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Research Article

Effectiveness of Cough Syrups for Pediatrics URTI Cough in Comparison to Bronchodilators in the Wise of the Outcome and Caregiver Satisfaction.

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Abstract

One of the most common (if not the commonest) medical complaint in the daily pediatrics clinics is the cough, And in pediatrics as most of you know the commonest cause of cough is URTI, among the last two decades it was noticed that most of the CS for pediatrics have not been used widely from the pediatrician and PHC physicians which made a big debate about their futures of usage which certainly will affect the believe about such types of syrups, not only in the children's CGs but also in the pediatricians and general practitioner that a believe built many years ago which ultimately will make a big difference in plans of academic teaching in the medical schools and boards scholarships about the futural treatment of cough in Childrens. What was interesting is replacing such CS by MDI-BD (with air chamber tube) and that thing noticed to be more effective and convincing the CG despite some difficulties in the initial acceptance from their side. From such a point I decided to do such study.

Keywords:

URTI: Upper respiratory tract infection. LRTI: Lower respiratory tract infection. CS: Cough syrup.

PHC: Primary health centers. CGs: Care givers.

MDI-BDs: Metered dose inhaler-Bronchodilators. AC: Aero chamber.

NGCSC: National guard comprehensive specialized clinics. RUH: Riyadh.

KSA: Kingdom of Saudi arabia. MAR: Maroom clinics.

HSMC: Haramayen shareefayen medicsl complex. HNH: Hayaat national hospital.

AAP: American Academy of Pediatrics. FU: Follow up.

BA: Bronchial asthma.

Hx: History.

PE: Physical examination.

Introduction

Orally administered anti-cough and cold medications contain a variety of active ingredients including acetaminophen, antihistamines (Loratadine), dextromethorphan, decongestants (e.g., alpha adrenergic agonists such as phenylephrine or pseudoephedrine), and ethanol. These medications frequently cause significant toxicity in children younger than six years of age.

Topical agents, such as imidazoline ophthalmic and nasal drops

(e.g., tetrahydrozoline or oxymetazoline), and camphor containing products are also frequently used to control cough and cold symptoms.

(1) URTI are a major burden to child health in developing countries like India [URTI, mainly of lower respiratory tract, are the leading cause of death among children under five years of age in such countries, resulting in nearly 1.9 million childhood deaths per year, of which 20 % are estimated to occur in India. Worldwide, about 85–88 % of URTI episodes are URTI while the remaining are LRTI.

(2) There are approximately 30,000 paediatric (<14 years) exposures to cold and cold preparations reported in USA on centres annually, with about 55 percent of these occurring in children less than six years of age. Approximately 25 percent of these ingestions cause moderate or major effects; fatalities in infants and children have been reported but are rare, occurring in <1 percent of exploratory ingestions, and, in infants, have only been described after exposures to supratherapeutic doses. Children under 2 years of age accounted for 70 to 74 percent of deaths in several studies in the middle east, with child maltreatment an important concern. In addition, cough and cold medications that contain antihistamines are commonly used recreationally by Children and adults and you can't imagine their dangerous side effects.

What are the oral CS agents (cough preparations) found in the markets?

They include liquid and solid formulations (e.g., pills, tablets, or capsules). Active ingredients, doses, and duration of action vary depending upon the manufacturer (Table 1) and commonly consist of one or more of the following agents:

- Antihistamines (e.g., chlorphenamine, brompheniramine, doxylamine, or diphenhydramine)
- Alpha1 adrenergic decongestants (e.g., phenylephrine, pseudoephedrine, or, outside of the United States, phenylpropanolamine)

- Antipyretic and analgesics (e.g., acetaminophen or ibuprofen)
- Cough suppressant (typically dextromethorphan)
- Expectorant (e.g., guaifenesin)
- Ethanol (adult formulations).

