Original Research Article

An observational study to assess reasons for lack of control among patients of bronchial asthma attending a tertiary care centre in India

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ABSTRACT

Background: Bronchial asthma is a common chronic respiratory ailment affecting both children and adults. Lack of control among asthmatics leads to adverse outcomes and increased health care costs. Studies from India evaluating level of control and reasons for inadequate control are lacking. Objective was to assess level of control and reasons for partly/poorly controlled asthma.
Methods: Consecutive patients of bronchial asthma (>8 weeks on treatment) presenting to a tertiary care centre and consenting for participation in the study were enrolled. Control was assessed used global initiative for asthma (GINA) guidelines and patients categorised into poor, partly or well control.[1] Enrolled patients were assessed by a questionnaire to record their demographic details including body mass index (BMI), duration of disease, smoking status, environmental smoke exposure/biomass fuel exposure, adherence to therapy, technique of inhaled medication and anxiety/depression, co morbidities including allergic rhinitis, gastro-oesophageal reflux (GER) symptoms, obstructive sleep apnoea (OSA) and allergic bronchopulmonary aspergillosis were also assessed.
Results: 150 consecutive patients, 58% females and 42% males with mean age of 40.03±14.77 years were enrolled. 19.3% of patients were well controlled while 50.7% were poorly and 30% were partly controlled. On comparing well controlled versus uncontrolled asthma (poor and partly controlled) adherence, device technique of inhaled medication, depression scores and eosinophilia showed a significant association. On application of logistic regression model, depression scores, inhaler adherence and device technique were associated with level of control.
Conclusions: Asthma is partly/poorly controlled in majority of asthmatics. Psychiatric co-morbidities, adherence to therapy and correct device technique are major reasons for partly/poorly controlled asthma. Addressing these modifiable factors can improve level of control among asthmatics.

Keywords: Adherence, Bronchial asthma, Depression, Level of control, Device technique of inhalational medication

INTRODUCTION

Bronchial asthma is a chronic respiratory ailment leading to substantial morbidity and mortality worldwide. World over it affected an estimated 262 million people in 2019, caused 461000 deaths and remains most common chronic disease among children.[1] It is a major public health problem which impacts quality of life of both patients, caregivers and also poses a substantial financial burden .Its management suffers from both under diagnosis and under-treatment especially in developing countries where sheer numbers pose formidable challenge.

Assessment of control is an integral part of asthma management and aids in titrating treatment. It is recommended at each patient visit, to decide up or down

titration of treatment. Various tools can be used to evaluate level of control among asthmatics. Asthma control test, asthma control questionnaire and global initiative for asthma (GINA) guidelines have been used to assess level of control in various studies.[1] An uncontrolled asthmatic suffers from poor quality of life, more loss of work days and higher risk of adverse events in disease course. Lack of control increases disease related burden both for patients and their caregivers.

Studies in Indian adults regarding level of control have been far and few. Moreover reasons for suboptimal control are also under evaluated. There are limited studies from India which have evaluated individual factors like gastro-oesophageal reflux, obesity, inhaled device technique and vitamin D levels with level of control.

Through this study, we have attempted to assess control among asthmatics attending a chest clinic at a tertiary care centre and evaluate various modifiable and non-modifiable factors, which could affect control.

