Inhalational Therapy for Airway Disease Among Adult Patients: Compliance is a Major Challenge Toward Effective Management

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Abstract

Objective: To determine proportion of correct inhalation technique amongst patients with asthma and chronic obstructive pulmonary disease.

Methodology: A cross-sectional study involving 100 known subjects of either disease condition using inhaler device for atleast one-year reporting at chest OPD of government hospital were interviewed using pre-tested semi-structured interview schedule and inhalation technique determined by standard observation checklist. Each step was given a score of ‘one’ if undertaken by patient and ‘zero’ in case of non-compliance.

Results: There were 62% male patients; 27% were illiterate; 92% were married; 32% were current smokers; average age was 50.3 (±14.5) years; 55% and 45% had asthma and COPD respectively; 60% were on MDI device and 40% were using DPI; 23% reported co-morbid (HT/DM) condition and 27% reported occupational dust exposure while more than one-third (36%) reported hospitalization during last one-year due to disease condition. Inspite of clinical requirement, 45% were not taking inhaler therapy regularly and reasons elicited were lack of knowledge (32%), casual attitude (07%), financial constraints (04%) and stigma (01%). On a positive note, patients undertaking regular visit to doctors were also taking inhaler regularly (P < 0.05). However, these positive practices did not translate into satisfactory inhaler performance. Majority (93%) of patients were not taking inhaler as per standard procedure i.e., only three were found undertaking all the 13-steps for MDI while four were following all the 8-steps for DPI use. Mean score (steps undertaken) for MDI user was 6.71 (±3.3) with a range of 0-13 points and 4.4 (±2.4) with a range of 0-8 score for DPI user. On further evaluation, satisfactory performance (minimum essential steps) with regard to either inhaler device was demonstrated by 25% patients only and found to be statistically associated with those not reporting any co-morbidity (P = 0.02). Conclusion: Proper training and compliance could improve inhalation technique.

Key words: Asthma, behavior, chest, communication, COPD, education, smoking, training

INTRODUCTION

Obstructive airway diseases including asthma and chronic obstructive pulmonary diseases (COPD) are leading causes of mortality and morbidity worldwide with profound economic and social burden. The global prevalence of asthma and COPD in general population ranges from 1%-18% and 3%-11% respectively.[1,2] Asthma affected nearly 150 million people worldwide (including 20 million in India).[3] An estimated 64 million people had COPD worldwide (2011) and more than 3 million died of COPD (2012) which is equivalent to 6% of all-deaths; 90% of these deaths occurred in low and middle income countries.[4] The disease burden, mortality, hospitalization and associated cost of care at individual, household, health system and country level is bound to increase in coming decades due to high population base in absolute number, increased life expectancy, rapid urbanization and risk exposure. These include tobacco, respiratory infections, air-pollution (biomass fuel/emission from vehicles/diesel generators/construction activity), occupational dust/chemicals (vapor/irritant/fumes), under-nutrition and adverse socio-economic conditions. It is pertinent to mention that air pollution caused seven million pre-mature deaths across globe in 2012 (WHO).

Various guidelines recommend use of inhaled medicines for medications in the pharmacologic management of asthma and COPD including exacerbations and stable state. The key inhaled medicines for asthma include primarily steroids in conjunction with bronchodilator (beta-agonists) whereas...
for COPD it is primarily bronchodilators (beta-agonists and anti-cholinergic) along with steroids.

Direct delivery of medication to lungs (inhalation therapy) is a major component of the treatment of asthma and COPD. Optimal inhaler technique allows maximal drug delivery to lungs improving the therapeutic benefit leading to improved symptom control. However several studies have demonstrated that more than 50–80% of patients fail to use their inhaler devices correctly.[5–10] Patients are often not aware that they use their inhaled medication inadequately, and overestimate their own abilities.[11] Incorrect use of inhalation devices may lead to uncontrolled disease state, unwanted side effects and can also cause higher treatment cost. Accordingly, it has been estimated that nearly 5-7 million dollars is wasted annually in the USA due to improper inhaler use.[12]

The use of an inhaler device involves a complex series of steps, which need to be performed correctly. Failing to perform one or more steps correctly can substantially reduce medicine delivery leading to questionable effectiveness, safety and cost. Further, difficulties occur because proliferation of inhaler devices has resulted in a confusing number of choices, and patients are rarely prescribed just one inhaled medication.[13] At our centre, increasing number of patients with obstructive airway diseases being experienced with poor inhaler device use and hence a study to assess the correctness of inhalation technique was planned. The objective of present study was to determine proportion of correct inhaler technique among adult patients with obstructive airway disease.

