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Research Article

A PROSPECTIVE OBSERVATIONAL STUDY ON DISTRIBUTION PATTERN OF ADVERSE EFFECTS OF BRONCHODILATORS AMONG BRONCHIAL ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS IN A TERTIARY CARE TEACHING HOSPITAL IN A RURAL AREA OF KANCHEEPURAM DISTRICT

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ABSTRACT

Objectives: The objectives of the study were (i) to study the distribution pattern of adverse effects of bronchodilators at initiation or during the course of therapy, (ii) to make a causality assessment of adverse effect identified using the WHO adverse drug reaction (ADR) probability scale, and (iii) to identify next drug tolerated better by him/her.

Methods: This is an observational study that lasted for duration of 2 months.
All patients reporting ADR after initiation of bronchodilator or during the course of bronchodilator therapy for bronchial asthma/ chronic obstructive pulmonary disease within the study period were included in the study. The suspected adverse effect was noted and documented. Causality assessment based on the WHO scale was employed.

Results: During the study period, ten patients reported to have ADR for bronchodilators were identified and the WHO Causality Scale for ADR was applied and the better drug tolerated by the patient was noted.

Conclusion: Inhalational forms of longer acting beta-2 agonists were better compliable to the patients with no observable adverse effects.

Keywords: Adverse effects, Bronchodilators, Shri Sathya Sai Medical College.

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INTRODUCTION

Asthma is characterized by chronic inflammatory disorder of airway in which many cells play a role including mast cells and eosinophil. In susceptible individuals this inflammation causes symptoms which are associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment and causes an associated increase in airway responsiveness to stimuli [1]. The patient usually presents with symptoms of breathlessness, wheezing, cough, and chest tightness with worsening at night. Asthma is quiet prevalent around the world with about 300 million people suffering from this disease. In India, it is estimated to be around 3–38% in children and 2–12% among adults. National burden is around 18 million [2].

The objective of this study is to find the distribution pattern of adverse effects of bronchodilators in tertiary care teaching hospital and to make a causality assessment of the adverse drug reaction (ADR) and thereby identifying the next better tolerated drug by the patient.

METHODS

This study was carried out in the Department of Respiratory Medicine, Shri Sathya Sai Medical College and Research Institute after getting the approval of Institutional Ethics Committee (IEC No: 2019/507 Dated: April 30, 2019). It was an observational study that lasted for duration of 2 months between July and August 2019.

Inclusion criteria

All patients reporting ADR after initiation of bronchodilator or during the course of bronchodilator therapy for bronchial asthma/chronic obstructive pulmonary disease (COPD) within the study period were included in the study. The suspected adverse effect was noted and documented.

Causality assessment based on the WHO scale was employed.

RESULTS

In this study period of 2 months, we were able to identify ten patients who reported ADR on usage of bronchodilators for COPD and bronchial asthma. Of these cases, six were female and four were male.

The adverse effects reported were entered into a Performa and CDSCO ADR reporting form. On doing the WHO causality assessment scale, all the above drugs suspected of causing ADR were subjected to de-challenge and the suspected ADR did not occur. Hence, the scale was probable or possible in relation to the causality assessment.

Since the study was of 2 months duration and as re-challenge was not possible, we were not able to make a definite association between the suspected ADR and the causative drug. However, on choosing an alternate drug therapy for the patients, the ADR that was reported with the previous drug did not occur with the alternate drugs.

Patients who were given prophylactic leukotriene antagonist such as Montelukast did not report any ADR with Montelukast.

