

PP095 Assessment Of Magmaris Resorbable Metal Stent In Patients With Angina

AUTHORS:

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INTRODUCTION:

Ischaemic heart disease is the leading cause of death worldwide. Magmaris™ is a new drug-eluting resorbable stent used for coronary reperfusion during a balloon angioplasty. Magmaris™ is composed of absorbable magnesium scaffold and its surface is coated with bioresorbable poly-L-lactide, which incorporates Sirolimus. Magmaris™ has theoretical advantages as the stent body disappears after vascular constrictive remodeling. It would provide the stability and elasticity of non-resorbable metal stents, but without long-term problems such as endothelial dysfunction, delay in endothelialization, risk of thrombosis and complications due to long-term antiplatelet medication. The objective of this work is to assess efficacy and safety of Magmaris™ in patients with angina or silent ischaemia.

METHODS:

Early assessment of Magmaris™ identified through the Early-Awareness and Alert-System, "SINTESIS-new technologies", of The Instituto De Salud Carlos III (AETS-ISCIII). The searched databases were: MEDLINE (PubMed), EMBASE, WOS, Clinical Trials and Cochrane Library. Clinical studies using Magmaris™ published in any language until December 2016 were reviewed.

RESULTS:

One prospective, non-randomized, non-controlled, multicenter, clinical trial with two publications was retrieved. The first publication (123 patients) showed mainly imaging outcomes of angiography, intravascular ultrasound and tomography at 6 months of follow up. The second publication (118 patients) with data from 12 months of follow up also reported: Target lesion failure in four patients (3.4 percent; 95 percent

Confidence Interval, CI:0.9–8.4); one target-vessel myocardial infarction (0.8 percent; one myocardial infarction (0.8 percent); two clinically driven target lesion revascularisation (1.7 percent) and two clinically driven target-vessel revascularisation (1.7 percent). No definite scaffold thrombosis was observed. No procedural complications were reported. This trial is expected to continue up to 36 months of follow up.

CONCLUSIONS:

Clinical data show that Magmaris™ seems to be an effective and safe treatment in patients with angina or silent ischaemia undergoing balloon angioplasty. More research specially randomized controlled trials are necessary to confirm these results.

PP096 European Union-Health Technology Assessments For Medical Devices - How To Overcome Reimbursement Divergence

AUTHORS:

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INTRODUCTION:

National Health Technology Assessments (HTAs) for medical devices are crucial to regulate the quality and costs of healthcare systems. However, there is diversity in several aspects among European countries. Consequently, controversial results might arise, generating contrary reimbursement decisions. The European Network for Health Technology Assessment (EUnetHTA) is an interface platform for the harmonization of HTA information across Europe. The European Commission expects national uptake of a European HTA. Thus, European HTAs might overcome the diversity of national HTA requirements.