five leading causes of death in Spain, with a mortality rate of around 75 deaths per 100,000 population. Currently, the principal treatment for *de novo* coronary lesions is percutaneous coronary intervention (PCI), using metal or drug-eluting stents. In 2011, the mean PCI rate in Spain was $1373/10^6$ population. Recently, a new generation of bioabsorbable stents (Bioabsorbable Vascular Scaffold, BVS) has emerged as a complement or alternative to metal or drug-eluting stents, aimed at providing support for the vessel for at least 2 years (period of reabsorption) without the potential long-term limitations entailed by the existence of a permanent metal structure.

Objectives: To ascertain the safety and efficacy of bioabsorbable everolimus-eluting coronary stents for treating IHD due to *de novo* lesions in native coronary arteries.

Methods: A systematic review of the literature was conducted in the following databases: Centre for Reviews and Dissemination (CRD); Medline (PubMed); EMBASE (Ovid); Institute for Scientific Information Web of Science (Web of Knowledge, WoK); and ClinicalTrial.gov. The strategy was implemented in October 2012, with monthly updates being conducted until the document's date of publication, in order to retrieve recently published studies. Two reviewers, acting independently, selected the papers on the basis of pre-established inclusion/exclusion criteria. The data were then summarised in evidence tables, and the methodological quality of the studies was separately assessed by two researchers using the scale drawn up by the Scottish Intercollegiate Guidelines Network.

Results: On applying the selection criteria, 11 studies were finally included in the systematic review. In terms of epidemiological design, all the studies included were multicentre case series showing the results of cohorts A (30 patients) and B (101 patients) of the ABSORB study. Cohort A (BVS 1.0 stent) (30 patients) showed an ischaemia-driven major adverse cardiac event (ID-MACE) rate of 3.3% over 4 years. There were 3 cases of binary restenosis in the first 6 months post-ICP, though revascularisation was not needed due to the absence of symptoms/signs of ischaemia. In cohort B (BVS 1.1 stent) (101 patients) there was an ID-MACE rate of 9% at 2 years, and 5% (2/39) presented with binary restenosis. No case of thrombosis was observed in either cohort.

Conclusions/recommendations: The studies reviewed indicate that BVS stents could be safe and efficacious for treatment of IHD due to *de novo* lesions, though further studies are needed to ascertain, both the safety and efficacy of BVS stents in patients with a more complex disease profile, and their clinical usefulness in comparison with metal or drug-eluting stents.