# Effectiveness of multimedia-assisted training on inhaler usage technique, which is the optimum technique?

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**Abstract.** – **OBJECTIVE:** In this study, we aimed to investigate the most appropriate education method for patients to use their inhaler devices with the proper technique.

PATIENTS AND METHODS: The study had a cross-sectional, multicenter design. 525 consecutive patients who had never used an inhaler therapy before were included in the study. Seven different types of inhalers were evaluated. 75 patients were included for each device type. For each device type, 25 patients were trained by their own physicians who personally demonstrated the use of the device [verbal education with physical demonstration (VEWPD)], 25 were given multimedia-assisted training (MAT), and 25 received both types of training together (first VEWPD followed by MAT). After the patients were trained, inhaler medications were used under the supervision of a physician. Correct use of the inhaler devices and perceptions of convenience were scored.

**RESULTS:** For Ellipta inhaler device and Levered Diskus inhaler device, the proportion of patients using their devices properly was significantly higher in patients who were instructed with both of the methods together compared to other education groups (p = 0.011, p = 0.015). The effects of different types of training on learning in Sanohaler, Diskus inhaler, and Pressurized metered dose inhaler devices were the same.

**CONCLUSIONS:** We could not come to a conclusion that multimedia training was more beneficial than other training. As an unexpected result, in almost all of the devices, patients who received multimedia training in combination with verbal training did not develop better learning despite being shown the use of the device twice (except Ellipta inhaler, and Levered Diskus inhaler device). Key Words:

Inhaler usage technique, Multimedia Assisted Training, Asthma, COPD.

# Introduction

In respiratory diseases, especially asthma and chronic obstructive pulmonary disease (COPD), inhaler therapies are the best way to selectively deliver the active ingredient of the medicine into the lungs<sup>1-3</sup>. When the patient inhales the drug, it directly reaches the lungs, where it acts. This minimizes the systemic effects of the active ingredient of the drug and provides the highest local effect<sup>4,5</sup>. Inhaler devices have complex handling features. The patients need to use the correct technique so that they may fully benefit from the drug. Using it with the right technique is possible with effective and correct device training<sup>6,7</sup>. The effectiveness of inhaler therapies in real life depends on the particle size of the active ingredient, the inspiratory flow rate, the particle fraction that can reach the target, and the ability to use the device correctly<sup>8</sup>. Different training methods are available for using inhalers: verbal education, brochure training, video training, physical demonstration, audio-visual demonstration, internet-based education, and interactive and multimedia tutorials<sup>8-10</sup>.

To our knowledge, few studies<sup>11,12</sup> in the literature investigate the effectiveness of multime-

dia-assisted training (MAT) on the use of inhalers. In today's era of technology and innovation, we need to bring the MAT method in inhaler device training to patients. This training method can be used alone or in addition to physician training. Hence, we aimed to determine the appropriate training protocol for each of the inhaler devices with three different educational interventions. The first was verbal education with physical demonstration (VEWPD), the 2<sup>nd</sup> was MAT, and the 3<sup>rd</sup> the combination of these two techniques, in employing the correct usage technique. Therefore, we want to measure which education can be more successful in every device and which is the optimum technique for operating the device.

# Patients and Methods

# Patients' Characteristics

This was a cross-sectional and multicentre study. After obtaining the Local University (Afyonkarahisar Health Sciences University, Faculty of Medicine) Ethical Committee Approval, this study was prospectively conducted between 01 April 2019 and 19 November 2019. Patients aged 18-85 who presented to the chest diseases outpatient clinic, were prescribed an inhaler therapy for their condition. Those who had never used inhaler therapy previously and had never heard how to use inhalers were included in the study. Patients and the inhaler devices to be prescribed were selected sequentially, and the type of training to be given was assigned randomly by the computer-based system. Seven different types of inhaler devices were included in the study. All device types were assigned 75 subjects each per type of training (VEWPD, MAT, and VEWPD/ MAT) and registered to the computer-based system. The coordination center randomly assigned a device and a type of training to each patient through the computer. All centers removed the medication and training combination assigned to the patient from the central computer system.

