Trial finds drug-coated balloon angioplasty less effective than second generation drug-eluting stents

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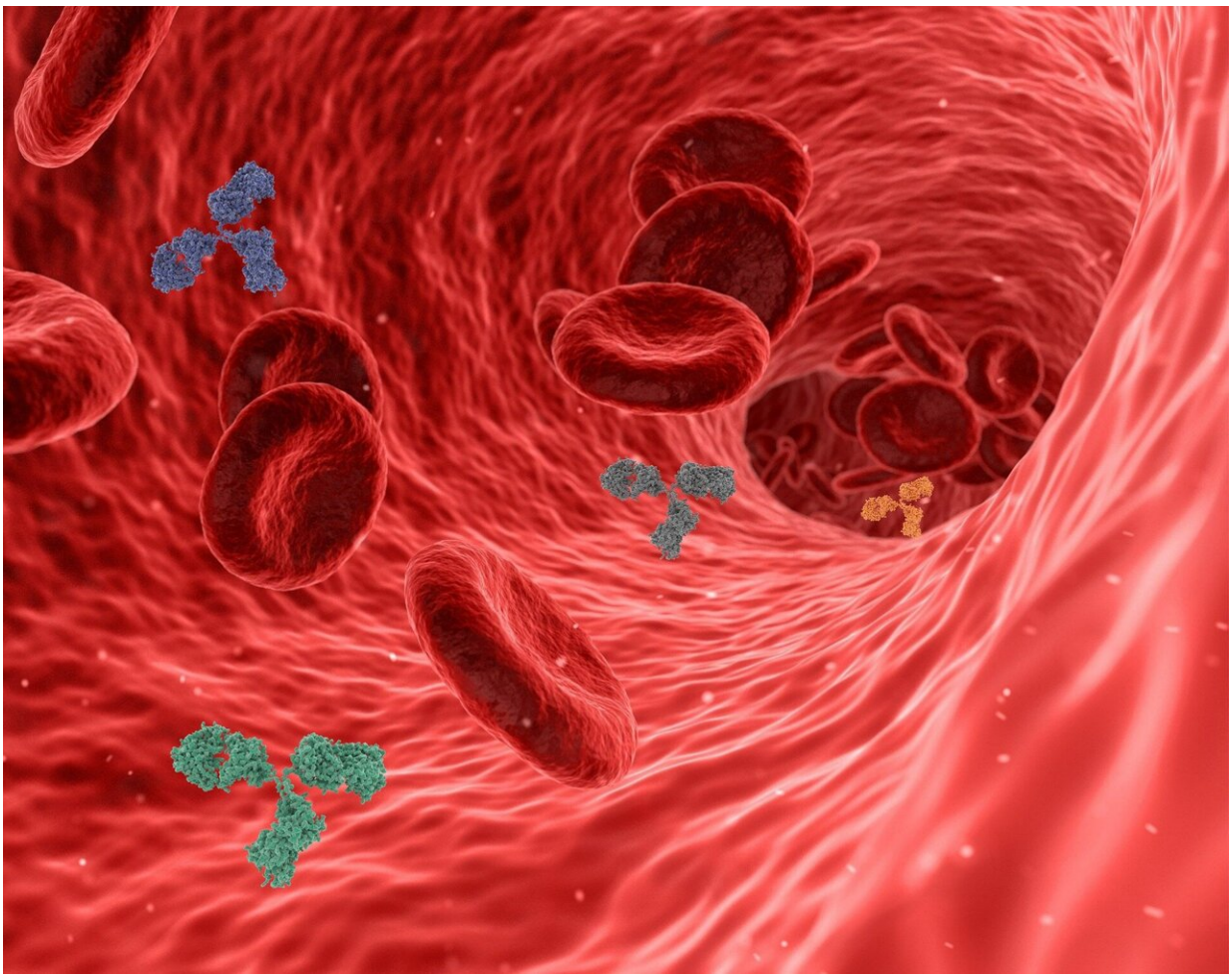

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Novel drug-coated balloons (DCB) did not outshine standard treatment with second generation drug-eluting stents (DES) as they were expected to, in a surprise finding of the first randomized trial to compare clinical outcomes in previously untreated patients with non-complex disease undergoing percutaneous coronary intervention (PCI). The study was presented in a Hot Line Session at this year's ESC Congress 2024 in London, UK (30 Aug.–2 Sept.).

