Fournier's Gangrene and Sodium-glucose Co-transporter 2(SGLT2) Inhibitors: Our Experience

Sir,

Recent drug safety communication from U.S. Food and Drug Administration reported cases of necrotizing fasciitis of the perineum - Fournier's gangrene with sodium-glucose cotransporter-2 (SGLT2) inhibitors. Their findings are according to the reports from FDA Adverse Event Reporting System and case reports from medical literature from March 2013 to May 2018.[1]

We work at 750 bedded tertiary referral hospital in South India with five consultant endocrinologists treating on average monthly 3000 patients through outpatient clinics of which 80% are type 2 diabetes mellitus (T2DM).

SGLT2 inhibitor- canagliflozin was launched in India during April 2015 followed by dapagliflozin and empagliflozin. Since then, we have used all three SGLT2 inhibitors in our hospital according to the recommendation of various international guidelines and as per approved local indications. We undertook this analysis to understand our local experience of SGLT2 inhibitors and Fournier's gangrene.

We identified total 23 cases of Fournier's gangrene in our hospital medical records from April 2015 to July 2018. All cases were reported in male patients with a mean age of 56.8 ± 5.5 years. In total, 70% of cases had a history of T2DM (mean duration of 5 ± 3.2 years). The mean score of severity of Fournier's gangrene severity index[2] was 5.08 ± 4.6. Mean HbA1c in the cohort of T2DM patients was 10.36 ± 1.1 (range 8.6–13). None had significant medical history of chronic liver disease. The mean serum creatinine level in people with diabetes was 1.83 + SD mg/dl as opposed to 1.1 + SD mg/dl in people without T2DM.

All cases required surgical intervention in form of debridement and received intravenous antibiotics. Three patients with diabetes underwent debridement twice during their hospital stay. Twenty-two cases had positive wound or excised tissue culture results with *streptococcus* and *Escherichia coli* being most common organisms. Mean hospital stay was 5 ± 3.2 days for entire cohort, and it was 8 ± 3.3 days in the cohort with T2DM. Five patients required additional Intensive Care Unit (ICU) stay during hospitalization. Three patients died due to multiple organ dysfunction associated with sepsis.

We found only one case of Fournier's gangrene with concomitant SGLT2 inhibitor (empagliflozin) treatment in combination with other anti-diabetic drugs. SGLT2i was started 12 months before date of admission, HbA1C was 10.5%. The patient was discharged after 10 days of hospital stay.

Our experience at present does not suggest SGLT2 inhibitors as a potential causative factor for Fournier's gangrene. We believe that warning of SGLT2 inhibitor and Fournier's gangrene needs to be looked from multifactorial perspective. There can be multiple risk factor associated with the development of Fournier's gangrene in T2DM patients such as poor glycaemic control, genital hygiene, recurrent fungal infection, obesity, smoking, urinary catherization, operative procedures, immunosuppressive disease or therapies, etc.[3] The limitation of our analysis is longer and continuous follow-up of all the patients prescribed different kind of anti-diabetic medications and reporting bias. Overall, as clinicians, we feel that benefits of SGLT2 inhibitors currently outweighs risk by manifold though close pharmaco-vigilance is warranted. It is important for clinicians to understand and focus on pertinent issue of controlling hyperglycemia and reduction of micro- and macro-vascular complication with judicious and safe use of SGLT2 inhibitors than panic and debate about Fournier's gangrene.

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Conflicts of interest

There are no conflicts of interest.

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