A total of 525 patients were enrolled in the study. Each inhaler was prescribed to 75 patients. Seven different device types were identified: Ellipta inhaler device, Levered Diskus inhaler device, Sanohaler device, Turbuhaler Device, Pressured Metered Dose Inhaler (pMDI) device, Diskus Without Lever (DWL) inhaler device and Dry Powder Inhaler (DPI) device. Dry-powder inhalers Ellipta, Diskus and Turbuhaler were evaluated separately. Although the three devices are all dry-powder inhalers, they have significantly different mechanisms and thus were evaluated individually regarding patient application skills. For each device, different training was given to patients to instruct its correct use. Consecutive correct usage steps of each inhaler were organized based on their respective internal dynamics following the World Health Organization (WHO) recommendations<sup>9</sup> (Appendix 1). The most important point is that regardless of whether the patients accurately turned the device on or off, if they were not able to inhale the medication completely, they were evaluated as 'not inhaled'. For 25 out of 75 patients in each device group, the physician who prescribed the medication gave face-to-face training to the patients by demonstrating and explaining each step of operating the device (the VEWPD group). In each center, this training was provided by the same physician to all patients. Each patient was given the same training. All participating physicians were chest disease specialists. These physicians were given training on the correct use of medications. Their proper and accurate use of devices was also ensured. For the other 25, training was carried out by playing multimedia videos prepared by us (MAT), in which the usage steps of each device are explained in detail and shown in the video as per the WHO recommendations (MAT group). The multimedia recordings prepared for the patients were played on a 19-inch TV screen in a quiet environment. For the remaining 25 patients, VEWPD and MAT were given sequentially. The multimedia-assisted was prepared by a chest disease specialist. In this video, the doctor has demonstrated the use of the device and recorded the description.

The patients were not allowed to handle, apply, or touch the devices prior to training on medication. They were given the medicine after description and training. Then, they were asked to demonstrate what they had learned. Hence, their application skills and understanding of the training were evaluated. The person who evaluated the patients' application skills (the assessor) was not the physician who provided the training. All patients were evaluated by the same assessor. The physician who provided the training left the room, and the patient and the assessor interacted electronically by video conferencing on a 35-inch monitor in the room. The assessor was in the coordination center and was blinded to the selection of the device and the training process, but only evaluated the application skills of the patients according to the predetermined steps.

# **Exclusion Criteria**

Patients who had previously used inhaler medication or had seen its use for any reason, patients under the age of 18 or over 85, patients with orthopedic limitations that hinder their ability to use the device, and patients with a history of neurological, psychiatric, ocular or ear-nose-throat conditions that may limit their seeing, hearing, and perceiving the instruction on how to use the device, as well as those who could not speak the Turkish language were not included in the study.

# Collection of Data

Each device was prescribed to 75 patients. Of these 75 patients, 25 were given VEWPD, 25 were given MAT, and 25 were given both trainings together. After the training, patients were asked to self-administer the inhalation. Patients used a disposable demo device. The physician prescribing the medicine gave a score of 1 for each step that the patient performed correctly and 0 points for each step that they performed wrongly, according to the usage steps set for each drug (Appendix 1). The inhaler usage steps ranged from 8 to 11 among the devices. The percentage of correct use of the device was determined by proportioning the scores received by the patients to the total score of the device. After using the drug, the patients were asked to rate the ease of use of this device on a Likert-type scale (1-5), easiest and most difficult, respectively. In addition, those who performed the delivery of medication without errors and those who made at least one error were divided into two groups for each device.

