PP095 Assessment Of Magmaris Resorbable Metal Stent In Patients With Angina

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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.

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METHODS:

We aimed to compare German and European HTAs for medical devices regarding processes, methods, timelines, and involvement of medical device companies. Therefore we analyzed guidelines, requirements, and output of EUnetHTA and compared those aspects with the German G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) standard and IQWiG (Institute for Quality and Efficiency in Health Care, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) methods.

RESULTS:

We found differences between the European and German HTAs for medical devices regarding timelines, involvement of medical device companies, body of evidence, use of surrogate endpoints, and methodology. European HTAs for medical devices reflect the clinical reality by integrating the existing evidence (including real world data) and by using comprehensive statistical methods for medical devices. In contrast, German HTAs for medical device-based technologies are long lasting and are often restricted to a small body of evidence.

CONCLUSIONS:

As a conclusion, similar to pharmaceuticals, the European HTA framework might also become a worldwide platform for HTAs of medical device-based technologies with the potential to harmonize reimbursement decisions and patients health care across countries on the basis of clinical reality.

PP097 Challenges Of Rapid Reviews In Health Technology Assessment: Case Study From An Italian Region

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INTRODUCTION:

Rapid reviews are an attractive tool for Health Technology Assessment (HTA) as they may be a support in decision making when time and resources are limited. Rapid reviews are carried out in few weeks (from 3 weeks to 6 months) and require adjustments from standard systematic review methods. Methodology on how to carry out rapid reviews is still debated and guidance regarding the most suitable method to apply is lacking. Kaltenthaler (1) has recently proposed a checklist of items to be considered when undertaking a rapid review. We appraised our rapid assessment on the use of frequency domain (FD)-optical coherence tomography in percutaneous coronary interventions, based on a rapid review of the literature, using the items proposed (1).

METHODS:

The checklist reports four key points to consider when planning a rapid review: (i) scoping search - needed to quantify the available evidence and to inform rapid review protocol, (ii) results reporting – considering heterogeneity of intervention, comparators, and outcomes, (iii) clear communication with policy makers - ensuring that review responds to the policy question and (iv) reporting on methods - methodology used, strengths and limitations.

RESULTS:

When we applied the checklist proposed by Kaltenthaler (1) to our rapid review on the use of FD-optical coherences tomography it resulted that: the scoping search revealed no useful systematic reviews to answer policy-makers questions and a high number of relevant studies. For results presentation, we used a narrative synthesis reporting outcome data grouped in domains previously defined by an evidence profile. Domains consisted of technical performance, safety, efficacy, and change in management. No meta-analysis was performed due to paucity of randomized controlled trials (RCTs) for the efficacy domain and high heterogeneity in outcomes measures for technical performance. Analysis of some of the outcomes was

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