

Case Report

Dapagliflozin induced balanitis in a patient with type two diabetes mellitus: a case report

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Received: 09 June 2026

Revised: 25 August 2026

Accepted: 26 August 2026

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ABSTRACT

Dapagliflozin, an SGLT2 inhibitor used to control high blood sugar in patients having type II diabetes mellitus by blocking the SGLT2, present in the early proximal tubules of the kidney, thereby preventing glucose reabsorption into the blood and promoting excess glucose removal through urine causing glucosuria. Increased glucose concentration in urine in genitourinary tract creates a hostile environment for bacterial and fungal growth. Balanitis, condition where the glans penis is inflamed characterized by pain, redness, and swelling. This condition affects the male genitalia, most common causes being poor hygiene, accumulation of smegma beneath the foreskin, diabetes, and the use of SGLT2 inhibitors in diabetic patients. This is a case of 75-year-old male patient with the history with type 2 diabetes, hypertension, and triple vessel coronary artery disease, underwent successful off-pump CABG, following the surgery dapagliflozin 5 mg OD was advised for diabetes management. After 3 weeks of dapagliflozin 5 mg administration patient experienced frequent urination, swelling of the glans penis, painful micturition, and itching that persisted for more than a week. The urinalysis showed the presence of glucose in the urine despite having nearly normal blood sugar levels confirmed the presence of balanitis which was dapagliflozin induced. Dapagliflozin was immediately discontinued, and symptoms subsided. Naranjo scale was used for causality assessment, which produced a score of 7, indicating a probable adverse drug effect. This case highlights the necessity of early detection of symptoms, pre-treatment guidance, and rapidly stopping the medication to prevent complications in patients undergoing SGLT2 inhibitor therapy.

Keywords: Adverse drug reaction, Balanitis, Dapagliflozin, Glycosuria, SGLT2 inhibitor, Type 2 diabetes mellitus

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterised by insulin resistance, impaired glucose metabolism, frequent urination, increased hunger, and dehydration. A few complications that can occur secondary to diabetes mellitus are Hypertension, coronary artery disease, high VLDL and HDL, and atherosclerosis. More than 400 million people worldwide have these problems, which are caused by both genetic and environmental factors. The most recent information from the NCD Risk Factor Collaboration (2022) says that type 2 diabetes is a disease of civilization that affects about 95% of the 800 million people who have diabetes.^{1,2}

The American Diabetes Association 2026 stresses person centred diabetes care with early use of CGM and insulin technology, controlling obesity and other co-occurring conditions, and focusing on nutrition intake. Overall, these guidelines will help people reduce and prevent the complications associated with diabetes.³

Balanitis is a condition where the glans penis is inflamed and characterized by pain, redness, and swelling of the glans penis. This condition affects the male genitalia, with the most common causes of this infection being poor hygiene, accumulation of smegma beneath the foreskin, diabetes, and the use of SGLT2 inhibitors to control high blood sugar. The 25% out of 100 men suffer from

balanitis at any age during their lifetime. Around 3% of uncircumcised males are affected worldwide.⁴

Dapagliflozin-induced balanitis is one of the increasingly recognized side effects related to the use of SGLT2 inhibitors. SGLT2 inhibitors, also known as sodium-glucose cotransporter-2 inhibitors, are antidiabetic medications that work by blocking the sodium-glucose transporter SGLT2, which is present in the early proximal tubules of the kidney, thereby preventing glucose reabsorption into the blood and promoting excess glucose removal through urine. This action lowers blood glucose levels in patients with T2DM. The glucose-rich genital environment supports the growth of organisms in the lower urinary tract, leading to genital infections such as balanitis (swollen glans penis) and balanoposthitis (inflammation of both the glans and the foreskin of the penis), which are observed as side effects of the drug.⁵⁻⁷

Recent reports signify the importance of patient counselling regarding genital hygiene, hydration, and monitoring of early symptoms (itching, erythema, white discharge) before the start of therapy, which reduces the risk of severe infections.⁸

