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Pharmacovigilance Study on Anti-Histamine Containing Cough Syrup in Pediatrics

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ABSTRACT

Cough and cold medicines especially anti histamine containing syrups are abound in Indian market despite the fact that majority of them lack scientific evidence of their use in this common condition. The use of any medication in pediatric age group must adhere to the strictest safety criteria and should not lead to unnecessary complications. Aim and objectives: To analyze the outcome of children taking antihistamine containing syrup for common cold and cough. Material and methods: In a Retrospective cohort study the investigator can quickly estimate the effect of an exposure on outcome status. A total of 100 children aged between 0- 5 years were taken in each group for this study. Results: Higher prevalence of Grunting, Fast breathing, Difficulty in taking feeds and Post tussive vomiting were there in children with antihistamine group. Conclusion: Efforts are needed to create awareness amongst the parents, caretakers and prescribers about the rational use of cough and cold medicines especially antihistamine containing syrups and also pay attention to adverse reactions caused by them. Hence the study has been conducted in small population; large trials will be needed for further analysis and conclusion.

KEYWORDS : Pharmacovigilance, antihistamine, prescribing practice, cough syrup

Introduction:

Most common conditions for which cough and cold medicines were prescribed were upper respiratory tract infections followed by lower respiratory tract infections, rhinitis, asthma, allergic cough, non-specific dry cough and others. Upper respiratory tract infections, the most common cause of cough, are mostly viral in origin Cough is a useful physiological mechanism that serves to clear the respiratory passages of foreign material and excess secretions. When excessive or bothersome, it is also one of the most common symptoms for which patients seek medical attention.[1] A recent survey done by Nielsen India noted that 56% of Indians (the highest in the country) suffered from cold in the year 2009-10 which was fourth highest globally and the next higher percentage of ailment was cough (54%).The most common causes of cough can be categorized according to the duration of the cough. Acute cough (<3 weeks) is most often due to upper respiratory infections like common cold, acute bacterial sinusitis, and pertussis. Subacute cough (between 3 and 8 weeks) is commonly post-infectious, resulting from persistent airway inflammation and/or postnasal drip. A cough which produces a significant quantity of sputum should usually not be suppressed, since retention of sputum in the tracheobronchial tree may interfere with the distribution of alveolar ventilation and the ability of the lung to resist infection.[1,3-5] Treatment of productive cough depends on determining the underlying cause and then initiating Cough and cold medicines are rampantly prescribed by physicians in many countries. A study done in Hong Kong showed that 400,000 litres of cough mixtures were dispensed by 48 government outpatient clinics in 2001 and the extent of cough mixtures use in private practice is likely to be even greater.[6] However, the clinical value of many cough mixtures is debatable and their use in children and the elderly is controversial.[7] Despite the increasing concern over the effectiveness and safety of these drugs, cough and cold medicines abound in Indian market, with more than 1300 formulations, and are increasing over the years.[8] Two different studies done by Manoj KS et al and Mohanty at al showed that out of total prescribed drugs, about 10% and 39% were cough preparations respectively.[9,10]specific therapy.[1,3] The Medical Council of India (MCI) dictates to its registered members that "Every physician should, as far as possible, prescribe drugs with generic names and He / she shall ensure that there is a rational prescription and use of drugs".[11] Seventeenth model List of Essential Medicines (WHO 2011) has not included any category for cough and cold medicines.[12] Though abundant literature from evidence-base is available focusing on the futility of formulations for 'cough and cold', more than 1300 such formulations flood the Indian market and prescribers prescribe them freely.[8] This leads not only to waste of scarce resources of our country; it may produce adverse and sometime harmful effects in the recipients. It was, therefore thought prudent to carry out this study to analyze the outcome of children taking antihistamine containing syrup for common cold and cough.

Materials and methods:

Retrospective cohort study was done in Department of Pediatrics, Kilpauk Medical College Medical College Hospital, Chennai. Ethics committee approval and consent from the parents were obtained. 100 Children in each from the age of 0 to 5 years were included in the study. Children in known case of allergic rhinitis, atopy getting treatment with anti histamine for long duration are excluded from the study. Group A was children prescribed without antihistamine; Group B was children prescribed with antihistamine. Structured questionnaire clinical assessment by a pediatric expert and oxygen satura-

tion was measured. Data were analyzed using SPSS software and Chi square test was used.

Results

100 children from 0 to 5 years were included in each group. 91 male children and 109 female children equally distributed in both group. Rhinorrhea and cold is the common illness among the children. The result of the observed side effects of the anti histamine has been provided in the tables.

