A study to monitor errors in use of inhalation devices in patients of mild-to-moderate bronchial asthma in a tertiary care hospital in Eastern India

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Abstract

Context: Bronchial asthma is a chronic respiratory disorder which affects over 300 million people worldwide. Inhalation pharmacotherapy is the cornerstone in treatment of asthma, which is administered using inhaler devices. Studies show high prevalence of incorrect technique while inhaler usage, which renders to compromised disease control and increased healthcare cost.

Aims: This study was aimed to monitor errors in use of inhalers and explore their relationship with patient characteristics and training given by healthcare providers, in patients suffering from mild to moderate bronchial asthma.

Settings and Design: This was an observational cross-sectional study conducted after approval of Institutional ethics committee in a tertiary care hospital.

Methods and Material: A total of 207 patients were recruited after they met the inclusion criteria and their informed consent was taken. Data regarding the patients’ socio-demographic information, education status and history of illness were logged on a case record form. Their inhalation techniques were assessed according to the checklist, errors were noted and patients were educated regarding correct technique using ‘teach-back training’ method.

Statistical analysis used: Chi-square test, SPSS software.

Results: Among the inhalers used, pMDI was most commonly prescribed (58%), followed by DPI (37.7%) and pMDI with spacer (4.3%). Irrespective of the type of inhaler used, overall 75.36% patients included in the study, showed errors in use of inhaler. Prevalence of errors in DPI, pMDI and pMDI with spacers was 78.2 %, 77.8% and 22.2% respectively. Our study showed that education status of patient, training by healthcare provider and duration of inhaler use have statistically significant association (p<0.05) with the prevalence of errors in inhaler usage.

Conclusion: It is emphasized that dedicated and trained staff should be available for instructing patients and reinforcing by follow up checks should be considered.

Keywords: Dry-powder inhalers, errors in inhalation technique, inhaler, pressurized metered-dose inhalers

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INTRODUCTION

Chronic respiratory diseases include bronchial asthma as the most common disease, followed by chronic obstructive pulmonary disease, occupational lung diseases, and pulmonary hypertension. The prevalence of bronchial asthma varies from 10% to 12% in adults and around 15% in children[1] which affected 339 million people worldwide in 2016.[2]

Bronchial asthma is classified as intermittent, mild persistent, moderate persistent, and severe persistent,[3] the treatment of which is tailored according to the severity of the disease. The drugs used for its treatment include corticosteroids, beta-2 agonists, methylxanthines, leukotriene antagonists, and mast cell stabilizers. Despite the availability of these recommended drugs, not every patient achieves complete asthmatic control.

To avoid or minimize adverse drug effects, many of the antiasthmatic drugs such as beta-2 adrenergic agonists, corticosteroids, and anticholinergics are administered by the inhalation route, using devices called inhalers, which include nebulizers, pressurized metered-dose inhalers (pMDIs), and dry-powder inhalers (DPIs). Difficulty in use of inhalers contributes to errors and suboptimal drug delivery to airways rendering compromised response and increased health-care costs. Lavorini et al. have shown that between 4% and 94% of patients, depending on the type of inhaler, do not use their inhalers correctly.[4] However, Klijn et al. have demonstrated that training on inhaler use resulted in correct use in more than 90% of patients.[5] A recent global position document from the Global Initiative for Asthma (GINA) gives a significant prominence to assessing and correcting the inhalation technique before escalating drug therapy.[6]

Although the technique of inhaler use can be improved by proper training of the target population, there is a paucity of such data in our country.[7] This study aimed to monitor errors in use of inhalation devices and explore the relationship between these errors, patient characteristics and training by health-care providers, of patients who are diagnosed as cases of mild-to-moderate bronchial asthma, attending respiratory medicine clinics of a tertiary care hospital.

