



SUSPENSION OF IBUPROFEN AND ACETAMINOPHEN INDUCED MACULOPAPULAR DRUG RASH - CASE REPORT

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ABSTRACT

A 3year 6 months old male child took Combiflam suspension which was a Fixed dose combination (FDC) of ibuprofen 100mg/5ml+ acetaminophen 162.5mg/5ml for otalgia following which he developed maculopapular rashes all over the body associated with pruritis eventually the patient was treated with intravenous antihistamines, antibiotics, oral antihistamines, proton pump inhibitors and topical lotions. The adverse drug reaction was classified as “Probable”(score-5) and “Probable/Likely” category as per Naranjo’s algorithm and WHO-UMC causality assessment scale respectively. Severity assessment as per Hartweig’s and Siegel scale classified the reaction as

level 3 (moderate) adverse drug reaction. This fixed dose combination suspension is available in India as over the counter (OTC) medication and hence awareness about such incidences needs to be communicated to both patient and physician level in view of patient safety.

KEYWORDS: Ibuprofen, Acetaminophen, OTC medications.

BACKGROUND

The most often prescribed medications are non-steroidal anti-inflammatory drugs (NSAID), which have antipyretic, pain-relieving, and anti-inflammatory properties.^[1] The data of global and Indian studies showed that the total number of NSAIDs prescription ranges from 15% to 40%.^[2] Acetaminophen and Ibuprofen are the most commonly used NSAIDs in the paediatric

age group for management of pain,^{[3][4]} Many NSAIDs formulations are marketed as oral tablets, syrups, suspensions etc. as over the counter(OTC)^[5] drugs and hence frequently used because of easy availability. Although, these drugs are generally considered safe for use in the paediatric population but still pose a significant risk of causing hypersensitivity reactions and dermatological drug reactions in patients. Ibuprofen is a major causative agent for drug hypersensitivity reactions.^[6] A study conducted by Hay et al proved that acetaminophen and ibuprofen combination is effective in treatment of fever and pain in children.^[7] A case report published by Rajpurakaret al 2015 reported a case of syrup paracetamol induced fixed drug eruptions ^{[8][9]}. There are many reports about NSAID-hypersensitivity in adult population however very few case reports about the same exists for the paediatric population. Here we report a case of maculopapular rash following administration of the suspension of acetaminophen and ibuprofen (Combiflam).

CASE REPORT

A 3 year 6 months old male child presented to Paediatrics OPD with complaints of rashes following the use of suspension acetaminophen and ibuprofen for ear pain along with complaints of ear discharge and fever. On primary survey the child was found to be febrile, had rashes associated with itching and ear discharge associated with pain. On inspection of the oral cavity the patient had congestion of the pharynx and the grade-I tonsillar enlargement. Patient was apparently normal six months back after which he developed runny nose not associated with sneezing and ear discharge yellowish in colour for 10 days, continuous foul smelling ear discharge is associated with pain, patient also complained of fever one episode intermittent high-grade along with rashes maculopapular type all over the body associated with itching. The child had undergone adenoidectomy with myringotomy three weeks ago, on post-operative day-20 the child presented to OPD with complaints of ear pain for which the syrup was prescribed. The patient ear discharge was collected using aural syringing and sent for AFB blood culture. The laboratory investigation revealed that neutrophilia along with elevated ESR and culture reports of ear discharge positive for gram positive bacilli and negative cocci. The result of Mantoux's test and CBNAAT were negative. The child was diagnosed with Otitis Media with Acute maculopapular drug rash. The patient was treated with intravenous pheniramine (22.75 mg), amoxicillin (325mg) and clavulanic acid (100 mg), lansoprazole (15 mg) and topical lotions for treating the rash. On day 5, the patient complained of aphthous ulcers for which patient was treated with choline salicylate (9

%w/v) gel and multivitamin syrup .The patient was symptomatically better after treatment and hence discharged on day 9.

DISCUSSION

The diagnosis was made based on both the clinical and laboratory investigations. The fixed dose combination of acetaminophen and ibuprofen are often considered safe for use in paediatric patients^[7] however these drugs can still cause adverse reactions like pruritis, urticaria, erythema and Steven Johnson syndrome. The adverse drug reaction was classified as “Probable”(score-5) and “Probable/Likely” category as per Naranjo’s algorithm^[10] and WHO-UMC causality assessment scale^[11] respectively. Severity assessment as per Hartweig’s and Siegel scale^[12] classified the reaction as level 3 (moderate) adverse drug reaction. It is therefore very crucial to check patient’s past medical history and hypersensitivity status prior prescribing these drugs in order to prevent such future occurrences. It is also of prime importance to educate the patient about their allergies and they should be advised to avoid using such medications.

Table 1: Daily progress chart of the patient.

Parameters	Day-1	Day-2	Day-3	Day-4	Day-5	Day-6	Day-7	Day-8	Day-9
Temp.(⁰ f)	100.0	98.8	Afeb	Afeb	Afeb	Afeb	Afeb	Afeb	Afeb
Resp. Rate(cpm)	30	32	32	30	28	29	26	30	30
Hr	102	108	100	106	100	102	102	104	100
Spo ₂ (%)	98	99	99	98	99	99	99	99	99

Table 2: Laboratory investigations.

Laboratory investigations		
Hemoglobin(g/dl)	11.4	10.9-15.0 g/dl
Total leucocyte count	8730	6000-1500 cells/mm ³
Neutrophils	68	55-70%
Lymphocytes	26	20-35%
Eosinophils	02	1-3%
Inflammation markers		
Erythrocyte sedimentation rate(mm/hr)	20	≤10mm/hr
C-reactive protein	6.7	1.8- 4.1 mg l ⁻¹
Blood culture reports		
Afb	Gram positiveve cocci, gram negative ive bacilli with a few pus cells	

Mantoux's test	Negative	
Cbnaat	Negative	

CONCLUSION

Although fixed drug combinations of Acetaminophen and Ibuprofen are frequently used to treat pyrexia and algesia in paediatric age group and tolerated well mostly but they are not safe altogether and are often correlated with serious side effects. Therefore it is necessary to create awareness about these drugs at both clinician and patient level in order to prevent such incidences. At physician level it is their primary duty to document patient past medical history prior to prescribing these drugs. This applies especially to Indian pharmaceutical market scenario where these drugs are marketed and readily available as OTC medications.

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