Advances in Bioresearch
Adv. Biores., Special Issue (3) 2025: 64-71
©2024 Society of Education, India
Print ISSN 0976-4585; Online ISSN 2277-1573
Journal's URL:http://www.soeagra.com/abr.html
CODEN: ABRDC3
DOI: 10.15515/abr.0976-4585. SPL3.25.6471

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Study of Inhalational Practices in Asthma Patients Attending Asthma Clinic in A Tertiary Care Hospital

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ABSTRACT
Bronchial asthma is estimated to impact approximately 300 million individuals globally. The primary aim of the study was to identify inhalation errors and assess the accuracy of inhalation techniques utilized by asthmatic patients, as well as to evaluate the effectiveness and safety practices in asthma patients. This prospective observational study on inhalation techniques was conducted in about 150 asthmatic outpatients. The people of age between 18-90 years were selected as per criteria considered. Subjects were enrolled over a period of six months. Each patient's inhaler technique was assessed using a checklist, and the types of mistakes made by each individual, along with the medications assigned for different inhalers, were recorded of 150 participants, it was found that 94% of the participants made errors in their inhaler technique, and 77% of the participants made more than one error. The most commonly used inhaler type was the DPI (53%), followed by PMDI (33%) and nebulizer (31%). The most commonly prescribed drug across all types of inhalers was formoterol + budesonide in combination with a common dose of 200 mcg in PMDI and DPI and 0.5mg in nebulizer. The study concludes that, 94% of participants made inhaler technique errors. Most patients made more than one error. The highest error rates were among illiterate and primary academic patients. It is important to provide repeated instructions and demonstrations for proper inhaler use. Safety is a priority, as most patients didn't experience side effects, raising awareness about accurate inhaler utilization is necessary.
Keywords: Asthma, Inhaler devices, Inhalational techniques, pMDI, DPI, Nebulizer, Errors.

Received 21.05.2025 Revised 23.06.2025 Accepted 19.07.2025

How to cite this article:
G. Pavan Kalyan, N Deepika, K. Madhumitha, G Chandrashekar, G Rajeev Kumar, M. Gangadhar Reddy , Krishna Prasad D. Study of Inhalational Practices in Asthma Patients Attending Asthma Clinic in A Tertiary Care Hospital. Adv. Biores. Special Issue [3] 2025. 64-71

INTRODUCTION

Bronchial asthma is estimated to impact approximately 300 million individuals globally [1]. The most effective method for drug administration is through inhalation [2], as it leads to a quicker onset of action, reduced dosage requirements, and a lower incidence of systemic side effects compared to oral administration [3].

Pressurized metered dose inhalers (PMDIs), dry powder inhalers (DPIs) and nebulizers are the predominant devices utilized for medication delivery. DPIs were developed as a more user-friendly option compared to PMDIs, as they necessitate less coordination between inhalation and the activation of the device. When employed properly, inhalers facilitate significant pulmonary drug deposition while reducing systemic bioavailability [4]. On the other hand, the improper use of inhalers, conversely, is linked to instability in asthma management, as each mistake can considerably impact the control of symptoms [5,6]. Errors in device use can affect the efficacy of the administered medication and thereby resulting in inadequate management of asthma [7-9]. Improper use of inhalers and inhalation technique have been frequently observed in clinical practice, and it is associated with decreased bronchodilation, reduced patient's adherence to the treatment regimen, ineffective drug delivery, and suboptimal disease management [10].

The aim of this research was to assess the inhalation techniques utilized by eligible patients with bronchial asthma, as well as to identify common errors made during these techniques.

MATERIAL AND METHODS

Study design

The research was designed to serve as a prospective observational one that would run for six months. The data shall be analysed to observe the inhalational practices considering severity of asthma.

Study Site

The work will be performed in the pulmonology department at Yashoda hospitals, secunderabad.

Study Duration

The work will be conducted for a duration of six months.

Study Population

100-150 Individuals of asthma with comorbidities which includes outpatients.

Inclusion criteria

This study included patients aged between 18 and 90 years, including both male and female participants. Specifically, asthmatic patients who also presented with co-morbidities, as well as outpatients.