SUBJECT AND METHODS

The study was conducted for a period of 1 year. The sample size was calculated to estimate 95% confidence interval for the proportion of mild-to-moderate cases of asthma correctly using inhalation devices as per guidelines with a 5% absolute error of margin. The sample size worked out to be 207 assuming that about 52% of mild-to-moderate cases of bronchial asthma are correctly following the inhaler technique[8] and assuming that there are 420 patients of mild-to-moderate bronchial asthma registered in asthma clinics (according to the hospital data). This was an observational cross-sectional study conducted on patients included as per inclusion and exclusion criteria at a single visit to the respiratory medicine outpatient department after obtaining their written informed consent and clearance from the institutional ethics committee. Inclusion criteria were patients of age more than 18 years with mild-to-moderate bronchial asthma who were using inhalers. Exclusion criteria were patients suffering from severe bronchial asthma and patients concurrently suffering from illnesses other than bronchial asthma, including psychiatric diseases. Data regarding the patients’ sociodemographic information, education status, and history of illness were logged on a case record form. Thereafter, inhalation techniques were assessed according to the undermentioned list of steps to be followed for the usage of pMDI with or without spacer and DPI, and errors made at any step were noted down. The checklist was marked accordingly. Once errors were noted, patients were demonstrated the correct inhaler technique, and “teach-back training” method was used.

For pMDI, steps for proper usage were as follows:[6]
1. Shake the inhaler
2. Hold inhaler upright
3. Exhale completely
4. Place mouthpiece between the lips and teeth and keep the tongue from obstructing the mouthpiece
5. Press the inhaler while inhaling deeply and slowly
6. Inhale completely
7. Hold the breath for as long as comfortable
8. Exhale out slowly.

For pMDI with spacer, steps for proper usage were:[6]
1. Shake the inhaler, attach it to the spacer
2. Remove the cap of the spacer
3. Exhale completely
4. Place mouthpiece of the spacer between the lips and teeth
5. Press the inhaler once
6. Inhale deeply and slowly
7. Hold the breath for as long as comfortable, before breathing out
8. Exhale out slowly.

For Rotahaler, a DPI, steps for proper usage were as follows:[8]
1. Take Rotacap and insert transparent end into the square hole
2. Press Rotacap firmly
3. Hold the mouthpiece firmly with one hand and rotate the base with another hand
4. Exhale completely
5. Grip the mouthpiece between the teeth and seal the lips around it
6. Inhale completely through the mouth
7. Hold the breath for as long as comfortable.

The technique was labeled as wrong if the patient committed at least one error. Once errors were noted, patients were demonstrated the correct inhaler technique, and “teach-back training” method was used.

Statistical analysis was done using Chi-square test, SPSS software IBM SPSS Statistics for Macintosh, Version 25.0.

RESULTS

A total of 207 patients were enrolled in the study, and information regarding patients and their treatment were formulated [Tables 1 and 2].

There were 113 (54.6%) males and 94 (45.4%) females. Their mean age was 39 years. The correctness of the technique used for pMDI was evaluated using the checklist mentioned above. Out of the total population 207, 51 (24.6%) patients performed the technique correctly. Ninety-three (77.5%) out of 120 patients using pMDI,
2 (22.2%) out of 9 using pMDI with spacer, and 61 (78.2%) out of 78 patients using DPI made errors in their inhalation technique [Table 3 and Figures 1-4].

**Patients on pressurized metered-dose inhalers**

Patients made errors in exhaling completely (step 3), pressing the inhaler while inhaling deeply and slowly (step 5), and holding the breath for as long as comfortable, before breathing out (step 7). Overall, 63 patients showed incorrect technique in step 5, the second most common mistake was in step 7; about 43 patients made this mistake, whereas 11 made errors in step 3 [Table 4 and Figure 5]. When individual parameters of patients on pMDI were evaluated, it was observed that 47 (86.7%) out of 53 patients who did their schooling up to 12th standard and 46 (68.7%) out of 67 patients who were graduates made errors ($P < 0.05$). All of them were trained about the technique by health-care providers. Forty-two (91.3%) out of 46 patients trained by pharmacists, 23 (71.9%) out of 32 trained by nursing staff, and 28 (66.7%) out of 42 trained by doctors made mistakes ($P < 0.05$). Thirty-nine (90.7%) out of 43 patients who had been using the inhaler for <6 months, 32 (76.2%) out of 42 patients who were using it for 6 months or more but <24 months, and 22 (62.9%) out of the 35 patients who were using inhalers for more than 24 months made mistakes ($P < 0.05$) [Table 5].

