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Title [Safety and efficacy of antibody-coated stent for the treatment of de novo coronary artery disease]

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Aim

The aim of this report was to assess the clinical utility of EPCC stents in the treatment of *de novo* coronary lesions as compared to routine clinical practice and the economic and organisational impact of implementing this technology in Spanish National Health System (NHS).

Conclusions and results

According to the evidence reviewed, the COMBO™ and GENOUS™ stents could be at least as safe as the DES (mainly 1st-generation- TAXUS DES) and BMS. In addition, both the GENOUS™ EPCC and the COMBO™ stents appear to be effective devices in the treatment of *de novo* coronary lesions, as they showed similar results to DES in the variables assessed. Attending to the study selection criteria, 18 primary studies were included, 6 were (randomised clinical trials) RCTs and 12 were case series. Of the trials selected, one of them assessed the safety and effectiveness of the COMBO™ EPCC stent against the TAXUS stent, while the remaining 5 compared the GENOUS™ EPCC stent to different generations of BMSs. All the case series assessed the GENOUS™ stent. With respect to the adverse events associated with the use of EPCC stents, the RCTs reviewed recorded a vascular complication rate of around 2-3% for the COMBO™ stent and no bleeding in patients treated with GENOUS™. As regards the effectiveness of EPCC stents, patients treated with GENOUS™ registered a higher frequency of target lesion revascularisations at 1 year of follow-up when compared to those treated with TAXUS. Patients treated with EPCC stents registered a lower use of antiagregant therapy at 1, 6 and 12 months as compared to those treated with TAXUS DESs. In contrast, one RCT reported no significant differences at 24 months. In comparison with BMSs, EPCC stents showed similar angiographic and clinical outcomes. Regarding the COMBO™ stent, it also appeared to display a clinical efficacy similar to the TAXUS stents, such as no significant differences were found in the variables assessed.

Methods

We made a systematic review of the literature in different sources. The search strategy was conducted in April 2016, with monthly updates until date of report's edition. Two independent reviewers selected the papers in accordance with pre-established inclusion/exclusion criteria. The data were summarised, and the methodological quality of the studies was assessed using GRADE system. In the case of RCTs, we performed a meta-analysis, if appropriate, using the *Review Manager* programme version 5.3 to obtain a pooled assessment of the variables of interest. In case series, means and SDs weighted by sample size were calculated using the SPSS statistics programme (version 19).

Further research/reviews required

Studies comparing EPCC stents versus 2nd-generation DESs are needed to assess their usefulness in routine clinical practice.

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