## Statistical Analysis

The SPSS software version 20.0 (Statistical Package for the Social Sciences Inc, Armonk, NY, USA) was used for statistical analysis. The Kolmogorov-Smirnov test was used to evaluate whether the variables were distributed normally. Continuous variables were expressed as mean (±) standard deviation (SD) or median (minmax) according to the distribution state. Nominal variables were expressed as numbers and percentages. Categorical variables were compared using the Chi-square test. The Student's t-test or Mann-Whitney U (Bonferroni) test was used to compare parametric or nonparametric variables for two independent group analyses. Oneway ANOVA or Kruskal Wallis test was used to compare parametric or nonparametric variables for more than 2 independent groups. Bonferroni correction was applied for post hoc analysis. A

post-hoc Power Analysis was conducted based on questionnaire scores for all inhalers after training, which revealed study power as 0.85 ( $\alpha$  value of 0.05 and effects size as: 0.30, with 75 patients in each inhaler group). (G\*Power 3.1.9.4 power analysis program). Statistical significance was set at p < 0.05

# Results

The demographic findings of the patients included in the study are provided in Table I. When 525 patients were examined in terms of gender, age and educational status by the type of education they received, there were 91 (52%) women receiving VEWPD, 80 (45.7%) women receiving MAT and 83 (47.4%) women receiving both educations (p = 0.477). Mean ages by the types of education were 52.82 ± 16.17, 53.82 ± 15.40, 54.68 ± 15.52 years old (p = 0.540), respectively. There was a high rate of asthma diagnosis in all three types of education: 101 (57.7%), 101 (57.7%), 106 (60.6%) (p = 0.733), respectively.

**Table I.** Demographic Data. Mean deviation unless otherwise indicated.

	N = 525
Gender, N (%)	
Female	254 (48.4)
Male	27 (51.6)
Age, years*	$53.77 \pm 15.69$
Female*	$52.30 \pm 15.54$
Male*	$55.6 \pm 15.72$
Education [n (%)]	
Primary School	400 (76.1)
High School	125 (23.9)
Preliminary diagnosis	
Asthma n, (%)	308 (58.7)
COPD n, (%)	195 (37.1)
Acute Bronchitis n, (%)	21 (3)
Bronchiectasis n, (%)	1 (0.2)
Smoking History	
Active Smoker n, (%)	137 (31.8)
Ex-Smoker n, (%)	102 (19.4)
Never Smoked n, (%)	256 (48.8)
Place of Residence	
Village n, (%)	139 (26.5)
Town n, (%)	111 (21.1)
Province n, (%)	275 (52.4)

COPD; Chronic Obstructive Pulmonary Disease, SD; standard deviation.

When we examined patients' proper usage scores by device type, the total score was significantly higher in the Ellipta inhaler device [100% pts (50-100)] in patients who received both VEW-PD and MAT (p = 0.011). For the Turbuhaler device, the correct use total score [90% pts (30-100)] of patients receiving VEWPD education was significantly higher compared to MAT [80% (30-100)] (p = 0.027). For the Levered Diskus Inhaler device, the correct use total score of patients who received VEWPD and MAT together [90% (40-100)] was significantly higher compared to the total scores in VEWPD [70% (40-100)] and MAT [70% (30-100)] (p = 0.015). For the dry powder inhaler, the correct usage total score in the VEWPD group [81% (30-100)] was significantly higher compared to the patients who received both VEWPD and MAT together [70% (27-100)] (p = 0.043). For other devices, there were no significant differences between total scores by type of education (Table II).

When we looked at the perception of ease of use for each device by the type of training, there was a significant difference between those who received both VEWPD and MAT compared to those who received only MAT in Ellipta inhaler device (p = 0.02). In Levered Diskus inhaler device, the perception of ease of use for those who received both VEWPD and MAT together was significantly different compared to VEWPD or MAT alone (p = 0.028) (Table III).

Table II. Percentage of correct usage score of each device according to training types.