**Patients on pressurized metered-dose inhalers with spacer**

Patients made errors in inhaling deeply and slowly (step 6) and holding the breath for as long as comfortable (step 7). One (50%) patient made error in step 6, whereas in step 7, 1 (50%) made mistake [Table 6 and Figure 6].

Two (66.7%) out of 3 patients educated up to 12th standard, and none among six graduates made errors ($P < 0.05$).

![Figure 4: Prevalence of errors in use of dry-powder inhalers](image)

![Figure 5: Distribution of patients making errors in various steps in use of pressurized metered-dose inhaler](image)

![Figure 6: Distribution of patients making errors in various steps in use of pressurized metered-dose inhalers with spacer](image)

![Figure 7: Distribution of patients making errors in various steps in use of dry powder inhaler](image)
Both the two patients who got their training from nursing staff and none of the 7 who were trained by doctors made errors (P < 0.05) [Table 7].

**Patients on dry-powder inhalers**

Patients made errors in inhaling completely through the mouth (step 6) and holding the breath for as long as comfortable (step 7). Overall, 49 patients showed errors in step 6 and the second most common error was in step 7 made by 22 patients [Table 8 and Figure 7].

Likewise, when individual parameters of patients on DPI were evaluated, 38 (92.7%) out of 41 patients educated up to 12<sup>th</sup> standard, and 23 (62.2%) out of 37 graduates made mistakes (P < 0.05). Twenty-eight (96.7%) out of 30 trained by pharmacists, 21 (88.5%) out of 26 trained by nursing staff, and 12 (40.9%) out of 22 trained by doctors made mistakes (P < 0.05) [Table 9].

**DISCUSSION**

A total of 207 patients were recruited for the study and assessment of their technique of usage of inhalational devices was carried out.

Among the inhalers used, pMDI was most commonly prescribed (58%), followed by DPI (37.7%) and pMDI with spacer (4.3%). Irrespective of the type of inhaler used, overall, 75.36% of patients showed errors in the use of inhaler. This high frequency of incorrect inhaler use is in accordance with results in previously conducted studies.[10,11]

The prevalence of errors in DPI, pMDI, and pMDI with spacers was 78.2%, 77.8%, and 22.2%, respectively. The use of spacer minimizes the error, as hand–mouth coordination is not required as in the use of pMDI. In our study, the frequency of errors with DPI use is almost similar to those with pMDI use which contrasts with previous studies[12,13] and is likely due to the difference in the study design and population. Although a systematic review of inhaler use also found that though DPIs are expected to perform better, error rates were surprisingly only slightly lower than MDI error rates.[14]

In patients using pMDI, 46.2% of the patients committed mistakes in inhaling deeply and slowly while pressing the inhaler, 25.8% of the patients made errors in holding their breath for the desired period before exhaling, and 4.3% of the patients did not exhale completely. In patients using DPIs, 63.9% of the patients made errors in inhaling completely through the mouth and 19.6% of the patients made errors in holding their breath for the desired period before exhaling. In patients using pMDI with spacers, 50% of the patients made errors in inhaling deeply and slowly and 50% of the patients made errors in holding the breath for the desired period before exhaling. Among the errors made in various steps by the patients, certain errors would
Table 7: Association of pressurized metered-dose inhaler with spacer use and patient factors

