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Latest advancement in diabetic healthcare management /increased risk of leg and foot amputations

Muhammad Raza Ullah
Islamia University, Pakistan

FDA confirms increased risk of leg and foot amputations with the anti-diabetic agent canagliflozin (Invokana, Invokamet, Invokamet XR). Based on new data from two large clinical trials, the U.S. FDA has concluded that the T2D medicine canagliflozin causes an increased risk of leg and foot amputations. Doctors before starting canagliflozin, should consider factors that may predispose the need for amputations. Factors include a history of prior amputation, peripheral vascular disease, neuropathy, & diabetic foot ulcers. Untreated, T2D can lead to serious problems, including blindness, nerve and kidney damage, and heart disease. Final results from two clinical trials – the CANVAS (Canagliflozin CV Assessment Study) and CANVAS-R (A Study of the Effects of Canagliflozin on Renal Endpoints in Adult Participants With T2D) – showed that leg & foot amputations occurred about twice as often in patients treated with canagliflozin compared to patients treated with placebo. Amputations of the toe and middle of the foot were the most common; however, amputations involving the leg, below and above the knee, also occurred. Some patients had more than one amputation, some involving both limbs. Other side effects include low BP, ketoacidosis; kidney problems; a high amount of potassium in the blood; serious UTI; low blood sugar when combined with other diabetes medicines; yeast infections; bone breaks; & increased cholesterol. Although it is not yet clear why and how it increases amputation risks, the European Medicines Agency EMA advises: "For canagliflozin, lower limb amputation should be listed as an uncommon side effect (occurring in between 1 & 10 patients in 1,000). Doctors should consider stopping treatment if patients develop significant foot complications such as infection or skin ulcers." The EMA investigation into the connection between canagliflozin and lower limb amputation began in April of 2016. Meanwhile, here at home, the FDA continues to sit on its hands. Last year, the US regulatory agency said that it "has not determined whether canagliflozin increases the risk of leg and foot amputations," but that it was "currently investigating this new safety issue" and would "update the public" when more information was available. So far, there has been no further word or action on the FDA's part beyond the release of a few safety notices.

Biography

Muhammad Raza Ullah has completed Doctor of Pharmacy from Hospital and clinical pharmacy Services, Dubai Health Authority UAE. He received Fsc pre medical, Doctor of Pharmacy (Pharm-D) from Islamia University, Bahawalpur Punjab Pakistan.

razaullah.pharmd@gmail.com

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