Figure 1 Distribution of children with complication

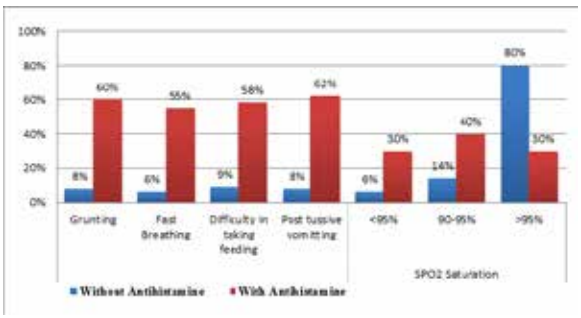

Table 1: Cross tabulation of Group A and Group B of Grunting

	Grunting		P value
	Yes	No	
Group A	8	92	<0.0001
Group B	60	40	

Table 2 Cross tabulation of Group A and Group B of Fast Breathing

	Fast Breathing		P value
	Yes	No	
Group A	6	94	<0.0001
Group B	55	45	

Table 3 Cross tabulation of Group A and Group B of Difficulty in taking feeding

	Difficulty in taking feeding		P value
	Yes	No	
Group A	9	91	<0.0001
Group B	58	42	

Table 4 Cross tabulation of Group A and Group B of Post tussive vomiting

	Post tussive vomiting		P value
	Yes	No	
Group A	8	92	<0.0001
Group B	62	38	

Table 5 Cross tabulation of Group A and Group B of SPO2 Saturation

	SPO_2 Saturation			P value
	<95%	90-95%	>95%	
Group A	6	14	80	<0.0001
Group B	30	40	30	

Discussion:

Common cold and cough are one of the most common causes of morbidity. Different drugs used in its treatment have insufficient evidence base and rationale for their use in these conditions. Among all the Over The Counter (OTC) drugs sold in India, cough and cold preparations had almost 18% of OTC healthcare market share in the year 2010.[14,15] The cough and cold preparations category was valued at INR 16,705.6 million ($384m) in 2009 and by the end of 2014 the cough and cold preparations category in India will be worth INR 21,524.1 million ($494.7m).[16] These figures are alarming considering the fact that most of them are irrational and serve no good purpose in treating common cold and cough. Not only this amounts to be a wasteful expenditure, it is often associated with undesirable effects, the management of which may further escalate the cost. In the present study, We infer that Age, Gender and pattern of disease distribution is same for both A and B group and statistically not significant. Among Antihistamine group 30 % of children were ≤ 1 years of age, 30 % were 1to 3 years and 40%were >3 to 5 years. Among non Antihistamine group 28 % of children were ≤ 1 years, 31 % were 1to 3 years and 41%were >3 to 5 years. The distribution is not statistically significant. 80% of children were given antihistamine for >4 days and 20 % were given 2 to 3 days. The Male & Female distribution in antihistamine group is 47 % and 53%. The Male & Female distribution in non antihistamine group is 44 % and 56%. The Rhinorhea with fever and Cough wih fever distribution in antihistamine group is 57 % and 43%. The rhinorhea with fever and Cough wih fever distribution in non antihistamine group is 54 % and 46%. The Grunting prevalence in antihistamine group is 60% than 8 % in non antihistamine group. (P value <0.0001) The odds ratio is 16.97. That means the children with antihistamine group had 16.97 times risk than non antihistamine group. The Fast breathing prevalence in antihistamine group is 55% than 6 % in non antihistamine group. (P value <0.0001) The odds ratio is 19.15. That means The children with antihistamine group had 19.15 times risk than non antihistamine group. The Difficulty in feeding prevalence in antihistamine group is 58% than 9 % in non antihistamine group. (P value <0.0001) The odds ratio is 13.96. That means The children with antihistamine group had 13.96 times risk than non antihistamine group. The Posttussive vomiting prevalence in antihistamine group is 62% than 8 % in non antihistamine group. (P value <0.0001) The odds ratio is 18.76. That means The children with Antihistamine group had 18.76 times risk than non antihistamine group. The Saturation <95 has 30 % prevalence in antihistamine and 6% prevalence in non anti histamine group. (P value <0.0001) It needs to be understood that cough is a useful physiological mechanism that serves to clear the respiratory passages of foreign material and excess secretions. Suppressing a productive cough can cause retention of sputum in the tracheobronchial tree and may interfere with the distribution of alveolar ventilation and the ability of the lung to resist infection.[1,3-5] Symptomatic or nonspecific therapy of cough should be considered when the cause of the cough is not known or specific treatment is not possible. This is worrisome considering the fact that suppressing cough with expectoration (productive cough) can do more harm than good. Most common conditions for which cough and cold medicines were prescribed were upper respiratory tract infections followed by lower respiratory tract infections, rhinitis, asthma, allergic cough, non-specific dry cough and others. Upper respiratory tract infections, the most common cause of cough, are mostly viral in origin, are usually self-limiting and require no drug therapy. Use of cough and cold medicines in this condition is largely ineffective. [1, 17, 18]

Conclusion

Cough and cold are two very common complaints of many. They are largely the manifestations of respiratory tract infections, many of which are self-limiting in nature Use of the so called cough and cold medicines, several of which are available as OTC medicines widely, have no role to play and may become the cause of adverse effects. This knowledge is nothing new, many evidence based articles published even 30 years ago [19-21, 23, 24, 27, 28] stand testimony to this fact. Though the study has given insight into prescribing it suffers from a fewer limitations, notably inclusion of a small sample size (only 100 responders).study in large population will be helpful.

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