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Original Article

Pharmacology Section

Impact of Clinical Pharmacological Intervention on Treatment Adherence among Adult Patients with Bronchial Asthma and COPD: A Randomised Clinical Study

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ABSTRACT

Introduction: Adherence to the management of asthma and Chronic Obstructive Pulmonary Disease (COPD) is often suboptimal, which increases morbidity and mortality associated with these chronic respiratory diseases. The effectiveness of asthma and COPD education and self-management programmes on medication adherence and health outcomes is less well evaluated.

Aim: To assess the impact of clinical pharmacological interventions, such as counselling and monitoring reinforcement, on treatment adherence in adult patients with asthma and COPD.

Materials and Methods: This randomised clinical study was conducted in the Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, Kolkata, Eastern India. Eighty screen-eligible patients were randomly divided into two groups: the Intervention Group (IG) and the Non Intervention Group (Non IG), and were followed-up bimonthly for one year. The intervention consisted of a basic introduction to asthma or COPD, factors causing exacerbations, prevention of attacks, appropriate inhaler use techniques, etc. The appropriateness of inhalation technique was assessed using a structured observation checklist and the Device Appropriateness Index (DAI). An 8-item Morisky Medication Adherence Scale (MMAS-8) was used to assess adherence. Additionally, the Adherence Index (AI) of the patients was calculated by multiplying the MMAS-8 score with the DAI score.

Results: In the study, there were 29 (52.73%) males and 26 (47.27%) females in the asthma group, while the COPD group comprised 18 (72%) males and 7 (28%) females, with mean ages of 42.86±14.3 years in the asthma group and 51.12±8.6 years in the COPD group. The MMAS-8 score was found to be better in the IG compared to the Non IG, with statistically significant differences observed from the 4th follow-up visit onwards. By the 6th follow-up visit in the IG, 42.5% demonstrated high adherence and 57.5% showed moderate adherence, with no patients falling into the low adherence category. There was significant improvement in the DAI in the IG compared to the Non IG from the first follow-up visit onwards and this improvement persisted across all subsequent visits.

Conclusion: The findings of the present study suggest that clinical pharmacological intervention is of great value in optimising treatment adherence among asthma and COPD patients, and it can be routinely incorporated into clinical care.

Keywords: Asthma, Clinical pharmacology, Educational activity, Inhalers, Medication adherence

INTRODUCTION

Chronic respiratory diseases, which primarily include bronchial asthma and COPD, are estimated to account for 7% of deaths and 3% of the loss of Disability Adjusted Life Years (DALYs) in India [1]. Asthma is a disease of the airways characterised by chronic airway inflammation and hyperreactivity to a wide variety of stimuli that can lead to obstruction of the airways with variable severity [2]. COPD, on the other hand, is a progressive condition characterised by chronic airflow limitation that is not fully reversible and refers primarily to the entities of emphysema and chronic bronchitis [2]. Estimates suggest that asthma affected approximately 262 million people in 2019 and caused 455,000 deaths, while COPD is the third leading cause of death worldwide, resulting in 3.23 million deaths in 2019, with nearly 90% of COPD deaths under the age of 70 years occurring in low- and middle-income countries [3].

According to the World Health Organisation (WHO), adherence is defined as "the extent to which a person's behaviour-taking medication, following a diet, and/or executing lifestyle changes-corresponds with agreed recommendations from a healthcare provider" [4]. Consequently, adherence and compliance refer to the patient's behaviour in relation to treatment and are measured in the same way. There are three classic types of non adherence to therapy: underuse, overuse and improper use. Underuse refers to a reduction in the apparent daily use of a medication compared to a standard dose for the treatment or prevention of a disease or condition [5]. Improper or inappropriate use is determined by evaluating whether a drug is ineffective, not indicated, or if there is unnecessary duplication of therapy [6]. Non adherence to therapy takes multiple forms, ranging from incomplete to total non use.

Another way of classifying non adherence to prescribed therapy is into unintentional (not understood) and intentional (understood but not followed) [7]. Unintentional non adherence includes misunderstanding the prescribed regimen or inappropriate aerosol device technique, whereas intentional non adherence may arise from a patient's myriad false assumptions, such as beliefs that drug therapy is ineffective, unnecessary, or dangerous, or from factors like forgetfulness, stress, a busy lifestyle, or the complexity of aerosol regimens [7].

