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(CASE REPORT)

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A rare rosuvastatin-induced urticaria in a high-risk cardiovascular patient: A case report

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Abstract

Statins are widely used lipid-lowering agents essential for the prevention and management of cardiovascular diseases. Despite their proven efficacy and safety, rare adverse drug reactions (ADRs), such as allergic skin reactions, can occur. This case report describes a 54-year-old male with ischemic heart disease, hypertension, and type 2 diabetes mellitus, who developed pruritic, red-pigmented skin lesions characteristic of urticaria within 10 days of starting rosuvastatin 40 mg daily. The symptoms resolved after discontinuation of the drug and administration of symptomatic treatment with cetirizine and calamine lotion. The likelihood of rosuvastatin causing the urticaria was assessed using the Naranjo Adverse Drug Reaction Probability Scale, which indicated a probable relationship. Although statins are generally well-tolerated, rare hypersensitivity reactions may occur due to immune-mediated mechanisms or mast cell activation. Early recognition and withdrawal of the offending agent are crucial for swift symptom resolution and prevention of further complications. In patients requiring continued lipid-lowering therapy, alternative agents such as pravastatin may be considered. This case highlights the importance of post-marketing surveillance in identifying rare ADRs, ensuring pharmacovigilance, and improving patient care. Increased awareness among clinicians is essential for timely detection and management of uncommon drug-related reactions to enhance treatment outcomes.

Keywords: Rosuvastatin; Urticaria; Adverse Drug Reaction; Hypersensitivity; Pharmacovigilance; Naranjo ADR Probability Scale; Cardiovascular drugs

1. Introduction

Hydroxymethyl glutaryl coenzyme A reductase inhibitors (statins) are first-line medication for lowering serum cholesterol levels in the prevention of cardiovascular disease [1]. Adverse drug reactions (ADR) are a common cause of hospitalization. It accounts for 16% of admissions in Great Britain and for 13% in France. In developing countries the number is assumed to be even higher. The most common causative drugs are NSAIDS and antibiotics [2]. As defined by the US Food and Drug Administration (FDA), any undesirable experience associated with the use of a medication is an adverse event. Thus, an adverse event is not necessarily caused by the medication. When caused by the medication, these undesirable experiences are called adverse effects or ADR [3].

Urticaria is a common condition and the chronic form usually has no allergic trigger. Urticaria is characterized by itchy, red, raised(wheal), and flared skin reactions that last usually for a few hours (typically <24 hours). It is classified as chronic urticaria (CU) if it lasts for more than 6 weeks [4]. Cardiovascular diseases are progressively rising as the major cause of death throughout the world. The implications of cardiovascular diseases are more significant in India. 3.75 million Deaths are reported due to cardiovascular diseases in 2010 across India. Out of these 2 million deaths were due to coronary artery diseases and heart attacks. All statins act by competitively inhibiting 3-hydroxy 3-methyl-glutaryl-

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coenzyme A (HMG-CoA) reductase, which is accountable for the change of HMG-CoA to mevalonate. This results in a compensatory increase in the number of LDL receptors, primarily in the liver, an increase in LDL plasma clearance and a reduction in LDL production) [5].

