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SEVERE IMMEDIATE ANAPHYLAXIS FOLLOWING ORAL TOLPERISONE (MYOTOP 150 MG): A CASE REPORT

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ABSTRACT Tolperisone is a centrally acting skeletal muscle relaxant widely prescribed for musculoskeletal conditions. Although generally considered safe, hypersensitivity reactions, including anaphylaxis, have been increasingly recognized through pharmacovigilance data. We report a case of a 60-year-old female who developed rapid-onset, life-threatening anaphylaxis within minutes of ingestion of Myotop 150 mg (tolperisone). The reaction was characterized by mucocutaneous symptoms, upper airway compromise, and cardiovascular collapse requiring emergency management with adrenaline and hospital admission. The patient had a background history of chronic intermittent cutaneous symptoms and prior non-anaphylactic drug reactions. Component-resolved diagnostics revealed sensitization to multiple allergens; however, none explained the index event. Based on temporal association, clinical features, and exclusion of alternative etiologies, a diagnosis of severe tolperisone-induced anaphylaxis was established. This case highlights the importance of recognizing tolperisone as a potential trigger of severe anaphylaxis and underscores the need for prompt diagnosis, appropriate management, and preventive strategies.

KEYWORDS : Tolperisone, Myotop, Drug-induced Anaphylaxis, Muscle Relaxant, Hypersensitivity, Case Report

INTRODUCTION

Anaphylaxis is a severe, potentially life-threatening systemic hypersensitivity reaction characterized by rapid onset and multi-organ involvement [1]. Drug-induced anaphylaxis represents a significant proportion of anaphylaxis cases and is associated with substantial morbidity and mortality [2]. While commonly implicated agents include antibiotics, NSAIDs, and radiocontrast media, other less frequently recognized drugs, such as skeletal muscle relaxants, may also act as triggers [3].

Tolperisone is a centrally acting muscle relaxant used for painful musculoskeletal conditions. Its mechanism involves membrane stabilization and inhibition of spinal reflex pathways [4]. Although widely used in Europe and Asia, tolperisone has been associated with hypersensitivity reactions ranging from mild cutaneous manifestations to severe systemic reactions, including anaphylaxis [5–7]. The European Medicines Agency (EMA) has highlighted hypersensitivity as a major safety concern associated with tolperisone [5].

Despite this, awareness among clinicians remains limited, particularly in outpatient and primary care settings. We present a detailed case of severe immediate anaphylaxis following oral tolperisone, emphasizing clinical recognition, diagnostic challenges, and implications for safe prescribing.

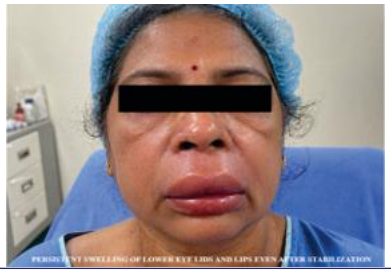
Case Presentation

A 60-year-old female from Hyderabad presented with a history of an acute systemic reaction following ingestion of a muscle relaxant. She had a background history of intermittent cutaneous symptoms since adolescence, characterized by episodic itching and erythema. These episodes were mild, non-progressive, and not associated with systemic involvement such as hypotension, airway compromise, or gastrointestinal symptoms. There was no history of prior hospitalizations for allergic reactions.

Her past drug history included a mild reaction to ofloxacin and ornidazole approximately 10 years prior, presenting as itching and pricking sensation within 30 minutes of ingestion, which resolved with antihistamines. She also reported a delayed swelling reaction occurring on the third day after ingestion of a suspected sulfonamide-containing drug, suggestive of delayed-type hypersensitivity. Importantly, there was no previous history suggestive of anaphylaxis.

On the day of the index event, the patient ingested Myotop 150 mg (tolperisone) at 5pm. Within approximately two minutes, she developed tongue tingling, followed by perioral swelling. This rapidly progressed to generalized itching, erythema, and a burning or needle-pricking sensation involving the extremities. Subsequently, she developed tongue swelling, voice change, and a sensation of throat tightness, indicating upper airway involvement.