The term "adherence" indicates the patient's behaviour in relation to therapy, the provider's behaviour regarding therapy, the patient-provider relationship, and the environmental conditions in which the patient and provider must operate, both individually and collectively [4]. It has been shown that adherence to treatments for chronic conditions is often suboptimal, and this is particularly true for adherence to asthma or COPD management. The treatment goals for asthma are that the patient should be free from symptoms and

have no limitations on daily activities, achieve normal lung function, avoid emergency visits, maintain a satisfactory quality of life and experience no dangerous side-effects from treatment. In contrast, the goal for COPD treatment is to reduce symptoms and improve quality of life [8,9].

The impact of asthma and COPD education and self-management programmes on medication adherence and health outcomes is less well evaluated. The present study aimed to investigate such impacts. In asthma and COPD, low rates of adherence to therapeutic and prophylactic medication are known to be associated with higher rates of hospitalisation and mortality [10]. Authors assume that gaps in care delivery may be addressed through supplementary support, like clinical pharmacological services, to optimise patient care. Therefore, the current study seeks to assess the impact of clinical pharmacological interventions, such as counselling and monitoring reinforcement, on treatment adherence in adult patients with asthma and COPD. A prestudy was conducted to evaluate the knowledge and skills of inhaler use among patients suffering from asthma or COPD, and after the completion of the study, the same patient pool was provided with educational intervention to determine the role of clinical pharmacological intervention on their treatment adherence.

MATERIALS AND METHODS

The randomised clinical study was conducted in the Department of Clinical and Experimental Pharmacology at the School of Tropical Medicine (a tertiary care teaching hospital) in Kolkata, Eastern India, from April 2013 to June 2014. This study was approved by the Clinical Research Ethics Committee of the Calcutta School of Tropical Medicine (CREC-STM IEC No: 15/2013, dated 09.02.2013). The study was conducted, and the informed consent process was undertaken in accordance with the Helsinki Declaration of 1975, as revised in 2013, as well as the latest Indian Council of Medical Research (ICMR) guidelines and Indian Good Clinical Practice (GCP) guidelines.

Inclusion criteria:

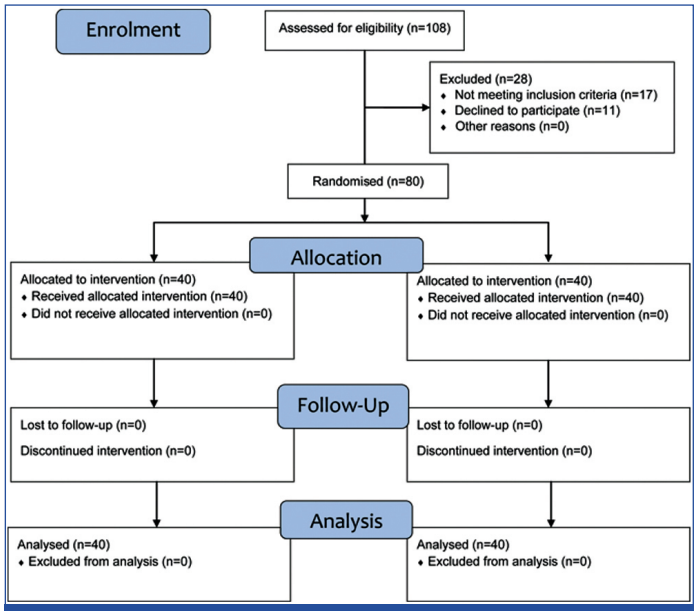
- Adult patients (18-65 years) diagnosed with asthma or COPD;
- Patients of either gender;
- Ambulatory patients who have been on treatment for at least six months;
- Patients on inhalational medication.

Exclusion criteria:

- Pregnant and lactating females;
- Patients suffering from any serious disease, such as unstable coronary heart disease, heart failure, or advanced kidney or liver failure;
- Individuals aged under 18 years or over 65 years;
- Patients who are audio and visually impaired.

