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Running Title: Ability to Use of pMDIs with Spacer Device**The Pharmacists' Ability to Use Pressurized Metered-Dose Inhalers with a Spacer Device and Factors Affecting It**

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Abstract

Objective: The aim of this study is to evaluate the pharmacists' ability to use pMDIs with a spacer device and the factors that affect this ability.

Method: Face to face interviews were conducted with the pharmacists. A nine item questionnaire was completed and the checklist for how to use pMDIs with a spacer device was filled out.

Results: A total of 307 pharmacists voluntarily participated in this study. Fifty-six (18.2%) of the pharmacists stated that they did not know how to use pMDIs with a spacer device. These pharmacists were excluded and remaining 251 pharmacists included in the study. Only 100 (39.8%) pharmacists demonstrated all of the inhaler spacer device usage steps correctly. The step in which pharmacists made the most mistakes was "take 5–6 deep and slow breaths, hold for 10 seconds and slow breaths." Those pharmacists who were more likely to correctly use pMDIs with a spacer device were younger ($p=0.023$), had dispensed more asthma medications per day ($p<0.001$), had dispensed more asthma medications per day for patients younger than six years of age ($p=0.016$), and sold inhaler spacer devices at their pharmacy ($p=0.042$).

Conclusion: Approximately one third of the pharmacists in the current study were able to

correctly demonstrate all of the steps for proper usage of pMDIs with a spacer device, which indicates that pharmacists should be included in the training program and be provided continuous training on the use of pMDIs with a spacer device.

Key words: asthma, children, pharmacists, spacer device, skill, ability

Introduction

Asthma is a serious global health problem affecting all. Its prevalence is increasing in many countries, especially among children [1]. The preferred method of administering bronchodilators and corticosteroids, which are essential drugs in the treatment of asthma, is by inhalation, as opposed to oral and parenteral routes. Inhalation therapy involves commonly used inhalers: pressurized metered dose inhalers (pMDIs) and dry powder inhalers (DPIs). pMDIs with spacer devices are preferable for children, the elderly, and adults with physical or mental disabilities. To achieve optimal effectiveness of this therapy, correct device technique is vital. Incorrect device technique with pMDIs is a common issue among asthmatic patients [2–5]. An inability to properly use pMDIs with a spacer device can have negative consequences, such as an inability to control the disease, the use of more drugs, additional side effects, frequent acute attacks and hospitalizations, and a waste of medication, all of which can cause a lack of confidence in the therapy and an additional burden on a country's health-related expenses [6,7]. Previous studies have shown that many asthmatic patients are unable to perform proper inhalation techniques, even after receiving instructions [2,3,8]. Therefore, frequent training on this issue can have more positive effects on the correct usage.

In Turkey, inhaler spacer devices are sold in pharmacies. For this reason, when inhaler spacer devices are prescribed to patients with asthma, it is important for pharmacists to know how to use the inhaler spacer device and how to train patients in terms of successful therapy. Few studies have been conducted among pharmacists regarding the inhalation techniques used in therapy for patients with asthma, especially regarding usage procedures for an inhaler spacer device [9–11].

The objectives of this study are (1) to identify the prevalence of pharmacists working in three selected regions of Turkey who report they know how to use pMDIs with a spacer device; (2) to determine the proportion of pharmacists who can correctly use pMDIs with a spacer device based on an itemized checklist; and (3) to describe the factors that are associated with a pharmacist's ability to properly use pMDIs with a spacer device.

Material and method

Study sample

The pharmacists were included in this study on a voluntary basis, and three centers located in different parts of Turkey were included. These study centers were Inonu University (Malatya), Istanbul Medeniyet University (Istanbul, Goztepe region), and Bakırkoy Sadi Konuk Education and Research Hospital (Istanbul, Bakırkoy region). There are a total of 743 pharmacies in the areas in which these three centers are located. Forecasting that the correct pMDIs with spacer device usage rate was 40% [12], with a 95% confidence interval ($\alpha=0.05$) and a 6% deviation rate, the minimum number of pharmacists that should have been included in the study was 256.

