Pharmacology Section

AVIJIT GANGULY¹, ANUP KUMAR DAS², ANINDYA ROY³, ANJAN ADHIKARI⁴, JOYASHREE BANERJEE⁵, SUMITRA SEN⁶

ABSTRACT

Objective: To examine the frequency of proper use of inhalation devices and influence of age and training on it.

Study of Proper use of

Asthma or COPD Patients

Inhalational Devices by Bronchial

Attending a Tertiary Care Hospital

Materials and Methods: One hundred and five subjects of bronchial asthma and Chronic Obstructive Pulmonary Disease (COPD); aged between 18 to 75 y (mean \pm SD; 46 \pm 28.55) were studied. Subjects were enrolled over a period of three months. Data like weight, height and concomitant medications were recorded. It was an observational and questionnaire based study. Parameters were chosen to demonstrate the inhalational technique, errors committed in different steps of use & nature of medical, paramedical, nursing personals and others imparting training for use of inhaler device and time devoted for it.

Results: Of total 105 patients, 31 were using dry powdered inhalers (DPI), 50 on metered dose inhalers (MDI), and 24 on MDI with spacer devices. Among study population 83.81% were trained by healthcare professionals (doctors, nurse,

pharmacists, paramedical or representatives of Pharmaceutical companies) and 16.19% are trained by general people. Among the MDI users (n=50) only 6%, 16.12% among the DPI users, 20.8%, among MDI with spacer users could use inhalers correctly. At 95% confidence limit there was significance of errors committed between DPI and MDI users (difference of SE is 2.56) and between spacer and MDI users (difference of SE 2.92). There was no difference found in regard of frequency of errors committed in taking different devices according to patient's socioeconomic, educational background and trainer.

Conclusion: It was concluded that use of MDI with spacer most convenient method. Doctors often did not have sufficient time to train patients regarding proper technique of inhaler use. With ever increasing and widespread use of inhalers patients' education is becoming more important. Proper training will surely make these drugs more effective and cost benefit ratio more favourable.

INTRODUCTION & BACKGROUND

Bronchial asthma is estimated to affect some 300 million people worldwide and accounts for about one per cent of all disabilityadjusted life years lost [1]. The preferred method of drug administration is by inhalation [2], as this result in a faster onset of action, lower required doses, and fewer systemic adverse effects [3] than with the oral route of delivery.

About 90% of patients show incorrect technique with either standard pressurised metered dose inhalers (pMDIs) [4] or dry-powder inhalers (DPIs). Although, these are designed to improve use, still significant rates of incorrect use among COPD and asthma patients [5-8].

With short-acting $\beta 2$ agonists (relievers), poor inhaler technique results in loss of bronchodilator effect [9,10]. Among patients using standard pMDIs without a spacer, failure to coordinate inspiration with actuation has been shown to result in reduced lung deposition of medication [11]. However, only few previous studies have investigated the frequency and impact on asthma control due to poor knowledge regarding correct use of inhalers by patients or health care givers [12].

Now a days, asthma and COPD (Chronic obstructive Pulmonary disease), are mainly treated by inhaled therapy [12]. This practice became widespread many years after the introduction of atropine and adrenaline, used as bronchodilators [13], only when efficient nebulizer ampoules and inhalers [14] finally became available. Three types of dispensers for lung deposition of drugs: A) nebulizers, B) pressurized inhalers and C) the dry powder inhalers; many models of each type are available. In patients with asthma or COPD who show poor inhaler technique with a pMDI, the addition of a large-

volume spacer and education from a health professional (rather than simply changing inhalers) might be the best initial strategy for improving inhaler technique [5].

Keywords: COPD, Bronchial asthma, Inhaler, Spacer device

Education about medications occurs mostly during doctor consultations at the time of prescribing, and yet evidence points to the passivity of the patient and a low level of information exchange during such consultations [8]. In recent years, pharmacists have become more active in patient care, and can demonstrate a positive impact on the outcomes of drug therapy in asthma patients, globally [9]. Incorrect use of pMDIs for inhaled corticosteroids (ICS) has been associated with increased reliever use, increased use of emergency medical services, worsening asthma [9]. Inefficient technique with DPIs may also lead to insufficient drug delivery and therefore insufficient lung deposition [2].

