



British Society of
Interventional
Radiology

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BSIR STATEMENT REGARDING DRUG ELUTING TECHNOLOGIES

BSIR Officers have been asked for help with the interpretation of the results of the recent article by Katsanos et al, which concludes that there is “increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limbs. Further investigations are urgently warranted”.

The Officers have been in contact with the Medicines and Healthcare products Regulatory Agency (MHRA) and are reassured to learn that the MHRA are already in the process of reviewing the available information from the literature, industry and clinicians. It is hoped that this will be able to reach conclusions early in 2019.

Until this review has been completed, individual clinicians should be aware that these products remain approved for use. Interventional Radiologists, and others, should consult with patients, making decisions with them, as to the most appropriate treatment for their clinical condition, with due regard to the options available. Clearly until this review outcome is known, there will be uncertainty.

BSIR Officers will remain in close contact with MHRA, and will do everything that we can to assist the MHRA in this complex, but urgent task.

***Dr Trevor Cleveland
on behalf of BSIR Officers'***

REFERENCE

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwiV87vspq_fAhUQTBUIHfLNA_AQFjAAegQICRAB&url=https%3A%2F%2Fwww.ahajournals.org%2Fdoi%2F10.1161%2FJAHA.118.011245&usg=AOvVaw07YtJZ_5HPUwS99xwNkTR6