



PANTOPRAZOLE AND DOMPERIDONE FIXED DOSE COMBINATION INDUCED RASH: A CASE REPORT

Dr. Shruti Vihang Brahmbhatt¹ Dr. Rushi Dewang Dave² Dr. Hitanshi Bharatbhai Patel³

¹ Professor and Head, Department of Pharmacology, Shrimati Bhikhiben Kanjibhai Shah, Medical Institute and Research Centre, Sumandeep Vidyapeeth Deemed to be University, Piparia, Ta: Waghodia, Vadodara- 391760, Gujarat, India.

² Second Year Resident, Department of Pharmacology, Shrimati Bhikhiben Kanjibhai Shah, Medical Institute and Research Centre, Sumandeep Vidyapeeth Deemed to be University, Piparia, Ta: Waghodia, Vadodara- 391760, Gujarat, India.

³ Second Year Resident, Department of Pharmacology, Shrimati Bhikhiben Kanjibhai Shah, Medical Institute and Research Centre, Sumandeep Vidyapeeth Deemed to be University, Piparia, Ta: Waghodia, Vadodara- 391760, Gujarat, India.

Corresponding Author: Dr. Rushi Dewang Dave

Email- rushidave1812@gmail.com

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Abstract

Drug induced rash on skin is considered as one of the most commonly reported adverse drug reaction in the clinical scenario. Pantoprazole and domperidone is commonly used as a Fixed Dose Combination (FDC) for dyspepsia and vomiting although they are not considered as rational combination. Present case report represent a rare case of rash in 24 year old male patient admitted in orthopaedic ward after consumption of FDC of pantoprazole and domperidone. According to modified Hartwig scale of preventability and severity of adverse drug reaction, this adverse drug reaction falls under level 3 (moderate) severity and was not preventable. As per the case report, FDC of pantoprazole and domperidone induced rash is considered as rare side effect. No similar adverse drug reaction was found in literature with the same fixed dose combination. It is important that clinicians should always be imperative about patient's condition and we should promote more vigilant reporting of such adverse drug reactions.

Key words: Fixed dose combination, Proton pump inhibitors, adverse drug reaction, Modified Hartwig scale, CDSCO

INTRODUCTION:

Drug induced rash on skin is considered as one of the most commonly reported adverse drug reaction in the clinical scenario. Itching and hives are the associated symptoms with skin rash. This falls under hypersensitivity reaction to a drug which shows the adverse symptoms.^[1] Proton-pump-inhibitors like Omeprazole, Pantoprazole are widely used drugs and they have become drug of choice for various diseases like gastric ulcers, gastroesophageal reflux etc. They are also used as stress ulcers protective agent.^[2] They act on $H^+ - K^+ - ATPase$ pump present in parietal cells of the stomach and reduces gastric acid secretion.^[3] D2 receptor antagonists like Domperidone predominantly act on Chemoreceptor Trigger Zone (CTZ) of the brainstem and are widely used for the management of nausea and vomiting, gastroparesis etc.^[4] Pantoprazole and Domperidone is commonly used in as Fixed Dose Combination (FDC) for dyspepsia and vomiting.^[5] Present case report represent a rare case of rash after consumption of FDC of Pantoprazole and Domperidone.

CASE PRESENTATION:

A 24 years old male patient admitted in orthopaedic ward for left side tibia-fibula infected non-union fracture with implant in situ. Initially the patient was given Injection Ceftriaxone 1.5g twice daily, Tablet Omshi DSR (Domperidone 30mg+Omeprazole 20mg) twice daily and Tablet Ultracet semi (Paracetamol 162.5mg+Tramadol 18.7mg) twice daily on 19/5/2023. Due to gastric discomfort patient's Tablet Omshi DSR was replaced with Fixed dose combination of Tablet Pandeep-D (Pantoprazole 40MG+Domperidone 10MG) on 26/5/2023. Suddenly patient developed rashes over nape of the neck and left arm on 26/5/23 which gradually increased in size. Tablet Pandeep-D was discontinued and Tab Avil (Pheniramine Maleate 25mg) once daily was given to the patient. Skin rashes then subsides gradually.