| Patient factors          | Number of patients (%) | $P$   |
|--------------------------|------------------------|-------|
|                          | Making no error | Making errors | Total  |
| Gender                   |            |      |       |
| Male                     | 4 (66.7) | 2 (33.3) | 6 (100) | 0.25 |
| Female                   | 3 (24)   | 0 (76)  | 3 (100) |       |
| Age (years)              |            |      |       |
| 18-45                    | 3 (75)   | 1 (25)  | 4 (100) | 0.23 |
| Above 45                 | 4 (20)   | 1 (80)  | 5 (100) |       |
| Educational status       |            |      |       |
| 12th and below          | 1 (33.3) | 2 (66.7) | 3 (100) | 0.03 |
| Graduate                 | 6 (100)  | 0      | 6 (100) |       |
| Educator                 |            |      |       |
| Pharmacists              | 0         | 0      | 0      | 0.002|
| Nursing staff            | 0         | 2 (100) | 2 (100) |       |
| Doctors                  | 7 (100)  | 0      | 7 (100) |       |
| Duration of use of inhalers (months) | | | |
| Below 6                 | 2 (66.7) | 1 (33.3) | 3 (100) | 0.66 |
| 6-24                    | 2 (100)  | 0      | 2 (100) |       |
| Above 24                | 3 (75)   | 1 (25)  | 4 (100) |       |

Table 8: Distribution of patients making errors in various steps in use of dry powder inhaler

| Step                                                                 | Number of patients (%) |
|---------------------------------------------------------------------|------------------------|
| Step 1: Take Rotahaler capsule and insert transparent end into the square hole | 0                     |
| Step 2: Press the Totacap firmly                                    | 0                     |
| Step 3: Hold the mouthpiece firmly with one hand and rotate the base with another hand | 0                     |
| Step 4: Exhale completely                                           | 0                     |
| Step 5: Grip the mouth piece between the teeth and seal the lips around it | 0                     |
| Step 6: Inhale completely through the mouth as comfortable, before exhalin   | 39 (63.9)             |
| Step 7: Hold breath for as long as                                 | 12 (19.6)             |
| Step 6 and 7: Details as above                                     | 10 (16.3)             |

In our study, the educational status of patients has shown to have a statistically significant role in determining the appropriateness of inhaler use. In patients who were educated up to 12th standard, the prevalence of errors in inhaler technique of patients using pMDI was 86.7%, while 68.7% in graduates. Similarly, in patients educated up to 12th standard, the prevalence of errors in the inhaler technique of patients using DPI was 92.7%, while 62.2% in graduates. In patients educated up to 12th standard, the prevalence of errors in the inhaler technique of patients using pMDI with spacer was 66.7%, while graduates made no errors. Similar findings were brought out in other studies asserting a statistically significant association between the education status of patients and errors in inhalation technique. The reason for this difference may be that, with better education, the patient is more cognizant of his/her disease and can understand the technique better, therefore making lesser errors. However, the sample size of patients using pMDI with spacer was too less to draw any significant conclusions.

It was observed that all patients were given training regarding the inhaler use and the trainer played a substantial role. If training was given by treating physicians, the tendency of patients to commit errors was significantly lesser vis-à-vis when it was imparted by pharmacists and nursing staff. When pMDI users were trained by the pharmacists, nursing staff, and doctors, the prevalence of errors was 91.3%, 71.9%, and 66.7%, respectively. Among the DPI users, the prevalence of errors was 96.7%, 88.5%, and 40.9% when the patients were trained by pharmacists, nursing staff, and doctors, respectively. When pMDI with spacer users were trained by the nursing staff and doctors, the prevalence of errors was 100% and 0, respectively. A parallel pattern of errors has been reflected in previously conducted studies. Periodic interactions with medical representatives and continuous medical education of physicians, as compared to other health-care workers such as pharmacists and nurses, can be the reason for this difference.

Clinicians play an important role in reinforcing inhaler technique as they are the primary point of contact with the patients and they choose the most appropriate inhaler device for the patient before prescribing. They can encourage their patients to ask any queries concerning the device handling, especially when an inhaler novel to their use is prescribed. Moreover, the clinicians can coach other health-care professionals including pharmacists and nursing staff by acquainting them with “check-correct-confirm” cycle to ensure the effective use of inhaler devices among their patients. Patient training is usually facilitated by demonstration with the help of video instructions.
Table 9: Association of dry-powder inhaler use and patient factors