METHODS

In this prospective observational study, consecutive patients of Bronchial asthma presenting to Outpatient department at a tertiary care centre and consenting for participation in the study were enrolled from January 2017-December 2018. The study is in accordance with ethical standards of Helsinki Declaration of 1975 as revised in 2000 and was approved by institutional ethics board (via letter no. IEC/IM/116/RC53). Inclusion criteria included age >18 years and on treatment for at least >8 weeks. Patients in acute exacerbation, uncontrolled diabetes mellitus, chronic renal failure, chronic liver disease, congestive heart failure, pregnant/lactating females and unable to perform spirometry were excluded from the study. Enrolled patients were assessed by a questionnaire to record their demographic details including body mass index (BMI), duration of disease, smoking status, environmental smoke exposure/biomass fuel exposure, adherence to therapy, device technique of inhaled medication and anxiety/depression by hospital anxiety (HADS A)/depression scale (HADS D).[2] Co morbidities including allergic rhinitis (AR), gastro-oesophageal reflux (GER) symptoms, obstructive sleep apnoea (OSA) and allergic bronchopulmonary aspergillosis (ABPA) were assessed. Allergic rhinitis was diagnosed on basis of symptoms or evaluation by an experienced ear, nose and throat (ENT) specialist, gastro-oesophageal reflux by presence of symptoms or intake of medications and OSA screening was done by STOP-BANG questionnaire.[3] Adherence to medication was defined as intake of 80% of prescribed doses while experienced doctor assessed device technique of inhaled medication by direct demonstration. Spirometry was performed by ATS/ERS compliant spirometer in all patients and forced expiratory volume in 1 second was recorded. Control was assessed used a simple 4 point tool proposed by GINA guidelines which includes daytime symptoms, restriction of daily activities, night time symptoms , need for reliever/rescuer medication in preceding 4 weeks .Based on this tool patients are categorised into poor, partly or well control. If there were no daytime/night time symptoms, no restriction of activity and no need of reliever medication, patient was categorized as well controlled. If anyone was present, patient was categorized as partly controlled and if ≥2 are present patient was categorized as poorly controlled.

Statistical analysis

All statistical analyses of the data were performed using the statistical package for the social sciences (SPSS) program V.22.0 (SPSS, Chicago, Illinois, USA). In descriptive statistics continuous variables were represented means±standard deviations (SDs), median (IQR) and categorical variables were represented as percentages as necessary. Statistical comparison was done using student's t-test for continuous variables and by χ^2 tests and Fisher exact test where appropriate. Binary logistic regression was applied for the variables with significant p value to obtain independent association of variables with outcome. For all applied statistical tests, a p value <0.05 was considered statistically significant.

RESULTS

150 consecutive consenting patients were enrolled. Females outnumbered males (58% females and 42% males) and mean age of patients was 40.03±14.77 years (Table 1). Among co-morbidities allergic rhinitis was present in 67.3%, GER symptoms in 54%, symptoms of OSA in 19.3% while mean BMI was 23.72±4.72 and ABPA was present in 2% (Table 1).

Majority were non-smokers while 45.3% had environmental or bio-mass fuel exposure.48% were adherent to their medication. Device technique of inhaled medication was incorrect in one or more steps in 57.3% patients. Eosinophilia (eosinophils >500 cells/mm^3) was present in 32% of patients (Table 2).

On assessment of control by GINA guidelines 19.3% of patients were well controlled while 50.7% were poorly and 30% were partly controlled. When well controlled versus uncontrolled asthma (poor and partly controlled) was compared with categorical variables adherence, device technique of inhaled medication, eosinophilia (>500 cells/mm^3) and depression scores showed a significant association (Table 3).

Among continuous variables age, duration of disease, BMI and FEV1 (pre-bronchodilator) showed no significant association (Table 4).

On logistic regression model application, depression scores along with adherence and inhaler device technique were associated with level of control (Table 5).

Table 1: Characteristics of study population.

Categorical variables	Frequency	%
Sex		
Female	87	58
Male	63	42
Allergic rhinitis		
Yes	101	67.3
No	49	32.7
GER symptoms		
Yes	81	54
No	68	45.3
Smoker		
Non	128	85.3
Current	8	5.3
Ex-smoker	14	9.3
ETS/BMF exposure		
Yes	68	45.3
No	82	54.7
***OSA**		
Yes	29	19.3
No	121	80.7
Adherence		
Yes	72	48
No	78	52
Inhaler technique		
Adequate	53	35.3
Inadequate	86	57.3
Not prescribed	11	7.3
Eosinophils		
<500	102	68
>500	48	32
BMI		
Under weight	20	13.3
Normal	47	31.3
Over weight	27	18
Pre obese	40	26.7
Obese	16	10.7

*OSA–by STOP BANG questionnaire

Table 2: Association of categorical variables with outcome.

Categorical variables	Outcome		Chi^2 value	P value
	Well controlled (n=29)	Uncontrolled* (n=121)		
Sex (%)				
Female	13 (14.9)	74 (85.1)	2.561	0.083
Male	16 (25.4)	47 (74.6)		
Allergic rhinitis (%)				
Yes	17 (16.8)	84 (83.2)	1.241	0.185
No	12 (24.5)	37 (75.5)		
GER symptoms (%)				
Yes	11 (13.6)	70 (86.4)	3.737	0.053
No	18 (26.1)	51 (73.9)		
Smoking history (%)				
Yes	5 (22.8)	17 (77.2)	0.19	0.66
No	24 (18.8)	104 (81.2)		

Continued.

Categorical variables	Outcome		Chi² value	P value
	Well controlled (n=29)	Uncontrolled* (n=121)		
ETS/BMF (%)				
Yes	14 (20.6)	54 (79.4)	0.126	0.723
No	15 (18.3)	67 (81.7)		
OSA (%)				
Yes	3 (10.3)	26 (89.7)	1.86	0.133
No	26 (21.5)	95 (78.5)		
Adherence (%)				
Yes	25 (34.7)	47 (65.3)		<0.001^
No	4 (5.1)	74 (94.9)		
Inhaler technique (%)				
Adequate	23 (43.4)	30 (56.6)	30.42	<0.001
Inadequate	6 (18.26)	91 (81.8)		
Eosinophil count				
<500	25 (24.5)	77 (75.5)		0.02
>500	4 (8.3)	44 (91.7)		
BMI				
Under weight	2 (10)	18 (90)		
Normal	9 (19.1)	38 (80.9)		
Over weight	6 (22.2)	21 (77.8)	2.565	0.633
Pre-Obese	10 (25)	30 (75)		
Obese	2 (12.5)	14 (87.5)		
HADS (D)				
<8	24 (24.5)	74 (75.5)	4.82	0.03
>8	5 (9.7)	47 (90.3)		
HADS (A)				
<8	29 (26.3)	86 (74.7)		
>8	0	35 (100)		

*Partly and poorly controlled asthmatics as per GINA guidelines; ^Fisher exact test

Table 3: Association of continuous variables with outcome (independent t test).

Continuous variables	Outcome		P value
	Well controlled (29)	Uncontrolled* (121)	
Age	40.66±15.43	39.88±14.66	0.802
Age at onset	33.76±14.94	30.66±15.41	0.330
Duration (years)	4 (3-7)	5 (3-12)	0.284
FEV1 pre	77.55±27.5	68.07±22.5	0.054

* Uncontrolled is poor and partly controlled, **median (IQR) and Mann Whittney U test used

Table 4: Logistic regression for independent association of variables with outcomes.

Variable	OR (95% CI)	AOR (95% CI)	P value
No depression	3.04 (1.08-8.54)	3.57 (1.06-12.02)	0.04
Adherence	9.84 (3.22-30.06)	7.15 (2.09-24.45)	0.002
Adequate inhaler technique	11.62 (4.35-31.23)	8.51 (2.90-24.96)	<0.001
Eosinophil count >500	0.28 (0.07-0.81)	0.33 (0.09- 1.22)	0.07

On applying binary logistic regression, it was found that having no depression (3.57), compliance with treatment (7.15), adequate inhaler technique (8.51) were affecting outcome independently with a p value <0.05

DISCUSSION

Bronchial asthma is a common chronic respiratory ailment affecting all age groups. Prevalence of asthma in India has been reported to be 2.05% among adults aged ≥15 years using questionnaire based approach.[4] Management of asthma necessitates assessment of control at each patient visit to decide titration of medication. Level of control among asthmatics affects quality of life, risk of adverse events like exacerbations, hospitalizations, death and economic burden of disease.[5]

Varied tools have been used for assessment of control in asthmatics. The asthma control test (ACT) and GINA guidelines (daytime symptoms, restriction of daily activities, night time symptoms and need for reliever/rescuer medication) are the most commonly used tools with studies demonstrating equivalence between the two.[1,6] In this study we have used GINA guidelines proposed tool for assessment and categorization of patients into well, partly and poor control. Ease of application of this 4 point scale in busy outpatient departments and equivalence with ACT is the reason for its use for control assessment.

There have been reports from various countries regarding level of control among asthmatics and control has varied from 50% in Spain to 34.6% in Algeria and 30.1% in Saudi Arabia.[7-9] Suboptimal control has also been reported from other European countries.[10] A multicentre study conducted in Asia-Pacific countries among 3630 asthmatic patients >12 years, using GINA guidelines as tool for control assessment, found only 7.6% of patients with well control with lowest levels in India (0%) and China (2%).[11] In our study 19.3% of patients were well controlled while 50.7% were poorly and 30% were partly controlled. A higher proportion of well controlled patients in our study can be possibly because of our study being a hospital based study.