**Materials and Methods**

A descriptive study was undertaken among known patients with asthma or COPD on inhaler therapy of at least one-year duration reporting to chest out patient department (OPD) of a newly established medical college in a government municipal hospital. Considering feasibility, a total of 100 subjects were recruited after clinical confirmation from November 2013 to January 2014. Every consecutive fifth patient was contacted in chest OPD with informed consent to demonstrate inhalation technique and data collection carried out using pre-designed, pre-tested, semi-structure interview schedule. These patients were not under medical care/follow-up of researchers prior to conduct of study. Protocol based advice, management, counseling, and correct training was imparted after completion of interview in a non-judgmental, non-obligatory, confidential and comfortable environment and each interaction lasted up to 45 minutes. Exclusion criterion included patients with exacerbations, suffering from other concomitant chest illness, pediatric age group or those who did not consented for free and voluntary participation in study.

Data variable gathered in this study included information on patient characteristics such as diagnosis, socio-demographic profile, tobacco consumption, duration of illness and inhaler use, occupational dust exposure, regularity of follow-up visit and inhaler use, education for disease condition and inhalation technique, knowledge for dust/smoke avoidance, hospitalization of at-least 24 hours (if any) due to disease condition in past one-year, reported co-morbidity (hypertension/diabetes mellitus) along with observational check list (Appendix 1 and 2) to determine correctness of each step of inhalation technique.

The standard checklist for meter dose inhaler (MDI) and dry powder inhaler (DPI) use had 13 and 8 steps/procedure respectively. Each step was given a score of ‘one’ if undertaken by patient and ‘zero’ in case of non-compliance. The data was further analyzed to examine ‘minimum essential’ steps (satisfactory performance) undertaken by patients for respective device use. Following ‘minimum essential’ 5 steps out of a total of 13 were considered for MDI use: Shaking MDI immediately before use; Holding mouth piece tightly around lips and avoiding obstruction by tongue; Activating inhaler only once with a single inhalation; Inhalation and start of breathing coordinated; Holding breath for at least 10 sec/as long as possible. Following minimum essential 4 steps out of a total of 8 were considered for DPI use: Insert capsule with transparent end down; Place the mouth piece of DPI between teeth and lips; Adequate inhalation (force and depth); and Hold breath for 10 seconds. Compliance for each step of inhaler technique was determined, expressed as proportion, mean score and association between satisfactory performances and co-variable was assessed using Chi-square test.

**Results**

Out of 100 patients, 62% were male; 27% were illiterate; 92% were married; 55% had asthma; 45% had COPD and average age was 50.3 (±14.5) years. The background and socio-demographic characteristic of patients is shown in Table 1. Average duration of illness was 5 years (median); 60% were using MDI and 40% were using DPI devices; 27% reported occupational dust exposure while more than one-third (36%) patients reported hospitalization during last one-year due to disease condition (asthma/COPD). On the contrary, high proportion (85%) of patients mentioned receiving education on disease condition from doctor and 80% were aware of dust/smoke avoidance [Table 2]. But none of the patient could recollect having specifically been told about steps of inhalation technique.

Table 3 depicts profile of patients with regard to follow-up visit to doctors vs. regularity of inhaler use. Out of 55 patients found to be taking regular inhaler therapy, higher proportion (45/55, 81.8%) were also found to be under-taking regular follow up visits to doctors in comparison to non-regular (10/55, 18.1%) patients ($P < 0.05$). The reasons elicited for not taking regular inhaler therapy were lack of knowledge (32%), casual attitude (07%), financial constraints (04%) and stigma (01%).

Majority (93%) of patients were not using inhaler therapy as per standard steps/procedure i.e., only three were found undertaking all the 13-steps for MDI use while four were following all the 8-steps for DPI use. Mean score for MDI user was 6.71 ($±3.3$) with a range of 0-13 points (steps undertaken); 34%, 16% and 10% patients scored up to 7 points, between 8-10 points
Table 1: Background profile of patients (n=100)

| Variable                          | Asthma (55%) | COPD (45%) |
|-----------------------------------|--------------|------------|
| Diseases                          |              |            |
| Age                               | 50.3 (±14.5) years |
| Sex                               | Male (62%)   |
|                                   | Female (38%) |
| Literacy status                   | Literate (73%) |
|                                   | Illiterate (27%) |
| Occupation                        | Skilled worker (42%) |
|                                   | Semi-skilled worker (14%) |
|                                   | Un-employed (44%) |
| Monthly income                    | Less than Rs. 5000/- (47%) |
|                                   | Rs 5000/- - 10000/- (37%) |
|                                   | More than Rs. 10000/- (16%) |
| Smoking status                    | Current smoker (32%) |
|                                   | Ex-smoker (18%) |
|                                   | Non-smoker (50%) |
| Marital status                    | Married (92%) |
|                                   | Unmarried (8%) |

Table 2: Description of patients (n=100) according to selected parameters

| Variable                                      | Yes (n=55) | No (n=45) |
|-----------------------------------------------|------------|-----------|
| Average duration of illness (Asthma/COPD)     | 5 years (median) |            |
| Average duration of inhaler use               | 2 years (median) |            |
| Undertaking regular follow-up visit to doctor | Yes (55%)  | No (45)   |
| Taking inhaler therapy regularly              | Yes (55%)  | No (45)   |
| Occupational dust exposure                    | Yes (27%)  | No (73%)  |
| Hospitalization during last year due to disease condition | Yes (36) | No (64) |
| Reported co-morbid disease condition (HT/DM)  | Yes (23)   | No (77%)  |
| Received health education on disease condition| Yes (85)   | No (15)   |
| Awareness regarding dust/smoke avoidance      | Yes (80)   | No (20%)  |
| Awareness regarding step up/down approach     | Yes (59)   | No (41)   |

Table 3: Follow-up visit to doctor vs. regularity of inhaler use by patients

| Undertaking regular follow-up visit to doctor | Taking inhaler regularly |
|-----------------------------------------------|--------------------------|
| Yes (n=55)                                    | 45                       |
| No (n=45)                                     | 10                       |

Discussion

This study re-affirms that vast majority of patients used their inhalers incorrectly, whether it is MDI or DPI. Inadequate compliance poses a challenge in terms of sub-optimal disease control including hospitalization (36%) since clinically all were suffering from moderate to severe illness. Literature revealed that as many as 25% of patients have never received verbal inhaler technique instruction. Those who have received some inhaler instruction reveal that this is almost always less than 10 min duration with no follow-up assessment in 45% of cases. Follow-up checks on inhaler technique are important when one considers that as early as 3 days after successful instruction, more than one-third of patients no longer use their inhaler correctly. Interestingly, patients who received inhalation instructions at least once more after the initial instruction have better inhalation technique compared with those who received a single inhalation instruction at the time of prescription. Training in correct inhaler use rather than instructions appears to be more important and it has also been shown that error rates increases with age irrespective of inhaler types. However, in our study age had no statistical bearing on satisfactory performance.

Providing training on correct inhaler technique is an integral component of asthma and COPD education plans. The key principles and component of health education plan are shown in Table 5. It is assumed that patient understands the nitty-gritty of managing devices in chronic diseases after imparting health education; however, this study clearly brings out the gap. In the light of poor monitoring and supervision, patients learn by trial and error method and continue the practice of faulty inhaler technique. Further, there appears to be a Dichotomy, at one end nearly 85% patients mentioned receiving health education on disease condition and on the other, none could recollect having been told about steps of inhalation technique and 32% reiterated lack of knowledge on account of regular use of inhaler. Either this component (training on inhalation technique) was not covered or could be recall bias. From sociological perspective, it boils down to KAP (knowledge, attitude and practice) gap!

In our study, patients undertaking regular visits to doctor were also found to be taking inhaler regularly (P < 0.05). However,
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Table 4: Association of satisfactory inhaler performance with selected co-variables

| Background variable                      | Satisfactory performance | P value |
|------------------------------------------|--------------------------|---------|
| Reported co-morbid (HT/DM) condition     |                          |         |
| Yes                                      | 10 (40%)                 | 13 (17.3%) | 0.02 |
| No                                       | 15 (60%)                 | 62 (82.6%)  |
| Taking regular inhaler therapy           |                          |         |
| Yes                                      | 19 (76%)                 | 36 (48%)  | 0.05 |
| No                                       | 06 (24%)                 | 39 (52%)  |

HT: Hypertension, DM: Diabetes mellitus

Table 5: Key principal and components of health education plan

| Principal                                      | Key components                          |
|------------------------------------------------|-----------------------------------------|
| Development of doctor-patient partnership     | Diagnosis                               |
| Acceptance of long term and continuous process| Risk assessment                         |
| Sharing information                           | Prevention of symptoms and attacks      |
| Expression of expectations, fears and concerns| Treatment options                       |
| Focus on self management                      | Difference between relievers and controllers |
| Feasible solutions                            | Use of inhaler devices                  |
| Consistent message                            | Potential side effects of medications   |
| Sustainable interventions                     | Adherence and follow-up                 |
|                                               | Monitoring                              |
|                                               | Smoking cessation                       |
|                                               | Management of co-morbidities            |

Adapted from GINA, 2014

These positive practices did not translate into satisfactory inhaler performance either. This is suggestive of quality of doctor-patient communication including in-a-dequate emphasis on each step of device use (poor training), follow-up/supervision problem, time/commitment/motivation issue, distractions and variable attention span including cognitive ability of patients.