| Patient factors                          | Making no error | Making errors | Total | Number of patients (%) | P  |
|-----------------------------------------|-----------------|---------------|-------|------------------------|----|
| Gender                                  |                 |               |       |                        |    |
| Male                                    | 7 (17.5)        | 33 (82.5)     | 40 (100) | 0.34                  |    |
| Female                                  | 10 (26.3)       | 28 (73.7)     | 38 (100) |                        |    |
| Age (years)                             |                 |               |       |                        |    |
| 18-45                                   | 12 (27.3)       | 32 (72.7)     | 44 (100) | 0.18                  |    |
| Above 45                                | 5 (14.7)        | 29 (85.3)     | 34 (100) |                        |    |
| Educational status                      |                 |               |       |                        |    |
| 12th and below                         | 3 (7.3)         | 38 (92.7)     | 41 (100) | 0.001                 |    |
| Graduate                                | 14 (37.8)       | 23 (62.2)     | 37 (100) |                        |    |
| Educator                                |                 |               |       |                        |    |
| Pharmacists                             | 2 (6.7)         | 28 (96.7)     | 30 (100) | 0.003                 |    |
| Nursing staff                           | 5 (11.5)        | 21 (88.5)     | 26 (100) |                        |    |
| Doctors                                 | 10 (59.1)       | 12 (40.9)     | 22 (100) |                        |    |
| Duration of use of inhalers (months)    |                 |               |       |                        |    |
| Below 6                                 | 5 (20.8)        | 19 (93.3)     | 24 (100) | 0.96                  |    |
| 6-24                                    | 7 (21.2)        | 26 (78.8)     | 33 (100) |                        |    |
| Above 24                                | 5 (23.8)        | 16 (76.2)     | 21 (100) |                        |    |

and written material,[23] but there must be an emphasis on tailored education according to the patient and re-training in case of erroneous technique exhibited on every visit. Follow-up studies are essential to assess improvement in inhalational techniques after an educational intervention as advised in the GINA strategy since errors often recur till 4–6 weeks after initial training.[6]

Among the pMDI users, when their duration of inhalers use was below 6 months, 6 months to 24 months, and above 24 months, 90.7%, 76.2%, and 62.9% of patients, respectively, committed mistakes. Hence, it was found that patients using pMDI with longer duration of device use had a better technique of inhalation than those with shorter duration. This possibly represents an improvement in the level of understanding of the device usage on part of the patient by repeated reinforcement on correct use in subsequent visits.

The prevalence of errors has not been found associated with the gender of patients in our study, which has also been reflected in other studies.[23] There has been no significant association between the age of the patients and the errors in the inhalation technique, which is in contrast to other studies.[11,16,19,20] The pretext to this contrariness could be that in our study, the range of age of patients enrolled was assessed to be 18–65 years, excluding the elderly and children population. Hence, the difference in error rates among different age groups might not have been brought out.

CONCLUSION

Inhalational medications are the cornerstone in the treatment of bronchial asthma. Incorrect inhaler use can act as a big obstacle in symptomatic management of asthma. From this study, it is concluded that the education status of the patient, training given by the health-care provider, and duration of use of inhaler play substantial roles in minimizing the error rates. There should be an emphasis on the need for new approaches to patient education and training. Moreover, dedicated and trained staff should be available for instructing patients and retraining should be enforced if needed at every opportunity.

