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ROSUVASTATIN INDUCED SKIN AND MUCOSAL ALLERGY (ERYTHEMATOUS PAPAULAR DERMATITIS)

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ABSTRACT

Rosuvastatin is a Lipid lowering agents which belong to class HMG Co-A Reductase inhibitors. In clinical trials, adverse drug reactions of rosuvastatin >10% were Neuromuscular & skeletal, in that Myalgia (2% to 13%). Only 1%, post marketing, and /or case reports reported hypersensitivity reaction (including angioedema, pruritus, skin rash, urticaria). Here we present a case with skin and mucosal allergy (erythematous papaular dermatitis) caused by Rosuvastatin.

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INTRODUCTION

Statins are by far the most widely used class of lipid-lowering drugs, it acts by inhibiting the rate-limiting enzyme in cholesterol biosynthesis- HMG-CoA reductase and they are the class of choice for LDL-C reduction [1], mostly used in cardio vascular disease, cerebrovascular disease, and atherosclerosis conditions.

Statins usually cause mild problems like: dyspepsia, headaches, fatigue, and muscle or joint pains. They can determine elevation in liver transaminases (ALT and AST). Severe myopathy and even rhabdomyolysis can occur rarely with statin. Recent studies reveal that there is a slightly increased risk of diabetes among statins treated patients. Cutaneous side effects are not very frequent but they deserve to be mentioned [2, 3]. It can induce some skin disorders like: collagenosis, bullous dermatoses, eczematous reactions or severe reactions like DRESS, pemphigoid. [4, 5, 6]

In clinical trials, adverse drug reactions of rosuvastatin >10% were Neuromuscular & skeletal, in that Myalgia (2% to 13%). Only 1%, postmarketing, and /or case reports reported hypersensitivity reaction (including angioedema, pruritus, skin rash, urticaria). We suspect that the rash observed in our patient may be a consequence of skin barrier dysfunction following inhibition of cholesterol biosynthesis.

Case Report

A 86 years old man presented with the complaints of difficulty in swallowing with discomfort in the mouth for last 1 week, itching with reddish skin rash involving in the extremities, upper trunk and both thigh region (Figure: A, B, C). He was a known hypertensive and had a history of cerebrovascular disease 1 month back, for which he was put on Tab. Rosuvas F, Tab. Acitrom, Tab. Olmesaratan and Tab. Phenytoin. Patient consent was obtained.

On examination he was found to be conscious, alert, soft palate, inflamed, edematous and erythematous. Multiple variable size reddish popular eruption distributed all over face, neck, bilateral upper limb, trunk and both thigh region. Lab Investigations revealed elevated eosinophil counts (14%), normal cell lines and normal creatinine.

Clinical examination revealed epiglottis, with extensive erythematous popular dermatitis with normal hemodynamics. It was felt that he was allergic to one of the above drugs. All the drugs were withheld, and he was started on Prednisolone and Antihistamines. After 2 days, the rash and oral symptoms were stabilized. On day 3, Tab. Rosuvastatin was rechallenged, after which he developed worsening skin rash and it was withheld. The most probable drug attributable was Rosuvastatin, but others like phenytoin, acitrom were excluded. He was continued only on Prednisolone, and antihistamines. With these, his skin rash and oral lesions were stabilized. He was advised to return for sequential challenge with drugs essential to his medical condition, anti-coagulants and anti-hypertensive. Then advised not to take statins and in strict diet control.

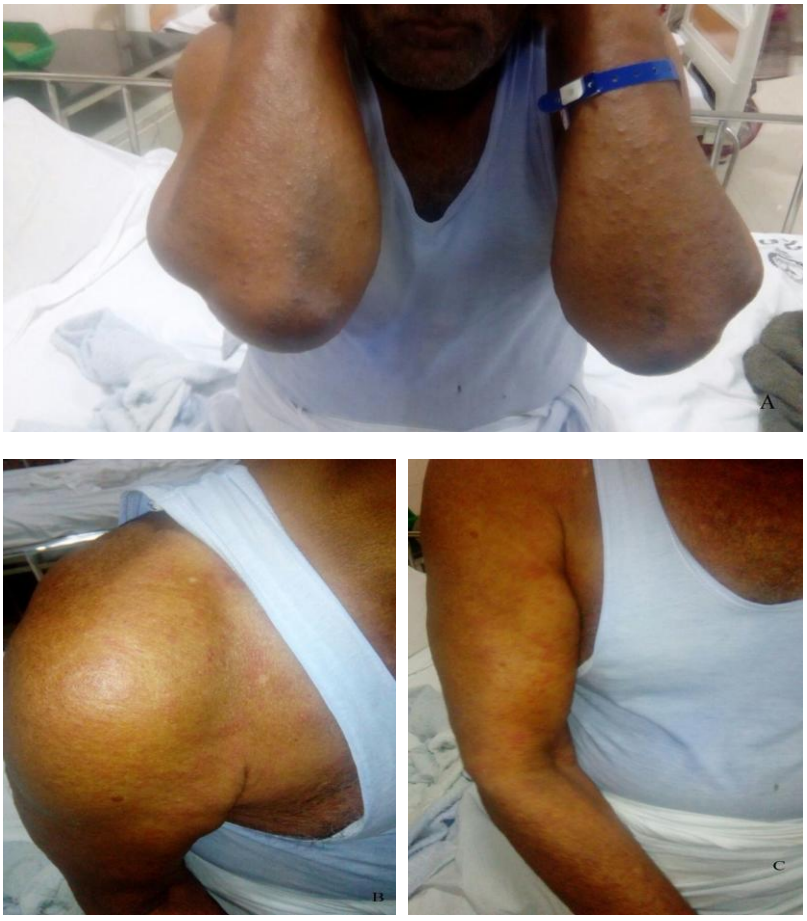

Fig: A, B, C.

DISCUSSION

Rosuvastatin- associated adverse drug reactions are wide ranging, from Myalgia (2% to 13%), Headache (6% to 9%), dizziness (4%), Diabetes mellitus (new onset: 3%), Nausea (4% to 6%), constipation (3% to 5%), Cystitis, Increased serum ALT (2%; >3 times ULN).

In general, allergic reactions to HMG-CoA reductase inhibitors appear to be rare, estimated to be 0.1%.[7] Despite the low frequency, the widespread use of these drugs has prompted reports of a wide variety of hypersensitivity reactions. These include rash, pruritus, eosinophilia, Stevens-Johnson syndrome, systemic lupus erythematosus-like syndrome, urticaria, and hypersensitivity pneumonitis

Based on the manufacturers' labeling, the prevalence of skin rash with statins ranges from 0.8% to 4% (a causal relationship is generally not established in these cases). Generalized eczematous reactions were reported which were attributed to dysfunction of the skin barrier rather than an immunologic phenomenon. [8]

The Naranjo criteria is frequently used for determination of causality of suspected ADRs. [9] A causality assessment of this ADR using Naranjo criteria revealed that an adverse drug reaction due to rosuvastatin was probable in the case (overall score, 5).

CONCLUSION

Allergic reactions caused by statins are very rare, it can induce some skin disorders like: collagenosis, bullous dermatoses, eczematous reactions or severe reactions like DRESS. Although the local adverse may be serious, they can be improved with close observation and appropriate treatment.

Disclosure Statement

The authors have no conflicts of interest to disclose.

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