"Drug-coated balloon angioplasty failed to achieve noninferiority compared to standard treatment with second-generation thin strut drug-eluting stents, mainly due to the need for more repeat procedures (revascularization)," said senior author Dr. Ling Tao from Xijing Hospital, Xi'an, China.

Each year, millions of people around the world undergo PCI, a non-surgical intervention to treat blockages in the coronary arteries (that supply blood to the heart).

The conventional treatment of coronary artery disease (CAD) usually involves a procedure known as balloon angioplasty, during which a deflated balloon attached to a catheter is inserted into a narrowed artery. Once in position, the balloon is inflated, opening up the narrowed blood vessel and restoring blood flow to the heart, followed by the deployment of a DES to provide an immediate scaffold and to reduce the long-term risk of restenosis (a re-narrowing of the treated artery and recurrence of symptoms that may require additional repair).

"While PCI with DES is highly effective, 2% of patients experience in-stent restenosis annually after the procedure," explained Dr. Tao. "Because of the metallic scaffold left behind, a DES may distort and permanently cage the coronary vessel from adaptive remodeling, impeding vessel pulsatility, interfering with cell signaling and mechano-transduction, and promoting chronic inflammation. Such stent related

adverse events have fueled interest in alternative stent free methods of local drug delivery, such as using drug coated balloons."

Previous studies have shown the strategy of DCB angioplasty with the option of stenting in case of an unsatisfactory result to be just as effective as DES for previously untreated small vessel CAD (diameter ≤ 3.0 mm). However, the long-term efficacy and safety of this strategy in previously untreated coronary lesions, regardless of coronary artery diameter, remains uncertain.

To find out more, the RECCAGEFREE I randomized, noninferiority trial enrolled patients requiring PCI who had previously untreated, noncomplex CAD (irrespective of target vessel diameter) from 43 sites across China.

Between February, 2021, and May, 2022, a total of 2,272 patients (aged 18 and older) who had achieved a successful target vessel pre-dilation were randomly assigned in a 1:1 ratio to receive either treatment with paclitaxel coated balloon angioplasty with the option of rescue stenting due to an unsatisfactory result (DCB; 1,133 patients), or deployment of a second-generation, thin strut, sirolimus eluting stent (DES; 1,139 patients). The average age of patients was 61 years, 69% were men, 27% had diabetes, and 6% were insulin dependent.

In total, around 9% (106/1,133) of patients had to undergo rescue DES after unsatisfactory DCB angioplasty.

The primary endpoint of the 2-year combined rate of cardiac death, target vessel myocardial infarction, and clinically and physiologically indicated target lesion revascularization (Device oriented Composite Endpoint [DoCE]) was 6.4% (72 patients) for DCB and 3.4% (38 patients) for DES, with an absolute risk difference of 3.04% (which was above the prespecified 2.68% threshold for non-inferiority). This was

mainly due to higher rates of clinically and physiologically indicated target lesion revascularization with DCBs (3.1% vs. 1.2%, difference:1.90%).

However, sub-group analysis found that there was a notable heterogeneity in the treatment effect across vessel diameters, which requires further confirmation in adequately designed trials. While DES was the more favorable option in the non-small vessel disease subpopulation (device diameter > 3.0 mm), in the small vessel disease subpopulation (≤3.0 mm), with more than 1,000 patients, the results were in line with previous studies showing that DCB and DES had similar rates of DoCE through the two-year follow-up (p-value for the interaction between treatment (DCB or DES) and the small vessel disease subgroup was 0.02)

"Our results show that the attempted strategy of 'leave nothing behind' by using paclitaxel-coated balloons in de novo non-complex coronary artery disease was disproven, and DES implantation should continue to be the standard of care for these patients," said Dr. Tao.

Provided by European Society of Cardiology

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