Sample size: For logistical reasons and considering time constraints, the sample size was planned to be restricted to 80, with 40 patients in each group. The subjects were drawn from adult patients diagnosed with asthma and COPD who were referred from Medical College, Kolkata. A total of 108 patients with asthma or COPD attending the Medication Reconciliation Clinic under the Department of Clinical and Experimental Pharmacology were assessed for participation in the study after obtaining IEC approval. Of these, 17 patients were excluded due to non fulfilment of the inclusion criteria, and 11 patients declined to participate. Thus, 80 patients were randomised into two study groups: an Intervention Group (IG), receiving counselling and monitoring reinforcement in addition to routine care and a Non Intervention Group (Non IG), receiving only routine care.

This study was designed to assess treatment adherence among adult patients with bronchial asthma and COPD who had been on a prescribed regimen for at least six months. Additionally, it aimed to compare the impact of counselling and monitoring reinforcement on these parameters in the patients, following the CONSORT guidelines [Table/Fig-1].



[Table/Fig-1]: The study's CONSORT 2010 flow diagram

Eighty screen-eligible patients were counselled for participation in the study and those providing informed consent were randomly divided into two groups: one receiving counselling and monitoring reinforcement in addition to routine care (IG), and the other receiving only routine care (Non IG). An online randomisation scheme (http://www.graphpad.com/quickcalcs/index.cfm) was used to generate the randomisation plan for educational intervention assignment to the patients. Baseline data, including the number of male and female patients in the asthma and COPD groups, their mean age, smoking history, duration of disease in years, medication history and distribution of inhaler device types, were collected.

In this study, the intervention refers to counselling and monitoring reinforcement. The IG was counselled by a patient counselling team developed a priori, comprising faculty members and postdoctoral students from the Department of Clinical and Experimental Pharmacology at the School of Tropical Medicine, Kolkata, West Bengal, India. The counselling sessions were conducted every two months for one year, each lasting approximately one hour. These sessions focused on appropriate steps for rational medication use, compliance and self-management strategies, utilising audio-visual aids, pictures, posters and demonstrations, in accordance with the latest Global Initiative for Asthma (GINA) [11] and Global Initiative for Chronic Obstructive Lung Disease (GOLD) [12] guidelines. Individual patients in the IG received education with an emphasis on self-care abilities and support tailored to their unique requirements and capacities to cope with their disease and treatment. The importance of self-care was highlighted during the counselling sessions. Patients were provided with a basic introduction to asthma or COPD, strategies for preventing attacks, appropriate inhaler use techniques, respiratory exercises, explanations of factors causing exacerbations and the dangers of smoking. Each patient also received a booklet (in Bengali, English, or Hindi, according to their preference) about the disease and its self-management.

For the Non IG, counselling and monitoring reinforcement were not provided. After the completion of the study, a group counselling session was conducted for the patients in the Non IG. At the end, efforts were made to establish a patient group among the attending patients to facilitate mutual support.

All the patients in the study were followed-up every two months for one year without any dropouts.

Assessment Parameters

During the study, the appropriateness of inhalation techniques among patients using different inhalational devices was assessed using a structured observation checklist. Each step was assigned a score of 1 for correctly performed steps and a score of 0 for incorrect techniques. General prerequisites were common for all patients, while specific steps varied according to the particular inhaler device used. The total score was obtained by summing the scores for different steps, which we referred to as the DAI, taking cues from previous studies [13]. Thus, the maximum score for the index was 14 for each patient (6 from General Prerequisites + 8 from Specific Steps as per inhaler device), while the minimum score was 0.

The MMAS-8 [14,15], a pretested questionnaire, was utilised to assess adherence after obtaining permission. The scale consists of eight questions, with the first seven items providing a dichotomous answer (yes/no) to indicate adherent or non adherent behaviour. For item 8, the patient can select an answer from a 5-point Likert scale, expressing how often they do not take their medications. MMAS-8 scores can range from 0 to 8 points. The degree of adherence was determined according to the sum of all correct answers: high adherence (8 points), average adherence (6 to <8 points), and poor adherence (<6 points) [15,16]. The questions are provided in [Annexure 1].

Since inhaler adherence depends on both compliance with regular inhaler use and the correct usage technique, an AI was devised for the patients by multiplying the MMAS-8 score by the DAI score, resulting in AI= MMAS-8×DAI. The maximum score was determined to be 112 (14 for DAI multiplied by 8 for MMAS-8), while the minimum score was 0 [17,18].