At our centre under government supply most of medications including inhalers are provided free of cost to the patients. However, it is noticed that there occurs supply-chain issues with provision of variable devices during a financial year. Patient may be started on MDI [Annexure 1] due to need and availability in the hospital but later on may have to switch to DPI [Annexure 2] due to non-availability of MDI device. Simultaneously, all relevant drugs (beta-agonists, anti-cholinergic and steroids) should be made available in one-form of inhaler only, but due to logistic issues provision of these drugs occurs in different forms i.e., some in MDI and other in DPI. It is well documented that adherence is inversely related to the number of medications taken by patients.\(^{19}\) Our patients due to financial problems are unable to purchase requisite inhaler from open-market and hence are forced to take multiple devices simultaneously. This switch over or multiple device practice leads to patient confusion and poor compliance. The administrative mechanism in these two-case scenarios need re-evaluation and solutions are required to be ironed for better care.

Air pollution status in Delhi has degraded from bad to worse in recent years. The urban air database released by WHO (2014) reported that Delhi has exceeded maximum particulate matter\(_{10}\) limit to 286 µg/m\(^3\) (WHO standard = 20 µg/m\(^3\)) with profound consequences on population cardio-respiratory system. A comprehensive study carried out under aegis of Central Pollution Control Board (2008) found that Delhi had 1.7 times higher prevalence of respiratory symptoms (in the past 3-months) compared with a control rural population of West Bengal (\(P < 0.001\)). Lung function was reduced in 40.3% individuals of Delhi compared with 20.1% in control group. Delhi showed a statistically significant (\(P < 0.05\)) increased prevalence of restrictive (22.5% vs. 11.4% in control), obstructive (10.7% vs. 6.6%) as well as combined (both obstructive and restrictive) type of lung deficits (7.1% vs. 2.0%).\(^{20}\) Vehicular population in Delhi has exceeded combined number of vehicles in other three metros to more than 75 lakhs contributing to variable...
and high emissions. Under influence of such environment, large number of people are suffering/reporting with adverse chest/sinuses outcome and conjunct poor practices leading to ineffective disease control with sub-optimum quality of life. National Green Tribunal and legislative courts have pulled up government to take stern steps for short and long term solutions however diverse political interests, concentrated lobbying and non-regulation is a huge barrier. Pollution control board in Delhi for the first time in country during 2015 would be informing citizens through advisories using coloured air quality index based on national ambient air quality monitoring system. Many diplomats, expats and economically upward citizens residing in Delhi have starting installing ‘air-purifiers’ (in addition to air-conditioners) at their residence to circumvent current critical situation.

To conclude, with in limitations of hospital based study, most patients (75%) with asthma and COPD are not using their inhaler correctly. On a parallel note, there is also high concomitant sensitization/training need for doctor on correct steps for inhalation technique. Proper training, compliance and demonstration of inhalation technique by patients on first and repeat clinic visits would boost morale and also lead to correction of deviant practices.

### Annexure 1: Check list for assessing inhalation technique of MDI device

| Procedure                                                                 | Yes/No |
|---------------------------------------------------------------------------|--------|
| Shaking MDI immediately before use                                         | Yes/No |
| Exhaling fully before activating the MDI                                   | Yes/No |
| Tilt head slightly back                                                    | Yes/No |
| Holding mouth piece tightly around lips and avoiding obstruction by tongue | Yes/No |
| Keeping the MDI with longest point pointing upwards                        | Yes/No |
| Activating inhaler only once with a single inhalation                      | Yes/No |
| Inhalation and start of breathing coordinated                               | Yes/No |
| Slowly inhaling after activating Inhaler                                    | Yes/No |
| No aerosol loss visible                                                     | Yes/No |
| Continue to inhale fully without interruption after delivery of dose       | Yes/No |
| Holding breath for at least 10 sec/as long as possible                     | Yes/No |
| Wait for 1-2 minutes for taking second puff                                | Yes/No |
| Rinsing                                                                    | Yes/No |

### Annexure 2: Check list for assessing inhalation technique of DPI device

| Procedure                                                                 | Yes/No |
|---------------------------------------------------------------------------|--------|
| Keep the DPI upright for insertion of capsule                             | Yes/No |
| Insert capsule with transparent end down                                   | Yes/No |
| Keep the DPI horizontal                                                    | Yes/No |
| Exhale to residual volume after deep inhalation                           | Yes/No |
| Place the mouth piece of DPI between teeth and lips                        | Yes/No |
| Adequate inhalation (force and depth)                                      | Yes/No |
| Hold breath for 10 seconds                                                 | Yes/No |
| Rinsing                                                                    | Yes/No |

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