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Case Study

Prednisolone-Induced Acneiform Eruption with Facial Flushing in A Kidney Transplant Recipient: A Probable Adverse Drug Reaction

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The problem of adverse drug reactions (ADRs) is a big issue for patients after kidney transplantation due to the use of immunosuppressive medications in prolonged course. Corticosteroids like Omnacortil (prednisolone) are the important part of immunosuppressive therapy in patients after transplantation but often cause dose-related skin adverse reactions. We present the case of the patient, a 39-year-old man, with steroid-acne and facial flushing after prednisolone therapy. The patient was discharged on 03 September 2025 with Omnacortil (prednisolone) 60 mg orally once per day (1-0-0) in connection with maintenance immunosuppressive therapy. During the scheduled visit he presented with inflammatory acneiform rash on the upper trunk and back and reddish discolouration (facial flushing) on the face. The patient had no history of acne vulgaris or other chronic skin diseases. The close connection of the beginning of high dose prednisolone treatment and appearance of skin manifestations and lack of alternative reasons made us suspect that this was the case of corticosteroid-induced adverse drug reaction. The ADR was detected during the follow-up period and reported to the Pharmacovigilance Programme on 10 September 2025.Management with respect to dermatology was appropriate along with patient education and monitoring. The causality relationship between Omnacortil and the adverse events seen in this case was assessed by using the WHO-Uppsala Monitoring Centre (WHO-UMC) scale and the Naranjo Adverse Drug Reaction Probability Scale, which concluded that there is a possible association between Omnacortil and the adverse reactions seen. It can be inferred from this case the significance of early detection and reporting of the adverse dermatological reactions associated with corticosteroids in the patients with kidney transplantations.

Keywords: Adverse drug reaction; Prednisolone; Omnacortil; Steroid-induced acne; Facial flushing; Kidney transplantation; Immunosuppressive therapy; Pharmacovigilance.

INTRODUCTION

The ideal therapy for end-stage renal disease (ESRD) is kidney transplantation since it is more advantageous in terms of survival, improved quality of life and reduced cost of healthcare. The success of transplantation requires lifelong immunosuppression so that acute and chronic rejection can be avoided. The immunosuppressive treatment usually involves corticosteroids, calcineurin inhibitors, antimetabolites and mammalian target of rapamycin (mTOR) inhibitors. Out of these, corticosteroids like prednisolone (Omnacortil) still play a crucial role in inducing and maintaining immunosuppression due to their potent anti-inflammatory and immunosuppressive nature. Nevertheless, the use of corticosteroids for prolonged periods or high doses carries with it the risk of experiencing various adverse drug reactions (ADRs) [**Error! Reference source not found.**,**Error! Reference source not found.**]. Cutaneous side effects are some of the most common

side effects seen with systemic corticosteroids. Steroid-induced acne is a well-known adverse drug reaction that features monomorphic papules and pustules that primarily appear on the face, chest, shoulders, and upper back. Other manifestations that may be caused by high-dose corticosteroids include flushing of the face, erythema, seborrhea, and other cosmetic effects that can have psychological consequences on the patient's life. Such side effects usually occur within days or weeks of corticosteroid administration and are dose-related, affecting patients taking high-dose corticosteroids [**Error! Reference source not found.**,**Error! Reference source not found.**].The transplant patients are highly vulnerable to adverse drug reactions due to polypharmacy, compromised immune system, and long-term use of immunosuppressive drugs. It is imperative that the occurrence of ADRs caused by corticosteroids be promptly diagnosed and treated to ensure compliance with immunosuppressant therapy and reduce morbidity associated with the treatment process. Pharmacovigilance serves a critical function in recognizing, reporting, evaluating, and avoiding ADRs in order to ensure safety and maximize effectiveness of the pharmacotherapy in transplantation patients. The causality assessment instruments, such as the WHO-UMC criteria and the Naranjo ADR Probability Scale, are used to assess ADRs objectively [**Error! Reference source not found.**]. In this paper, we are presenting a case of acneiform eruption along with facial flushing due to the usage of Omnacortil 60 mg once a day in a 39-year-old male patient undergoing renal transplant surgery. The case has been discovered post-hospitalization and submitted to PvPI, which highlights the need for active surveillance and interventions in such patients being treated with high-dose steroids.