STATISTICAL ANALYSIS

Data were analysed at the end of the study. Descriptive statistics were expressed as mean±standard deviation, range and percentage (%). Data were analysed using standard statistical tests as applicable for both numerical and categorical variables, with a two-tailed significance level set at p-value<0.05. For this purpose, the Statistical Package for the Social Sciences (SPSS) Windows version 16.0 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel spreadsheets (Microsoft, Redmond, WA, USA) were utilised. Comparisons between groups for numerical variables were performed using the Mann-Whitney U-test and Student's t-test, while categorical variables were compared using the Chi-square test with Yates' correction or Fisher's exact test as appropriate. Prior to this, a test for normality, such as the Kolmogorov-Smirnov test, was conducted for numerical variables.

RESULTS

Among asthma patients, 29 (52.73%) were male and 26 (47.27%) were female. In the COPD cohort, 18 (72%) were male and 7 (28%) were female. The mean age was 42.86±14.3 years for asthma patients and 51.12 ± 8.6 years for COPD patients. Of the asthma patients, 20 (36.36%) and of the COPD patients 16 (64%) were current or past smokers. As depicted in [Table/Fig-2], out of the total participants, 55 patients were suffering from asthma and 25 patients from COPD. The data indicated that the majority of asthma patients were using SABA inhalers, followed by ICS, while the majority of COPD patients were using LAMA inhalers, followed by LABA. On analysing the distribution of devices, 31 (56.36%) of asthma patients and 11 (44%) of COPD patients were using Metereddose Inhaler (MDI); 12 (21.82%) of asthma patients and 4 (16%) of COPD patients were using Dry Powder Inhalers (DPI), while 12 (21.82%) of asthma patients and 10 (40%) of COPD patients were using MDI with a spacer device [Table/Fig-2].

Assessment of Adherence

[Table/Fig-3] shows the MMAS-8 scores at baseline and in subsequent follow-up visits. It was seen in IG, the mean MMAS-8 score was 6.76±0.36, which improved to 7.61±0.38 at the sixth follow-up visit. On the other hand, in Non IG, the mean MMAS-8 score was 6.94±0.75 and slightly improved to 7.03±0.72 at the sixth follow-up visit.

[Table/Fig-4] indicates that in the IG, 17.5% of patients had low adherence, 67.5% had moderate adherence, and 15% had high medication adherence. At the sixth follow-up visit, there were no patients in the low adherence category; 57.5% of patients exhibited moderate adherence, and 42.5% demonstrated high adherence. In the Non IG, 12.5% of patients had low adherence, 75% had moderate adherence, and 12.5% had high medication adherence. At the sixth follow-up visit, 7.5% of patients were in the low adherence category, with 77.5% showing moderate adherence and 15% indicating high adherence.

[Table/Fig-5] illustrates that in the IG, the mean DAI was 10.9±1.08 at baseline, significantly improving at each follow-up visit, with a mean DAI of 13.86±0.14 at the sixth follow-up. Conversely, in the Non IG, the mean DAI at baseline was 10.9±1.35; it also improved significantly from one follow-up to another, reaching a mean DAI of 11.36±1.13 at the sixth follow-up visit.

Characteristics		Asthma (n=55)	COPD (n=25)
Medications used n, (% Total)	LABA	38 (69.09%)	20 (80%)
	LAMA	12 (21.81%)	22 (88%)
	SABA	45 (81.81%)	8 (32%)
	SAMA	10 (18.18%)	4 (16%)
	ICS	40 (72.73%)	15 (60%)
	Theophylline and others	8 (14.54%)	6 (24%)
Distribution of inhaler devices	MDI	31 (56.36%)	11 (44%)
	DPI	12 (21.82%)	4 (16%)
	MDI with spacer	12 (21.82%)	10 (40%)

[Table/Fig-2]: Descriptive statistics.
SD: standard deviation; LAMA: Long-acting muscarinic antagonist; LABA: Long-acting β2-agonists; SAMA: Short-acting muscarinic antagonist; SABA: Short-acting β2-agonists; ICS: Inhaled glucocorticosteroids; MDI: Metereddose inhaler; DPI: Dry powder inhalers

