



Sociedad Española de Cardiología
Comprometida en la salud cardiovascular

According to a number of studies published in the New England Journal of Medicine (NEJM)

THERE IS NO CAUSE FOR ALARM OVER THE SAFETY AND EFFICACY OF DRUG ELUTING STENTS IN THE TREATMENT OF HEART DISEASE

- Out of five studies published in the New England Journal of Medicine (NEJM), four, prospective and randomized, agree that drug eluting stents are similar to conventional stents in terms of the appearance of thrombosis and mortality in heart patients. In the fifth study, more late thrombosis was recorded with drug eluting stents, although the study was not randomized and was not as scientifically rigorous.
- In the same journal, the FDA confirmed the efficacy and safety of drug eluting stents, when used in the circumstances described in these large trials, emphasizing that longer-term studies with all types of patients are required to determine more fully the safety of these devices.
- Patient education, randomized trials, longer-term studies and adherence to treatment by patients and healthcare personnel (especially dentists and surgeons) are the main objectives of the hemodynamics and interventional cardiology section of the Sociedad Española de Cardiología (Spanish Cardiology Society - SEC).

Madrid, 12th March 2007. In 20-30% of cases, the use of conventional bare metal stents is followed by intrastent restenosis in the subsequent months, a situation associated with a high percentage of patients requiring further revascularization due to repeat angina.

The appearance of drug eluting stents has enabled this type of problem to be controlled, showing a high degree of efficacy in the treatment of these patients with a minimum incidence of restenosis.

At the World Congress of Cardiology, held last September in Barcelona, a number of studies were presented, some of which suggested that the use of drug eluting stents could be associated with an increase in thrombosis and mortality, compared to metal stents.

Due to the alarm this has caused, last December the FDA convened a panel of experts to clarify the safety and efficacy of drug eluting stents. The conclusions



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of the panel were clear: if used in the cases indicated in the trials, DES are more effective and just as safe as bare metal stents. If used in more complicated, higher-risk cases, an increase in the number of complication is logically to be expected (this also occurs with bare metal stents). The FDA recommends long-term studies and increased patient and healthcare personnel education to ensure anti platelet treatment for as long as necessary.

In the opinion of the hemodynamics and interventional cardiology section of the SEC, whose governing board is made up of the doctors Fina Mauri, Agustín Albarrán, Eduardo Pinar and José Antonio Baz, there is currently no data to cause alarm over the safety of these devices and the members want to convey a message of assurance, given that “the information available to date does not show an increase in thrombosis or mortality in patients with drug eluting stents, which are effective and safe”.

Of the five studies on drug eluting stents published in the NEJM, four of them, signed by doctors Greg Stone, Laura Mauri, Adnan Kastrati and Christian Spaulding, agree that the appearance of thrombosis and mortality after four years between conventional bare metal stents and drug eluting stents is similar.

However, there is a fifth, Swedish study, published by Sr. Lagerqvist, which shows that after six months, an increase in mortality is observed in patients treated with drug eluting stents. These results have led to the Swedish healthy authorities recommending restrictions in their use, limiting it to cases where there is no alternative. However, this study has a number of design defects: it is not randomized or prospective and it has a much more limited scientific value.

The hemodynamics and interventional cardiology section of the SEC considers three initiatives that can improve the efficacy and safety of treatment with drug eluting stents.

Firstly, randomized, long-term studies with a larger number of patients should be carried out, given that in patients with complex lesions it is difficult to calculate the risk-benefit ratio. They emphasize that in these cases “the final decision depends on the interventional cardiologist”.

Education of the stent patient is another key factor in the safety of the treatment. Thus, the on-going treatment is a key factor, requiring the participation of patients, because they should be treated with double platelet antiaggregation treatment for 12 months.

Also, both patients and healthcare personnel (especially surgeons and dentists) should be aware of the “potentially catastrophic consequences” of stopping anti platelet treatment without first consulting the interventional cardiologist.



For its part, the hemodynamics and interventional cardiology section of the SEC intends to promote this healthcare education among patients with drug eluting stents and extend the information to the scientific societies of other medical specialties (GPs, surgeons, endoscopists and dentists).

For further information:

Berbés Asociados – María González and Clara Castaño.

Phone: 91 563 23 00 – 677 456 806 – 6