Should Cough Syrups be Used In children?

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Abstract :
Many over the counter available cough and cold medications contain combination of a decongestant, cough suppressant, antihistamine, expectorant, or antipyretic, which are irrational. Parents administer these medications to children for giving temporary relief from the discomfort caused by the of upper respiratory infections such as runny nose, congestion, cough, and fever. As per the recommendation of US Food and Drug Administration, children under the age of two should never be given these preparations. Most of the labels of products mention that cough and cold preparations should not be given to children under the age of four. Yet the practice continues.

Keywords : Rational use, Pharmaceutical sale monitoring, Prescription sale

In pediatric patients in outpatient department common complaint seen is cough. Cough is physiologically useful protective reflex that clears the respiratory tract of the accumulated mucus and foreign substances. It occurs due to stimulation of mechano/ chemo receptors in throat, respiratory passage or stretch receptors in the lung.[1]

Commonly cough may be of nonproductive type serving no useful purpose, rather increasing the discomfort of the patient. For treating this type of cough antitussive agents are useful. The other type is productive cough, characterized by presence of excessive sputum which may be associated with conditions such as chronic bronchitis and bronchiectasis in which expectorants are useful.

Treatment of cough is based on the etiology. As cough is a common presenting complaint, pediatricians evaluate cough to diagnose and determine appropriate therapy.[1] Causes of cough differ depending on the symptoms being acute (lasting less than four week) or chronic (were the cough is persisting for more than four weeks). For acute cough, the common cause is viral upper respiratory tract infection (URTI) and for chronic cough, the common causes are asthma, gastro esophageal reflux disorder (GERD), postnasal drip, or foreign body aspiration which may result in persistent cough.[1]

Treatment of cough is aimed at the management of the underlying ailment. Antibiotics are given for bacterial pneumonia, bronchodilators and anti-inflammatory active pharmacological ingredients (API) are used in asthma. Children with viral infections should receive supportive care, oxygen and/or bronchodilators as needed. Use of nonspecific API for cough suppression should be discouraged in children.[2]

In some patients the use of cough suppressants and mucolytic agents have been supported. Coughing is an important mechanism for clearing secretions from the airways and can assist in recovery from respiratory infections. Use of nonspecific medicines for cough suppression is discouraged in children.[2]

Availability of cough syrups in India

Many allopathic as well as ayurvedic/herbal anticough preparations are available in India which are adviced for treatment of cough. Commonly available over the counter (OTC) cough and cold preparations contain either single medicine or combination of two or more such as a decongestant, cough suppressant, antihistaminic, expectorant, and antipyretic. Parents usually administer cough and cold medications to provide temporary relief from the symptoms of URTI in children, including running nose, congestion, cough, and fever.[3]

Some of the cough mixtures have a mucolytic agent and suppressing agents contain combination medicines such as codeine and diphenhydramine, codeine and chlorpheniramine. There are cough syrups containing powerful combination ambroxol and terbutaline, levosalbutamol and ambroxol. Some Ayurvedic anticough formulations contain ingredients like honey, tulsi and sunthi.[4]

Recommendation for use of cough syrup:

The safety, efficacy with appropriate dosing of the medicines used for cold and cough in children of different age should be the prime consideration of practitioners. Education should be imparted to the parents regarding the appropriate use of cough and cold medications in children.[3]

Derivatives of opium such as codeine are banned for use in children below 12 years of age in many countries but unfortunately these are freely available in India as popular cough syrups. In 2013, countries like the United States, United Kingdom, European Union, Canada, Australia and New Zealand banned the formulations containing codeine for children under 12 and lactating mothers, as a safety review revealed serious side effects in children, including fainting, seizures and death. Many codeine containing cough syrup brands lack warning on the label the potential side effects of the content for children and breastfeeding women. Many companies had stopped selling codeine based cough syrup brands in India, after regulators banned as it was likely to stance a risk to consumers.[5]

Over the counter (OTC) availability of cough syrup:

Various categories of cough syrups are available for kids in drug store and are freely available to the buyers. These are cough suppressants containing dextromethorphan (DM), cough expectorants containing guaifenesin, decongestants containing medicines like pseudoephedrine and phenylephrine. Certain antihistamines such as brompheniramine, chlorpheniramine maleate, and diphenhydramine are also available OTC.[6]

Allpervasive omnipotent use of cough syrup:

Since decades cough syrups have been looked as panacea for cough management and are popular OTC medicines, even though some of these should be sold on prescription. The manufacturers therefore advertise these products heavily on all media. Every home with children has these stored in their homes because these are self used and heavily depended upon for cough suppression. In opium growing States of India, the dried fruit of poppy (dodi) after extraction of morphine and poppy seeds for commercial use, are used for multiple conditions in children. Symptoms like fever, diarrhea, cough, are treated with water extract of poppy as home remedy. The other advantage the user mothers recommend is that the recipient sick children have a good sleep under its effect.

