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PCI with polymer-free BA9 drug-coated stent better than bare metal stent in ACS patients

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Patients with acute coronary syndromes (ACS) who are at high risk for bleeding have significantly lower rates of target lesion revascularisation and fewer adverse events after undergoing percutaneous coronary intervention (PCI) with a polymer-free biolimus-A (BA9) drug-coated stent than with those receiving a bare metal stent (BMS) in results from a sub-study of the LEADERS FREE trial reported for the first time in a late-breaker session at EuroPCR 2016.

"Patients with acute coronary syndromes have a high risk of bleeding after PCI because of the medication they are taking, but they have never previously been systematically studied," explains lead author Christoph Naber from the Contilia Heart and Vascular Center, Essen, Germany.

Previous research shows that at least one in six patients undergoing PCI is at high risk for bleeding and they are typically treated with bare-metal stents followed by one month of dual antiplatelet therapy to minimise their risk of bleeding. However, this carries a higher risk of restenosis and need for a further intervention than PCI with a drug-eluting stent. The LEADERS FREE trial investigated use of a polymer-free and carrier-free drug-coated stent that transfers umirolimus (also known as biolimus A9), a highly lipophilic analogue of sirolimus, into the blood vessel wall over a one-month period.

Dr Naber reported new results from a prespecified sub-study of 659 patients with acute coronary syndromes: 554 having had a non-ST-segment elevation myocardial infarction (NSTEMI) and 105 an ST-segment elevation MI (STEMI). They were randomised to receive either the polymer-free BA9-coated stent or to a bare metal stent. All patients received one month of dual antiplatelet therapy.

Results at 12 months follow-up showed patients receiving the polymer-free BA9-coated stent had less than half the rate of clinically driven target lesion revascularisation compared to those receiving a bare metal stent (3.92% vs 8.96%, p=0.009). They also had a significantly lower risk of adverse events, which was a composite of cardiac death, MI and stent thrombosis (6.92% vs 9.32%, p=0.049).

"The most important take-home message is that using a BA9-coated stent plus one month of dual antiplatelet therapy not only improves the efficacy of PCI in patients with ACS and high risk of bleeding compared to use of a bare metal stent but also increases safety, with less cardiac death, myocardial infarction and stent thrombosis," says Dr Naber.

"Current guidelines may need to be revised and bare metal stents can no longer be recommended for these patients," he suggests. "Given the lack of data for second-generation drug-eluting stents with shortened dual antiplatelet therapy the polymer-free DA9-coated stent is currently the device with the strongest evidence supporting its use in this group of patients."

Results from the study as a whole, for a total of 2466 patients, reported last year in the New England Journal of Medicine showed a 50% lower rate of target lesion revascularisation in patients randomised to the drug coated stent compared to those receiving the bare metal stent and a one-month course of dual antiplatelet therapy (hazard ratio 0.50, p<0.001).

Commenting on the new results from the ACS sub-study, the EuroPCR discussant Thomas Cuisset, from University Hospital, La Timone, Marseille France, points out, "The benefit of the drug coated stent over the bare metal stent was even greater in patients with ACS than in the study population as a whole." He adds, "The information from this sub-study is key because this specific population has not been included in previous clinical studies and, until now, treating these patients was like working in a 'data-free' zone."

For the future, Dr Cuisset suggests, "The respective roles of new-generation drug eluting stents, drug coated stents and potentially fully resorbable devices will require further investigation. Also, the optimal duration of dual antiplatelet therapy used with the drug coated stent in this study should probably not be extrapolated to other populations, including those at low bleeding risk."

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PCR