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# ANAPHYLACTOID REACTION TO ORAL ONDANSETRON: A CASE REPORT

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**ABSTRACT**
Ondansetron is a widely used antiemetic for gastroenteritis in paediatric population. Hypersensitivity to oral ondansetron is a very rare adverse effect. The uniqueness of this case report is that to the best of our knowledge, it is the first case of hypersensitivity to oral ondansetron in paediatric population. The reaction is of anaphylactoid type and on causality assessment it was found to be probable as per Naranjo scale.

## INTRODUCTION

Ondansetron Hydrochloride is the commonly used 5 hydroxy- tryptamine (5 HT3) antagonist in the treatment of nausea and vomiting following gastroenteritis in children [1]. Gastro Intestinal side effects like constipation, diarrhoea are the commonly reported adverse effects of Ondansetron [1]. Even though a few cases of hypersensitivity have been reported to intravenous (iv) ondansetron in paediatric population, hypersensitivity to oral ondansetron has not been reported.

## CASE REPORT

A 2-year-old male child weighing 12 kg was treated with syrup amoxicillin and syrup cetirizine for upper respiratory tract infection from a local hospital. On the second day of treatment, he had three episodes of vomiting for which he was treated with a single dose of syrup ondansetron 4mg (emeset, Cipla pharmaceuticals limited India)**.** Thirty minutes after ondansetron ingestion, he developed itching followed by maculopapular rashes all over the body, swelling around eyelids and low grade fever. He was treated with injection dexamethasone 4mg iv stat and pheniramine maleate 10mg iv and referred to a tertiary hospital for further evaluation and management. Routine investigations were within normal limits except for polymorpholeucocytosis. His vitals was stable. He was treated with injection hydrocortisone 50mg iv stat, injection pheniramine maleate 10mg stat, syrup amoxicillin 250mg thrice daily, syrup cetirizine 5mg twice daily and topical application of lacto-calamine lotion for 3days. The lesions subsided completely on the next day and he was asymptomatic at 48hrs follow-up.

The child had no history of exposure to ondansetron or any past history of food or drug allergy. Causality assessment using Naranjo's scale had shown score 6 indicating a probable reaction to oral ondansetron [2]. WHO-UMC causality assessment scale also showed a probable reaction to oral ondansetron, as rechallenge was not done [3]. By using modified Hartwig and Siegel scale the severity of the reaction was found to be moderate [4].

## DISCUSSION

Amongst the $5HT_3$ receptor antagonists, ondansetron is widely used in paediatric age group for the treatment of nausea and vomiting due to gastroenteritis. It

has a wide margin of safety. Reeves et al had demonstrated the efficacy and safety of ondansetron in the treatment of nausea and vomiting associated with gastroenteritis [1]. Most commonly reported adverse events in paediatric population include diarrhoea or constipation, headache and dizziness [1].Rare adverse effects are chest pain, dystonia and tonic-clonic seizures [1,5,6].Hypersensitivity to oral ondansetron is a very rare reported adverse effect. Ondansetron and Tropisetron have an indole heterocyclic ring while Granisetron lacks it, a probable reason for cross reactivity between the former two drugs [7].Some authors have an opinion that anaphylaxis can be a class effect, while others have suggested that it may be drug specific effect [7].The hypersensitivity may be IgE mediated or non-IgE mediated anaphylactic or anaphylactoid reaction respectively [7].In this child there is no previous exposure to ondansetron .Intradermal test for ondansetron hypersensitivity, Serum Ig E level and Serum Tryptase level ( for mast cell degranulation) were not done in this patient after the event which can be considered as limitations of this case report. The reaction might be anaphylactoid, as there was no prior sensitisation to ondansetron. The above reaction was probable as per Naranjo and WHO scale and they were moderate in severity as per Modified Hartwig and Siegel scale [4,8].

To the best of our knowledge, this is the first case of oral ondansetron induced anaphylactoid reaction in paediatric population to be reported in India. The easy and the widespread availability of 5HT3 receptor antagonists have promoted the off label use of these drugs for the treatment of gastroenteritis, migraine and many other emetogenic conditions [7,8]. This adverse reaction was reported to the regional pharmacovigilance centre which is registered under the National Pharmacovigilance Programme in India.

**Figure 1. Case Report**

## CONCLUSION

The use of ondansetron need to be judicious in treating gastroenteritis and other emetogenic conditions. Paediatricians should always consider the possibility of hypersensitivity reaction to ondansetron and over the counter sale of this drug should be avoided.

## Competing interests

There are no competing interests to declare.

## REFERENCES


1. Cohen IT. (2007). An overview of the clinical use of ondansetron in preschool age children. *Ther Clin Risk Manag*, 3(2), 333–9.
2. Elizabeth K.E, Koshy.G. (2014). Adverse Drug Reactions. In Suraj Gupte (eds) Recent Advances in Paediatrics-RAP 22Hot Topics, Jaypee Brothers, New Delhi, 445 – 457.
3. Syed Ahmed Zaki. (2011). Adverse drug reaction and causality assessment scales. *Lung India*, 28(2), 152–153. doi: 10.4103/0970-2113.80343.
4. Hartwig S, Siegel J, Schneider P. (1992). Preventability and severity assessment in reporting adverse drug reactions. *American J Hosp Pharm*, 49, 2229–2232.
5. Russell D, Kenny GNC. (1992). 5HT3 antagonists in postoperative nausea and vomiting. *Br J Anaesth*, 69, 63-68.
6. Sharma A, Raina V. (2001). Generalised seizures following Ondansetron. *Ann Oncol*, 12(1), 131-2.

7. Mehra KK, Gogtay NJ, Ainchwar R, Bichile LS. (2008). Hypersensitivity to intravenous ondansetron: a case report. *J Med Case Reports*, 2(1), 274.
8. Demir HA, Batu ED. (2010). Anaphylactic reaction owing to ondansetron administration in a child with neuroblastoma and safe use of Granisetron. *J Pediatr Hematol Oncol*, 32(8), e341-2.