



Multi-Specialty and Multi-Society Coalition for Patient Safety with Paclitaxel-Coated Endovascular Devices Talking Points Document: Background

The U.S Food and Drug Administration (FDA) tasked the Multi-Specialty and Multi-Society Coalition for Patient Safety with Paclitaxel Technologies, (composed of the American College of Cardiology, American College of Radiology, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society of Interventional Radiology, Society for Vascular Surgery, Vascular and Endovascular Surgery Society, and the Society for Clinical Vascular Surgery) to develop a set of talking points concerning the risks and benefits of using paclitaxel devices.

These talking points were developed after productive discussions across specialties and the FDA with Society of Interventional Radiology Coalition's representative being Robert Lookstein, MD, MHCDL, FSIR, FAHA, FSVM and Sanjay Misra, MD.

The Coalition bullet points reflect the current evidence surrounding this complex topic and is designed to help institutions and members when discussing potential concerns of increased rates of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents. The statements are intended to summarize the current state of the evidence and to serve as starting points for discussion. We recognize this is a complex issue and the talking points are not intended to take the place of thoughtful, individualized discussions with patients. The ability to effectively communicate risks and benefits of revascularization is a key part of patient management. Please consider the following statement as helpful guidance in your discussions and informed consent process.



Peripheral Vascular Intervention Talking Points for Informing Patients about the Paclitaxel Safety Signal

A recent meta-analysis of randomized trials suggests an increased mortality rate after two years in peripheral artery disease (PAD) patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal disease compared to patients treated with uncoated balloons or bare metal stents. The FDA recommends that physicians discuss the risks and benefits of all available treatment options with their PAD patients.¹

To this end, a Multi-Specialty Paclitaxel Coalition (American College of Cardiology, American College of Radiology, American Heart Association, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society of Interventional Radiology, Society for Vascular Surgery, Vascular and Endovascular Surgery Society, and the Society for Clinical Vascular Surgery), representing the majority of specialists who evaluate and treat patients with PAD, developed the following talking points, which have been reviewed by the FDA, that physicians/providers may consider when discussing PAD treatment options with their patients:

- Some balloons and stents used to treat symptoms resulting from blocked blood vessels in leg(s) are coated with the drug paclitaxel.
- Research studies show that paclitaxel-coated balloons and stents improve the chance that the treated blood vessel in your leg will remain open after your treatment and lower the likelihood that you will need a repeat procedure to re-open the vessel.
- However, an analysis in 2018 that combined the results from multiple studies indicated that the use of paclitaxel-coated balloons and stents may increase your chance of dying starting about 2 years after treatment. Although this analysis has limitations and further research is still ongoing, the available information as of April 2020 suggests that paclitaxel-coated device use may increase your chance of dying over the next 2-5 years compared to treatment with uncoated balloons or bare metal stents.
- There may be other options for the treatment of your symptoms, including medications, exercise, balloons, stents or other devices that do not contain paclitaxel, and surgery. You and your doctor should discuss the possible risks and benefits of all treatments to identify those options that are best for you.

The Multi-Specialty Paclitaxel Coalition is actively working with the FDA, medical device manufacturers, and clinical investigators to advance our understanding of the long-term safety and effectiveness of paclitaxel-coated devices.

On behalf of the Multi-Specialty and Multi-Society Coalition for Patient Safety with Paclitaxel Technologies

¹ <https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel>