Original Research Article

Evaluation of Outpatient Pharmacological Treatment Choices in Chronic Obstructive Pulmonary Disease in Primary Care Practice

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Abstract: Primary care physicians provide treatment to the majority of patients of COPD in India. Worldwide significant gaps exist between recommendations and actual COPD management in primary care practice. In India there is paucity of data about the outpatient treatment and practice patterns in COPD management in primary care. The aim is to evaluate the outpatient pharmacological treatment choices in primary care practice in management of COPD. We studied the prescriptions details of the already diagnosed and on treatment COPD patients of more than 40 years of age in out patient department. The inhaler devices, inhaled medications, oral medications were physically verified by the authors. The results were tabulated and analyzed on percentage scale. Study included 4287 patients of COPD. 29.5% patients were on inhaled medication and majority 70.5% were on oral medications. 35.8% were prescribed inhaled SABA and ICS combination, 25.9 % LABA and ICS combination, 7.8% SABA and SAAC, 4.1% triple inhaler with ciclesonide, tiotropium and formoterol, 13.5% SABA and 11.3% were prescribed ICS. Among oral medications methylxanthines were prescribed to 30.5%, a combination of oral β-agonists and methylxanthines to 19.8%, oral β-agonists to 15.2%, leukotriene modifiers to 3.6%, steroids to 6.9% and 24.1% were on multiple drugs. Our study concludes that the COPD management in primary care is extremely sub optimal as majority of the patients are being prescribed oral medications instead of inhaled medications and the choices of inhaled medications are also not according to the guidelines.
Keywords: COPD, Evaluation, Outpatient, Primary Care, Treatment choice.

INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is 4th largest cause of death in the world killing more than 3 million people every year [1] and will become the third biggest cause of death by the year 2030. Half a million people die every year due to COPD in India, which is over 4 times the number of people who die due to COPD in USA and Europe [1]. COPD is now regarded as a preventable and treatable disease with greater focus on early diagnosis and appropriate treatment which may prevent and improve symptoms, reduce the rate and severity of exacerbations, improve quality of life, improve exercise capacity and physical activity and prolong survival [1]

Primary care physicians provide treatment to the majority of patients of COPD in India. Worldwide significant gaps exist between recommendations and actual COPD management in primary care practice [2-5] Inspite of international and national clinical practice guidelines for management COPD, their influence on primary care practice is unclear [2]. In India little is known about the outpatient pharmacological treatment and practice patterns in COPD management in primary care.

Aims and Objectives:

The present study was designed to evaluate the outpatient pharmacological treatment choices in primary care practice in management of COPD.

MATERIALS AND METHODS

To investigate the outpatient pharmacological treatment choices in primary care practice in COPD management, we studied the prescriptions details of the already diagnosed and on treatment COPD patients in out patient department. Verbal informed consent was taken from all the patients. Patients more than 40 years of age were included in the study. The inhaler devices, inhaled medications, oral medications were physically verified by the authors. Those patients who did not carry prescriptions or medications with them, they were asked to bring the devices and medications on next visit. Those who failed to bring the inhaler devices or medications were not included in the study. Prescriptions details of a total number of 4287 COPD patients were evaluated and analyzed. The results were tabulated and analyzed on percentage scale.

RESULTS

Study included 4287 patients of COPD already on treatment in primary care practice. Results are shown in tables below.

Table: 1. Prevalence of Use of Inhaler and Oral Medication in COPD Patients.

Number of COPD patients evaluated	4287
Prevalence of inhaler use in COPD patients.	29.5 (1263)
Prevalence of use of oral medications in COPD patients.	70.5 (3024)

Table: 2. Outpatient Pharmacological Treatment Choices and Inhaler Devices in Management of COPD Patients.

Inhaler Medication		Inhaler Devices			
		DPI	**pMDI**	**pMDI Spacers**	**Nebulizers**
		57.1(721)	28.3 (358)	11.5 (145)	3.1 (39)
SABA	13.5 (171)	16.1 (116)	12.8 (46)	6.2 (9)	0.00(0)
LABA	0 (0)	0.00 (0)	0.00 (0)	0.00 (0)	0.00(0)
SAAC	0(0)	0.00 (0)	0.00 (0)	0.00 (0)	0.00(0)
LAAC	0(0)	0.00 (0)	0.00(0)	0.00(0)	0.00
ICS	11.3 (143)	5.4 (39)	19.3 (69)	17.9 (26)	23.1 (9)
SABA/SAAC	7.8 (98)	6.2 (45)	5.6 (20)	7.6 (11)	56.4 (22)
LAAC/ICS	1.6 (20)	0.00 (0)	3.4 (12)	5.5 (8)	0.00(0)
SABA/ICS	35.8 (452)	50.2 (362)	16.2 (58)	16.6 (24)	20.5 (8)
LABA/ICS	25.9 (328)	20.7 (149)	35.2 (126)	36.6 (53)	0.00(0)
LABA/LAAC/ICS	4.1 (51)	1.4 (10)	7.5(27)	9.6 (14)	0.00(0)

SAAC: short-acting anticholinergic; LAAC: long-acting anticholinergic; SABA: short-acting B2-adrenergic receptor agonist; LABA: long-acting B2-adrenergic receptor agonist; ICS: inhaled corticosteroid.