[Fig: 1]



[Fig: 2]

DISCUSSION:

Fixed dose combination (FDC) of Pantoprazole and Domperidone is not in the banned list of CDSCO (Central Drugs Standard Control Organisation) ^[6] and that's why it is commonly used

and easily available in the market. Its widespread use encourage manufacturer to make more bioequivalent brands. As Ceftriaxone is commonly used in preoperative prophylaxis and associated with most common side effect of vomiting, nausea, diarrhoea ^[7,8,16], the FDC of proton pump inhibitor and domperidone was used prophylactically. Most commonly prescribed combination available for Pantoprazole+ Domperidone are 20mg+10mg, 40mg+10mg, 40mg+30mg. ^[5] Common adverse drug reactions reported with domperidone are gastric discomfort, extrapyramidal side effects. ^[9] Common side effects of Pantoprazole includes nausea, abdominal discomfort, constipation, flatulence and diarrhoea. Less common side effects include myopathy, arthralgia, and headaches. ^[10] Ceftriaxone was not considered as suspected drug because it was continued throughout the treatment period and during the remission of rash. Although Pantoprazole and/or Domperidone induced rash, anaphylactic reaction are rare ADRs ^[11], it is suspected as culprit drug in this case report. No drug interaction was found among the drug prescribed to the patient. The adverse drug reaction was graded as probable following causality assessment as per Narjo's scale and WHO-UMC causality assessment scale. ^[12,13,17] According to modified Hartwig scale of preventability and severity of adverse drug reaction, this ADR falls under level 3 (moderate) severity and was not preventable. ^[14, 15, 18]

CONCLUSION:

As per the case report FDC of Pantoprazole and Domperidone induced rash is considered as rare side effect. No similar adverse drug reaction was found in literature with the same Fixed Dose Combination. It is important that clinicians should always be imperative about patient's condition and we should promote more vigilant reporting of such adverse drug reactions.

Additional Information:

Disclosures:

Participant was well informed and consent was taken for this study

Conflict of interest: NIL

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REFERENCES:

1. Wick JY. Drug-induced rash: nuisance or threat? Consult Pharm. 2013 Mar; 28(3):160-6.

2. Dharmarajan TS: The use and misuse of proton pump inhibitors: an opportunity for prescribing. *J Am Med Dir Assoc.* 2021, 22:15-22.
3. Shin JM, Sachs G: Pharmacology of proton pump inhibitors. *Curr Gastroenterology Rep.* 2008, 10:528-34.
4. Brunton L, Knollmann B. Goodman & Gilman's the pharmacological basis of therapeutics. 13th Ed. New York: McGraw-Hill Education; 2018. GI Motility and Water flux, Emesis, Biliary and Pancreatic disease; Chapter 50;p.922-923
5. Deolekar P et al. Pharmacoeconomic Analysis of Fixed-Dose Combinations of Proton Pump Inhibitors Available in India. (March 14, 2023) *Cureus* 15(3): e36112.
6. Website:<https://cdsco.gov.in/opencms/opencms/en/consumer/List-Of-Banned-Drugs>
7. Goldberg H et al. Predictors of surgical site infection after radical cystectomy: should we enhance surgical antibiotic prophylaxis?. *World Journal of Urology.* 2019 Jun 1; 37:1137-43.
8. Lamb HM, Ormrod D, Scott LJ, Figgitt DP. Ceftriaxone: an update of its use in the management of community-acquired and nosocomial infections. *Drugs.* 2002;62(7):1041-89.
9. Biswas M et al. Prescription pattern & adverse drug reactions of prokinetics. *Indian J Med Res,* June 2019.
10. Hoofnagle JH. Proton Pump Inhibitors; Clinical and Research Information on Drug-Induced Liver Injury [Internet]. National Institute of Diabetes and Digestive and Kidney Diseases; 2019 Apr 15.
11. James J et al. Anaphylaxis to Pantoprazole: A Case Report and Prerequisite for Vigilant Prescribing Practises for Proton Pump Inhibitors. *Curr Drug Saf.* 2022; 17(1):78-80.
12. Narjo CA, Busto U, Sellers EM, Sendor P, Ruiz I, Robert EA, et al. A method of estimating the probability of adverse drug reactions. *Clin Pharmacol Ther.* 1981; 30:239-45.
13. World health organisation (WHO) – Uppsala Monitoring Centre. The use of who umc system for standardized case causality assessment.
14. Petrova G, et al. Assessment of the expectancy, seriousness and severity of adverse drug reactions reported for chronic obstructive pulmonary disease therapy. *SAGE Open Med.* 2017 Jan 31; 5:2050312117690404.
15. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. *Am J Hosp Pharm* 1992; 49: 2229–2231.
16. Brahmbhatt S, Brahmbhatt V, Baria D, Shah T. Adherence to Medications and Awareness about Diabetes among Type 2 Diabetic Patients: A Prospective Study. *International Journal of Pharmaceutical Research* (09752366). 2020 Jan 2.
17. Brahmbhatt SV, Dave VD, Pandya PD. Evolution of Pharmacotherapy of Hypertension: A Brief Review. *African Journal of Biological Sciences;* 6(8) 2024 pg.2192-2208.
18. Brahmbhatt S, Brahmbhatt V, Mehta M, Shah T. Diabetes in Covid 19: Management. *International Journal of Forensic Medicine & toxicology;* January-March 2021, Vol.15 pg.1944-1947