A few studies suggest that SGLT2 inhibitors also cause Fournier gangrene, which is a severe kind of infection affecting the genitals and associated with higher deaths, and the US FDA also issued a warning regarding this issue.^{10,11}

According to a retrospective study reported in 2024, many patients reported urology-related issues after taking SGLT2 inhibitors for their diabetes control.⁶ A prospective observational study similarly confirmed elevated genital infection risk with SGLT2 inhibitors use in a tertiary care setting.⁹ Another case series shows that diabetic patients, even if glucose levels are maintained, due to SGLT2 inhibitor-induced glycosuria, developed balanitis with candida.⁸

Most of Dapagliflozin-induced balanitis cases are mild to moderate and treated using topical and oral antifungals, as the majority of the cases involve candidal species.^{7,8,15}

Initial treatment includes maintenance of self-hygiene with regular washing and drying of the genital area and avoiding the use of irritants. First line agents include the use of topical antifungal agents such as clotrimazole 1% cream or miconazole 2% cream to be applied twice for 1- two weeks in case of candidal balanitis, and in the cases of inflammation, a mild topical corticosteroid can be used.

In the cases of severe or recurrent balanitis, use of oral antifungals becomes important, and temporary discontinuation of dapagliflozin with use of an alternative antihyperglycemics can be considered. Most commonly used drugs are fluconazole 150mg once daily or more as prescribed.^{15,16}

The present case discusses a 75-year-old male who developed balanitis when SGLT2 inhibitor was given for treatment of diabetes mellitus.

CASE REPORT

A 75-year-old male patient presented to the emergency department with chief complaints of dyspnoea on exertion from the past few days, duration unspecified, along with nocturnal dyspnoea, ankle oedema, and palpitations. Patient has a known condition of T2DM for 15 years and hypertension and was on medication T. Glyciphage SR 500 mg (Metformin sustained release) and T. Amlodipine 5 mg for diabetes and hypertension, respectively. The patient weighed 45 kg, had a peripheral oxygen saturation (SpO₂) of 92%, and had a blood pressure of 140/80 mmHg, indicating low body weight and mild hypoxaemia. In the second assessment, another 2 episodes of severe chest pain class-2, with the last episode of chest pain occurring a day before admission, and mild chest pain on exertion for 2 months. Further assessment is mentioned in (Table 1).

The patient was diagnosed with CAD- triple vessel disease + Branch vessel disease (Calcific), and Off pump CABG×4 grafts was performed. Post-CABG, medications were prescribed as mentioned in Table 2. Dapagliflozin 5 mg OD and Onderomet 2.5/850 mg BD were advised for maintaining blood glucose levels post CABG. After ~3 weeks of continuing medications, the patient developed symptoms including increased urination with swelling over the glans penis, burning micturition, and itching for over a week, upon physical examination it was observed as swollen glans penis and urine analysis as presence of glucosuria upon which the patient was diagnosed with the dapagliflozin induced balanitis.

The use of the dapagliflozin 5 mg OD was immediately stopped, and symptoms improved upon withdrawal.

Treatment chart

The expected outcome of the therapy was to maintain the BP, diabetes, and good heart health, and prevent progression of heart condition, but balanitis appeared as an adverse drug outcome of Dapagliflozin (SGLT2 inhibitor). The treatment provided is categorised into Pre-SGLT2 Inhibitor phase, SGLT2 Inhibitor phase, and Drugs continued during both phases in (Table 2). Glycemic parameters before and after initiation of Dapagliflozin and development of balanitis in (Table 3) and Timeline for the development of adverse drug reaction (ADR) in (Table 4).

Causality assessment

The ADR Probability Scale or Naranjo algorithm was used to assess the severity of the ADR (Dapagliflozin-induced balanitis) observed in this patient.¹³ The patient had a Naranjo probability score of 7 out of 10, indicating

a Probable ADR as shown in the table. Naranjo algorithm for Dapagliflozin induced balanitis given in (Table 5).