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Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Fauci AS, Kasper DL, Hauser SL, Jameson JL, Loscalzo J. Harrison's principles of internal medicine. Longo DL, editor. New York: Mcgraw-hill; 2012.
2. GBD 2016 Causes of Death Collaborators. Global, regional, and national age-sex specific mortality for 264 causes of death, 1980-2016: A systematic analysis for the Global Burden of Disease Study 2016. Lancet 2017;390:1151-210.
3. Peters SP, Ferguson G, Deniz Y, Reisner C. Uncontrolled asthma: A review of the prevalence, disease burden and options for treatment. Respir Med 2006;100:1139-51.
4. Lavorini F, Magnan A, Dubus JC, Voshaar T, Corbetta L, Broeders M, et al. Effect of incorrect use of dry powder inhalers on management of patients with asthma and COPD. Respir Med 2008;102:593-604.
5. Klijn SL, Hiligsmann M, Evers SM, Román-Rodríguez M, van der Molen T, van Boven JF. Effectiveness and success factors of educational inhaler technique interventions in asthma; COPD patients: A systematic review. NPJ Prim Care Respir Med 2017;27:24.
6. Global Initiative for Asthma; 2019. Available from: https://ginasthma.org/. [Last accessed on 2019 Dec 18].
7. Boulet LP, FitzGerald JM, Reddel HC. The revised 2014 GINA strategy report: Opportunities for change. Curr Opin Pulm Med 2015;21:1-7.
8. American Thoracic Society. Available from: https://www.thoracic.org.
9. van der Palen J, Klein JJ, Schildkamp AM. Comparison of a new multidose powder inhaler (Diskus/Accuhaler) and the turbuhaler regarding preference and ease of use. J Asthma 1998;35:147-52.
10. Chrystyn H, van der Palen J, Sharma R, Barnes N, Delafont B, Mahajan A, et al. Device errors in asthma and COPD: Systematic literature review and meta-analysis. NPJ Prim Care Respir Med 2017;27:22.
11. Giraud V, Roche N. Misuse of corticosteroid metered-dose inhaler is associated with decreased asthma stability. Eur Respir J 2002;19:246-51.
12. Chrystyn H, Price DB, Molimard M, Haughney J, Bosnic-Anticevich S, Lavorini F, et al. Comparison of serious inhaler technique errors made by device-naïve patients using three different dry powder inhalers: A randomised, crossover, open-label study. BMC Pulm Med 2016;16:12.
13. Ramadan WH, Sarkis AT. Patterns of use of dry powder inhalers versus pressurized metered-dose inhalers devices in adult patients with chronic obstructive pulmonary disease or asthma: An observational comparative study. Chron Respir Dis 2017;14:309-20.
14. Sanchis J, Gich I, Pedersen S, Aerosol Drug Management Improvement Team. Systematic review of errors in inhaler use: Has patient technique improved over time? Chest 2016;150:394-406.
15. Melani AS, Bonavia M, Cilenti V, Cinti C, Lodi M, Martucci P, et al. Inhaler mishandling remains common in real life and is associated with reduced disease control. Respir Med 2011;105:930-8.
16. Capanoglu M, Dibek Misirlioglu E, Toyran M, Civelek E, Kocabas CN. Evaluation of inhaler technique, adherence to therapy and their effect on disease control among children with asthma using metered dose or dry powder inhalers. J Asthma 2015;52:838-45.
17. Usmani OS, Lavorini F, Marshall J, Dunlop WC, Heron L, Farrington E, et al. Critical inhaler errors in asthma and COPD: A systematic review of impact on health outcomes. Respir Res 2018;19:10.
18. Arora P, Kumar L, Vohra V, Sarin R, Jaiswal A, Puri MM, et al. Evaluating the technique of using inhalation device in COPD and bronchial asthma patients. Respir Med 2014;108:992-8.
19. Sestini P, Cappiello V, Aliani M, Martucci P, Sena A, Vaghi A, et al. Prescription bias and factors associated with improper use of inhalers. J Aerosol Med 2006;19:127-36.
20. Basheti IA, Reddel HK, Armour CL, Bosnic-Anticevich SZ. Improved asthma outcomes with a simple inhaler technique intervention by community pharmacists. J Allergy Clin Immunol 2007;119:1537-8.
21. Bouwmeester C, Kraft J, Bungay KM. Optimizing inhaler use by pharmacist-provided education to community-dwelling elderly. Respir Med 2015;109:1363-8.
22. de Blaquiere P, Christensen DB, Carter WB, Martin TR. Use and misuse of metered-dose inhalers by patients with chronic lung disease. A controlled, randomized trial of two instruction methods. Am Rev Respir Dis 1989;140:910-6.
23. McFadden ER Jr. Improper patient techniques with metered dose inhalers: Clinical consequences and solutions to misuse. J Allergy Clin Immunol 1995;96:278-83.