Title	**Efficacy, Safety, and Effectiveness of Drug Eluting Stents**
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Reference	Eficacia, seguridad y efectividad de los stents recubiertos de farmacos, June 2003

Aim

To review the scientific evidence related to efficacy, effectiveness, and safety of drug eluting stents used to revascularize primary lesion in the native coronary artery and to treat in-stent restenosis. A secondary objective is to review costs and economic analysis reports published on drug eluting stents.

Conclusions and results

In the past few years, studies have been developed to assess the effectiveness of drug eluting stents. The initial studies, FIM, RAVEL, and SIRIUS, present sufficient evidence on safety and efficacy in small groups of patients for the revascularization of coronary artery primary lesions with sirolimus coated stents. The evidence from these controlled and randomized trials suggests that stents with sirolimus are efficacious and safe in preventing angiographic restenosis and major cardiac adverse events in de novo lesions with specific, non-complex characteristics (only 12 months of followup). The TAXUS, ELUTES, and ASPECT trials also suggest that stents coated with paclitaxel are efficacious and safe in revascularizing primary lesions in coronary arteries. However, followup data from long-term clinical trials are lacking. Low-quality scientific evidence suggests that drug eluting stents for treatment of in-stent restenosis lesions are effective in preventing restenosis. Nevertheless, the results of international in-stent restenosis registry studies are optimistic in this high-risk group.

Recommendations

Although enough evidence suggests the effectiveness of the technology in specific primary lesions in native coronary arteries, further long-term studies are required to confirm the optimistic results. The technology must be used under study conditions in subgroups of patients different from those presented by the published scientific evidence. The use of drug eluting stents in these patients is essentially experimental and, as such, should be subject to ethics committee approval and informed consent by patients. A system for ongoing monitoring and evaluation should be established to assess long-term efficacy and safety.

Methods

The following electronic databases were searched: MEDLINE, INAHTA, and NHS CRD databases (DARE, HTA Database, NHS-EED Database Economic Evaluations of Health Care Interventions), Cochrane Database of Systematic Reviews, and the Controlled Clinical Trials Database.

Further research/reviews required

To clarify benefits of the technology in particular patients with complex lesions and higher risk of restenosis it is necessary to develop new studies that overcome the limitations of the existing studies.

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