The score was driven by: Previous literature reports linking SGLT2 inhibitors with urogenital infections. A

clear relationship between initiation of Dapagliflozin and the onset of balanitis. Improvement was observed following withdrawal of the drug and glycosuria was observed on urinalysis, which served as an indicator for the development of balanitis.¹³

Table 1: An initial assessment of patient before the SGLT2 inhibitor was prescribed.

Parameters	Results	Reference range	Interpretation
Fasting blood sugar (mg/dL)	160 [▲]	70-110	Diabetic range
Post-lunch blood sugar (mg/dL)	232 [▲]	90-140	Diabetic range
Random blood glucose (RBS)	203	70-200 mg/dl	Diabetic range
HbA1c (%)	6.5 [▲]	≤6.4	Diagnostic threshold for DM
Haemoglobin (gm%)	12.8 [▼]	14-18	Mild anaemia
SpO ₂ (%)	92 [▼]	95-100	Mild hypoxaemia
Blood pressure (mmHg)	140/80 [▲]	<130/80	Partially controlled HTN
Body weight (kg)	45	-	Underweight
RBC count	4.04 mill/mm [▼]	4.5-6.5	Decreased
PCV (Haematocrit)	37.3 % [▼]	40-50	Decreased
MCV	94.3 fl	83-101	Normal
MCH	31.8 pg	27-32	Normal
RDW	14.1 % [▲]	11.6-14.0	Increased
WBC total count	6,200 cells/cmm	4,000-11,000	Normal
Platelet count	3.2 Lakhs/cmm	1.5-4.5	Normal
Peripheral blood smear	RBC-Mild erythropenia; WBC-Mild eosinophilia; Platelets-Adequate with normal morphology	Normal	Mild abnormality
cGlucose (ABG + Creatinine)	236	3.9-6.1 mmol/l	Indicates a high blood glucose level
cLactulose (ABG + Creatinine)	2.5	0.5-1.6 mmol/l	Indicates hypoxia condition
eGFR	79.44	>85 ml/ min/ 1.73 m ²	
2D-ECHO/ echocardiography	EF=42%, moderate LV dysfunction, grade I LV diastolic dysfunction	Normal	Abnormal 2D-ECHO
ECG	LVH repolarization abnormalities, possible ischemia-Anterior ST elevation	Normal	Abnormal ECG
Angiography	CAD- triple vessel disease + Branch vessel disease (Calcific)	Normal	Abnormal angiography

*[▼]=below reference range; [▲]=above reference range; MCV: Mean corpuscular volume; MCH: Mean corpuscular haemoglobin; ABG: Atrial blood gas; eGFR: estimated glomerular filtration rate; EF: Ejection fraction; LV: Left ventricular, LVH: Left ventricular hypertrophy; CAD: Coronary artery disease; DM: Diabetes mellitus; HTN: Hypertension; SGLT2i: Sodium-glucose cotransporter-2 inhibitor. HbA1c diagnostic threshold per ADA 2026 standards of care (Diagnosis and classification).¹²

Table 2: Treatment chart-pre-SGLT2 inhibitor phase, SGLT2 inhibitor phase, and drugs continued during both phases.

Brand name	Generic name	Dose	ROA	Freq	Duration	Drug class
Pre-SGLT2 inhibitor phase (Pre-CABG)						
Tab. Glyciphage SR	Metformin	500 mg	Oral	BD	-	Biguanide
Tab. Amlodipine	Amlodipine	5 mg	Oral	OD	-	Calcium channel blockers
SGLT2 inhibitor phase						
Tab. Udupa	Dapagliflozin	5 mg	Oral	OD	Continue	SGLT2 inhibitor (afternoon)
Tab. Altacef 500 mg	Cefuroxime	500 mg	Oral	BD	3 days	Cephalosporin
Tab. Dolo 650	Paracetamol	650 mg	Oral	TID	5 days	Antipyretic and analgesic
Syp. Ambrodil syrup	Ambroxol	10 ml	Oral	TID	5 days	Mucolytic
Cap. Velgut.	Probiotic	-	Oral	BD	Continue	Probiotic
Tab. Pan 40	Pantoprazole	40 mg	Oral	OD BBF	5 days	Proton pump inhibitors
Tab. Supraoya.	Multivitamin	-	Oral	OD	Continue	Nutritional supplement
Syp. Aptivate syrup.	Cyproheptadine+multivitamins	-	Oral	BD	Continue	Appetite stimulant