Group	Baseline	FU1	FU2	FU3	FU4	FU5	FU6
Intervention Group (IG)							
Mean± SD	6.76± 0.36	6.91± 0.33	7.13± 0.35	7.24± 0.34	7.41± 0.34	7.54± 0.32	7.61± 0.38
p-value w.r.t baseline		0.0078	0.0002*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Non intervention group (Non IG)							
Mean± SD	6.94± 0.75	6.96± 0.74	6.97± 0.73	6.99± 0.70	6.99± 0.69	6.99± 0.73	7.03± 0.72
p-value w.r.t baseline		0.1031	0.0329	0.0582	0.1092	0.1324	0.0028
p-value between groups	0.3215	0.7632	0.3065	0.1106	0.0044*	0.0004*	<0.0001*

[Table/Fig-3]: Morisky 8-item medication adherence scale scores in IG and Non IG groups.
FU: Follow-up visit; *p-value is statistically significant; p-values for between-group comparisons are from Student's unpaired t-test, whereas for before-after within-group comparisons; p-values are from Student's paired t-test

Adherence level	Baseline visit n (%)		After last follow-up visit n (%)	
	Intervention Group (IG)	Non-Intervention Group (Non IG)	Intervention Group (IG)	Non-Intervention Group (Non IG)
Low	7 (17.5%)	5 (12.5%)	0	3 (7.5%)
Moderate	27 (67.5%)	30 (75%)	23 (57.5%)	31 (77.5%)
High	6 (15%)	5 (12.5%)	17 (42.5%)	6 (15%)

[Table/Fig-4]: Adherence level based on MMAS-8 scores for baseline and last (6th) follow-up visits in Intervention (IG) and Non Intervention Group (Non IG).

Group	Base-line	FU1	FU2	FU3	FU4	FU5	FU6
Intervention Group (IG)							
Mean± SD	10.9± 1.08	12.60± 1.08	13.08± 0.36	13.47± 0.29	13.71± 0.17	13.86± 0.09	13.86± 0.14
p-value w.r.t baseline		<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Non Intervention Group (Non IG)							
Mean± SD	10.9± 1.35	10.92± 1.27	11.08± 1.35	11.19± 1.27	11.19± 1.27	10.92± 1.24	11.36± 1.13
p-value w.r.t baseline		0.3236	0.0106*	0.0017*	0.0017*	0.0031*	<0.0001*
p-value between groups	1.00	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*

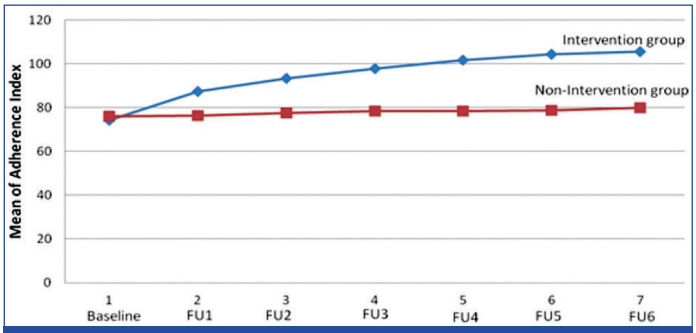
[Table/Fig-5]: Device Appropriateness Index (DAI) in Intervention (IG) and Non Intervention groups (Non IG).

[Table/Fig-6] showed AI was significantly better at follow-up visits and was also significantly better in the IG compared to the Non IG. The mean AI in the IG at baseline was 74.26±16.26, which improved to a mean AI of 105.55±7.11 at the sixth follow-up visit. In the Non IG, the mean AI at baseline was 75.96±15.26, while the mean AI at the sixth follow-up visit was 80.01±12.03.

Group	Base-line	FU1	FU2	FU3	FU4	FU5	FU6
Intervention Group (IG)							
Mean± SD	74.26± 16.26	87.46± 13.96	93.39± 12.09	97.86± 11.95	101.75± 10.26	104.36± 8.64	105.55± 7.11
p-value w.r.t baseline		<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Non Intervention Group (Non IG)							
Mean± SD	75.96± 15.26	76.33± 15.09	77.48± 13.80	78.42± 12.81	78.35± 12.79	78.67± 12.99	80.01± 12.03
p-value w.r.t baseline		0.0972	0.0009*	0.0004*	0.0003*	<0.0001*	<0.0001*
p-value between groups	0.7763	0.0011*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*

[Table/Fig-6]: Adherence Index (AI) in Intervention (IG) and Non Intervention Groups (Non IG).
*p-value is statistically significant
p-values for between group comparisons are from student's unpaired t-test whereas for before-after within group comparisons, p-values are from student's paired t-test

[Table/Fig-7] presents graphs showing that the mean AI in the IG was significantly better from the first follow-up visit and continued to improve up to the last follow-up visit, remaining higher in the IG.



