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Case Report

Drotaverine induced urticaria: a case report

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ABSTRACT

Drotaverine belongs to the hydroisoquinolone class of drugs. It is an effective antispasmodic drug used in the symptomatic treatment of various conditions such as GI diseases, biliary dyskinesia and smooth muscle spasms. There are a very few hypersensitivity reactions reported with this drug. Drotaverine induced cutaneous lesions is a very rare adverse effect and one such occurrence is discussed here. Diagnosis is a clinical one, made usually on the basis of knowledge obtained by medical history and physical examination.

Keywords: Hydroisoquinolone, Antispasmodic, GI diseases, Smooth muscle spasm, Cutaneous lesions

INTRODUCTION

Cutaneous adverse reactions, also known as toxidermia, are skin manifestations resulting from systemic drug administration. These reactions range from mild erythematous skin lesions to much more severe reactions such as toxic epidermal necrolysis (TEN).[1] Cutaneous adverse drug reactions comprise 2-3 % of all adverse drug reactions (ADRs) and approximately 1 in 1000 hospitalized patients has a severe cutaneous drug reaction. In a study examining skin eruptions 45% of all ADRs were manifested in skin. Most drug eruptions are mild self-limiting and usually resolve after the offending agent is discontinued. Mortality rates for erythema multiforme (EM) major are significantly higher. Steven Johnson syndrome (SJS) has a mortality rate below 5% whereas the rate for TEN approaches 20–30% and most patients die from sepsis. The incidence of ADRs is higher in women than in men and elderly patients have an increased incidence of ADRs.[2] Drotaverine, an antispasmodic has a good relaxing effect on intestinal smooth muscles, which helps in alleviating pain & does not have any side effects like anticholinergics. Drotaverine inhibits PDE-4 activation leading to increase in cyclic AMP levels thereby producing smooth muscle relaxation. Drotaverine is indicated in gastric colic, intestinal colic, pyloric spasm, cholelithiasis, gastritis, dysmenorrhea and irritable bowel syndrome. The safety and efficacy of drotaverine has been validated in many controlled trials in patients with recurrent abdominal pain, gastritis, irritable bowel syndrome (IBS).[3,4] Adverse effects such as skin rash and urticaria were reported in some of the patients but none of them needed to be hospitalised for this. A case of severe urticaria due to drotaverine requiring hospitalization is presented here.

CASE REPORT

An apparently normal 24-year-old female was brought to the emergency room with complaints of multiple erythematous rashes on the body over upper limbs, lower limbs, abdomen, back and neck (Figure 1). She had given history of consumption of a single dose of drotaverine tablet (80 mg) for menstrual cramps following which the symptoms occurred. There was associated itching all over the lesions. Her blood pressure was on the lower side but all other vitals were stable. She also gave a history of two episodes of fall coupled with loss of consciousness & nausea earlier that day. There was no history of breathlessness, fever, chills or any oral lesions. She is a known case of hypothyroidism and had discontinued her medications without any consultation. There was no other

significant medical history. Dermatology referral was immediately done. A closer look on the cutaneous lesions revealed multiple cutaneous urticarial wheals over both upper & lower limbs, abdomen, chest & back. There were no oral or genital lesions. She was given injection dexamethasone and pheniramine maleate stat. IV fluids were started and calamine lotion was applied over all lesions. She was advised admission in dermatology ward for further evaluation. Upon admission she was started on IV antibiotics (Cefotaxime 1 g BD), Pantoprazole 40 mg and other supportive measures. (IV fluids, Ondansetron injection, vitamin B complex tablets). Dexamethasone and pheniramine maleate injections was also continued. Calamine lotion was given for local application. Neurosurgery consultation was done in view of multiple syncopal falls and examination revealed no significant findings. General medicine consultation was done and was advised investigations such as CBC, LFT, KFT, blood sugars, chest X-ray, ECG and ultrasound scan of the abdomen. Results of all tests were within normal limits. Lesions on all limbs subsided but the ones on neck, back & abdomen were still persisting. Associated itching also subsided. Vitals were stable. There were no new lesions.

On day two post admission all the medications were continued. Injection metronidazole 100 mg was newly added along with ongoing cefotaxime injection. Cutaneous examination revealed wheals still over the neck but subsided in the remaining areas. On day three post admission, patient showed significant improvement on all parameters. Same medications were continued. All the lesions completely subsided and the general health condition was also satisfactory. She was discharged with oral medications (cefixime 200 mg, metronidazole 400 mg, dexamethasone 4 mg, chlorpheniramine maleate 10 mg and pantoprazole 40 mg tablets). Calamine lotion was given for topical application. She was asked to review in the OPD after five days.

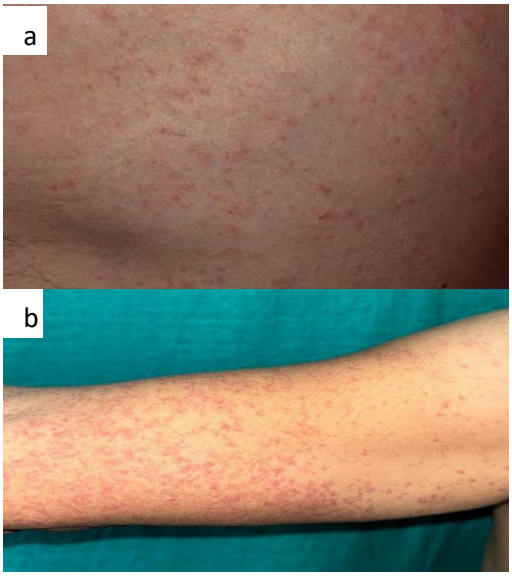

Figure 1 (a and b): Multiple erythematous rashes on the abdomen, and right upper limb.

DISCUSSION

Drotaverine is an antispasmodic drug which got central drugs standard control organisation (CDSCO) approval in 2008. It is used to treat gastrointestinal & genitourinary smooth muscle spasms. Though literature mentions allergic skin reactions as an adverse effect of drotaverine, there are only a few hypersensitivity reactions reported with this drug. This case report suggests a strong association between drotaverine and allergic skin reactions. Diagnosis of drotaverine induced allergic skin reactions is based on the temporal association between onset of symptoms and administration of the drug and absence of any other causative factor in this patient.

There are very few reports of skin reactions with drotaverine reported in literature and as mentioned earlier these are usually mild and rarely require hospitalisation. On extensive literature search we could find a case report mentioning drotaverine induced serum sickness in a pregnant woman. She underwent a rapid seven step oral drotaverine desensitization protocol without recurrence of serum sickness like reaction.[5]

In a randomized double blind placebo controlled trial comparing the safety & efficacy of drotaverine in children with recurrent abdominal pain, out of 64 children randomized into drotaverine, four patients developed maculopapular rash.[3] Allergic skin reaction with drotaverine has been a concern in the anecdotal reports from public sector.[6] We even searched for various articles which assessed the efficacy and safety of Drotaverine for different indications, but most of these studies do not mention even mild skin reactions as adverse effects in the Drotaverine group.[7,8] Considering these factors, this case report can be considered highly significant for clinicians who prescribe Drotaverine for different indications.

CONCLUSION

Drug induced cutaneous drug reactions are one of the rare adverse effects of drotaverine. This case report brings about one such situation into limelight. Awareness about such a reaction can be beneficial to all physicians so that such a possibility should be taken into consideration because drotaverine has a promising efficacy in most of the gastro-intestinal symptoms.

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