Prior to questionnaire development, a literature review was performed to identify articles assessing pharmacists with knowledge about usage of inhaler asthma medication and factors associated with correct inhaler technique. The questionnaire contained nine questions and a checklist for how to use pMDIs with a spacer device; the checklist was derived from the Guidelines for the Diagnosis and Management of Asthma, National Asthma Education and Prevention Program (Table 1) [13]. The questionnaire form included the demographic data, such as the pharmacists' ages, genders, and years in the profession, self-reported information about the number of prescriptions for inhaler forms of asthma medication per day and other related information and the usage steps for pMDIs with a spacer device (Table 2).

Use and technique assessment for pMDIs with a spacer device

Face to face interviews were conducted with the pharmacists and then they completed the nine-item questionnaire. The pharmacists who answered "yes" to item 9 indicated that they knew how to use the device, and they were then asked to demonstrate proper usage of the device (with a placebo) both verbally and physically. The inhalation technique was evaluated by a trainer, who recorded the findings on a standardized checklist. The inhalation technique was considered to be correct when all of the essential steps were properly performed. Pharmacists were excluded from the study if they answered "no" to the question about knowing how to use the inhaler spacer device. The research protocol was approved by the ethics committee of Inonu University (2019/5-19), and all of the pharmacists provided written informed consent.

Statistical Analysis

Statistical analysis was performed with the Statistical Package for Social Sciences (SPSS) 17.0 software (SPSS Inc. Chicago, IL). Normality was evaluated by Kolmogorov-Smirnov test. Descriptive statistics were expressed as the frequency and percentage for

categorical variables, whereas quantitative data were expressed as the median [interquartile range (IQR)] for non-normally distributed data. To examine whether pharmacist demographic or dispensing characteristics are associated with correct inhaler technique, categorical variables were compared by using the Pearson chi-square test or Fisher's exact test, and quantitative variables were compared with the Mann-Whitney U test. A 2-sided $p < 0.05$ was considered statistically significant.

Results

A total of 307 pharmacists voluntarily participated in this study. One hundred seventy-seven (57.7%) pharmacists were males and the median age was 32 [28-40] years old. The median professional experience time of the pharmacists was 10 [5-19] years. The median number of prescriptions for inhaler forms of asthma medication was 5 [3-8] per day. The median number of prescriptions for inhaler forms of asthma medication for patients younger than six years of age was 2 [1-3] per day. Two hundred and forty-two (78.8%) of the pharmacists stated that they sold inhaler spacer devices in their pharmacy. Fifty-six (18.2%) of the pharmacists stated that they did not know how to use pMDIs with a spacer device and these pharmacists were excluded from the study. Of the 251 remaining pharmacists, only 100 (39.8%) showed all of the steps for proper usage of pMDIs with a spacer device. The step that resulted in the least mistakes was "connect the pMDI to the spacer" while the step that resulted in the most mistakes was "take 5-6 deep breaths, hold for 10 seconds and slow breaths" (Table 3).

Those pharmacists who were more likely to correctly use pMDIs with a spacer device were younger (Mann-Whitney U test value=6273; $z=-2.270$; $p=0.023$), had dispensed more asthma medication per day (Mann-Whitney U test value=5611; $z=-3.504$; $p<0.001$), had dispensed more asthma medication per day for patients younger than six years of age (Mann-Whitney U test value=5915; $z=-3.163$; $p=0.016$), and sold inhaler spacer devices at their pharmacy (Chi-square test value=5.017; $df=1$; $p=0.042$) (Table 4).

Discussion

In Turkey, pharmacists usually provide information to patients regarding pMDIs with a spacer device and asthma because they are the final link in the asthma therapy chain before patient self-administration. For more effective treatment, spacer devices are preferable for children, the elderly, and adults with physical or mental disabilities. These devices are also sold in pharmacies. For this reason, it is important for pharmacists and pharmacy workers to know how to correctly use pMDIs with a spacer device and to be able describe this technique

to their patients in order to ensure successful therapy for asthma. Our study showed that the correct usage rate for pMDIs with a spacer device was very low among the pharmacists. Approximately one fifth of the pharmacists were unfamiliar with inhaler spacer devices, and although the rest stated that they knew how to use them, approximately one third could show their usage correctly.

In a study conducted by Osman et al. [10] using a metered dose inhaler with a spacer, 41% of the pharmacists were “totally unfamiliar” with the device, and 42.2% did not know how to use it correctly. Only 7.2% of the pharmacists demonstrated an “adequate technique.” Based on the results of that study, the researchers concluded that many participating community pharmacists lacked the basic knowledge and practical skills that are required to demonstrate the correct inhalation techniques of the available bronchial asthma inhaler delivery systems. This will clearly have a serious negative impact on patient education and training, as well as on the global push for better asthma care. Similar to the results of that study, 18.2% of the pharmacists in our study were unfamiliar with the inhaler spacer device, and only 39.8% of the participants who stated that they knew how to use pMDIs with a spacer device could demonstrate correct usage.

In a limited number of studies regarding pharmacists’ correct usage of pMDIs with a spacer devices, the participants most frequently made mistakes in the following step “take 5–6 deep and slow breaths” [11,14,15]. The most frequently made mistakes occurred in this step in our study as well. The fact that there are several steps in the application of pMDIs with a spacer device and that the aforementioned step is more complex could explain why mistakes in this step were more common.

In their study, Adnan et al. [9] examined the rates of pharmacists correctly showing the application steps of pMDIs with a spacer device, and only 7% of the pharmacists were able to show all eight steps recommended in the asthma guidelines. With the experience the researchers gained from that study, they made the following recommendation, “In the light of these experiences, the community pharmacists should be given brief instructional sessions and training that may improve the quality of demonstration by them.” Similarly, only 39.8% of the pharmacists were able to correctly show all of the steps for pMDIs with a spacer device. We believe that the pharmacists in Turkey should be trained regarding the use of pMDIs with a spacer device.

Community pharmacists are valuable contributors to the primary healthcare team, and they have been shown to be an effective resource for improving asthma management in the community. They have the advantage of being strategically placed to identify patients with

poorly controlled asthma because they are far more accessible, and they have the opportunity to see patients more frequently when they pick up repeat medications[15,16].In particular, management interventions by community pharmacists have had positive effects on asthma control by improving medication adherence, inhaler techniques, knowledge about asthma, and changes in the patients' perceptions of their disease and their behavior[16,17].Therefore, community pharmacists are able to play a significant role in improving the management of asthma in patients.

In our study, we found that pharmacists who were younger, those who sold inhaler spacer device in their pharmacy and more frequently dispensed asthma medication had more correct inhaler spacer device use. The high rate of correct use in younger pharmacists may depend on that they were likely to be new graduates and therefore might have recently received device usage training in the faculty of pharmacy. The study by Nguyen et al. [18] which showed that there was significant improvement in the information level and skills of inhaler techniques after pharmacists received training about asthma and inhaler techniques supported the above stated finding of our study. Moreover, pharmacists who sell inhaler devices in their pharmacy and therefore meet this group of patients more frequently may need to correct what they know about the use of inhaler devices and repeat their training because of the questions that may be asked by the patients and/or parents about the device use. Considering all these factors that we suggested for the correct use of the inhaler device, it is highly important to give inhaler device training both theoretically and practically in the process of providing pharmaceutical services. As a consequence, we believe that training pharmacists for the application steps of pMDIs with a spacer device could have positive effect on the overall success of asthma therapy.

Asthma is a growing health problem worldwide [1]. Therefore, important responsibilities fall to the competent institutions of the states (ministry of health), pharmacy, and chest, allergy-immunology associations in providing the necessary trainings in order to ensure proper spacer device use. It is highly important that these institutions should act jointly. Moreover, governments may set legal criteria and play a supportive role in ensuring that individual responsible should demonstrate the correct use of these devices as a trainer in places where inhaler spacer devices are sold (eg; pharmacy).

There are a few limitations of the current study. Firstly, this study was carried out with the pharmacists who work in the Turkey. Therefore, the result of this study cannot be generalized as being worldwide. Secondly, our direct visit to community pharmacy professionals at their workplace could affect their responses. Finally, investigators were not

the same person for the three study centers located in different parts of Turkey. Therefore, each investigator's judgment may lead to bias.

Conclusions/key findings:

Approximately one third of the pharmacists in the current study could correctly show all of the steps for pMDIs with a spacer device. Pharmacists who were younger, those who sold inhaler spacer device in their pharmacy and more frequently dispensed asthma medication had more correct inhaler spacer device use. Therefore, pharmacists should receive training on the use of pMDIs with a spacer device at regular intervals after graduation. Increasing the pharmacists' level of knowledge on this topic with ongoing training will have positive effects on the success of asthma therapy.