MATERIALS AND METHODS

Selection criteria

Study subjects were patients of (1)COPD or bronchial asthma (2) aged between 18 to 75 y, either sex, (3) attending spirometry clinic at Dept. of Physiology, of R. G. Kar Medical College & Hospital in a span of three months between July and September 2013 (4) using inhalational therapy by either pMDI or DPI. But who either required hospitalization or on nebulizer therapy were excluded. The study was an observational questionnaire based.

The study was approved by the Ethics Committee of R. G. Kar Medical College and Hospital, Kolkata, in July 2013.

Diagnosis was done by attending physicians at Chest OPD of R. G. Kar Medical College. This study did not intervene in the treatment

| Age | Male(%) | Female(%) | Total(%) | | | |
|-------------------------------------------------------------------|----------|-----------|----------|--|--|--|
| <20 | 5(9) | 3(6) | 8(7.6) | | | |
| 20-29 | 4(7.3) | 7(14) | 11(16.5) | | | |
| 30-39 | 4(7.3) | 15(30) | 19(18.5) | | | |
| 40-49 | 8(14.5) | 9(18) | 17(16.2) | | | |
| 50-59 | 14(25.5) | 7(14) | 21(20) | | | |
| 60-69 | 14(25.5) | 6(12) | 20(19) | | | |
| >69 | 6(10.9) | 3(6) | 9(8.6) | | | |
| Total | 55(52.6) | 50(47.6) | 9(8.6) | | | |
| [Table/Fig-1]: Age and sex distribution among participants n= 105 | | | | | | |

| Trainer | Correctly done | Incorrectly done | Total | | | | |
|--------------------------------------------------------------------------------------------------|----------------|------------------|-------|--|--|--|--|
| Medical persons | 11 | 77 | 88 | | | | |
| Non-medical Persons | 2 | 15 | 17 | | | | |
| Total | 13 | 92 | 105 | | | | |
| Table /Fig 01 . Distribution of different parson on trainer to individual patients taking | | | | | | | |

inhalers 1st time and result of training ; n=105., λ^2 =0.00681, Not significant at p>0.05

| Distribution of wrongly done steps among MDI users (n=31) | | IDistribution of wrongly done steps among DPI users (n=50) | | Distribution of wrongly done steps among MDI with spacer users (n=24) | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|------------------------------------------------------------------|--------------------------------|-----------------------------------------------------------------------------|--------------------------------|--|--|
| Steps (Step No.) | Wrongly done (frequency) | Steps(step No.) | Wrongly done (frequency) | Steps (Step No.) | Wrongly done (frequency) | | |
| I | Nil | Į | Nil | I | 1 | | |
| II | 1 | II | 13 | II | 1 | | |
| | 16 | Ш | 22 | 111 | 2 | | |
| IV | 10 | IV | 17 | IV | 3 | | |
| V | 15 | V | 25 | V | 8 | | |
| VI | 14 | VI | 26 | VI | 12 | | |
| VII | 11 | VII | 16 | VII | 15 | | |
| VIII | 5 | VIII | 11 | VIII | 14 | | |
| IX | 4 | IX | 11 | IX | 13 | | |
| Total | 76* | Х | 9 | Х | Nil | | |
| | | XI | 9 | XI | 1 | | |
| | | Total | 159* | XII | nil | | |
| | | | | XIII | Nil | | |
| | | | | Total | 70* | | |
| [Table/Fig-3]: Distribution of wrongly done steps during inhalation by different subjects in different inhaler devices they were using *Multiple responses | | | | | | | |

protocol. Finally, subjects were included only if the participant provided written informed consent. Interview was taken at 1st visit.

Aims and Objectives

- A) Use of inhaler devices by the patients according to standard steps by asking them to show the inhalational technique with the inhaler.
- B) Errors committed in different steps of use.
- C) Nature of medical, paramedical, nursing personals and others imparting training for use of inhaler device and time devoted for it.

Activities at Time of Visit

The screening assessment after diagnosis was confirmed, the selection criteria were checked. Written informed consent was sought. A general examination including weight, length/height of the subject was undertaken. Then the subject was asked to take their inhaler device out and to show his own technique of inhaler use. Every step and noted the error(s) according to standard checklist [15] (Referred to Annexure I) and guideline was checked. After completion of actuation training was given to each participant to prevent errors of inhalation technique in future. Investigations; like PFT and other common investigations were noted. In study protocol there was no scope for any follow up visit.

RESULTS AND STATISTICAL ANALYSIS

Among 105 participants, 55 were male and 50 female. Of them, 31 were using DPI, 50 on MDI, 24 on MDI with spacer devices. Among the total population 52.4% male and 47.6% female. Maximum from 50-59 years age group (20%) and minimum from <20 years age group (7.6%) [Table/Fig-1]. Among total subjects 28.5% people are illiterate or just literate 32.4% are having primary education, 13.3% have middle school education; 18.2% have secondary education, 3.8% have higher secondary education & 3.8% have more than senior/higher secondary qualified. In the study population 15.24% of participants are having monthly income \geq 10,000 Rupees.

Among male subjects 38.1% were smoker, 36.4% ex-smokers & 25.5% non-smoker. No female subject has smoking habit. Among whole population (n=105), 83.81% are trained by medical persons (doctors, nurse, pharmacists, paramedical or representatives of Pharmaceutical companies) and 16.19% are trained by others like familymembers, neighbours. There is no significant difference in the two groups in the outcome of training [Table/Fig-2].

In DPI users mean time of training is 4.23minutes with SD \pm 2.61; in MDI users mean is 3.48, SD \pm 2.01; in spacer users mean is 4.3 and SD \pm 2.64. No significant difference between these groups in this regard. (p-value in unpaired t-test (two tailed) between DPI user & MDI user = 0.1516 between MDI & spacer user 0.1458) [Table/ Fig-3]. Among the MDI users (n=50) only 3 (6%) can perform the total process correctly. Distribution of wrongly done steps among the MDI users is shown in [Table/Fig-3]. Among the spacer users (n=24) 5 persons can do all the steps correctly (20.8%) [Table/ Fig-3].

The participants doing all steps correctly are 16.12% among the DPI users, 6%, among MDI users and 20.8% among spacer users. At 95% confidence limit there is significance of this proportion between DPI and MDI users (difference of SE is 2.56) and between spacer and MDI users (difference of SE 2.92).

DISCUSSION

Using different devices as inhaler medications correctly is a really challenging task in Indian patients especially after considering their educational and socio-economic background. But this study showed that proper training by any persons (even by non-professionals can reduce errors irrespective of participants' educational status. In this study total 105 patients were observed. It was found that most easy technique of inhalation was use of MDI with spacers. There was least chance of using erroneous technique comparing with other two. Another important observation was found that proper training of use of devices is very important. But prescribers often have not much time to educate the patients regarding proper methods of use and cleaning the devices.

One of the important reasons of poor asthma and COPD control in spite of optimum dosage of inhalational agents is improper methods followed. This may be due to insufficient time given to teach the patients by prescribers or lack of proper communication. In this regard very important role should be played by pharmacist who dispenses the medicines. It has been seen that physicians often like switch over to more potent inhalational corticosteroid or simply increase the dose after seeing inadequate disease control. This study compelled to think whether patients are taking the inhalers properly before changing the medicines altogether. Sample size was moderate in this study. This study was conducted with limited resources and budget. So far in India there is not much study regarding this topic were conducted. But quite a few reports are there studied and done abroad [2,16].

A large body of evidence from randomised clinical trials has shown that patients' inhaler technique can be improved by education from a health professional [17-19] or other person trained in correct technique [20]. The amount of instruction on inhaler technique given by health care professional's influences patients' likelihood of correct technique. However, published studies from around the world suggest that as many as 25% of patients with asthma or COPD have never received verbal inhaler technique instruction. When given, instruction is often rushed, poor quality and not reinforced [4]. Only an estimated 11% of patients receive follow-up assessment and education on their inhaler technique [6]. Several studies have demonstrated that community pharmacists can provide effective training in correct inhaler technique [15]. In patients with asthma, interventions to correct inhaler technique have been shown to improve measures of asthma control such as patient-reported perceived asthma control [3], scores for asthma-related quality of life questionnaires [15], asthma severity classification [4], and lung function measures such as peak expiratory flow (PEF) [15] or PEF variability [5]. In patients with asthma who showed poor timing and rapid inhalation when using a salmeterol pMDI, the use of a spacer achieved a greater increase in expiratory flow after bronchodilator and this benefit persisted for 6h [21]. There also concerns were expressed about improper techniques used by the patients leading to suboptimal control over asthma and COPD.

ANNEXURE I

Standard Checklist [22]

Pressurised metered dose inhaler suggested checklist

- 1. Remove cap
- 2. Hold inhaler upright and shake well
- 3. Breathe out gently
- 4. Put mouthpiece between teeth without biting and close lips to form good seal
- 5. Start to breathe in slowly through mouth and press down firmly on canister
- 6. Continue to breathe in slowly and deeply
- 7. Hold breath for about 10 seconds or as long as comfortable
- 8. While holding breath, remove inhaler from mouth
- 9. Breathe out gently away from mouthpiece
- 10. If an extra dose is needed, wait 1 minute and then repeat steps 2 to 9
- 11. Replace cap

Pressurised metered dose inhaler plus spacer suggested checklist

- 1. Assemble spacer
- 2. Remove inhaler cap
- 3. Hold inhaler upright and shake well
- 4. Insert inhaler upright into spacer
- 5. Put mouthpiece between teeth without biting and close lips to form good seal
- 6. Breathe out gently
- 7. Hold spacer level and press down firmly on canister once
- 8. Breathe in slowly and deeply then hold breath for about 10

seconds or as long as comfortable OR Breathe in and out normally for 4 breaths

- 9. Remove spacer from mouth
- 10. Breathe out gently
- 11. Remove inhaler from spacer
- If an extra dose is needed, wait 1 minute and then repeat steps 3 to 11
- 13. Replace cap and disassemble spacer

DPI-suggested checklist

- 1. Unscrew and remove cover
- 2. Keep inhaler upright while twisting grip around and then back until click is heard
- 3. Breathe out gently away from mouthpiece
- 4. Place mouthpiece between teeth without biting and close lips to form a good seal
- 5. Breathe in strongly and deeply
- 6. Remove inhaler from mouth
- 7. Breathe out gently away from mouthpiece
- 8. If an extra dose is needed, repeat steps 2 to 8
- 9. Replace cover

CONCLUSION

With ever increasing urbanization and industrial, automobile pollution the prevalence of both asthma and COPD is growing fast. Inhaled corticosteroids and $\beta 2$ agonists have now become 1st line of therapy in both. Proper training of different devices is extremely important for proper control and cost effectiveness relating to long term disease control.

This study pointed out that how poor the knowledge of patients using those inhalers irrespective of educational and socioeconomic status. It is recommend starting of wide range awareness programme regarding the importance and utility of proper use of different inhalational devices not only for patients' education but also prescribers, healthcare associates, pharmacists and all concerned parties. Manufacturers should also come forward in this regard.

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PARTICULARS OF CONTRIBUTORS:

- Assistant Professor, Department of Pharmacology, R. G. Kar Medical College & Hospital, Kolkata, India. 2
- Professor and Head, Department of Pharmacology, R. G. Kar Medical College & Hospital, Kolkata, India. Assistant Professor, Department of Physiology, R. G. Kar Medical College & Hospital, Kolkata, India. З.
- Associate Professor, Department of Pharmacology, R. G. Kar Medical College & Hospital, Kolkata, India. 4.
- Assistant Professor, Department of Physiology, R. G. Kar Medical College & Hospital, Kolkata, India. 5.
- 6. Postgraduate Trainee, Department of Physiology, R. G. Kar Medical College & Hospital, Kolkata, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Avijit Ganguly,

BG 116, Rabindrapalli, Krishnapur, P. O. Prafullakanan, Kolkata-700101, India. Phone : 09830220324, E-mail : avijitdec81@gmail.com

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