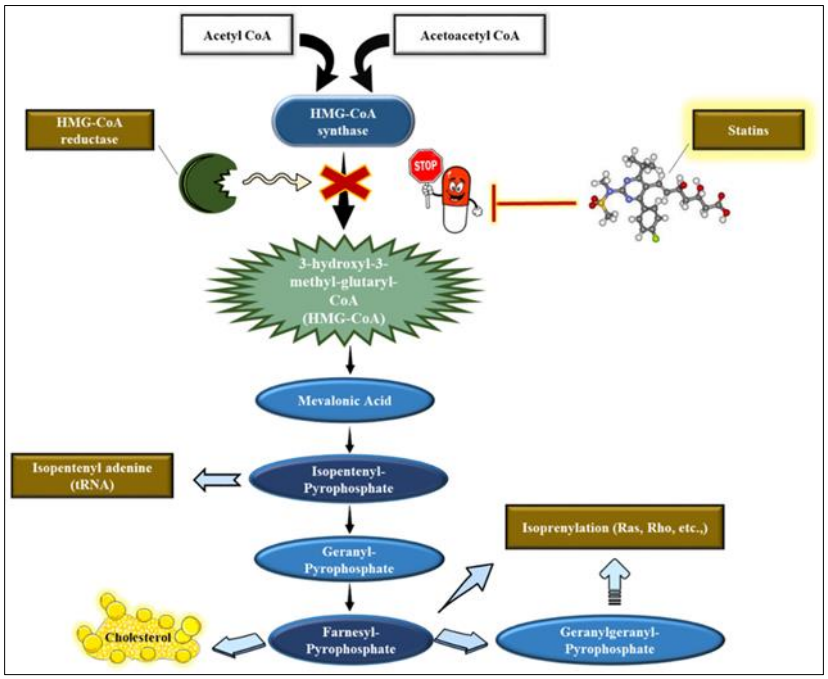

Figure 1 Statins mechanism of action. Statins inhibit the HMG-CoA reductase to block the synthesis of mevalonic acid and, consequently, the production of cholesterol [6]

Statins are commonly used worldwide. Common ADRs related to statins include gastrointestinal (GI) reactions such as abdominal pain, constipation, gastritis and nausea, hepatic reactions such as increased transaminases, and neuromuscular reactions such as increased creatine phosphokinase and myalgia [7]. Severe adverse effects are rare, and the benefits associated with the reduction in cardiovascular events outweigh the increase in incidence of diabetes.2 Allergic reactions are not even mentioned in respected textbooks [8]. Drug-associated adverse reactions can manifest with a wide range of symptoms. Some are widely reported, while others are less commonly observed [9]. ADRs are usually detected during clinical trials; however, small sample sizes, relatively short duration of studies and limited selection of patients can interfere with their detection during clinical trials [7].

This report presents a rare case of rosuvastatin-induced urticaria in a 54-year-old male patient with ischemic heart disease, highlighting the importance of post-marketing surveillance and careful monitoring of adverse drug reactions, particularly hypersensitivity reactions, associated with commonly prescribed medications like statins.

2. Methods

The likelihood of rosuvastatin causing the observed urticaria was assessed using the Naranjo Adverse Drug Reaction (ADR) Probability Scale, a tool that evaluates causality based on clinical factors, temporal relationship, and patient history. The patient, diagnosed with ischemic heart disease, was on rosuvastatin 40 mg daily. Urticaria developed after initiation of the drug, and symptoms improved upon discontinuation. The patient's history of hypertension and type 2 diabetes mellitus was also considered. The Naranjo scale was used to assign a probability score, aiding in the assessment of the ADR.

3. Case Report

A 54-year-old male with a history of hypertension and type 2 diabetes mellitus presented with ischemic heart disease (NSTEMI) and was prescribed rosuvastatin 40 mg once daily for lipid management. After 10 days of therapy, he developed red-pigmented, itchy skin lesions, characteristic of urticaria, which led to him seeking medical attention. Upon diagnosis of rosuvastatin-induced urticaria, the medication was promptly discontinued.

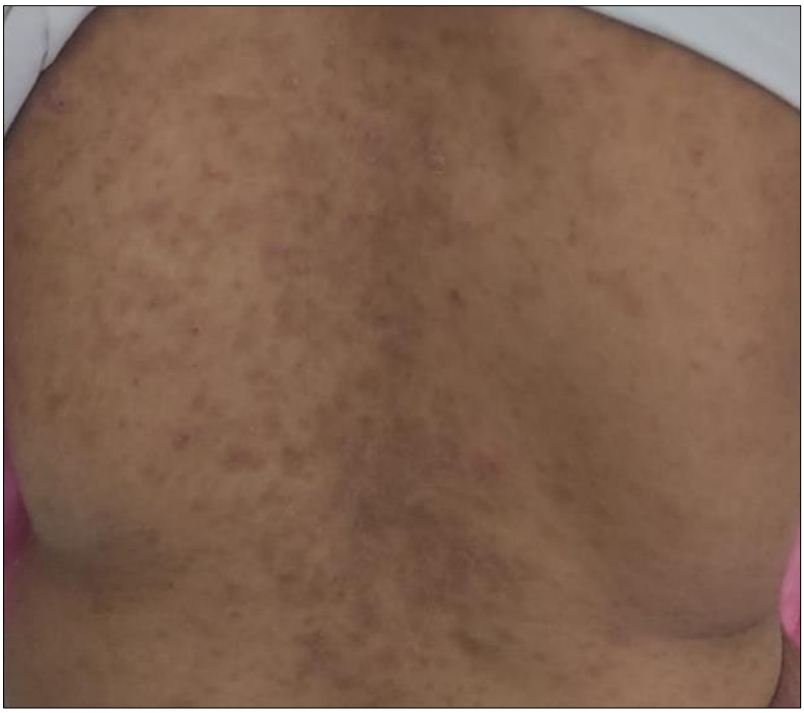

Figure 2 Urticaria with pruritic rashes and initial redness following rosuvastatin use, with the inflammation now resolved

The patient was treated symptomatically with cetirizine 10 mg daily and calamine lotion. He showed significant improvement in symptoms within a few days of stopping the statin. Given his underlying cardiovascular risk, the patient was switched to tab pravastatin 40 mg, and close follow-up was advised to monitor his lipid levels and cardiovascular health.

