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## **Dapagliflozin Induced Severe Pruritis – A Rare Adverse Drug Reaction**

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### ABSTRACT

Dapagliflozin is an SGLT2 inhibitor that is used to treat type 2 diabetes, as well as those with heart failure and chronic renal disease. We report a case report of a 57-year-old male diabetic who presented with severe pruritis which was later found to be due to dapagliflozin and was totally subsided after discontinuing dapagliflozin.

**Keyword-** SGLT2 inhibitor - Selective sodium-glucose transporter-2 inhibitor.

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Received 12 November 2025, Accepted 07 December 2025

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## INTRODUCTION

Dapagliflozin is an SGLT2 inhibitor that may be used to treat type 2 diabetes mellitus. Its primary mechanism was to reabsorb filtered glucose from the tubular lumen. This is carried out by selective sodium-glucose transporter-2 (SGLT2) inhibitor, which are expressed in the proximal renal tubules.<sup>1</sup> By decreasing glucose reabsorption and lowering the renal threshold for glucose, SGLT2 inhibitors increase the excretion of glucose in the urine. SGLT2 inhibitor can also lower the heart's pre- and afterload and downregulates sympathetic activity, among other physiological processes.<sup>2</sup> It also decreases sodium reabsorption and increases salt supply to the distal tubule. The drug has a 78% oral bioavailability and a peak plasma concentration in about 2 hours while fasting; when taken with a high-fat meal, this can increase to around 3 hours. Interestingly, the peak plasma concentration can drop by as much as 50% after a high-fat meal. Approximately 91% of the medication is attached to plasma proteins after absorption. It is extensively metabolized, mostly by the enzyme UGT1A9, which results in the formation of the inactive metabolite dapagliflozin 3-O-glucuronide. In humans, CYP-mediated metabolism plays a very small role in its removal. The medicine is mostly eliminated by the urine (75%) and, to a lesser extent, the feces (21%). Its terminal elimination half-life is roughly 12.9 hours<sup>3</sup>

Although dapagliflozin is usually well tolerated, there are a number of negative medication responses linked to it. Genital mycotic infections (vulvovaginal candidiasis and balanitis), urinary tract infections, increased urination, dyslipidemia, back discomfort, and nausea are among the frequent adverse effects. It may raise the risk of hypoglycemia when used with insulin or sulfonylureas. Dehydration and hypotension can result from volume depletion, and there may be a minor rise in creatinine initially. Acute renal injury, sepsis, bone fractures, Fournier's gangrene, and diabetic ketoacidosis—which is frequently euglycemic—are serious but uncommon adverse events. Although a direct causal relationship has not been proved, preliminary research has suggested a possible association with bladder cancer.<sup>4</sup>

## CASE REPORT

A 57-year-old man who reported for routine diabetic evaluation and collecting medications complaint of severe pruritis and some scratch marks over his left leg. While looking into the

patient's medication history, it was discovered that he was taking 5 mg of T. dapagliflozin once daily in the morning for nearly 1 month. According to ongoing laboratory tests, his microalbumin creatinine ratio was on high (1028.64), his HBA1C was 10%, and his RBS was 249. His medical history includes diabetes (5 years) with peripheral neuropathy, nephropathy and a left foot ulcer which was almost healing. The patient was taking 50 mg of T. Vildagliptin twice a day, 5 mg of T. Dapagliflozin once in the morning, and 30-0-22 units of biphasic insulin 30/70 IU, T. Dapagliflozin 5mg was discontinued and his underlying issues were addressed while monitoring the patient's medications and blood sugars.

#### DISCUSSION:

Pruritis brought on by dapagliflozin is a rare and uncommon adverse drug response (ADR). When the medicine is stopped, the reaction is frequently reversible and may be dose independent.

With a score of 7, the Naranjo Adverse Drug Reaction Probability Scale in this instance classifies the incident as likely to be an adverse drug reaction. Furthermore, the reaction is classified as mild to severe on the Modified Hartwig Severity Assessment Scale. Management primarily involves either dose reduction or complete discontinuation of Dapagloflozin, depending on the severity of the patient's clinical status. Continuous monitoring of developing pruritis is essential to assess the extent of pruritis and to guide therapeutic decisions.<sup>5,6</sup>

#### CONCLUSION:

Dapagliflozin is widely used and typically well tolerated in the treatment of type 2 diabetes and its complications, uncommon side effects like pruritis can sometimes develop and may be overlooked. This case emphasizes the need for vigilant monitoring of patients for unexpected symptoms and considering medication as a potential cause. Prompt recognition and discontinuation of the drug can help prevent further issues and support better clinical outcomes. Increasing awareness of such rare reactions can improve drug safety practices and promote more effective use of SGLT2 inhibitor.

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