To Study the Gap between Guidelines and Clinical Practice and Barriers to Asthma Management in Primary Care Practice

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Abstract: Asthma causes significant morbidity and mortality in India where its prevalence is about 2%. Generally primary care physicians are responsible for management of asthma and this study aims to document the gap between guidelines and clinical practice. OPD patients of stable asthma were audited prospectively for diagnostic criteria, treatment profile and status of control, inhaler techniques and barriers to adequate control. Results were analyzed on percentage scale. 114 (44.7% males & 55.3% females) stable asthma patients completed the study. Asthma was diagnosed clinically in 74.6% patients, by peak flow meter in 17.5% and 7.9% by spirometry. 71.9% patients used oral medications, 26.3% inhalers and 1.8% used nebulizers. 22.8% patients were having adequate control and 77.2% had inadequate control of asthma. 27.2% patients were taking oral B-agonists, 34.2% methylxanthines and 10.5% were on combination of oral B-agonists and methylxanthines. Patients on inhalers included 6.1% on SABA inhaler, 3.5% on ICS, and 10.5% on ICS-SABA combination, 7.0% on ICS-LABA and 0.9% patient was on ICS-LABA-LAMA combination. Among the causes for inadequate control of asthma insufficient dose was the cause among 60.5% patients, irregular dose 57.0%, unacceptability of inhalers 27.2%, did not know about inhalers 30.7% and faulty inhaler technique was the cause in 16.7% patients. There is a wide gap between the guidelines and actual clinical practice in management of stable asthma and we recommend larger studies also exploring the barriers to management of stable asthma according to the guidelines.
Keywords: Bronchial Asthma, B-agonists, ICS-LABA.

INTRODUCTION

Bronchial asthma is one of the most common chronic diseases worldwide with prevalence ranging from 1-18% in different populations with estimated global prevalence of 4.5% and prevalence of asthma in India is estimated to be least 2%[1,2]. It is an important public health problem in India with significant morbidity. Asthma is defined as a chronic inflammatory disorder of the airways which manifests itself as recurrent episodes of wheezing, breathlessness, chest tightness and cough. It is characterized by bronchial hyper responsiveness and variable airflow obstruction, that is often reversible either spontaneously or with treatment [1]. The diagnosis of asthma remains largely clinical due to the absence of a gold standard. A clinical diagnosis of asthma should be suspected in the presence of recurrent/episodic wheezing, breathlessness, cough, and/or chest tightness with no alternative explanation for these symptoms. For confirming diagnosis, assessing severity of airflow limitation and monitoring asthma control, wherever available, spirometry is recommended for all suspected patients. A normal spirometry does not rule out asthma [1]. Peak expiratory flow (PEF) measurements further aid in the diagnosis and monitoring of asthma [4]. Chest radiograph is not routinely recommended for patients suspected to have asthma, but may be considered when alternate diagnosis or complication of asthma is

suspected. Optimal control of asthma is considered when the patient has no night time or diurnal symptoms, has no hospitalizations, and can do daily activities, including exercise [1] Generally primary care physicians are responsible for management of asthma and this study aims to document the gap between guidelines and clinical practice because much of the morbidity associated with asthma is thought to arise from lack of use of the evidence based asthma guidelines and inadequate preventive medicine.

MATERIALS AND METHODS

Prescriptions of all patients of stable asthma attending the OPD were studied and a perform was filled for criteria used for diagnosis of asthma, treatment being given oral or inhalers, type of inhalers being used, assessment of inhaler technique to identify errors in inhaler techniques, factors to determine the status of control of asthma and those with inadequate control of asthma barriers to adequate control were documented in the performa. Asthma control was classified as adequate or inadequate based on day time symptoms (or rescue medication use), night time symptoms/ awakening, limitation of activities and pulmonary function (PEF, FEV1%) as described in the Table below [1].

Level of current asthma control (over the preceding 4 weeks)		
Components	Adequately controlled (All 4 need to be present)	Inadequately controlled (any one)
Day time symptoms or rescue medication use	Twice or less in a week	More than twice a week
Night time symptoms/ awakening	None	Any
Limitation of activities	None	Any
Pulmonary function (PEF, FEV1%)	Normal (FEV1% >80% predicted, PEF >80% personal best*)	Decreased (FEV1% <80% predicted, PEF <80% personal best*)
when personal best is not known PEF <80% of the predicted can be used, FEV1: Forced expiratory volume in the first second, PEF: Peak expiratory flow		

Patients with respiratory tract infection or significant asthma exacerbation and use of systemic steroids in past 4 weeks, serious medical illnesses, tuberculosis and other lung diseases, smoking and pregnancy were excluded from the study. Results were analyzed on percentage scale.