[Table/Fig-7]: Graphical representation of changes of mean of Adherence Index (AI) in Intervention (IG) and Non Intervention Groups (Non IG) in different visits.

DISCUSSION

The study was designed as a prospective, parallel-group randomised interventional study, where the intervention involved counselling and monitoring with periodic (2-monthly) reinforcement for one year, focusing on education regarding self-care ability. The intervention consisted of a basic introduction to asthma or COPD, factors causing exacerbations, prevention of attacks, and appropriate inhaler usage techniques, among other topics. Baseline data indicated that most of the patients were male and of middle age; many asthma and COPD patients were current or former smokers, and they were using a variety of medications as inhalers for their conditions. The majority of asthma patients were using MDI with medications like SABA and/or ICS, while most COPD patients were using MDI with medications like LAMA and/or LABA. These findings were consistent with various previous studies conducted in India and around the world [19-22].

In this study, the MMAS-8, an index of adherence, was found to be better in the IG compared to the Non IG-but this was particularly evident and statistically significant from the fourth follow-up visit onwards. When within-group comparisons were made between baseline values and subsequent follow-up values, the IG showed a significant improvement in MMAS-8 scores from the third follow-up visit onwards. However, no such improvement was observed in the Non IG.

According to MMAS-8 score grading, it was noted that after the sixth follow-up visit, 42.5% of patients in the IG were classified as having high adherence, and 57.5% as having moderate adherence, with no patients in the low adherence category (at baseline, 15% were high, 67.5% moderate, and 17.5% low adherence). In contrast, in the Non IG, only 15% were classified as having high adherence, 77.5% as moderate, and 7.5% as low adherence (at baseline, 12.5% were high, 75% moderate, and 12.5% low adherence).

In present study, there was significant improvement in the DAI in the IG compared to the Non IG from the first follow-up visit onward, and this improvement persisted in all subsequent visits. A similar finding was confirmed when comparing the index between different follow-up visits and the baseline visit in the IG. Notably, significant improvements in device handling were also observed in the Non IG from the second follow-up visit onwards when compared to their baseline data. Although this was not expected, it can be explained by potential confounding caused by the frequent visits of study subjects in both groups and possible interactions with participants from the other group.

Authors combined these two scores (MMAS-8 and DAI) to calculate the AI, as appropriate adherence to asthma or COPD medication which depends not only on actual compliance but also on the correct technique for using inhaler devices. The AI was found to be significantly better in the IG compared to the Non IG from the very first follow-up visit and continued to show improvement in subsequent visits. When within-group comparisons were made between baseline values and subsequent follow-up values, the IG showed significant improvement in AI scores from the first follow-up visit onwards. In contrast, significant improvement in the Non IG was observed from the second follow-up visit onwards.

According to studies by Morisky DE et al., and Armour C et al., such interventions had a clear effect on adherence [14,23]. However, the impact of self-management education on adherence to asthma medications studied by Janson SL et al., revealed that mean adherence did not differ between the intervention and control groups [24]. Similarly, in the study by Côté J et al., a complex educational intervention did not improve adherence to medications [25]. Although the intervention resulted in an increase in asthma knowledge scores over the course of the study, it had no effect on the associated asthma morbidities. Another study by Santos DO et al., revealed no difference between the groups regarding reported adherence, though inhaler technique showed improvement in the IG [26]. The intervention carried out by Hardwell A et al., resulted in a statistically significant increase in the number of patients using their MDIs correctly after two and three educational sessions; however, a majority of patients still used faulty inhaler techniques [27].