Common active ingredients of orally administered over-the-counter cough and cold preparations*

Ingredient	Typical single adult dose	Typical single pediatric dose
Antihistamine		
First generation		
Brompheniramine	4 mg	1 mg
Diphenhydramine	25 mg	1 to 1.25 mg/kg up to 25 mg
Chlorpheniramine	2 to 4 mg	1 to 2 mg
Doxylamine	6.25 to 12.5 mg	2.5 to 6.25 mg
Clemastine	1 to 2 mg (base)	0.5 to 1 mg (base)
Dimenhydrinate	50 mg	1.25 mg/kg up to 25 mg
Triprolidine	2.5 mg	1.25 mg
Second generation		
Loratadine	5 to 10 mg	5 mg
Fexofenadine	60 mg (IR); 180 mg (ER)	15 to 30 mg
Cetirizine	5 to 10 mg	2.5 to 5 mg
Decongestant		
Phenylephrine	5 to 10 mg	2.5 mg
Pseudoephedrine	30 to 60 mg (IR); 120 to 240 mg (ER)	1 mg/kg up to 15 mg (IR)
Phenylpropanolamine [†]	25 mg (IR) to 50 mg (ER)	6.25 to 12.5 mg (IR)
Cough suppressant		
Dextromethorphan	10 to 20 mg (IR); 60 mg (ER)	2.5 to 7.5 mg (IR); 15 mg (ER)
Antipyretic/analgesic		
Acetaminophen (paracetamol)	325 to 1000 mg (IR); 1300 mg (ER)	10 to 15 mg/kg up to 650 mg
Ibuprofen	200 to 400 mg	4 to 10 mg/kg up to 300 mg (age ≥12 years: up to 400 mg)
Analgesic		
Naprosyn	200 mg (base)	5 mg/kg up to 200 mg (base)
Ketoprofen [‡]	12.5 to 25 mg (IR); 100 to 200 mg (ER)	0.5 mg/kg up to 25 mg (IR)
Expectorant		
Guaifenesin	200 to 400 mg (IR); 600 to 1200 mg (ER)	50 to 200 mg (IR)

IR: immediate release; ER: extended release.

* Over-the-counter (OTC) preparations may contain combinations of several active ingredients. If possible, the clinician should obtain the container with the listed ingredients rather than relying upon the reported brand name because different preparations can have similar or the same brand names. Doses reflect the recommended over-the-counter dose. Higher doses may be approved for patients under medical supervision.

[†] Not available in United States.

[‡] Available OTC in many countries; requires a prescription in the United States.

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Table 1: The common types of cough preparations in the markets, (3).

The aim of the study:

To estimate the efficacy of MDI-BD versus CS in solving cough problems caused By URTI in children and their impact on family satisfaction.

The design: Cross-sectional study.

SeFngs: The study done on NGCSC, also in a private clinic in RUH (MAR, HSMC and HNH) since 01/11/2019.

Tool: via the operational FU from the main dependent official operating system of the four medical centers the study done. In all the targeted medical centers, operational FU systems are implanted by the medical records departments in each. The number of patients undergone within the study were as follows: 281 children from the NGCSS, 62 children from MAR, 17 children from HSMC and 13 from HNH. All such patients from that centers were more than 4 years old (to avoid the unpleasant SE of the CS according to the AAP precautions) and have been diagnosed only with URTI as the cause of the cough (BA asthma rolled out from the review of the Hx and P/E) then they have been interviewed about the treatment plane that it will be MDI-BDs for the cough and also a CS which was (Antihistamine=Loratadine). such CS has been left with them as extra if they changed their opinion in home about the plane of the treatment, the whole 373 patients contacted after 10 days from the first visit and asked about their selected treatment and its outcome to compare their efficacy which is which?

Method Of The Study:

The style of the study was achieved as cross-sectional one, the field of the study was in the out- patients' clinics of the targeted medical centers, every patients involved should be above 4 years old (According to the AAP regarding to the age limit of the CS administration) has been activated by the front reception of the clinic and the medical records patents information's have been confirmed then proceeded to the vital signs records among which the nurses asked the CG about any significant previous medical history mainly presence of BA and the vital signs have been registered. Then the Childrens transferred to the physicians who concerned During which a counselling with each CG again with detailed Hx and PE taken among which also we Labeled the patients diagnosis as URTI (No element of BA) and after that we offer the kit of the medication to them, which is consist of a CS of Loratadine, Salbutamol MDI-BD and aero chamber (Figure 1).