Exclusion criteria

This study excludes participants from the pediatrics category, pregnant and lactating women, unconscious patients and inpatients.

A comprehensive examination, which included measuring the subject's age, weight and height, was performed. Subsequently, the subject was instructed to retrieve their inhaler device and demonstrate their inhalation technique. Each step was evaluated, and any errors were documented in accordance with the established checklist and guidelines. Upon completion of the demonstration, training was provided to each participant to mitigate the risk of future inhalation technique errors.

Statistical analysis

The collected data was subsequently transferred and analyzed utilizing SAS® version 9.4. Descriptive statistics, including means and standard deviations, were employed to summarize the quantitative variables. Frequencies and percentages were utilized to summarize the categorical variables. Chi-squared tests were conducted to examine the association between clinical characteristics in relation to asthma device usage and the asthma control test. A significance level of p-values less than 0.05 was established. Multiple logistic regression models were applied to identify risk factors linked to the improper use of asthma inhaler devices. The odds ratios (ORs) along with 95% confidence intervals (CIs) were reported to illustrate the strength of these associations [11,12].

RESULTS

Table 1 reveals that out of 150 individuals diagnosed with asthma, 105 (70%) were female, while 45 (30%) were male, showing no statistically significant difference between the two groups (p=0.2581). Regarding age distribution, the study cohort comprised 17 individuals (11%) aged 18-30, 52 individuals (34%) aged 31-50, and 81 individuals (54%) aged over 50. These results indicate that a greater proportion of the asthmatic population is found among those aged above 50. Additionally, the mean age of the 150 patients with asthma does not demonstrate a statistically significant difference.

Table: 1 Sample distribution of populations according to age and gender criteria

Age	Male	Female	Total	P-Value
18-30	6	11	17	0.2581
31-50	13	39	52	
>50	26	55	81	
Total	45	105	150	

Table 2 illustrates that among the 150 asthmatic patients in our study, 50 individuals were diagnosed with hypertension (19 males and 31 females), 27 with diabetes mellitus (10 males and 17 females), and 21 with hypothyroidism (3 males and 18 females). Additionally, 16 patients presented with both hypertension and diabetes mellitus (7 males and 9 females), while 4 had hypertension and thyroid issues (1 male and 3 females). One patient was found to have both diabetes mellitus and thyroid issues (1 female), and 3 patients were diagnosed with all three conditions: hypertension, diabetes mellitus, and thyroid issues (all females). The data indicates that the mean comorbidities among the 150 asthmatic patients do not exhibit a statistically significant difference.

Table 2: Study population distribution according to comorbidities

Distribution based on Comorbidities				
Comorbidities	Male	Female	Total	P-Value
Hypertension	19	31	50	0.2475
Diabetes Mellitus	10	17	27	
Hypothyroidism	3	18	21	
HTN+DM	7	9	16	
HTN + Hypothyroidism	1	3	4	
DM +Hypothyroidism	0	1	1	
HTN + DM + Hypothyroidism	0	3	3	
Total	40	82	122	

Table 3 indicates that among 150 asthmatic patients, 74 are classified as upper middle class, 54 as lower middle class, 17 as upper class, and 3 as lower class. Within this group of 150 asthmatic individuals, the primary category (1-5) exhibited the highest error rate at 34%, followed by the illiterate category at 31%. The secondary school category (6-10) accounted for 26% of errors, while both the intermediate category and the Graduate and PG category recorded the lowest error rates at 19% each.

Table 3: Distribution based on socioeconomic status and different Education status

Distribution based on socioeconomic status		
Socioeconomic Status	N	%
Upper class	17	11.30%
Upper middle	74	49.30%
Lower middle	56	37.30%
Lower class	3	2%
Total	150	100
Distribution based on % errors done in different Education status		
Education status	Total questions (1500)	%error
Illiterate	380	31%
I-V	70	34%
VI-X	420	26%
Intermediate	120	19%
Graduates	510	19%

Table 4 indicated that among the 150 individuals in the asthmatic study population, the largest group utilizing dry powder inhalers (DPI) comprised 80 individuals (53.33%). This was followed by pressurized metered-dose inhalers (PMDI) with 50 users (33.33%), and nebulizers with 47 users (31.33%). Additionally, 13 individuals (8.66%) used both DPI and nebulizers, while 11 individuals (7.33%) employed PMDI in conjunction with nebulizers. The combination of PMDI and spacers was used by 4 individuals (2.66%), and the least common usage was the combination of PMDI and DPI, with only 3 individuals (2.0%). Furthermore, within this population of 150 asthmatic patients, the highest error rates were observed with nebulizers (26%) and PMDI (26%), followed closely by PMDI combined with spacers (25%). The next highest error rates were recorded for the combination of PMDI and nebulizers (24%) and DPI with nebulizers (24%). The lowest error percentages were noted for DPI (20%) and the combination of PMDI and DPI (20%).

Table 4: Study population distribution according to inhaler type and Inhalation device errors

Distribution based on type of inhaler and % Error made by type of inhaler		
Type	N(%)	% Error
PMDI	50 (33.33)	26
DPI	80 (53.33)	20
Nebulizer	47 (31.33)	26
PMDI + Spaces	4 (2.66)	25
PMDI + Nebulizer	11 (7.33)	24
PMDI+DPI	3 (2.0)	20
DPI + Nebulizer	13 (8.66)	24

Table 5 demonstrated that Among 150 asthmatic study population ,50 patients using PMDI, the most commonly prescribed drug Formoterol + Budesonide 30 (60%), followed by Formoterol + glycopyrolate + Budesonide 5 (10%) and salmeterol + fluticasone propionate 5 (10%) and other drugs 10 (20%). 80 patients using DPI, the most commonly prescribed drug was formoterol + Budesonide 43 (54%) followed by vilanterol + fluticasone propionate 14 (17.50%), salmeterol + fluticasone propionate 8 (10%), formoterol + fluticasone propionate 6 (7.50%) and others 9 (11%) and 47 patients using Nebulizer, the

most commonly prescribed drug was formoterol + Budesonide 32 (68%), followed by Levosalbutamol + ipratropium 6 (13%), Levosalbutamol 3 (6%) and others 6 (13%).

Table 5: Distribution based on commonly prescribed drugs

Commonly prescribed drugs in PMDI		
Drugs	N	%
Formoterol + Budesonide	30	60
Formoterol+ Glycopyrrolate +Budesonide	5	10
Salmeterol+ Fluticasone Propionate	5	10
other drugs	10	20
Commonly prescribed drugs in DPI		
Formoterol + Budesonide	43	54
Salmeterol + Fluticasone Propionate	8	10
Formoterol + Fluticasone Propionate	6	7.50
Vilanterol + Fluticasone Propionate	14	17.50
others	9	11
Commonly prescribed drugs in nebulizer		
Formoterol + Budesonide	32	68
Levosalbutamol + Ipratropium	6	13
Levosalbutamol	3	6
Others	6	13

Figure 1 shows that out of 150 patients, for 50 PMDI users the highest number of individuals (26) have made errors at step 6 (Holding of breath for 5-10 seconds after drug inhalation) followed by step 8 (1-minute gap between each dose/puff).