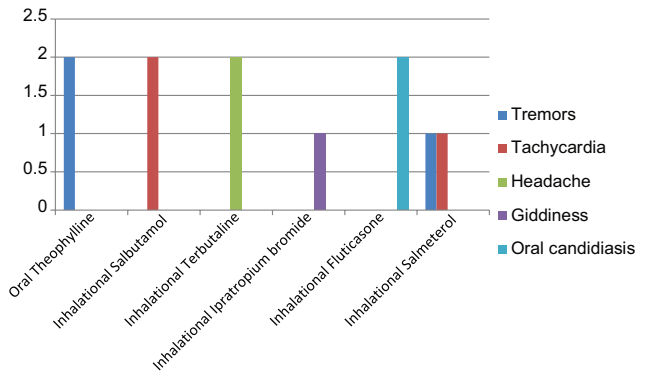
DISCUSSION

In our study, the common adverse drug reactions that were reported were tremors, giddiness, tachycardia, and headache. In a study

Table 1: ADRs reported and the suspected

S. no	Drug name	Suspected ADR	No. of cases	Alternate therapy that was devoid of ADR
1.	Oral theophylline	Tremors	2	Doxyphylline
2.	Inhalational salbutamol	Tachycardia	2	Formoterol
3.	Inhalational terbutaline	Headache	2	Levosalbutamol
4.	Inhalational ipratropium bromide	Giddiness	1	Tiotropium bromide
5.	Corticosteroids- inhalational Fluticasone	Oral candidiasis	2	Inhalational Budesonide
6.	Inhalational salmeterol	Tachycardia, tremor	1	Formoterol

ADR: Adverse drug reaction



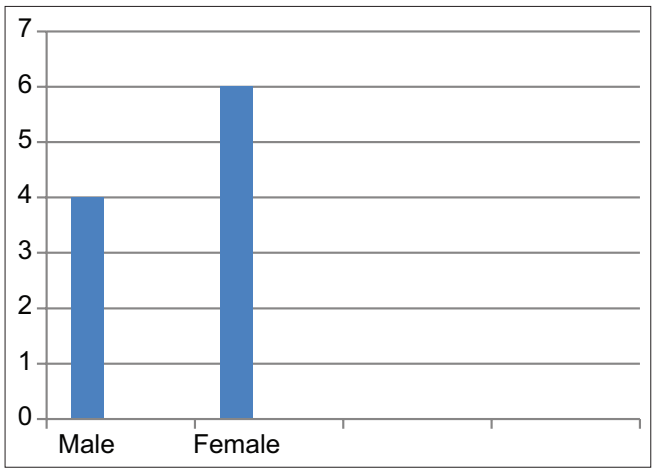


Fig. 1: Gender distribution

done by Morley, there were similar adverse effects such as tremors and tachycardia on usage with short acting beta-2 agonists such as salbutamol and terbutaline [3]. Oral candidiasis on usage with inhalational fluticasone was reported by a patient in our study and this was similar to a study done by Gonneli *et al.* [4] and Casale *et al.* [5].

Budesonide is a better inhalational corticosteroid with lesser adverse effects compared to fluticasone and this was evident according to a study done by Rohatagi *et al.* [6]. In a study done by Voss *et al.*, the adverse effects were lesser seen with longer acting beta-2 agonists such as salmeterol and formoterol [7]. However, in our study, we were able to say that among the longer acting beta-2 agonists, formoterol was well tolerated by the patient. It is also supported by a study done by Cazzola *et al.* who showed inhalational formoterol as a better option for long-term treatment for COPD [8]

Montelukast was a well-tolerated drug and did not produce any adverse effect.

CONCLUSION

In our study, a total of ten adverse effects were reported for bronchodilators on patients with bronchial asthma or COPD with a female:male ratio of 6:4. Tremors and tachycardia were common with short acting beta-2 agonist like salbutamol and terbutaline. These adverse effects were not seen on usage of long acting beta-2 agonists such as formetorol. Inhalational forms of longer acting beta-2 agonists were better compliable to the patients with no observable adverse effects. Inhalational budesonide did not have adverse effect compared to fluticasone.

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AUTHOR'S CONTRIBUTION

All the authors contributed equally for this study.

CONFLICT OF INTEREST

The authors declared that there is no conflict of interest related to this study.

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