Devices	Verbal education with physical demonstration	Multimedia- assisted training	Verbal and multimedia- assisted training together	P
Ellipta Inhaler	75 (30-100) <sup>1</sup>	75 (25-100) <sup>2</sup>	100 (50-100) <sup>1,2</sup>	<b>0.011</b> <sup>1,2</sup>
Levered Diskus	70 (40-100) <sup>1</sup>	70 (30-100) <sup>2</sup>	90 (40-100) <sup>1,2</sup>	<b>0.015</b> <sup>1,2</sup>
Sanohaler	77 (22-100)	66 (33-100)	66 (22-100)	0.442
Turbuhaler	90 (30-100) <sup>1</sup>	80 (30-100) <sup>1</sup>	80 (20-100)	<b>0.027</b> <sup>1</sup>
Pressured Metered Dose Inhaler	90 (30-100)	80 (30-100)	80 (20-100)	0.361
Discus Without Lever	77 (33-100)	77 (33-100)	77 (22-100)	0.517
Dry Powder Inhaler	81 (36-100) <sup>1</sup>	58 (9-100)	70 (27-100)1	0.0431

<sup>1,2</sup>Shows the difference between the groups. Median (minimum-maximum) deviation unless otherwise indicated.

 Table III. Convenience detection values of each device according to training types. Median (minimum-maximum) deviation unless otherwise indicated.

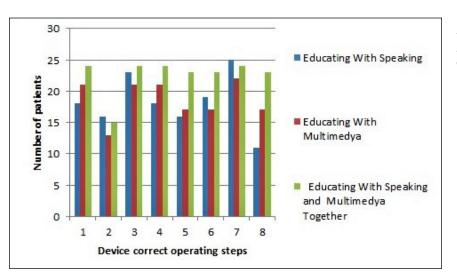
Devices	Verbal education with physical demonstration	Multimedia- assisted training	Verbal and multimedia- assisted training together	Ρ
Ellipta Inhaler	2 (1-5)	2 (2-1.1) <sup>1</sup>	3 (1-5) <sup>1</sup>	0.0201
Levered Discus	3 (1-4) <sup>1</sup>	3 (1-4) <sup>2</sup>	2 (1-3) <sup>1,2</sup>	0,0281,2
Sanohaler	2 (1-3)	2 (1-5)	2 (1-3)	0.460
Turbuhaler	2 (1-5)	2 (1-5)	3 (1-5)	0.368
Metered Dose Inhaler	2 (1-5)	2 (1-5)	3 (1-5)	0.147
Diskus Without Lever	2 (1-5)	2 (1-4)	3 (1-4)	0.131
Dry Powder Inhaler	2 (1-5)	2 (1-5)	2 (1-5)	0.828

<sup>1,2</sup>Shows the difference between the groups.

Each device has 9-11 usage steps. (**Appendix** 1) The number of individuals who applied it correctly is specified at each step based on the type of training. In these figures, we see the number of people who used the inhaler correctly in each device and in every step (according to the type of training). Thus, we can see which training is more effective in every step (Figure 1-7).

When we compared the correct usage scores in all patients by the type of inhaler devices, the score value of Ellipta was statistically significantly higher than the dry powder inhaler (p =0.047) and Sanohaler inhaler device (p = 0.044). The correct usage score was the highest in the Ellipta inhaler device  $(79.50 \pm 19.12)$ , followed by the Turbuhaler device  $(77.6 \pm 22.04)$  and Diskus inhaler device  $(77.03 \pm 19.78)$ . The lowest score was in the Sanohaler device  $(69.03 \pm 21.94)$ (Table IV).

Those who made no errors in the use of devices are listed in Table V for each device. When we looked at the number of patients who made no errors by type of education, the number of patients who were given both VEPWD and MAT together in the Ellipta inhaler group [13 (52%)] was significantly higher compared to VEWPD alone [N = 5 (20%)] and multimedia training alone [N = 4 (16%)] (p = 0.009) (Table V).



