

Updated CIRSE Position Statement on the use of paclitaxel-coated balloons and stents in peripheral arterial disease (PAD)

Recent debates at various global meetings, corrections to original papers and an FDA update suggest that there is a safety signal associated with the use of paclitaxel-coated balloons and stents in PAD patients. A preliminary review by the FDA of the three pivotal RCTs (975 patients with 5-year follow-up data) comparing paclitaxel-coated balloons or stents with standard balloon angioplasty or uncoated stents has confirmed a higher mortality in patients treated with paclitaxel products. There was an approximate 50% increased crude risk of mortality in patients treated with paclitaxel products.

[The latest FDA update can be found on this link](#)

Clearly, these results are preliminary and should be interpreted with caution. The trials involved mainly claudicants, and involved exclusively femoropopliteal lesions and not BTK lesions.

Moreover, a specific cause and mechanism of the increased mortality is unknown, few trials have long term follow-up data and it will take more time and possibly new trials to determine the veracity of the increased safety signal.

In the meantime, and until more information is available, CIRSE sees no alternative but to take the position that:

1. In the majority of patients undergoing lower limb recanalization therapies, alternatives to drug eluting devices should be used.
2. For some individual patients at particularly high risk for restenosis, clinicians may decide that the benefits of using a paclitaxel-coated device may outweigh the risks.
3. Drug-eluting devices should only be used after a full informed consent process that has discussed the mortality implications from the Katsanos meta-analysis (1).
4. All patients who have already received paclitaxel-eluting devices should be followed up to assess for a potential effect on mortality.

(1) Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D. 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. J Am Heart Assoc. 2018

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