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Title Safety and effectiveness of Bioresorvable Vascular Scaffold (BVS) for the treatment of de novo coronary artery disease

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Reference http://www.sergas.es/Docs/Avalia-t/avalia-t201304StentsBVS.pdf

Aim

To ascertain the safety and efficacy of BVS stents for treating the ischaemic heart disease (IHD) due to de novo lesions in native coronary arteries.

Conclusions and results

The studies reviewed indicate that BVS stents could be safe and efficacious for treatment of IHD due to de novo lesions.

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.

Recommendations

Given the poor evidence that is available, BVS stents should be used in a case register in order to ascertain its safety and effectiveness in the treatment of ischemic heart disease due to de novo lesions prior to incorporation into the health system.

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.

Further research/reviews required

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.

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