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PLAIN LANGUAGE SUMMARY

Effectiveness of the antihistamine and anti-PAF effects of rupatadine in allergic diseases: off-label use in a case series study

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Background

Children frequently experience allergic diseases, which may range from mild conditions to more severe diseases that may negatively affect their quality of life. In many paediatric allergic reactions, histamine causes allergy-related symptoms, for example, itching, sneezing, hives and swelling.

Antihistamine drugs are medications that relieve allergy symptoms by blocking the action of histamine, and are considered the standard drug treatment for allergic diseases. However, another important molecule involved in allergy and inflammation is platelet-activating factor (PAF), which also contributes to swelling, redness, itching, and severe hives, and can worsen reactions such as anaphylaxis, insect bite reactions, or cold-induced urticaria.

Rupatadine is a modern antihistamine compound approved for treating allergic rhinitis and urticaria in adults, adolescents and children over 2 years of age. Unlike other antihistamines, rupatadine also blocks PAF and has additional beneficial anti-inflammatory effects. This dual action of rupatadine makes it a useful treatment in cases of more complex allergic conditions in which blocking the release of histamine is not sufficient for improving the symptoms of patients. Also, elevated PAF levels appear to maintain increased disease activity and resistance to treatment with antihistamines.

Although rupatadine is approved for certain uses, doctors sometimes prescribe it off-label when they believe that the medicine may benefit the patient based on scientific rationale and their clinical experience. In general, off-label use can be defined as prescriptions of a medication outside of the formal indications, in a different age group, or at a different dose than those approved. A previous review of the literature showed that off-label prescription of rupatadine was associated with remarkable success in a variety of clinical scenarios, including improvement of oral immunotherapy tolerance in food allergy, conjunctival allergies, mast cell activation disorders, skin diseases-related pruritus, or cutaneous allergy after mosquito bites. However, real-world clinical experiences of the off-label use of rupatadine are still limited.

What is this study about?

This real-world study describes five clinical cases of children, one of them as young as 6 months old, and one adolescent with various challenging allergic or skin conditions successfully managed with off-label use of rupatadine. In all these cases, the pharmacological action of rupatadine was adequate for targeting the underlying mechanisms of diseases causing the clinical manifestations. These diseases were urticaria induced by cold, food allergy, allergic rhinitis, large local reaction by wasp sting, allergic rhinoconjunctivitis due to grass/rye pollen allergy, and hives and urticaria by insect bites. Rupatadine was administered by the oral route at doses between 20 mg and 2.5 mg a day depending on the severity of symptoms and criteria of the attending paediatrician.

What this evidence indicates?

This collection of five clinical cases provides evidence of the beneficial dual antihistamine and anti-PAF effects of

rupatadine for the management of complicated allergic diseases and skin eruptions in real-world clinical practice. The off-label use of rupatadine, however, should always be based on a careful evaluation of each patient and the clinical judgement of the physician.