**Figure 1.** Histograms of patients who correctly performed the operating steps on the Ellipta inhaler device.

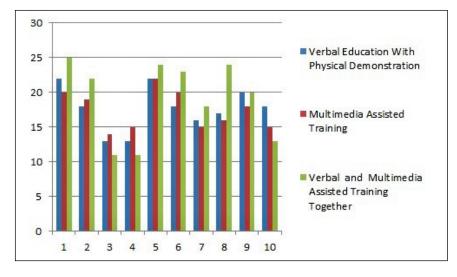
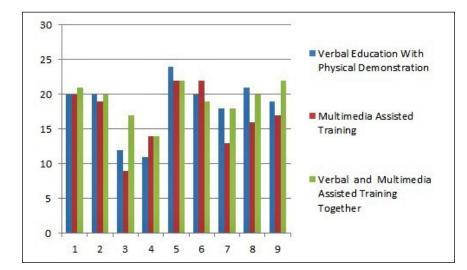
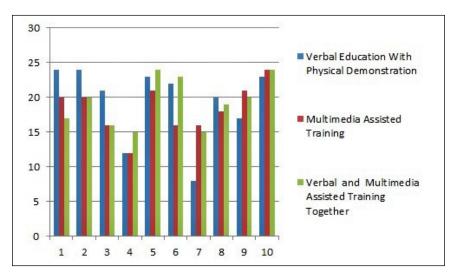


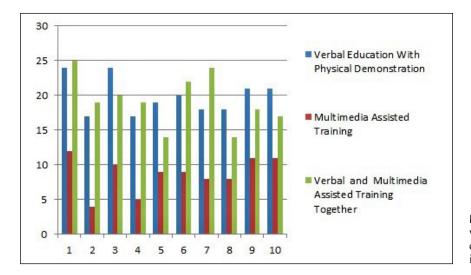
Figure 2. Histograms of patients who correctly performed the operating steps on the Levered Diskus inhaler device.



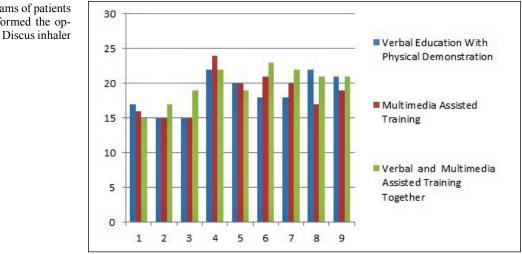
**Figure 3.** Histograms of patients who correctly performed the operating steps on the Sanohaler device.

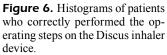


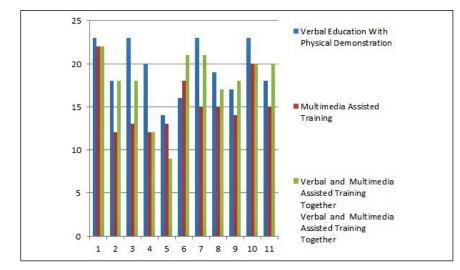
**Figure 4.** Histograms of patients who correctly performed the operating steps on the Turbuhaler device.



**Figure 5.** Histograms of patients who correctly performed the operating steps on the Metered-dose inhaler device.







**Figure 7.** Histograms of patients who correctly performed the operating steps on the Dry Powder inhaler device.

Table IV. Total score value and error making rates per device. Median (minimum-maximum) deviation unless otherwise indicated.

	Ellipta Inhaler (N = 75)	Levered Discus (N = 75)	Sanohaler (N = 75)	Turbu- haler (N = 75)	Metered Dose Inhaler (N = 75)	Discus Without Lever (N = 75)	Dry Powder Inhaler (N = 75)	p
Total Score	87.50 (25-100) <sup>2,4</sup>	80 (30-100)	66.66 (22.22-100) <sup>1,2,3</sup>	80 (20-100) <sup>3,5</sup>	80 (10-100)	77.77 (22.22-100) <sup>1</sup>	72.72 (9.09-100) <sup>4,5</sup>	0.015
Correct User	22 (29.3%)	9 (12%)	10 (13.3%)	15 (20%)	12 (16%)	17 (22.7%)	11 (14.7%)	0.078
At least one error	53 (70.7%)	66 (88%)	65 (86.7%)	60 (80%)	63 (84%)	58 (77.3%)	64 (85.3%)	0.078

<sup>1,2,3</sup>Shows the difference between the groups.