Various factors have been reported to be associated with level of control among asthmatics. Association of control among asthmatics has been reported with age, sex with difference in perception also being reported, duration of disease, pet exposure, educational level, co-morbidities like allergic rhinitis, GERD, OSA, smoking status or smoke exposure with variable and sometimes conflicting results from different geographical areas.[12-15] In a similar study among 182 asthmatics in Ethiopia presenting to clinics, with female predominance (68.1% females), only 24.2% subjects had well-controlled asthma. On multivariate analysis longer duration of asthma (>30 year), incorrect inhaler technique, asthma exacerbation in the last year, and use of biomass fuel for cooking were found to be associated with lack of control among asthmatics.[15] In Asia Pacific survey by Gold et al which included Indian subjects found no association between gender, pet exposure and level of asthma control.[11] In our study we did not find any significant association between control and age, sex or duration of disease (Tables 2 and 3).

Adherence to treatment and device technique of inhaled medication have been reported to be associated with control in studies from Oman and Ethiopia.[16,17] In our study 52% were non-adherent to prescribed therapy. Our study shows that adherence to therapy (OR 9.84) has significant association with level of control (Tables 2 and 4).

In another study from India more than 1/3 patients of bronchial asthma had faulty device technique of inhaler devices[18].Patients with poor device technique or lower spirometric FEV1 (pre bronchodilator) values had significant association with control.[18] In our study 57.3% of patients had faulty device technique and logistic regression showed inhaled device technique (OR 11.62) to be significantly associated with level of control while FEV1 was not significantly associated with level of control (Table 4). This is important as it shows that modifiable factors like adherence and inhaler device technique are more important in improving control than even spirometric severity of asthma in terms of FEV1.

Psychological factors have been reported to be associated with asthma control. In a study among 60 women out of which 62% did not have well controlled asthma, emotional liability and both moderate depression and mixed anxiety-depressive disorders were found associated with asthma control.[19] In a study among 100 Indian asthmatic patients evaluated using beck depression inventory (BDI) score and GINA guidelines for level of control found 65% to have depression and reported an inverse correlation between depression and patient's perception of control.[20] In our study we found 34.7% i.e. almost 1/3rd of patients suffering from symptoms of depression while 23.3% had symptoms of anxiety using questionnaire based tools. Depression shows a significant association with control on logistic regression model (OR 3.04).

Our study found no association of control with age, gender, duration of disease, smoking status, biomass fuel exposure/ETS, AR, OSA symptoms, GER symptoms, BMI though association was seen with adherence to therapy, device technique of inhaled device, eosinophil counts >500 and depression scores. On applying logistic regression model depression, adherence to therapy and device technique of inhaled medication had a significant association with control.

There have been studies evaluating non-modifiable /modifiable factors among asthmatics but closer home lack of compliance and faulty inhaler device technique may be bigger reasons for lack of control. Incorporation of these simple remediable steps- stressing on adherence to prescribed medications and correct device technique of appropriately chosen device can potentially significantly improve level of control among asthmatics. Similarly screening for psychiatric co-morbidities and their management can go a long way in improving sub-optimal control levels seen among asthmatics.

Limitations

Our study is a single center hospital based study, larger multicentric studies/community based studies may be planned for better understanding of reasons for lack of control. Evaluation of co-morbidities was questionnaire or expert opinion based as it is more practical and feasible approach in outpatient facilities. Investigations like polysomnography for OSA, upper gastro-intestinal endoscopy with/without biopsy or culture for GER may be a more accurate although invasive approach for assessment of co-morbidities.

CONCLUSION

This study reveals that among asthmatic patients control is sub-optimal. All asthmatics with partly or poorly controlled asthma should be screened for depression and managed accordingly. In spite of recommendations from various national and international guidelines adherence to therapy and improper device technique of inhaled medication pose formidable challenge to improving control among asthmatics. Awareness among both patients and health providers about these modifiable factors can potentially improve control among large number of patients who suffer from this chronic disorder.

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