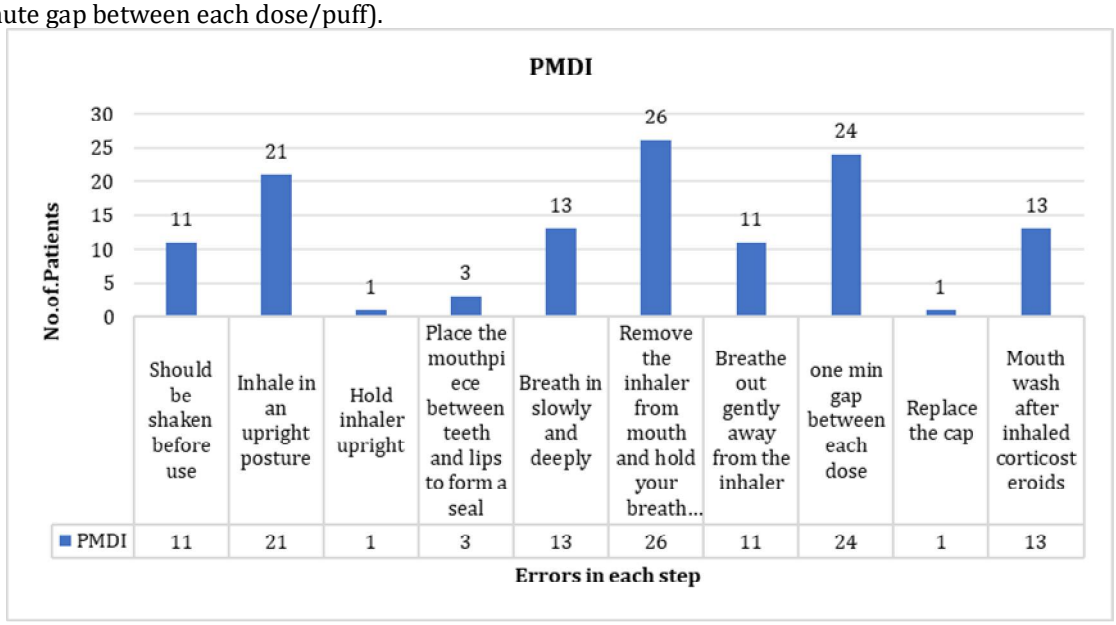

Figure 1: Frequency of errors at each step in PMDI

Figure 2 shows that out of 150 patients, for 80 DPI users the highest number of individuals (43) have made errors at step 6 (Holding of breath for 5-10 seconds after drug inhalation) followed by step 2 (32) (Inhale in an upright posture(seated/standing).

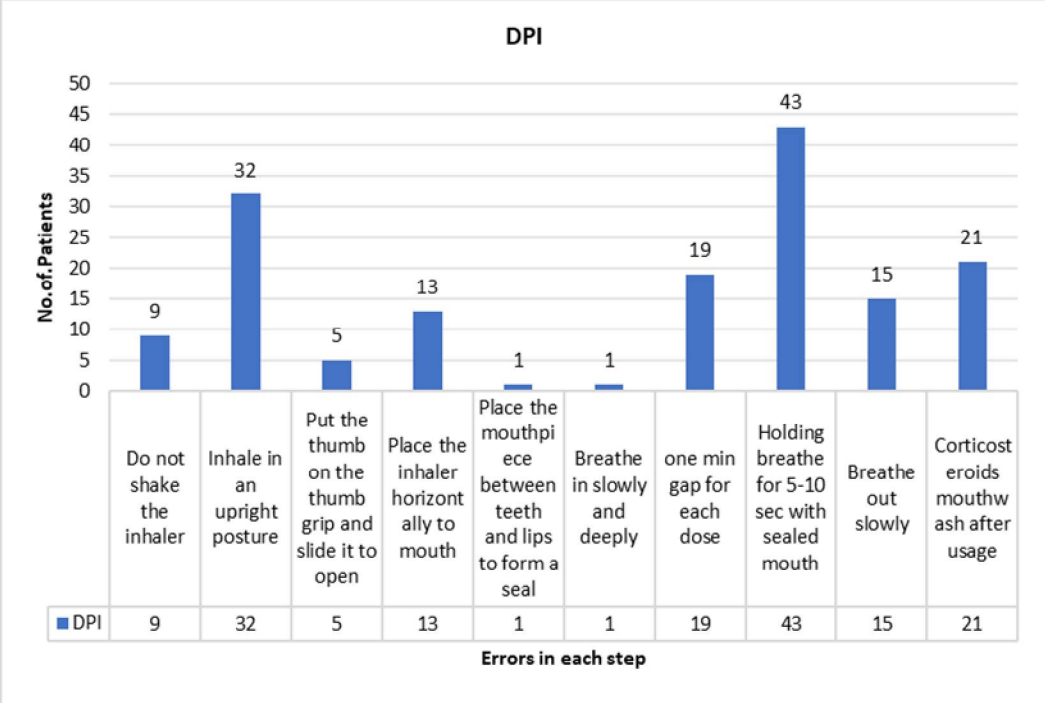

Figure 2: Frequency of errors at each step in DPI

Figure 3 shows that out of 150 patients, for 47 Nebulizer users, the highest number of individuals (43) have made errors at step 9 (On completion of treatment, patient to cough after several deep breathes), followed by step 5 (Shaking of cup downward to make sure all the medicine has come through).