Declaration of Interest Statement and Financial Disclosure

The authors report no conflict of interest. This study has received financial support as a scientific research project from Inonu University Coordination Department of Scientific Research Projects (Grant number: TSA-2019-1733). All authors contributed significantly to the present study, they have approved and take full responsibility for the final manuscript.

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Table 1. Steps required for the proper use of the pMDIs with spacer device.

1. Shake the pMDI and remove the cap.*
2. Connect the pMDI to the spacer.*
3. Hold the pMDI upright.
4. Place the mouthpiece between the teeth and lips or place a facemask over the nose and mouth to form a seal.*
5. Activate the pMDI only once.*
6. Take 5–6 deep breaths, hold for 10 seconds and slow breaths.*
7. Wait for at least 30 seconds before the next actuation.*
8. Rinse the mouth after the use of a steroid inhaler.

*Essential steps, pMDI: pressured metered dosage inhaler

Table 2. Questionnaire form

QUESTIONNAIRE
Answer the following questions? 1. Age of participant (years): 2. Gender of participant: 3. How many years have you worked as a pharmacist? 4. On average, how many patients do you give asthma medications per day? 5. Do you teach the patient and/or his or her parents how to use asthma medicines, especially inhaler forms? 6. How many asthmatic patients under the age of 6 do you administer asthma medication on a daily or weekly or monthly basis? 7. Did you know that asthmatic patients under the age of six need to use inhaler spacer device for using asthma medications? 8. Do you sell an inhaler spacer device in your pharmacy? 9. Do you know how to use the inhaler spacer device? <i>If answer to this question is NO, the questionnaire will be terminated.</i> <i>If answer to this question is YES, move on the next step.</i>
The checklist for how to use pMDIs with a spacer device Step 1. Shake the pMDI and remove the cap Step 2. Connect the pMDI to the spacer Step 3. Hold the pMDI upright Step 4. Place the mouthpiece between the teeth and lips or place a facemask over the nose and mouth to form a seal Step 5. Activate the pMDI only once Step 6. Take 5–6 deep breaths, hold for 10 seconds, and slow breaths Step 7. Wait for at least 30 seconds before the next actuation Step 8. Rinse the mouth after the use of a steroid inhaler

pMDIs: pressured metered dosage inhalers

Table 3. Correct demonstration of the assessment steps for the pMDIs spacer device

Assessment steps	n (%)
Shake the pMDI and remove the cap.*	154 (61.4)
Connect the pMDI to the spacer.*	245 (97.6)
Hold the pMDI upright.	167 (66.5)
Place the mouthpiece between the teeth and lips or place the facemask.*	228 (90.8)
Activate the pMDI only once.*	226 (90.0)
Take 5–6 deep breaths, hold for 10 seconds and slow breaths.*	151 (60.2)
Wait for at least 30 seconds before the next actuation.*	153 (60.9)
Rinse the mouth after the use of a steroid inhaler.	160 (63.7)
Correctly demonstrated all of the steps	100 (39.8)

*Essential steps, pMDI: pressured metered dose inhaler

Table 4. Factors associated with the correct demonstration of the pMDIs with spacer device

Variables	Group 1 (n=100)	Group 2 (n=151)	p-value
*Gender, male	60 (60)	88 (58.3)	0.786
**Age, years	30 (30–36)	34 (29–40)	0.023
**Professional experience, years	10 (5–18)	12 (7–19)	0.246
**Number of prescriptions giving inhaler forms of asthma medication, daily	5 (3–10)	4 (3–6)	<0.001
**Number of prescriptions giving inhaler forms of asthma medication before the age of six years old, daily	2 (1–3)	2 (1–3)	0.016
*Teaching the patient and/or his or her parents how to use asthma medicines	99 (99)	145 (96)	0.249
*Knowing that asthmatic patients under the age of six need to use inhaler spacer device for using asthma medications	100 (100)	145 (96)	0.084
*Selling inhaler spacer devices in the pharmacy	94 (94)	128 (84.8)	0.042

*n (%); ** median (IQR) pMDIs: pressured metered dose inhalers

Group 1. Demonstrated the assessment steps of the inhaler spacer device correctly.

Group 2. Demonstrated the assessment steps of the inhaler spacer device incorrectly.