

## **Angioedema caused by over the counter use of dicyclomine hydrochloride and paracetamol fixed dose combination in a child: a case report**

**Latesh B. Raghute<sup>1\*</sup>, Sujata Dudhgaonkar<sup>1</sup>, Kavita M. Jaiswal<sup>1</sup>, Akhilesh Singh Parihar<sup>1</sup>, Swapna M. Bhalerao<sup>2</sup>, Sagrika R. Jumle<sup>2</sup>**

<sup>1</sup>Department of Pharmacology,  
<sup>2</sup>MBBS Student, Government  
Medical College Gondia,  
Gondia, Maharashtra, India

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**\*Correspondence to:**

Dr. Latesh B. Raghute,  
Email: [latesh\\_raghute@yahoo.co.in](mailto:latesh_raghute@yahoo.co.in)

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### **ABSTRACT**

Authors describe a case of angioedema in a male child due to over-the-counter (OTC) use of fixed dose combination (FDC) of Tab. dicyclomine hydrochloride (20mg) and paracetamol (500mg) for abdominal pain. Use of OTC drugs in children without a doctor's suggestion can lead to unnecessary medication use and is not free of risks. Here, there is a probable causal relationship between the suspected drug and angioedema according to WHO-UMC criteria for Causality Assessment. This case was also reported to the Pharmacovigilance Programme of India (PvPI) through PvPI ADR android application.

**Keywords:** Angioedema, Dicyclomine hydrochloride, Over-the-counter drugs, Paracetamol

### **INTRODUCTION**

According to World Health Organization, an adverse drug reaction (ADR) is defined as "a reaction to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for modification of physiological function".<sup>1</sup> The incidence of reported cutaneous ADRs in India is 2.85%.<sup>2</sup>

Angioedema refers to abrupt non pitting swelling of the skin, mucous membranes, or both, including the upper respiratory and gastrointestinal tracts, which typically lasts

from many hours to 3 days.<sup>3</sup> It is caused by various drugs, foods or it can be idiopathic. Among drugs, angiotensin converting enzyme inhibitors, non steroidal anti-inflammatory drugs and antibiotics like penicillin, cephalosporins and sulfonamides are common to cause angioedema.<sup>4</sup>

Preparations containing paracetamol can cause hypersensitivity reactions in children however, the reports in literature about angioedema caused due to fixed dose combination (FDC) of dicyclomine and paracetamol are rare. Here we describe a case of angioedema in a male child due to over-the-counter (OTC) use of FDC of Tab.

dicyclomine hydrochloride (20mg) and paracetamol (500mg) for abdominal pain.

### CASE REPORT

A 9-year-old male child was brought to the Paediatric outpatient department (OPD) with complaints of itchy, raised, red colored hives on the skin all over the body but more specifically on face and lower limbs (Figure 1 and Figure 2). There was no similar history of such complaints in the past. Other systemic examination was found to be normal. A diagnosis of angioedema was made. The child had received half tablet of FDC of dicyclomine hydrochloride (20mg) and paracetamol (500mg) OTC for abdominal pain at 4 pm and half tablet at 10 pm on previous day before developing symptoms. The suspected offending FDC was stopped immediately. The patient was given Inj. pheneramine maleate (10ml) IM. He was also prescribed with calamine lotion for local application and syrup hydroxyzine hydrochloride (2mg/kg/day QID). A follow-up was done and the reaction completely resolved after 3 days.



**Figure 1: Raised, red colored hives on the face.**



**Figure 2: Arrow indicates raised, red colored hives on the lower limb.**

Here, there is a probable causal relationship between the suspected drug and angioedema according to WHO-UMC criteria for Causality Assessment. This case was also reported to the Pharmacovigilance Programme of India (PvPI) through PvPI ADR android application.

### DISCUSSION

Tab. Paracetamol and Tab. dicyclomine hydrochloride are one of the most commonly available OTC drugs. OTC drugs are defined as safe and effective medications for use by the general public without a doctor's prescription. But, the use of such drugs in children without a doctor's suggestion can lead to unnecessary medication use and is not free of risks.<sup>5</sup>

In therapeutic doses, paracetamol is considered to be safe drug. Cases of acute hypersensitivity have been reported in the literature ranging from self limiting cutaneous symptoms such as urticaria and maculopapular rashes to severe systemic circulatory failure, bronchospasm and angioedema.<sup>6</sup> Dicyclomine is tertiary amine anticholinergic drug used frequently by oral and parenteral route as an effective anti-spasmodic agent. It generally causes anticholinergic side effects.<sup>7</sup> But the incidents of skin related side effects due to dicyclomine are rare.<sup>8</sup>

In the present case, the child developed angioedema due to OTC consumption of FDC of Tab. dicyclomine hydrochloride (20mg) and paracetamol (500mg) for abdominal pain. The causal relationship between the drug and the adverse drug reaction was found to be probable. The severity assessment was done according to modified Hartwig and Siegel scale and this ADR was found to be of moderate severity (Level 3), because according to this level, the ADR requires that the suspected drug should be withheld, discontinued, otherwise changed, and/or an antidote or other treatment is required and there is no increase in the length of stay.

Treatment of such cases requires immediate withdrawal of suspected drugs and prompt management of symptoms. In this case, the FDC of Tab. dicyclomine hydrochloride (20mg) and Tab. paracetamol (500mg) was immediately stopped and antihistaminics were given. The patient responded well to this treatment and his parents were given advice to avoid this drug combination in future to prevent development of such symptoms.

### CONCLUSION

It is a case report describing an angioedema in a male child due to OTC use of FDC of Tab. dicyclomine hydrochloride (20mg) and paracetamol (500mg) for abdominal pain. Here we cannot directly point out which drug in combination is responsible for the present ADR. There is a probable causal relationship between the suspected drug and angioedema according to WHO-UMC criteria for Causality Assessment. In case of fever, paracetamol facilitates sweating reducing the fever whereas

dicyclomine being an anticholinergic drug blocks sweating. Thus, both actions are antagonistic to each other and this is an irrational combination. Such combination should be avoided in children and hence it is recommended to use dicyclomine alone for abdominal pain in case of children. As far as possible, parents should avoid self-medication and use of OTC drugs for their children without doctor's consultation.

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## REFERENCES

1. Edward IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis and management. *Lancet.* 2000;356:1255-9.
2. Ghosh S, Acharya LD, Rao PG. Study and evaluation of the various cutaneous adverse drug reactions in Kasturba hospital, Manipal. *Indian J Pharm Sci.* 2006;68(2):212-5.
3. Kaplan A. Angioedema. *WAO Journal.* 2008;1(6):103-13.
4. Inomata N. Recent advances in drug induced angioedema. *Allergology International.* 2012;61:545-57.
5. Pileggi C, Mascaro V, Bianco A, Pavia M. Over-the-Counter Drugs and Complementary Medications Use among Children in Southern Italy. *BioMed Res Int.* 2015;2015:413912.
6. Stephenson I, Nightingale JMD. Commentary - anaphylactic reactions to Paracetamol. *Postgrad Med J.* 2000;76:503.
7. Tripathi KD. Anticholinergic drugs and drugs acting on autonomic ganglia. In: Tripathi M, ed. *Essentials of Medical Pharmacology.* 7th ed. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2013:113-123.
8. Divyalasya TVS, Krishnaiah V, Yashoda HT, Pundarikaksha HP, Kudagi BL, Pathapati R. Adverse drug reactions in paediatric patients in a tertiary care hospital in India: a prospective observational single centre study. *Int J Basic Clin Pharmacol.* 2016;5:2130-7.

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