Table 1 Naranjo Adverse Drug Reaction Probability Scale Assessment for Rosuvastatin-Induced Urticaria

Question	**Yes**	**No**	**Do not know**	**Patient 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 re-administered?	+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 the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	0
Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
Total score				7

The likelihood of rosuvastatin causing the observed urticaria was assessed using the Naranjo Adverse Drug Reaction Probability Scale (Table 1). The patient received a total score of 7, indicating a Probable relationship between rosuvastatin and the adverse drug reaction.

4. Discussion

Statins, including rosuvastatin, are widely used for managing hyperlipidemia and preventing cardiovascular diseases, with common adverse drug reactions (ADRs) being gastrointestinal symptoms, muscle pain, and elevated liver enzymes. However, allergic reactions, including urticaria, are rare and underreported.

In this case, a 54-year-old male with hypertension, type 2 diabetes, and ischemic heart disease (NSTEMI) developed a pruritic rash and red, raised lesions characteristic of urticaria within 10 days of starting rosuvastatin 40 mg. The symptoms resolved after discontinuing the drug and administering cetirizine and calamine lotion. The causality of the urticaria was assessed using the Naranjo Adverse Drug Reaction Probability Scale, suggesting a probable relationship with rosuvastatin. While rosuvastatin-induced pruritus and dizziness have been reported by a study done by Malik S, Cohen P R [10], statin-induced urticaria is less commonly documented. Statins may cause allergic reactions due to immune-mediated hypersensitivity or histamine release from mast cells. However, further studies are needed to better understand these mechanisms. Although most statin-associated reactions are mild, urticaria may require discontinuation of therapy. In this case, symptoms improved after stopping rosuvastatin, emphasizing the importance of recognizing and managing ADRs promptly.

Clinicians should be aware of rare ADRs like statin-induced urticaria, especially in patients with multiple comorbidities. Alternative lipid-lowering therapies, such as atorvastatin or pravastatin, should be considered in cases of adverse reactions. This case contributes valuable insights into the spectrum of rosuvastatin-related ADRs and highlights the need for close monitoring and timely intervention.

5. Conclusion

This case highlights the occurrence of a probable rosuvastatin-induced urticaria in a patient with ischemic heart disease, hypertension, and type 2 diabetes mellitus. Although statins are generally well-tolerated and widely prescribed for their proven cardiovascular benefits, clinicians should remain vigilant for rare adverse drug reactions such as allergic skin reactions. Early identification and prompt withdrawal of the offending agent can lead to swift symptom resolution and prevent further complications. In patients who require continued lipid-lowering therapy, alternative agents like pravastatin or atorvastatin may be considered. This report underscores the importance of post-marketing surveillance in detecting and documenting rare ADRs, contributing to better pharmacovigilance and improved patient care.

Compliance with ethical standards

Disclosure of conflict of interest

Authors have declared no conflict of interests.

Statement of ethical approval

The present research does not involve any studies conducted on animals. Ethical approval for the case report was not required. Informed consent was obtained from the patient for the publication of the case, including details of the treatment and medical history, while maintaining confidentiality.

Statement of informed consent

Written informed consent was obtained from the patient for the publication of this case report and associated image, with confidentiality maintained. The image does not reveal any identifiable facial features.

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Author's short Biography

	**Dr. Malvika Bablad** is a Pharm D graduate with a strong passion for pharmacovigilance and regulatory affairs. Her academic excellence is complemented by her active participation in extracurricular activities, earning the Best Dancer Award. Malvika is committed to enhancing patient safety and advancing healthcare practices. Her dedication to both professional growth and creative pursuits makes her a well-rounded and driven individual.
	**Dr. Akshay Das** is a Pharm D graduate with a strong interest in pharmacovigilance and clinical research. He received the Best Outgoing Student Award for his academic and extracurricular contributions. Akshay is passionate about improving patient care through better ADR documentation and has experience in both clinical and research settings. His future aspirations include contributing to pharmacovigilance and advancing healthcare practices.