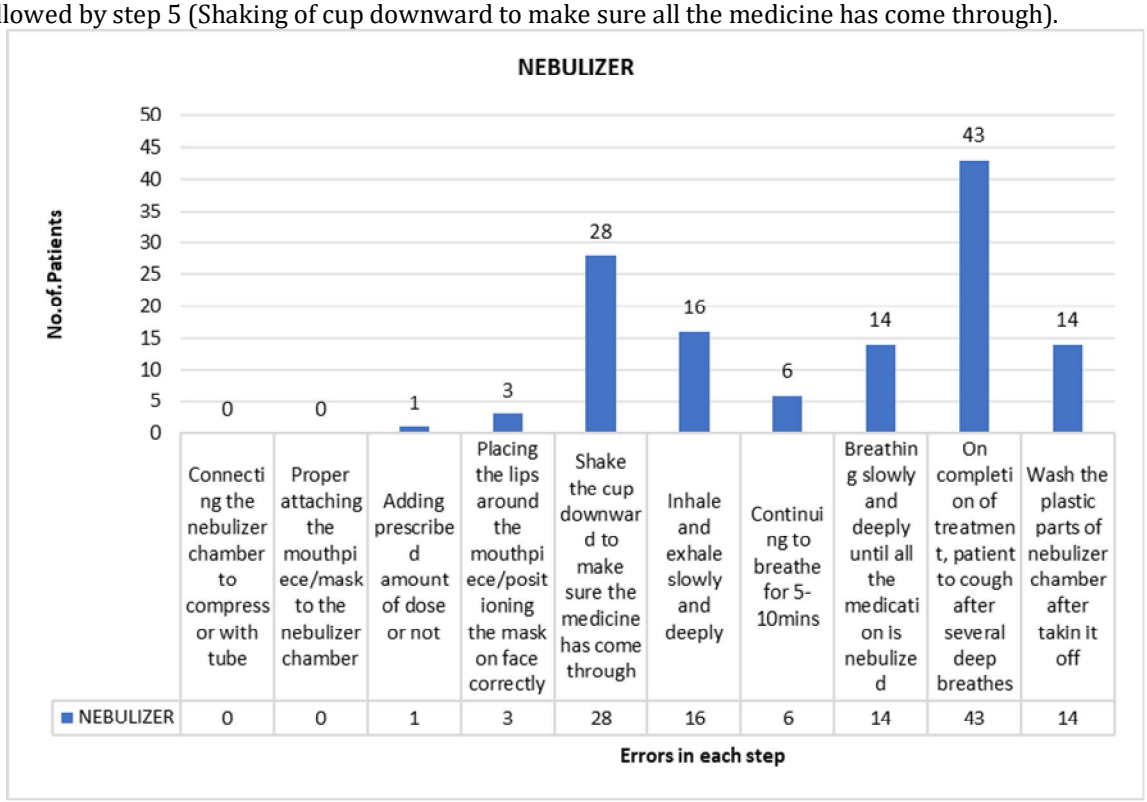

Figure 3: Frequency of errors at each step in Nebulizer

Table 6 demonstrated that out of 150 asthmatic patients, 6 experienced side effects like nausea 4 (66%), hoarseness + headache 1 (17%) and nausea + dizziness 1 (17%).

Table 6: Study population breakdown according to side effects

Distribution based on side effects		
Side effects	N	%
Nausea	4	66
Hoarseness + Headache	1	17
Nausea + Dizziness	1	17

DISCUSSION

Inhalers are considered as the cornerstone of asthma treatment globally. Inadequate control of asthma is likely to occur if inhalers are not used correctly [13]. An analysis was conducted on the inhaler usage techniques among our patients, followed by educational efforts to inform them about the necessary measures to enhance drug delivery for improved clinical management.