RESULTS

114 (44.7% males & 55.3% females) stable asthma patients completed the study. Asthma was diagnosed clinically in 74.6% patients, by peak flow meter in 17.5% and 7.9% by spirometry. 71.9% patients used oral medications, 26.3% inhalers and 1.8% used nebulizers. 22.8% patients were having adequate control and 77.2% had inadequate control of asthma. 27.2% patients were taking oral B-agonists, 34.2% methylxanthines and 10.5% were on combination of oral B-agonists and methylxanthines. Patients on inhalers included 6.1% on SABA inhaler, 3.5% on ICS, and 10.5% on ICS-SABA combination, 7.0% on ICS-LABA and 0.9% patient was on ICS-LABA-LAMA combination. Among the causes for inadequate control of asthma insufficient dose was the cause among 60.5% patients, irregular dose 57.0%, unacceptability of inhalers 27.2%, did not know about inhalers 30.7% and faulty inhaler technique was the cause in 16.7% patients. Results are shown in tables below.

Table-1: Characteristics of stable asthma patients regarding criteria for diagnosis, treatment and status of control. %(n)

Gender	Diagnosis			Treatment			Status of Control	
	Clinical	PEFR	PFT	Oral	Inhalers	Nebulizer	Adequate	Inadequate
Male 44.7(51)	34.1(39)	5.3(6)	5.3(6)	28.9(33)	14.9(17)	0.9(1)	14.0(16)	30.7(35)
Female55.3(63)	40.5(46)	12.2(14)	2.6(3)	43.0(49)	11.4(13)	0.9(1)	8.8(10)	46.5(53)
Total 114	74.6(85)	17.5(20)	7.9(9)	71.9(82)	26.3(30)	1.8(2)	22.8(26)	77.2(88)
PEFR: Peak expiratory flow rate. PFT: Pulmonary function test.								

Table-2: Treatment profile of stable asthma patients. % (n)

Gender	Oral Medications n-82			Inhalers and nebulizer n-32						
	B-Agonists	Xanthines	Combination of B-agonists and Xanthines	SABA	SAMA	LABA	ICS	ICS-SABA	ICS-LABA	ICS-LABA-LAMA
Males 44.7(51)	11.4(13)	14.0(16)	3.5(4)	1.8(2)	0.0(0)	0.0(0)	1.8(2)	7.0(8)	4.4(5)	0.8(1)
Females 55.3(63)	15.8(18)	20.2(23)	7.0(8)	4.4(5)	0.0(0)	0.0(0)	1.8(2)	3.5(4)	2.6(3)	0.0(0)
Total 144	27.2(31)	34.2(39)	10.5(12)	6.2(7)	0.0(0)	0.0(0)	3.6(4)	10.5(12)	7.0(8)	0.8(1)

SAMA-Short acting b-agonist, SAMA-Short acting muscarinic agonists, LABA- Long acting b-agonists, ICS- Inhaled corticosteroids, LAMA- Long acting muscarinic agonists.

Table-3: Treatment profile of asthma patients with adequate and inadequate control of asthma % (n)

Control	Oral 71.9 (82)				Inhalers and nebulizer 28.1(32)							
	Total	B-Agonists	Xanthines	Combination B-agonists and Xanthines	Total	SABA	SAMA	LABA	ICS	ICS-SABA	ICS-LABA	ICS-LABA-LAMA
Adequate 22.7(26)	13.2(15)	1.8(2)	7.9(9)	3.5(4)	9.5(11)	0.0(0)	0.0(0)	0.0(0)	1.7(2)	3.5(4)	3.5(4)	0.8(1)
Inadequate 77.3(88)	58.7(67)	25.4(29)	26.3(30)	7.0(8)	18.6(21)	6.3(7)	0.0(0)	0.0(0)	1.8(2)	7.0(8)	3.5(4)	0.0(0)
Total n-114	71.9(82)	27.2(31)	34.2(39)	10.5(12)	28.1(32)	6.3(7)	0.0(0)	0.0(0)	3.5(4)	10.5(12)	7.0(8)	0.8(1)

SAMA-Short acting b-agonist, SAMA-Short acting muscarinic agonists, LABA- Long acting b-agonists, ICS- Inhaled corticosteroids, LAMA- Long acting muscarinic agonists.

