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Experimental coronary stent combines ultrathin structure with biodegradable material

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A new generation of coronary artery stent that combines a biodegradable component with an ultrathin scaffold showed promising results compared with the current gold standard, in a large population of coronary artery disease patients, according to a new study.

The BIOSCIENCE trial was presented as a Hot Line at the ESC Congress 2014, and published simultaneously in *The Lancet*.

The experimental stent "represents the next logical step in stent refinement by combining an ultrathin platform with a polymer that completely degrades,"
said BIOSCIENCE investigator Thomas Pilgrim, MD, from the Swiss Cardiovascular Center at University Hospital, in Bern, Switzerland.

Coronary artery stents are metal scaffolds that are inserted to unblock the small arteries supplying the heart. For well over a decade, stents have been "drug-eluting", meaning coated with medication to prevent re-blockage of the artery. Earlier drug-eluting stents were coated with non-biodegradable polymers and had thick stainless steel struts – both features that have been linked with an increased rate of complications.

In contrast, the experimental stent combines both a biodegradable polymer and an "ultrathin" cobalt-chromium strut - the thinnest strut currently available.

Subjects in the trial had coronary artery disease and were randomly assigned to receive either the experimental stent (n=1063) or the standard stent (n=1056) during percutaneous coronary intervention.

They were then followed for 12 months, with the primary endpoint of the study being a composite of cardiac death, heart attack caused by a re-blockage in the treated artery, and the need for revascularisation of the treated artery within the study period.

The trial was designed to show non-inferiority of the experimental stent compared to the standard stent and indeed, the composite endpoint occurred in 6.5% versus 6.6% of subjects respectively.

The non-inferiority for the experimental stent is noteworthy, in that "it matched the outcomes of one of the safest and most effective new generation drug-eluting stents," explained Dr. Pilgrim.

"Because of the low event rates of contemporary stents it is becoming increasingly difficult to establish superiority of newer stents in clinical trials," he added.

However, in a subgroup of patients presenting heart attack, the experimental stent showed superiority over the standard stent, with the primary endpoint occurring in only 3.3% versus 8.7% respectively (relative risk [RR] 0.38, p=0.024).

The study was not powered to assess differences in this subgroup, "therefore we cannot exclude that these findings are due to chance alone," he said.

"But future studies will need to explore whether such differences can be reproduced in this patient population, which is at highest risk for ischemic adverse events."

Provided by European Society of Cardiology