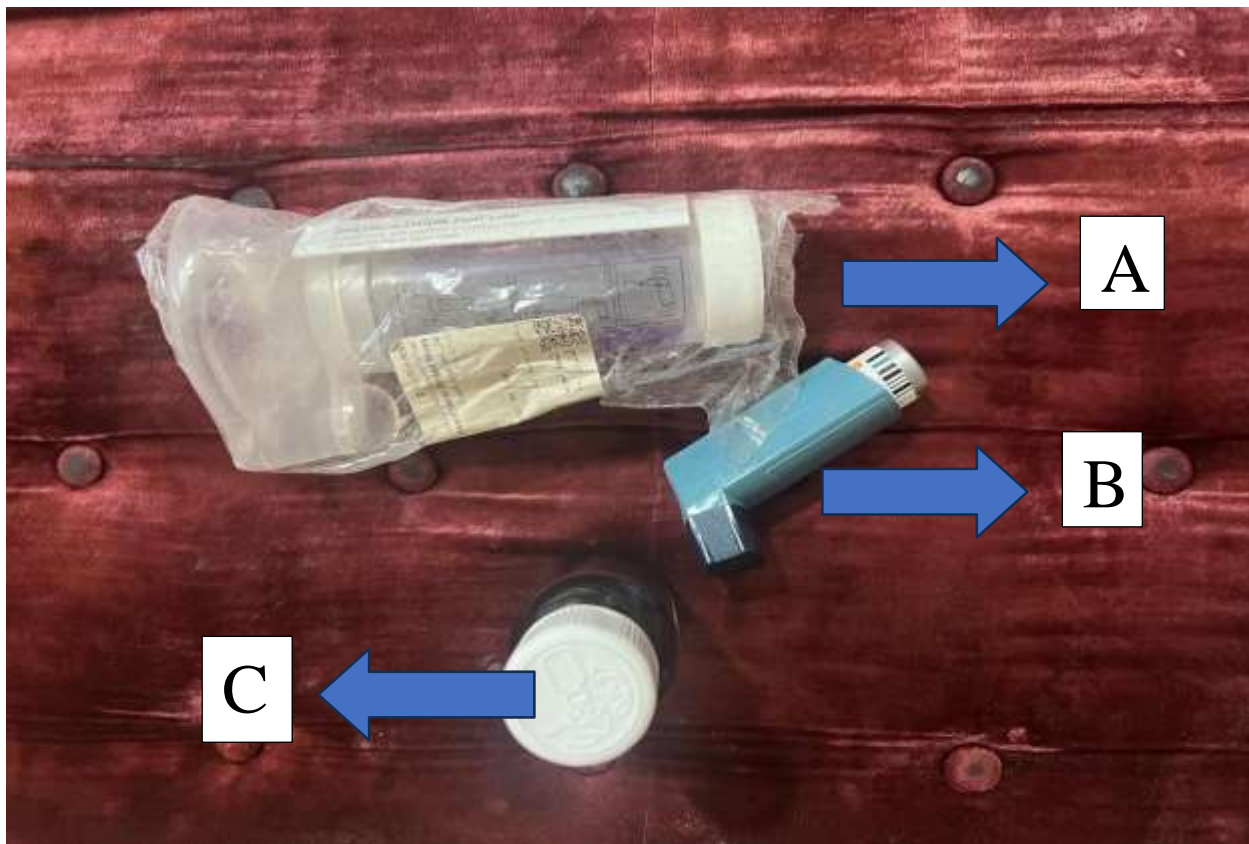


Figure 1: The simple kit of medications used in the study. A=AC, B=MDI-BD, C=CS.

After finishing from the visit, I collected more than one way of communication with CG (Mobile number, Email) and agreed with them to contact after 10 days to answer the following questions:

- A) In which day the cough disappeared?
- B) Which medication you selected for the cough initially?
- C) Have you been unsatisfied with the management plan, and you did not give any medication?
- D) Have you shifted the type of treatment from one to another and why?
- E) what is your estimation of the efficacy of treatment if we classify that into:

- *Excellent as A.
- *Very good as B.
- *Good AS C.
- *Weak AS F.

Then after we collected all the data, we summarized the net analysis of the study on the table which is coming in the next section of the result of the study.

Be informed that among this study we standardized the medication given to the sample in the wise of the generic and commercial names to avoids the baizes in the results.