Table- 4: Type of inhalers used and errors in inhaler techniques among adequate and inadequate control of asthma patients. % (n)

Control	Type of Inhalers					
		Total	DPI	MDI	MDI Spacer	Nebulizer
Adequate 22.7(26)	Good technique	7.0(8)	5.3(6)	0.9(1)	0.9(1)	0.0(0)
	Error in technique	2.6(3)	1.7(2)	0.9(1)	0.0(0)	0.0(0)
Inadequate 77.3(88)	Good technique	6.1(7)	3.5(4)	1.8(2)	0.9(1)	0.9(1)
	Error in technique	12.3(14)	6.1(7)	4.3(5)	0.8(1)	0
Total n-114		28.0(32)	16.6(19)	7.9(9)	2.6(3)	0.9(1)

DPI-Dry powder inhaler, MDI- Meter dose inhaler,

DISCUSSION

Several international guidelines for diagnosis and management of asthma are available like the Global Initiative for Asthma (GINA), British Thoracic Society (BTS) and National Asthma Education and Prevention Program of the National Heart, Lung, and Blood Institute and India specific guidelines are endorsed by the Indian Chest Society (ICS) and the National College of Chest Physicians (NCCP) of India with an aim to assist physicians at all levels of healthcare in diagnosis and management of asthma in a scientific manner. Guidelines suggest that wherever available, spirometry is recommended for all patients suspected to have asthma for confirming diagnosis, assessing severity of airflow limitation and monitoring asthma control. But in our study asthma was diagnosed clinically in 74.6% patients, by peak flow meter in 17.5% and only 7.9% patients under went spirometry for diagnosis of asthma exposing gross discrepancy in practice and guidelines in primary health care. Almost similar results were observed in a study where objective confirmation of asthma by spirometry was don e in only 10% of patients [6]. Despite suggested by guidelines and the evidence in favor of spirometry, it is grossly underused in primary care practice. In a Canadian study, only 42.7% of 465,866 patients with newly diagnosed asthma had any spirometry testing performed within 1 year before or 2.5 years after the diagnosis [7]. Similarly, in a study from US, only 47.6% of 134,208 patients had spirometry performed within 1 year of diagnosis [8]. Interestingly, this study found that the use of spirometry actually decreased after publication of

guidelines from the National Asthma Education and Prevention Program [9] that recommended spirometry. Various guidelines suggest inhaler medication is preferred over oral medications but in our study majority of patients (71.9%) were on oral medications and 26.3% were on inhalers and 1.8% used nebulizers which is contrary to recommendations. Guidelines suggest that methylxanthine monotherapy is inferior to ICS monotherapy and oral beta agonists should not be used as rescue medications, but in our study, 27.2% patients were taking oral B-agonists and 44.7% were on methylxanthines. ICSs are the controller medication of choice for management of stable asthma and LABA monotherapy should not be used, whereas addition of LABA to ICS is the preferred choice when symptoms are uncontrolled despite ICS. Tiotropium may be used as add on therapy if asthma remains uncontrolled despite ICS and LABA combination therapy [1]. In our study 6.1% patients were on SABA inhaler, 3.5% on ICS, 10.5% on ICS-SABA combination, 7.0% on ICS-LABA and 0.9% patient was on ICS-LABA-LAMA combination. Results of our study show that majority of patients were not being treated according to guideline recommendations in primary care practice. In a study, Marcus and colleagues showed that 81.9% of patients had uncontrolled asthma in pulmonary clinics [10]. In another study 58% of patients who visited their primary care clinics for various reasons had uncontrolled asthma [11]. Results of a study documented that 64%, 31%, and 5% of patients had uncontrolled, well-controlled, and fully controlled asthma [12]. Results of our study show that 22.8% patients were adequate control and 77.2% had inadequate control of asthma. Knowing the factors that hinder asthma control will help in the management of asthma and improve the quality of health care and probable reasons for inadequate control of asthma in our study included insufficient dose in 60.5% patients, irregular dose 57.0%, unacceptability of inhalers 27.2%, ignorance about inhalers 30.7% and faulty inhaler technique was the cause in 16.7% patients. All the factors documented in our study can be improved with education and motivation of the patients and making the primary care physicians about the guideline recommendations.

CONCLUSION

Results of our study show that a wide gap exists between the guidelines and actual clinical practice in management of stable asthma. The present study confirmed the high prevalence of inadequately controlled asthma in primary care outpatient setting and identified factors that can contribute to inadequate asthma control. All the factors documented can be improved with education and motivation of the patients and making the primary care physicians aware about the guideline recommendations. We recommend larger studies exploring the barriers to management of stable asthma according to the guidelines and education and motivation programmers are initiated for asthma patients as well as primary care physicians.

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