Continued.

Brand name	Generic name	Dose	ROA	Freq	Duration	Drug class
Continued through both phases						
Cap. Clopitab-A	Clopidogrel + aspirin	75 mg + 150 mg	Oral	OD	Continue	Antiplatelet
Onderomet 2.5/850	Linagliptin + metformin	2.5 mg + 850 mg	Oral	BD	Continue	DPPIV inhibitors, biguanide (morning-night)
Tab. Storvas 40	Atorvastatin	40 mg	Oral	OD	Continue	Statin
Tab. Fruselac	Furosemide + spironolactone	20 mg +50 mg	Oral	BD	Continue	Diuretic
Tab. Met-XL	Metoprolol succinate	12.5 mg	Oral	OD	Continue	Beta-blocker
Tab. Beplex Forte	Multivitamins (B-complex)	-	Oral	OD	Continue	Nutritional supplement
Post SGLT2 inhibitor induced balanitis for diabetes control and balanitis treatment						
Onderomet 2.5/850	Linagliptin + metformin	2.5 mg + 850 mg	Oral	BD	Continue	DPPIV inhibitors+ biguanide
Tab. Tolterodine	Tolterodine	2 mg	Oral	HS	10 days	Urinary antispasmodic
Tab. Fesobig 4	Fesoterodine	4 mg	Oral	OD	10 days	Urinary antispasmodic
Tab. Pantoprazole	Pantoprazole	40 mg	Oral	OD BBF	5 days	Proton pump inhibitors
Tab. Combiflam	Ibuprofen + paracetamol	400 mg +325 mg	Oral	BD	2 days	NSAID + analgesic
Tab. Silodosin	Silodosin	8 mg	Oral	HS	10 days	Alpha 1 blocker
Tab. Zifi	Cefixime	200 mg	Oral	BD	5 days	Cephalosporin
Tab. Soliten	Solifenacin	5 mg	Oral	BD	1 month	Urinary antispasmodic

*SGLT2: Sodium glucose cotransporter 2; ROA: Route of administration; CABG: Coronary artery bypass grafting; DPP4I: Dipeptidyl peptidase 4 inhibitors; OD: Once daily; BD: Twice daily; TID: 3 times daily; HS: At bed time.

Table 3: Glycaemic parameters before and after initiation of dapagliflozin and development of balanitis.

Parameters	Before initiation of dapagliflozin			Before initiation of dapagliflozin	
	25 Apr, 2025	25 Jun, 2025	21 Aug, 2025	07 Sep, 2025 (Drug start)	1 Oct, 2025 (Balanitis confirmed)
Fasting blood sugar	127 ↑	160 ↑	109	-	112 ↑
Post-lunch blood sugar	208 ↑	232 ↑	185 ↑	-	-
HbA1c	-	6.5 ↑	6.7 ↑	7.0 ↑	6.5 ↑
RBS (mg/dl)	-	-	-	212 ↑	178
Urinalysis-glucose (post dapagliflozin)	-	-	-	-	+++ Glucosuria

↑dapagliflozin and development of balanitis

Table 4: Timeline for the development of ADR.