Table-3. Outpatient Pharmacological Treatment Choices of Oral Medication in Management of COPD Patients.

Drugs	B Agonists	B Agonists + Methylxanthines	Methylxanthines	Steroids	Leukotriene	Multiple drugs
Total; 3024	15.2(459)	19.8 (601)	30.5 (921)	6.9(209)	3.6 (108)	24.1(726)

DISCUSSION

Across guidelines, inhaled medications are the primary therapy used to treat COPD [2] and inhaled drugs are preferred to oral preparations [2] Oral therapy is slower in onset and has more side effects than inhaled treatment. Contrary to the recommendations for treatment of COPD, in our study only 29.5% (1263/4287) patients were on inhaled medication and majority 70.5% (3024/4287) were on oral medications. Literature is less clear about the choices of delivery device, particularly in view of ever increasing number and types of devices along with paucity of RCTs directly comparing the efficacy and safety of different inhaler devices in COPD patients. A systematic review comparing the efficacy and safety of drugs administered with different inhaler devices concluded that at the drug

doses used, no significant differences between devices could be found for any of the efficacy outcomes [2].

Results of our study show that 57.1% (721/1263) patients used dry powder inhalers (DPIs), 28.3% (358/1263) used pressurized Metered Dose Inhaler (pMDI), 11.5% (145/1263) used pMDI with spacer devices and 3.1% (39/1263) used nebulizers for treatment of COPD in primary care practice. More number of patients using DPIs in our study is in line with the published data and guidelines which state that DPIs may be more convenient and possibly provide improved drug deposition, although this has not been established in COPD [9] In our study only 3.1% (39/1263) patients were using nebulizers. In general, nebulized therapy for stable patients is not appropriate unless it has been shown to be better than conventional dose therapy [2].

Bronchodilator medication is central to the symptomatic management of COPD [2] and is prescribed on an as needed or regular basis to prevent or to reduce symptoms. Long -acting B2-adrenergic receptor agonist (LABA) are more effective and convenient than Short-acting B2-adrenergic receptor agonist (SABA). Combination of LABA and inhaled corticosteroid (ICS) is preferred therapy as it can decrease the rate of decline in lung function [9] Combining LABA and ICS in one inhaler seems a convenient way of delivering treatment [2] More over combination therapy as compared with its components showed a significant additional effect on pulmonary function and a reduction in symptoms [2]. In contradiction with the published data and guidelines suggesting LABA+ ICS as preferred combination, in our study SABA and ICS combination was most frequently (35.8%) prescribed inhaled medication to COPD patients, where as only 25.9 % patients were prescribed a combination was LABA and ICS. SABA was prescribed to 13.5% and ICS to 11.3% of COPD patients. A greater change in spirometry over 3 months was observed with combination of SABA and short-acting anticholinergic (SAAC) than with either agent alone [2]. In our study this combination was prescribed to only 7.8% of COPD patients. A triple inhaler is available in India with once daily ciclesonide, tiotropium and formoterol, something the developed world needs but isn't currently available to them. In our study this triple drug inhaler was used only by 4.1% (51/1263) patients.

Contrary to the published data and guidelines 70.5% (3024/4287) of the patients in our study were on oral medications instead of inhaled medications. In our study methylxanthines were prescribed to 30.5% (921/3024) patients, a combination of oral β-agonists and methylxanthines to 19.8% (601/3024), oral β-agonists to 15.2% (459/3024) and multiple drugs were prescribed to 24.1% (726/3024) patients. GOLD guidelines state that leukotriene modifiers have not been adequately tested in COPD patients and can not be recommended, but in our study 3.6% (108/3024) patients were prescribed leukotriene modifiers. Long term treatment with oral glucocorticosteroids is not recommended in COPD because of lack of evidence of benefit and increased side effects9, but in our study 6.9% (209/3024) patients of COPD were on steroids.

Limitation of our study is the failure to analyze the data in relation to sex, education, rural or urban, smoker or non smokers and also to correlate the treatment choices and frequency of inhaler use to stages of COPD. Whether patients using nebulisation are stable COPD patients or patients where inhalers can't be used and oral medications are having side effects. Another important limitation is failure to explore the patient or the doctor factors for increased use of oral medications instead of inhaler medications.

CONCLUSIONS

This study presents a snapshot of outpatient pharmacological treatment choices in management of COPD in Primary Care Practice. Our study concludes that the COPD management in primary care is extremely sub optimal as majority of the patients are being prescribed oral medications instead of inhaled medications. The present study also exposes deficiencies in prescription choices of inhaled medications which are not according to the guidelines. The landmark GOLD guidelines and other national or international guidelines for management of COPD are not being followed causing discrepancies relating to COPD management in primary care pointing to important knowledge gaps. We suggest that extensive surveys should be carried out to audit the prescription in primary care practice to explore the COPD management patterns in an effort to improve COPD care in primary care.

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