



Society of Interventional Radiology Clinical Notification on Paclitaxel

Peripheral arterial disease (PAD) affects more than 12 million patients in the United States[1]. The Society of Interventional Radiology (SIR) and its members are committed to the comprehensive clinical care for patients with PAD. For patients with symptomatic lower extremity PAD in the femoropopliteal segment, revascularization using a paclitaxel-based therapy has become the gold standard due to level one data showing improved patency compared to controls [2, 3]. However, a meta-analysis that pooled the data on these devices showed a possible harm to patients treated with paclitaxel devices compared to controls[4]. What this meta-analysis means and its application in real-world clinical practice continues to be debated since its publication in December 2018[5-7].

In response to the FDA's communications over 2019, a team of interventional radiologists have met several times with representatives of the agency to clarify the findings of the meta-analysis and advocate for our patients' continued access to this technology. SIR has been working for the past year as part of a Paclitaxel Coalition with other professional societies including ACC, AHA, ACR, ESVS, SVM, SCAI, SVS, and SCVS. This multi-society, multi-specialty coalition has engaged in a continued dialogue with the FDA and device manufacturers to address the concerns of our membership and the patient's we serve.

In summary, the meta-analysis has identified a signal of increased late mortality following the use of paclitaxel-based balloons and stents for patients with peripheral arterial disease. The signal has been questioned as to its strength but despite all subsequent analyses, it persists. At present there is no consensus regarding the mechanism of the signal or whether a dose effect of the drug actually exists. The devices in question have uniformly demonstrated consistent clinical efficacy at improving vessel patency and reducing reinterventions in all clinical studies to date. The greatest benefit of these devices is likely to be seen in those at greatest risk for restenosis.

The SIR recommends that physicians who want to use these devices follow the FDA recommendations in their most recent letter[8]. All symptomatic patients who are offered this technology for revascularization should participate in an informed consent process that includes a discussion of the reported risks and benefits. The discussion should include the possible risk of increased mortality for patients that have received the paclitaxel coated devices with a discussion of the reduced vascular patency of non-paclitaxel coated devices. In addition, patients should be followed for overall clinical assessment, and specifically of their vascular intervention. Our patient safety is our utmost priority; the principle of shared decision making

should be used when discussing all potential therapies for symptomatic peripheral arterial disease including medical, endovascular, and surgical options.

Accordingly, SIR continues to monitor the paclitaxel events and additional data that are continuing to be published and presented at meetings. As new information becomes available, SIR will update these recommendations. For additional information, please email or contact SIR at 703-691-1805.

References:

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