The general lack of adherence to prescribed aerosol therapy has been documented in numerous studies, including those involving patients with asthma as well as COPD. Many international studies have shown that adherence to asthma and COPD medications is generally poor, with only 40-80% of asthma medications [28-30] and 45-60% of COPD medications being appropriately used as prescribed [31,32]. Poor adherence to the regular use of inhaled corticosteroids is considered a significant causal factor in the increased morbidity and mortality of asthma patients [33,34]. Furthermore, elderly patients with asthma or COPD who receive inhaled corticosteroids and adhere to their treatment plans have lower rates of hospitalisation [35]. A study on asthma has also shown that the necessity/concerns framework helps us understanding patients' evaluations of inhalational medication and helps to explain non adherence [36].

Lack of adherence to aerosol therapy can stem from a misunderstanding of the correct use of aerosol devices or medications, leading to what is termed 'unintentional non adherence'. Farber HJ et al., found that 23% of parents (n=131) misunderstood the role of inhaled anti-inflammatory medication, believing it was intended for the treatment of symptoms after they occurred rather than for prevention, with decreased adherence to its daily use [37]. Several studies have documented the problems patients encounter while using aerosol devices, noting common patient errors due to suboptimal skills in handling devices, whether MDIs, DPIs, or MDIs with spacers [13,38-41]. Consequently, suboptimal therapeutic response and poor control of airway disease can arise from faulty technique along with inadequate supervision and insufficient repeated instructional behaviours from prescribers. The low adherence to inhalers observed in present study may result from these inherent issues, as larger populations with fewer doctors often make repeated inhaler training difficult. Additionally, the complexity of an inhalation regimen may contribute to suboptimal adherence, influenced by the frequency with which inhaled medications must be taken, the number of medications to be administered, and use of different types of aerosol devices.

Limitation(s)

Present study had some notable limitations. Due to logistical reasons, this study had to be completed within a short time frame and was therefore conducted with a small sample size. The study setting was a government three-tier (referral) hospital in West Bengal, where one of the primary motivations for seeking care is the affordability of healthcare and the poor socio-economic conditions of the patients, which may also affect adherence parameters. Secondly, present study findings were based on the judgments of investigators and educators' judgments and although we attempted to co-ordinate these observations, they have a subjective basis.

Future recommendations: The AI was devised for the purpose of this study by the authors, who plan to utilise this index in future research to investigate holistic adherence patterns in larger studies. Additionally, future outcome studies that incorporate educational interventions addressing various health-related quality of life parameters and levels of disease severity are needed to better understand the true nature of behavioural and clinical pharmacological inputs for the long-term management of chronic respiratory illnesses.

CONCLUSION(S)

The present study found that the use of educational interventions can contribute to adherence among asthma and COPD patients, allowing us to better understand the complex concept of adherence. However, this is an aspect of therapy that many clinical practice guidelines do not emphasise as a necessary precursor to adequate treatment. One must acknowledge that adherence requires behavioural change, which is related to individual interests and expectations; consequently, patients must be managed on an individual basis. Clinical pharmacological interventions are of significant value in optimising treatment adherence in asthma and COPD patients and should be incorporated routinely into clinical care.

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[ANNEXURE 1]

Study Title: Impact of clinical pharmacological intervention on treatment adherence among adult patients of bronchial asthma and COPD- A randomised clinical study

Subject ID: Date:

1. **Patient particulars:**
   1. Name: 2. Age: 3. Sex:
   4. Disease
   5. Address and Contact No.:

8. The 8-item Morisky Medication Adherence Scale

MMAS-8	Baseline	FU1	FU2	FU3	FU4	FU5	FU6
1. Do you sometimes forget to take medicine? (No=1, Yes=0)							
2. People sometimes miss taking their medicines for reasons other than forgetting. Over the past 2 weeks, were there any days when you did not take your medicine? (No=1, Yes=0)							
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it? (No=1, Yes=0)							
4. When you travel or leave home, do you sometimes forget to bring your medicine? (No=1, Yes=0)							
5. Did you take all your medicine yesterday? (Yes=1, No=0)							
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine? (No=1, Yes=0)							
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan? (No=1, Yes=0)							
8. How often do you have difficulty remembering to take all your medicine? (A) Never/ rarely (B) Once in a while (C) Sometimes (D) Usually (E) All of the time {(A)=4, (B)=3 (C)=2, (D)=1, (E)=0}							
MMAS-8 score:							
Score: <6=Low adherence; 6-<8=Medium adherence; 8=High adherence							