The Result Of The Study

Among the patients whom we could contact (369) we found that through the 10 days post-treatment observation, 346 patients improved completely on using the MDI-BDs only and satisfied about that (291=A, 50=B& 5=C) , 20 patients improved on the CS only with satisfaction of 2=A,2=B & 16 =C , and only 3 patients started on CS then shifted to MDI-BDs then they got improved with satisfaction degree of C.(Table-2) is simplifying the whole results of the study in a simple manner.(Table 2).

Rx /Satisfaction	A	B	C	F
MDI-BD (346 P)	291	50	5	ZERO
CS (20 P)	2	2	16	ZERO
Both (3)	ZERO	ZERO	3	ZERO

Table 2: The net results of the study including the number of the Childrens involved in the study who categorized according to the medication given and to their CG satisfaction.

Discussion

From the results it looks very clear the dramatical effect of the bronchodilators on treating URTI cough (for the non- BA cough) a way by which we can at least bypass the worse side effect of the CS and at the same time we gain the CG satisfaction after relived their children's cough.

Antihistamines — The common antihistamines found in OTC cough and cold formulations have traditionally included first-generation antihistamines such as chlorphenamine

brompheniramine, doxylamine, and diphenhydramine. At lower doses, these agents can cause sedation and mild lethargy through effects on the H1 histamine receptors.

More recently, second-generation antihistamines such as loratadine, cetirizine, and fexofenadine have

become common ingredients in cough syrups. Most children remain asymptomatic, even after large overdoses (over 60 times the maximum recommended therapeutic dose). Among symptomatic patients, minor drowsiness or restlessness without major toxicity is typical.

With higher doses of first-generation antihistamines, anticholinergic poisoning may occur with typical findings associated with the anticholinergic toxidrome as follows:

- Flushed and dry skin
- Hyperthermia
- Dilated pupils and blurry vision
- Agitation, tremor, picking movements, delirium, hallucinations, coma, and, especially in children, seizures
- Urinary retention and absent bowel sounds

Cough syrups and cold medicines are among the most used medications. Several agencies, including the United States Food and Drug Administration (FDA), the Medicine and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom and Health Canada, and the AAP recommend against the use of these products in children, although age limits vary. Prior to voluntary withdrawals of infant cold medicines, approximately 10 percent of children living in the United States had used a cough and cold medication in any given week. Cough syrups and cold medications are also widely used for paediatric upper respiratory infections throughout the world despite lack of proven efficacy.

Among my search about any study supported and evaluating the impact of MDI-BD on the URTI cough, in Segal journal (*Global Paediatric Health* Volume 6, January-December 2019) © The Author(s)

2019, Article Reuse Guidelines)(4) done by Sankaran Krishnan, MD, MPH - Vicki Ianotti, MD, and Allen J. Dozor, MD was taking about only the selection of the type of the treatment for cough according to the type of cough itself (dry or wet) and one of the modalities of the treatment was MDI-BD and the result of that showed:

- Children prescribed bronchodilators were more likely to have a history of previous cough encounter within the past year, history of asthma, pneumonia, or dysphagia, and more likely to have fever, nasal congestion, and wheezing. There was no relationship between the use of bronchodilators and cough characteristics or

duration of coughing. Another study mentioned on journal of thoracic disease (Vol 10, No 11 -November 28, 2018 //Clinical Practice Guidelines for Diagnosis and Management of Cough—Chinese Thoracic Society (CTS) Asthma Consortium) (5) done by Kefang Lai¹, Huahao Shen², Xin Zhou³, Zhongmin Qiu⁴, Shaoxi Cai⁵, Kewu Huang⁶, Qiuping Wang⁷, Changzheng Wang⁸, Jiangtao Lin⁹, Chuangli Hao¹⁰, Lingfei Kong¹¹, Shunan Zhang⁹, Yaolong Chen¹², Wei Luo¹, Mei Jiang¹, Jiaxing Xie¹, Nanshan Zhong¹, that study was taking about the role of the MDI-BC in treating the URTI cough in adults and it concluded that Regular use of MDI-BD is not necessary, however, for adult patients with acute bronchitis and concomitant asthma, MDI-BD may be beneficial.

Conclusion

It seems that the MDI-BD plays a dramatical role in treating the cough resulted from the URTI and it looks more efficient than the CS for that purpose at least saving Childrens from the CS unpleasant SE.

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