2. CASE PRESENTATION:

A 39-year-old male diagnosed with end stage renal disease (ESRD) had received his kidney from a living donor at a tertiary care center. He is doing quite well post-surgery and graft functioning has been stable. He was discharged from the hospital on 03 September 2025 with routine immunosuppression which includes Omnacortil (prednisolone) 60 mg orally once daily (1-0-0). The baseline investigations of the patient at the time of follow up show the following values: Blood Urea – 63 mg/dL; Serum Creatinine – 2.2 mg/dL; Hemoglobin – 11.5 g/dL; Neutrophils – 94%; Lymphocytes – 4%; Erythrocyte Sedimentation Rate (ESR) – 35 mm/hour; Packed Cell Volume (PCV) – 34.7%; Total Red Blood Cells (TRBC) count – 4.08 x 10^6/µL.On his next scheduled appointment, the patient presented with the acute development of acneiform lesions over the upper trunk and back with associated redness (facial flushing). Clinical examination of the lesions showed multiple monomorphic inflammatory papular and pustular lesions mainly occurring over the upper back and trunk along with diffuse facial erythema. The patient had no history of acne vulgaris, chronic skin disease, or any drug allergies. The patient denied the use of topical steroids, cosmetics, or any other drugs that may cause acneiform eruptions. In a detailed review of the patient's drug history, there was a temporal correlation noted with the starting of high dose prednisolone (Omnacortil 60 mg/day) and development of skin lesions. Based on the patient's clinical findings and the chronology of the drug intake, the patient's reaction was diagnosed as prednisolone induced steroid acne with facial flushing. The adverse drug reaction was detected at the follow-up visit, and it was reported to Pharmacovigilance Programme of India (PvPI) on 10 September 2025. The patient was medically managed with proper dermatological management and counseling about skin care, along with the continued use of an immunosuppressant regime under strict supervision of the nephrology department in order to maintain graft functioning. Follow-up visits were recommended in order to assess the healing of the lesions and the response to treatment. The causality analysis using WHO-Uppsala Monitoring Centre (WHO-UMC) scale and Naranjo adverse drug reaction probability scale revealed the adverse drug reaction to be Probable.

DISCUSSION

The potent anti-inflammatory and immunosuppressive properties of corticosteroids continue to be a mainstay of immunosuppressive therapy after kidney transplantation. Prednisolone is regularly used early in the post-transplant phase to minimise the chances of an acute rejection of the

transplanted organ. Systemic steroids, however, have many side effects, especially dermatological, that can hinder adherence and quality of life. In the present case, a patient with kidney transplantation (KT) receiving the drug, Omnacortil (prednisolone), developed acneiform eruptions over the upper trunk and back within 1 week of starting the treatment which is considered as a very close temporal relationship between the drug and the adverse event. Systemic corticosteroid therapy is known to cause acne. Steroid acne is different from acne vulgaris in that it presents with monomorphic inflammatory papules and pustules with a distinctive distribution of lesions to the face, upper back, shoulders and the chest. Pathogenesis includes increased activity of the sebaceous glands, hyperkeratinization of the follicles and immune system dysfunction in the area that favor the development of inflammation. Another common dose-dependent adverse effect of systemic glucocorticoids is vasodilation, which is seen with flushing of the patient's face[**Error! Reference source not found.**,**Error! Reference source not found.**].This is a drug induced reaction as there is no previous history of acne, lesions occur soon after introduction of high dose prednisolone and other etiological factors have not been seen. The patient's laboratory parameters have been seen in other systemic corticosteroid use, with elevated neutrophils 94%, and lymphopenia 4%. The patient's underlying clinical condition after transplant was considered to account for mild anemia (Hb 11.5g/dL) and elevated ESR (35 mm/hour) and these were not deemed to reflect the dermatological adverse reaction [**Error! Reference source not found.**,**Error! Reference source not found.**] Treatment of corticosteroid-induced acne is mainly symptomatic, keeping the corticosteroid dose to a minimum level necessary to maintain the graft function. However, reducing or stopping cortisone may not be possible right after transplant, because of the danger of acute rejection. Thus, early diagnosis, patient counseling, dermatological therapy, and monitoring are critical to prevent the progression of skin lesions and enhance compliance with treatment. In this instance the causality assessment obtained was Probable both according to the WHO–Uppsala Monitoring Centre (WHO–UMC) criteria and the Naranjo Adverse Drug Reaction Probability Scale (ADRPS), supporting the probable culprit of prednisolone for the cutaneous manifestations observed. The reporting of these adverse drug reactions to Pharmacovigilance Programme of India (PvPI) helps to add to the expanding safety database of immunosuppressive drugs and increases awareness amongst health care professionals. The case highlights the need for regular pharmacovigilance and multi-specialty follow-up in kidney transplant patients on high dose corticosteriod therapy to avoid delayed detection and treatment of preventable adverse drug reactions [**Error! Reference source not found.**].