Her condition deteriorated further with the onset of marked apprehension and a sense of impending doom, followed by collapse and profound hypotension (50/30 mm of Hg). She was transported to the emergency department at approximately 5:30 PM, where she received immediate resuscitative treatment, Fluids, including intramuscular adrenaline, Adrenaline Infusion, oxygen supplementation, and supportive care. She was admitted for monitoring and managed over a period of two days, with complete resolution of symptoms.



Investigations

Component-resolved diagnostics were performed on OPD follow up to evaluate allergic sensitization. The patient demonstrated sensitization to multiple allergens, including walnut (Jug r 2), apple (Mal d 2, PR-10 protein), honeybee venom (Api m1), paper wasp venom (Pol d), latex (Hev b3), and environmental allergens. However, these findings were not clinically relevant to the index event.

There was no history of food ingestion immediately preceding the reaction that could explain the event, nor was there any exposure to latex or insect stings. Thus, alternative causes of anaphylaxis were excluded based on clinical correlation.

Diagnostic Assessment

The diagnosis of anaphylaxis was established based on WAO and EAACI criteria [1,8]. The patient demonstrated: 1. Acute onset following exposure to a likely trigger. 2. Mucocutaneous involvement. 3.Upper airway compromise and 4. Cardiovascular instability.

These findings confirm severe anaphylaxis.

Causality assessment using the WHO–UMC system indicated a probable to highly probable relationship between tolperisone and the reaction, given the strong temporal association, known adverse effect profile, and lack of alternative explanations [9]. Rechallenge was not attempted due to the severity of the reaction.

DISCUSSION

This case represents a classic presentation of immediate drug-induced anaphylaxis triggered by tolperisone. The rapid onset of symptoms, progression to airway compromise, and cardiovascular collapse are hallmark features of severe anaphylaxis.

Tolperisone-associated hypersensitivity reactions have been documented in pharmacovigilance databases and clinical studies. The EMA has reported that hypersensitivity reactions constitute a significant proportion of adverse reactions to tolperisone, including urticaria, angioedema, dyspnea, tachycardia, hypotension, and anaphylactic shock [5,6]. Observational studies have identified female sex and prior allergic history as potential risk factors [7].

One of the key challenges in this case was the presence of background chronic cutaneous symptoms, which could potentially obscure recognition of anaphylaxis. However, the index event was clearly distinguishable by its rapid onset, systemic involvement, and severity.

Another important consideration is the interpretation of CRD findings. While sensitization to multiple allergens was identified, none were clinically relevant to the acute reaction. This highlights the well-recognized distinction between sensitization and clinically meaningful allergy, an important concept in allergy practice [10].

The mechanism of tolperisone-induced anaphylaxis is not fully understood. It may involve IgE-mediated pathways or non-IgE-mediated mast cell activation, similar to other drug-induced hypersensitivity reactions [11]. Further research is needed to elucidate the underlying immunopathogenesis.

Differential diagnoses included chronic urticaria exacerbation, food-induced anaphylaxis, latex allergy, venom hypersensitivity, vasovagal syncope, and panic disorder. However, these were excluded based on clinical presentation and absence of supporting evidence.

The patient was advised strict avoidance of tolperisone and related formulations. She was provided with an anaphylaxis alert card and counseled regarding early recognition of symptoms. The use of an adrenaline auto-injector was discussed. Future drug prescriptions should be undertaken with caution, and supervised administration may be considered where necessary. Rechallenge with tolperisone is contraindicated.

Tolperisone can cause severe life-threatening anaphylaxis, although it is often under-recognized. Rapid identification and treatment are essential. Background allergic symptoms may complicate diagnosis, but systemic involvement should guide clinical decision-making. Laboratory sensitization does not always indicate clinical allergy. Strict drug avoidance and patient education are critical to prevent recurrence.

ICD / Coding

- ICD-10: T78.2 – Anaphylactic shock, unspecified
- ICD-10: T88.6 – Anaphylactic reaction due to correct drug
- ICD-10: Y40–Y59 – Adverse drug reactions
- SNOMED CT: 39579001 – Drug-induced anaphylaxis

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