

Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers

January 17, 2019

Dear Peripheral Interventionalists and Vascular Medicine Physicians:

We are writing to inform you that the FDA is evaluating recent information regarding the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents to treat peripheral arterial disease (PAD) in the femoropopliteal artery.

A **recent meta-analysis** (<https://www.ahajournals.org/doi/10.1161/JAHA.118.011245>) of randomized trials published in the Journal of the American Heart Association (JAHA) suggests a possible increased mortality rate after two years in PAD patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared to patients treated with control devices (non-coated balloons or bare metal stents). The specific cause for this observation is yet to be determined.

BACKGROUND

Paclitaxel-coated balloons and paclitaxel-eluting stents are intended to treat de novo or restenotic lesions in the femoropopliteal artery. The balloon and stent work to mechanically open the obstructed vessel. Paclitaxel is released from the balloon or stent to prevent scar tissue formation in the blood vessel that can re-obstruct the artery (restenosis).

In the U.S., paclitaxel-coated balloons are also marketed for the treatment of stenotic lesions in dysfunctional native arteriovenous dialysis fistulae. While paclitaxel-coated stents have been approved for use in the treatment of coronary artery disease, no paclitaxel-coated balloons or paclitaxel-eluting stents are currently marketed for this use.

RECOMMENDATIONS

The FDA recommends that health care providers:

- Continue surveillance of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents per the current standard of care.

- In clinical decision-making, discuss the risks and benefits of all available treatment options for PAD with your patients.
- Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents. Voluntary reports can be submitted through **Med-Watch, the (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)FDA Safety Information and Adverse Event Reporting program (http://www.fda.gov/Safety/Med-Watch/HowToReport/default.htm)**. Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)**. Health care personnel employed by facilities that are subject to **FDA's user facility reporting requirements (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

FDA ACTIONS

The FDA is currently evaluating available long-term follow-up data to determine if there are any long-term risks associated with paclitaxel-coated products. This will include an evaluation of long-term follow-up data from studies that supported approval of paclitaxel-coated balloons or paclitaxel-eluting stents in the U.S. and other available data sets. This review will focus on causes of death, the paclitaxel dose delivered, and patient characteristics that may impact clinical outcomes. Additional statistical analyses will be performed to clarify the presence and magnitude of any long-term risks. We are working with manufacturers of paclitaxel-coated balloons and paclitaxel-eluting stents to better understand this issue.

There are a number of paclitaxel-coated balloons or paclitaxel-eluting stents approved or under study for peripheral vascular use in the U.S. Currently, the FDA believes that the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use.

The FDA will communicate with the public as new information becomes available.

CONTACT US

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 1-800-638-2041 or 301-796-7100.

Sincerely,

/s/

William Maisel, MD, MPH

Chief Medical Officer

Center for Devices and Radiological Health

U.S. Food and Drug Administration

ADDITIONAL RESOURCES

- [Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials \(JAHA, December 6, 2018\) \(https://www.ahajournals.org/doi/10.1161/JAHA.118.011245\)](https://www.ahajournals.org/doi/10.1161/JAHA.118.011245)

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