A research study conducted by Dalal S et al., which involved participants with a mean age of 52.5 years, found no significant associations between age or gender on correct inhaler technique [14]. In contrast, a study by Melani et al., which included a larger sample size (n=1664) and a mean age of 62 years, indicated that the likelihood of critical errors in inhaler device usage increased with advancing age (10). This variation in findings may be attributed to the differences in the average age of the participants in each study. Additionally, our research also aligns with the Dalal S et al study, revealed that mean age (52 years) did not correlate with improper inhaler technique.

In our research involving 150 patients, only 50 were utilizing a pressurized metered-dose inhaler (PMDI), and among these, 26% exhibited improper technique and made errors. A comparable study conducted in Nigeria revealed that 79.8% of participants misused the PMDI. This discrepancy may be attributed to the smaller number of patients using PMDI in our study. Research indicates that a slow and deep inhalation, followed by a breath-hold of at least 10 seconds, is vital for optimal drug deposition. Our findings also showed that the majority of patients did not perform this step correctly, identifying it as the most frequent error. Similarly, the Nigerian study found that most patients failed to execute this step adequately. It is important to maintain a gap of 30 to 60 seconds between doses to allow the medication to take effect and to facilitate airway relaxation [15].

In our study, the most used inhaler therapy was DPI. When we assessed the technique of using DPI, the most common error was holding breathe for 5-10 sec with sealed mouth. It was observed in 43 (53.33%) patients. This result matches well with a similar study done in Pakistan in which holding breathe for 5-10 sec with sealed mouth was the most common error observed in DPI users [16]. Another error observed was inhaler upright to mouth, which is the most crucial step in effective drug delivery to airways. A similar error is found in a study done in Madhya Pradesh, India [17]. The findings of this study was parallel to those of the previous studies, in that the majority of the patients were making errors in the inhaler technique, irrespective of inhaler type [18]. In this study additionally we assessed the technique of using nebulizer, the most common error observed was, on completion of treatment patient to cough after several deep breathes.

A previous study by Melani AS indicated that patients with higher education levels exhibited a lower percentage of incorrect inhaler techniques, a finding that aligns with our own results. Additionally, our data suggest that females demonstrate a similar level of incorrect inhaler technique when compared to males. This observation is consistent with other studies that have reported no significant gender differences in inhaler technique [19].

Budesonide/formoterol PMDI, budesonide/formoterol DPI, and budesonide PMDI demonstrated a favorable safety profile, exhibiting a low overall rate of adverse events. Notably, the tolerability profiles for both budesonide/formoterol therapies were consistent with those previously reported for budesonide/formoterol DPI [20]. Similarly, in our study also, the majority of patients were treated with budesonide/formoterol PMDI, budesonide/formoterol DPI, and budesonide/formoterol nebulizer, with a low incidence of adverse events were noted [21-25].

CONCLUSION

The study concludes that incorrect inhalational technique occurred in 94% of the total sample and 77% have made more than one error. The percentage of errors were made by 50 patients using pMDI was 26% and by 80 patients using DPI was 20% and by 47 patients using nebulizer was 26%. The maximum errors were made by illiterate and primary academic patients, so repeated instructions with demonstration of inhaler devices is necessary for them. The above all inhalational errors were evolved by using a checklist for different types of inhalers. Almost all patients (except 6) have not experienced any side effects with the inhalational therapy, so it concludes that it is very safety to use inhalers. Addressing these errors

necessitates raising awareness among patients about accurate utilization and efficacy of these medical devices. Even COVID-19 has brought an impact in the population bringing more susceptible for infections in immunocompromised patients.

Acknowledgements
Authors would like to thank Management Yashoda Hospitals for the continuous support and special thanks to Dr. M. Gangadhar Reddy, MD, DNB, FCCP(USA), professor and HOD department of pulmonology and our guide Mr. G. Rajeev Kumar, M. Pharm, (Ph. D) Assistant Professor, and Department of Pharmacy practice, School of Pharmacy, Anurag Group of Institutions.

Funding
No funding sources

Conflict of interest
None declared

Ethical approval
The study was approved by the Institutional Review Board of Anurag university bearing the research proposal number: IRB-AGI/2023-2024/02.

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