Table 1. Naranjo Causality Assessment of Prednisolone-Induced Acne with Facial Flushing

No.	Question	Yes	No	Do Not Know	Score
1	Are there previous conclusive reports on this reaction?	+1	0	0	+1
2	Did the adverse event appear after the suspected drug was administered?	+2	−1	0	+2
3	Did the adverse reaction improve when the drug was discontinued or the dose was reduced?	+1	0	0	+1
4	Did the adverse reaction reappear when the drug was re-administered?	+2	−1	0	0
5	Are there alternative causes that could have caused the reaction?	−1	+2	0	+2
6	Did the reaction reappear when a placebo was given?	−1	+1	0	0
7	Was the drug detected in blood or other fluids at toxic concentrations?	+1	0	0	0
8	Was the reaction more severe with increased dose or less severe with decreased dose?	+1	0	0	0

9	Did the patient have a similar reaction to the same or similar drugs previously?	+1	0	0	0
10	Was the adverse event confirmed by objective evidence (clinical examination of acneiform eruptions and facial flushing)?	+1	0	0	+1

Total Naranjo Score = 7

Causality Category: Probable ADR

Score Interpretation:

- ≥9 = Definite
- 5–8 = Probable
- 1–4 = Possible
- 0 = Doubtful

Table 2. WHO–Uppsala Monitoring Centre (WHO–UMC) Causality Assessment of Prednisolone-Induced Acne with Facial Flushing

WHO–UMC Category	Assessment in the Present Case
Certain	No. Rechallenge was not performed, and the reaction was not confirmed by withdrawal of the drug.
Probable/Likely	Yes. The adverse reaction occurred within a reasonable time after initiation of Omnacortil (prednisolone 60 mg once daily), with a clear temporal relationship. The reaction is a recognized adverse effect of systemic corticosteroids, no alternative cause was identified, and the clinical findings were consistent with steroid-induced acne and facial flushing.
Possible	No. Although the temporal relationship exists, the absence of alternative causes and the known association with prednisolone make the "Probable" category more appropriate.
Unlikely	No. The chronology and clinical presentation strongly support a drug-related reaction.
Conditional/Unclassified	No. Adequate clinical information was available for assessment.
Unassessable/Unclassifiable	No. The case contained sufficient information for causality assessment.

Causality evaluation by WHO-UMC revealed that the adverse drug event is "Probable/Likely" due to the presence of temporal sequence between the administration of prednisolone and the development of steroid-induced acne along with flushing, lack of any other causes for this effect, and the known occurrence of these skin effects from systemic corticosteroids. The rechallenge was not performed due to the need for immunosuppressive therapy after transplantation of the kidney.

CONCLUSION:

In this particular case report, steroid-induced acne and flushing of the face has been described as an adverse drug reaction linked to omnacortil 60mg daily in a 39-year-old kidney transplant recipient male. The short time span between the commencement of high doses of prednisolone treatment and the development of the skin condition, along with the lack of any other possible cause of the skin conditions, helps confirm the diagnosis. In causality evaluation using the criteria of WHO-Uppsala Monitoring Centre (WHO-UMC) scale and Naranjo adverse drug reaction probability scale, the reaction was deemed Probable, further confirming the link between prednisolone and the cutaneous adverse reactions. Despite being critical for the prevention of allograft rejection, doctors need to be aware of the possibility of dose-dependent dermatologic adverse reactions caused by corticosteroids which could affect compliance.Moreover, the documentation of such side effects associated with corticosteroid use in the Pharmacovigilance Programme of India (PvPI) helps

in improving the national pharmacovigilance database and the safe and rational use of corticosteroids in transplant patients. The current case highlights the need for pharmacovigilance interventions in order to achieve better patient and graft outcomes.

Consent

As per international standards or university standards, patient(s) written consent has been collected and preserved by the author(s).

Ethical Approval

It is not applicable.

Disclaimer (Artificial Intelligence)

Author(s) hereby declares that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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