Who recommends these medicines:

It has been observed that many pediatricians use cough syrups for cold and cough to provide the immediate but temporary relief of the symptoms of cold and cough.[7]

Problems with use of cough syrups in children:

In year 2004 and 2005, around 1519 children below the age of two years were treated in emergency departments for either overdose or adverse event associated with cough and cold medications.[8]

Among the OTC cough suppressants dextromethorphan is frequently combined with the expectorant guaifenesin. Dextromethorphan, is the d-isomer of the codeine analogue levorphanol, which acts centrally to suppress cough center in the medulla. Drowsiness, dizziness, nausea, and gastrointestinal disturbance are common side effects associated with its use. Diphenhydramine, an antihistaminic, is also used as a cough suppressant for children. The exact mechanism of action of first-generation antihistamines antitussive effects is not clear, even though it is thought that first-generation antihistamines may depress respiratory reflexes, due to their CNS depression effects.[9]

Other antihistamines like chlorpheniramine, and brompheniramine are also found in pediatric anti-cold and anti-allergy formulae. These act by blocking the action of histamine at the H1 receptor site present on the cells in the respiratory tract, gastrointestinal tract, and blood vessels and decrease congestion related to mast cells in the respiratory tract.[10]

In studies it has been found that in response to common cold, viral infection and flu, along with inflammatory mediators all variables except histamine are raised in direct proportion to the severity of cold symptoms.

This suggests that neither antihistamines have any role in the treatment of the common cold nor they reduce the span of symptoms. They are helpful only in managing the symptoms of allergic rhinitis. Moreover, in children and infants, sympathomimetic-antihistamine mixed combinations are dangerous because they may cause respiratory depression.[9.10]

Guaifenesin is another API used in management of cough as oral mucolytic agent. It acts by reducing the surface tension and viscosity of the mucus, which increases the ease of expectoration. Respiratory mucus ejection is facilitated by increased flow of the thinned secretions by ciliary action. Studies on the efficacy of guaifenesin have failed to demonstrate either improved pulmonary function or decreased sputum viscosity, hence its clinical usefulness remains questionable.[9]

What should be done to enforce rationality of use of cough syrup?

In 2008, The FDA recommended that ant-cough and cold medications should not be prescribed to children below two years of age and caution should be taken when prescribing to children aged two to six years. The manufacturer warning to the consumers, should state on product labels not to give these medicines to children under four years. The differences between formulations such as infant drops, elixirs or suspensions, chewable tablets, and dispersible strips should be discussed with parents, and parents should be enlightened to look at the strength of each medication before administration. To encourage safe use of medications, it is important to encourage parents to contact the health care provider before administering any new OTC medication to their child.[3,6]

In 2014, the American Academy of Pediatrics (AAP) recommended the FDA to make manufacturers to use weight as basis of recommendation of dose rather than age, stating that weight is more accurate for determining the correct dose of an OTC cold/cough drug. The AAP also asked that dosing devices have a flow-limiting capacity to prevent against overdose.[6] The American College of Chest Physicians evidence-based practice guidelines state limited efficacy of cough suppressants in patients with cough due to the common cold and do not recommend the use of cough suppressants for URTI.[9]

Recommendation:

Parents of the infants and young children should be informed, enlightened and educated about nonpharmacological care of cold, such as removing secretions with a bulb syringe in infants and toddlers, for which suction pumps are available in market (neti kriya), the use of saline nasal drops for the ease of stuffy nose, and the use of a humidifier or plain water steam inhalation can be used when child is uncomfortable because of URTI symptoms. A "homemade" cough syrup of herbs like licorice, tulsi, sunthi and honey to children above 12 months gives parents an alternative to OTC anti-cough medication to relieve cough. Frequent and irrational use of cough formulations should be discouraged. Pharmaceutical companies should be advised not to manufacture cold and cough formulations with irrational combinations.[6]

Pediatricians and physicians should restrict prescribing the cough syrups containing codeine and hydrocodone for the patients below 18 years. These compounds are harmful as they are sedative and have abuse potential, and their sale has been banned by FDA in many countries.[7]

Conclusion:

The anti-cough and cold preparattions are more used irrationally and hence their production, availability and sale should be monitored. The sale should be strictly made on authorized and valid prescription only. There should be heavy penalization for sale OTC. The media advertising of these products should be banned. All stakeholders should be involved in effective communication about stopping the irrational usage of these products. There are many State Governments, health agencies and NGOs who do not have these items on their purchase lists, neither approve the bills for payment if directly purchased by their beneficiaries. It remains to be seen how the public reacts to harsher, stricter curbs and controls.

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