Lower rate of stent thrombosis found with second-generation drug-eluting stent than with bare metal stent

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The second generation drug-eluting stent Xience V performs well in patients having primary PCI for ST elevation myocardial infarction, and has a better safety profile than that of bare metal stents, according to results of the EXAMINATION (Evaluation of Xience-V stent in Acute Myocardial INfArcTION) trial.

The study was a randomised controlled trial with an "all-comers" design to evaluate the Xience V stent in the complex setting of STEMI and to provide data that may be applicable to the real world population.

Dr Sabate said that the first generation drug-eluting stents (DES) had been evaluated in randomised controlled trials in the setting of STEMI, with positive results overall. However, he added, most of these trials lacked "good generalisability" to real world circumstances because of their highly selected inclusion/exclusion criteria. Moreover, no safety and efficacy data exist for the new generation of DES in this high risk group of patients with STEMI. The all-comers design of the EXAMINATION trial applied wide inclusion and few exclusion criteria, "which may result in a more representative sample of the target population".

The study was an investigator-initiated, multicentre, multinational trial involving 1498 STEMI patients randomised to either a Xience V stent (everolimus-eluting) or cobalt chromium bare metal stent. The primary endpoint was a composite of all-cause death, any recurrent myocardial infarction and any repeat revascularisation at one-year follow-up. Individual components of the primary endpoint and stent thrombosis were the main secondary endpoints. Patients included in the trial represented up to 70% of all STEMI patients being attended in the centres during the recruitment period, reflecting the "real world" nature of the design.

Results presented during the Hot Line session in Paris included 98% of patients with one-year follow-up data. In terms of primary endpoint, there was a non-significant trend towards benefit with the Xience-V stent by virtue of a lower rate of new revascularisations during follow-up as compared to the bare metal stents.

In terms of safety, the rates of definite and definite/probable stent thrombosis at one-year follow-up were significantly lower with the Xience V stent as compared to the bare metal stent, accounting for 0.5% (definite) and 0.9% (definite or probable) at one year with Xience V and 1.9% and 2.6% with the bare metal stent (both p=0.01).

"These are the first 'real world' results we have from a randomised trial about the performance of the new generation drug-eluting stents in the high-risk context of STEMI," said Dr Sabate, "and I think we can be reassured over any concerns about stent thrombosis."

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