

SGLT2 Inhibitors May Cause Fournier's Gangrene

On August 29th, 2018, the FDA advised a safety announcement that there have been twelve reported cases of Fournier's gangrene in patients who were taking sodium-glucose cotransporter-2 (SGLT2) inhibitors. Of these 12 cases, all were hospitalized and required surgery and in one case, the patient died. FDA approved SGLT2 inhibitors are listed as the following: canagliflozin (Invokana), canagliflozin and metformin (Invokamet), canagliflozin and metformin extended-release (Invokamet XR), dapagliflozin (Farxiga), dapagliflozin and metformin extended-release (Xigduo XR), dapagliflozin and saxagliptin (Otern), empagliflozin (Jardiance), empagliflozin and linagliptin (Glyxambi), empagliflozin and metformin (Synjardy), empagliflozin and metformin extended-release (Synjardy XR), ertugliflozin (Steglatro), ertugliflozin and metformin (Segluromet), and ertugliflozin and sitagliptin (Steglujan). The FDA is now requiring a new warning about the risk of Fournier's gangrene to be added to the prescribing information of all SGLT2 inhibitors and the patient medication guide. Currently, the prescribing information has been updated for Invokana, Invokamet, Invokamet XR, Farxiga, Otern, Jardiance, Glyxambi, Synjardy, Synjardy CR, Steglatro, Segluromet, and Steglujan.

Fournier's gangrene is an infection where there is widespread necrosis of the superficial fascia and muscle of the limbs, specifically in the scrotum, perineum, and abdominal area. Initially, patients will present with symptoms of swelling, pain, and redness in the pubic region, followed by ulceration. There will be rapid progression of the infection where necrosis occurs at a rate of 3 cm/hour. As the ulcer enlarges it will be surrounded by a purple ring that will fade into a hue of pink. If not promptly treated, additional ulcers will emerge. Patients who have poor hygiene and are immunosuppressed (e.g., diabetes mellitus, human immunodeficiency virus, liver failure, etc) are the most susceptible to acquiring Fournier's gangrene. *S. aureus*, the *B. fragilis* group, *Peptostreptococcus* species, *Clostridium* species, *Fusobacterium* species, and members of the family *Enterobacteriaceae* are the common organisms that cause this infection. Treatment consists of emergency debridement, early broad-spectrum antimicrobial administration, and aggressive systemic resuscitation. Fournier's gangrene is a serious condition and if suspected, use of SGLT2 inhibitors should be immediately discontinued and patients should seek help.

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