FDA investigating paclitaxel-coated balloons, paclitaxel-eluting stents

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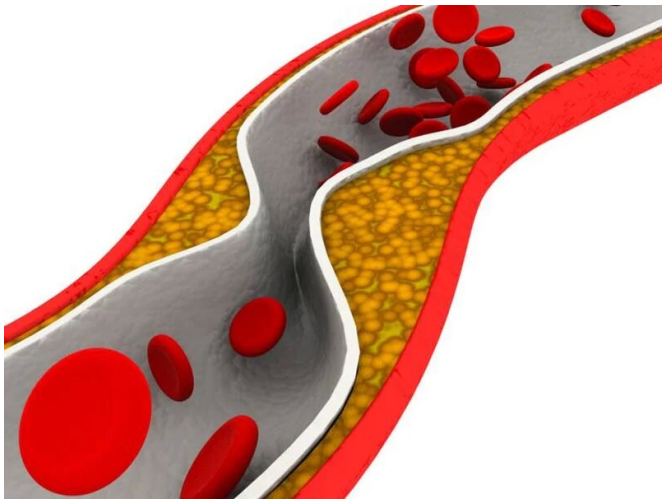

(HealthDay)—The U.S. Food and Drug Administration alerted health care providers on Thursday that the agency is investigating the use of paclitaxel-coated balloons and paclitaxel-eluting stents to treat peripheral arterial disease (PAD) in the femoropopliteal artery because of a potentially increased mortality risk in the long term.

In a letter to peripheral interventionalists and vascular medicine physicians, the FDA referenced data from a recent meta-analysis published in the *Journal of the American Heart Association*. The analysis of randomized trials revealed a possible increased mortality rate at two years postoperatively in PAD patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared with patients treated with noncoated balloons or bare-metal stents.

Despite this investigation, the agency noted the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used according to their indications for use. The FDA recommends physicians continue to follow patients who have been treated with the devices based on the current standard of care. The agency also recommends physicians discuss with PAD patients the risks and benefits of all available treatment options. Physicians should report any adverse events or suspected adverse events through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

To determine whether there are long-term risks, the agency is evaluating long-term follow-up data on paclitaxel-coated products, including data from studies that supported FDA approval of the products. Additional statistical analyses are also being performed to clarify the presence and extent of any risks.

More information: More Information