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TULOPLAST TRANSDERMAL PATCH INDUCED CUTANEOUS ADVERSE DRUG REACTION IN AN ELDERLY PATIENT WITH COPD: A CASE REPORT

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Abstract:

Tuloplast is a bronchodilator available as a transdermal patch and is commonly used in the management of chronic obstructive pulmonary disease (COPD) to ensure sustained drug delivery and better patient compliance. Transdermal drug delivery systems offer advantages such as controlled drug release and avoidance of first-pass hepatic metabolism. However, they are also associated with cutaneous adverse drug reactions, particularly in elderly patients due to age-related skin changes. We report the case of a 73-year-old male with COPD who developed localized dermatitis following the application of a Tuloplast patch. The patient developed erythematous to violaceous discoloration at the patch application sites on the abdomen and upper limb within 24 hours of use. There was no past history of drug allergy or dermatological disease. The transdermal patch was immediately discontinued, following which gradual improvement was observed, with near-complete resolution of the lesions within one week. Causality assessment using the WHO-UMC scale categorized the reaction as probable, while severity assessment using the Hartwig and Siegel scale classified it as moderate. This case highlights the importance of close monitoring for skin reactions when prescribing transdermal patches in elderly patients.

Keywords: *Transdermal drug delivery, Tuloplast patch, Cutaneous adverse drug reaction, Dermatitis.*

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INTRODUCTION:

Transdermal drug delivery systems are commonly used for chronic disease management due to their sustained drug release, improved compliance, and avoidance of first-pass metabolism[1]. They are especially useful in elderly patients with polypharmacy or difficulty swallowing. However, transdermal patches may cause cutaneous adverse reactions such as erythema, irritant or allergic dermatitis, hyperpigmentation, and skin discoloration[3]. These reactions may result from the drug, adhesives, or penetration enhancers[1,3]. Age-related skin changes further increase vulnerability in elderly individuals[3]. Tuloplast, used in COPD management, has limited evidence regarding patch-induced skin reactions, emphasizing the importance of reporting such cases to support pharmacovigilance[5].

CASE PRESENTATION

A 73-year-old male patient with a known history of chronic obstructive pulmonary disease (COPD) presented with localized skin lesions at the sites of transdermal patch application. The patient was prescribed with Tuloplast transdermal patch of 1 mg once daily as part of his COPD management. As advised, the patch was applied over the abdominal region for two days and over the upper limb for one day. Within 24 hours of application, the patient developed well-defined erythematous to violaceous discoloration and itching at the patch application sites, as shown in Figures 1 and 2. The lesions were localized to the areas in direct contact with the patch and were not associated with pain, burning sensation, or systemic symptoms. There was no history of fever, breathlessness, or worsening of COPD symptoms. The patient had no prior history of drug allergy, contact dermatitis, or pre-existing dermatological conditions. No new oral or topical medications, cosmetics, or soaps were used during this period.

Based on the temporal relationship between the patch application and the onset of skin lesions, a transdermal patch induced cutaneous adverse drug reaction was suspected. The Tuloplast patch was immediately discontinued, and no rechallenge was attempted due to ethical concerns. The patient was managed conservatively, and no additional topical or systemic treatment was required. Following withdrawal of the suspected drug, gradual improvement of the skin lesions was observed, with near-complete resolution occurring after more than one week, without any residual scarring or pigmentation. Clinical photographs of the lesions were documented for records.

The redness observed in Figure 1 is quite intense compared to images shown in Figure 2, because the patient received the injection of heparin on the same day, which may have contributed to internal bleeding and increased skin discoloration at the site. Additionally, the Tuloplast patch was applied on the abdomen for two days, whereas on the upper limb it was applied for only one day. The longer duration of application on the abdomen may have further intensified the local skin reaction seen in Figure 1.

Figure 1: On physical examination, the patient exhibited redness over the abdomen.

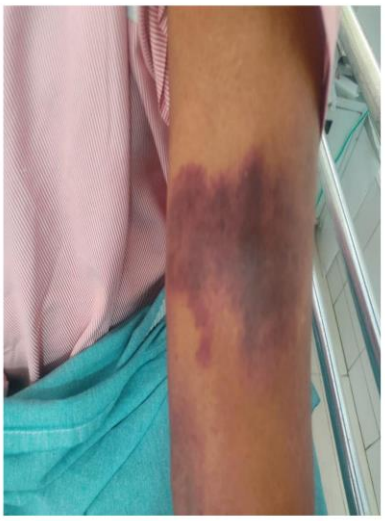

Figure 2: The physical examination revealed redness over the upper limb.

Causality and Severity Assessment

Causality assessment was performed using the WHO–Uppsala Monitoring Centre (WHO–UMC) scale, and the reaction was categorized as probable. Severity assessment using the Hartwig and Siegel scale classified the reaction as moderate, as withdrawal of the suspected drug was required and the reaction resolved without long-term sequelae. The adverse drug reaction was reported to the Pharmacovigilance Programme of India (PvPI) using the Suspected ADR Reporting Form.

DISCUSSION

Cutaneous adverse drug reactions are one of the most frequently reported complications associated with transdermal drug delivery systems, particularly when used for long-term therapy in chronic illnesses such as COPD. Although transdermal systems are preferred due to advantages like controlled drug release and avoidance of first-pass metabolism, they are not free from adverse effects. Local skin injury may occur either because of the pharmacological action of the drug itself, or due to excipients such as adhesives and penetration enhancers that irritate the epidermal barrier and produce inflammatory reactions[1,3]. Occlusion caused by a patch increases hydration beneath the skin surface, leading to maceration and increased absorption, which can worsen irritation. This risk is amplified in elderly patients, as advancing age leads to thinning of the epidermis, reduced lipid content, and impaired barrier function, making them more vulnerable to dermatitis when exposed to transdermal systems[3].

Skin reactions associated with transdermal therapies generally remain localized to the application site and often present as erythema, itching, discoloration, or pigment changes, which may clinically resemble leukoderma or other inflammatory dermatoses[2]. While similar cutaneous reactions have been previously reported with other transdermal drugs, including Rotigotine and fentanyl patches[2,4], literature reporting reactions specifically linked to Tuloplast remains extremely scarce, highlighting the clinical relevance of the present case. In this patient, the development of erythematous-violaceous patches within 24 hours of Tuloplast application, combined with symptom resolution following drug withdrawal, strongly suggests a causal association[5]. Such findings emphasize the need for continuous clinical surveillance whenever a new or less-reported transdermal therapy is used in an elderly individual.

The outcome of this case also reinforces the importance of early identification and management of cutaneous ADRs associated with patches. Prompt discontinuation prevented progression, eliminating the need for topical or systemic treatment and avoiding permanent sequelae. Cutaneous reactions can significantly reduce patient adherence to COPD treatment, potentially affecting disease stability and quality of life. Therefore, clinicians should routinely inspect application sites, educate patients on warning signs, and implement rotation of patch placement to reduce localized irritation[1,3]. Reporting suspected ADRs through pharmacovigilance systems such as the WHO-UMC model facilitates improved data generation, promotes safer prescribing, and supports post-marketing surveillance[5]. Hence, this case contributes meaningful clinical evidence, emphasizing cautious monitoring and documentation whenever Tuloplast or similar patches are administered to high-risk elderly populations.

CONCLUSION

Transdermal patches, though convenient and effective, can cause localized cutaneous adverse drug reactions, particularly in elderly patients. Regular inspection of application sites, patient education regarding early symptoms, and prompt discontinuation of the suspected patch are essential. Reporting such reactions to pharmacovigilance programs helps improve drug safety data and promotes safer use of transdermal therapies.

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