Parameters	25 Apr, 2025	25 Jun, 2025	21 Aug, 2025	7 Sep, 2025	1 Oct, 2025
Dapagliflozin dose 5 mg OD	Not started	Not started	Not started	Started	Continued
Balanitis ADR (SGLT2I induced)	Absent	Absent	Absent	Absent	Present (~3 weeks after dapagliflozin initiation)

*ADR: Adverse drug reaction, SGLT2 I: Sodium-glucose cotransporter 2 inhibitor, OD: Once daily.

Table 5: Naranjo algorithm: dapagliflozin-induced balanitis.

Questions	Yes	No	Do not know	Score
Are there previous conclusive reports on this reaction?	+1	0	0	+1
Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	+1
Did the adverse event reappear when the drug was readministered?	+2	-1	0	0
Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	+2
Did the reaction reappear when a placebo was given?	-1	+1	0	0
Was the drug detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	0
Was reaction more severe when dose was increased/less severe when dose decreased	+1	0	0	0
Did patient have similar reaction to same or similar drugs in any prev	+1	0	0	0

Continued.

Questions	Yes	No	Do not know	Score
exposure?				
Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
Total score	7			

*Total score: ≥ 9 =Definite; 5-8=Probable; 1-4=Possible; ≤ 0 =Doubtful.¹³

DISCUSSION

This case describes a 75-year-old male with T2DM, high blood pressure, and CAD triple vessel disease, who developed balanitis approximately 3 weeks after initiation of dapagliflozin 5 mg OD, post CABG, with complete reversal of the condition after withdrawal.

The HbA1c was 7.0% with RBS about 212 mg/dL when the drug was initiated, and on the day of reporting of balanitis, almost 3 weeks later, the patient was considered nearly normoglycemic with HbA1c reduced to 6.5%, RBS about 178 mg/dL, and +++ glycosuria on urinalysis. The patient was advised of an alternate medication, Onderomet 2.5/850mg (Linagliptin + Metformin) for glycaemic control, which has no documented risk of genital infections, and other medications provided were Tab. Tolterodine (Tolterodine), Tab. Fesobig (Fesoterodine), Tab. Zifi (Cefixime), Tab. Soliten (Solifenacin) and to maintain personal hygiene, avoid the use of any alcohol-based cleansers and soaps.

Dapagliflozin is an SGLT2 inhibitor, which lowers the blood glucose levels by promoting urinary glucose excretion. According to a case series, dapagliflozin induced balanitis can occur even after achieving normoglycemia, and glycosuria is present as it is a part of the drug's mechanism to eliminate excess glucose levels from the body.⁸

A systematic review and meta-analysis have demonstrated that use of these medications for diabetic control increases the urogenital risk by up to 8-fold when compared to placebo or other antidiabetic medications.¹⁴ Despite the benefits, these can lead to the development of urogenital infections with the most common organism being Candida, a fungus. The risks and benefits must be discussed with the patient, and alternate hypoglycaemic agents must be considered if the risks are higher than the benefits. A few patients can be affected with severe UTI with severe complications, such as the development of candidemia, which shows around 50% mortality rates if individual susceptibility is high.¹⁴

CONCLUSION

Dapagliflozin-induced balanitis is one of the increasingly recognized adverse effects related to the use of SGLT2 inhibitor therapy primarily associated with glucosuria. This case highlights the importance of careful patient selection, pre-treatment counselling regarding genital hygiene and adequate hydration and educating patient

about early symptoms such as itching, erythema and white discharge. Early recognition and prompt management of symptoms can prevent severe infections and improve treatment outcomes. This case underscores the need for increases awareness among healthcare professionals and patients regarding preventable and manageable ADR.

ACKNOWLEDGEMENTS

Authors would like to thank to Prof. M. Sumakanth, Principal, RBVRR Women's College of Pharmacy, and the management and the staff of RBVRR Women's College of Pharmacy for their valuable support and guidance.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Not required

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Cite this article as: Kumari P, Fatima A. Dapagliflozin induced balanitis in a patient with type two diabetes mellitus: a case report. *Int J Community Med Public Health* 2026;13:6093-8.