Devices	Verbal education with physical demonstration	Multimedia- assisted training	Verbal and multimedia- assisted training together	Ρ
Ellipta Inhaler	5 (20%)	4 (16%)	13 (52%)	0.009
Levered Discus	2 (8%)	3 (12%)	4 (16%)	0.685
Sanohaler	4 (16%)	1 (4%)	5 (20%)	0,223
Turbuhaler	8 (32%)	3 (12%)	4 (16%)	0.174
Pressured Metered Dose inhaler	4 (33.3%	4 (33.3%)	134 (33.3%)	1
Discus Without Lever	5 (20%)	4 (23.5%)	8 (47.1%)	0.372
Dry Powder Inhaler	5 (20%)	3 (12%)	3 (12%)	0.653

	Table V	Error-making	rates according	to the type	of education.
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## Discussion

According to the results of our study, where we compared the effect of education on the correct use of inhalers, the patients used Ellipta and Levered Diskus inhalers more accurately when they received both VEWPD and MAT together (p< 0.05). Turbuhaler and dry powder inhalers were used more accurately with VEWPD (p < 0.05). In other devices, the difference was not significant.

In our study, we wanted to evaluate the importance of multimedia training for the correct use of inhaler devices and their usability in patients. We could not come to a conclusion that multimedia training was more beneficial than other training. As an unexpected result, in almost all of the devices, patients who received multimedia training in combination with verbal training did not develop better learning despite being shown the use of the device twice (except Ellipta, Levered Diskus).

Inhaler drugs include Metered Dose inhaler, Turbuhaler, Dry Powder inhaler, Ellipta inhaler, Levered Discus inhaler, Non-Levered Discus inhaler and Sanohaler. The devices have complex as well as varied operating mechanisms. It is possible to ensure patient device compatibility with correct training<sup>12-15</sup>.

Different studies<sup>3-5</sup> have reported that the dose of medication accumulating in the lungs varied by inhaler use techniques and it was possible to deliver the maximum drug dose with the correct training. In the literature, many studies have evaluated how patients used their devices, and faceto-face training was provided on the correct use technique. Afterward, how correctly patients used the devices after training was measured and re-evaluated. According to the results of these studies<sup>1-3</sup>, VEWPD was very valuable in terms of accurately learning the device and correcting an error on the spot. In their study, Usmani et al<sup>16</sup> described that disease management was difficult due to the errors in using dry powder inhalers and that VEWPD can reduce these errors.

Many studies<sup>17,18</sup> are proving that multimedia is an effective education method. Multimedia training can be memorable as it appeals to its recipient with both visual and auditory components at the same time and enables patients to learn the technique of using the drug correctly and properly.

There are a few studies about inhaler education using technology like YouTube videos and multimedia videos. In a study conducted by Müller et al<sup>11</sup>, the authors trained the patients using videos as well. Patients were evaluated immediately after the training and after 4-8 weeks. According to the results of the study, 82% of the patients understood the training videos, 76% used the device completely after the training, and 72% used their medicines with the right technique after 4-8 weeks. They observed that the correct use rate increased by 95% after video training (p < 0.0001). Unlike our study, the study investigated only the benefits of video education, and no comparison was made with other types of education. Only metered dose and dry powder inhalers were evaluated in the above study. In our study, the effect of VEWPD on the correct use of the device was similar to the literature. Purohit et al<sup>19</sup> studied the correct usage rates of dry powder inhalers in 100 patients in 2017. The authors divided the patients they treated using dry powder inhaler patients into two groups and gave a pictorial leaflet to one group and video education to the other. They scored patients' correct use with the same scoring system as our study. In the video education group, the correct usage scores increased statistically significantly after the training (p < 0.001). This study is one of the few studies comparing types of education. Unlike us, only metered dose inhalers were evaluated in this study<sup>19</sup>. Von Schantz et al<sup>20</sup> investigated the effectiveness of video education on Diskus, Turbuhaler, Easyhaler and Ellipta inhaler devices in 31 patients. This study made no comparisons with other types of education and involved only young patients. The participants had questions that they could not answer and reported that their questions remained unanswered after video-assisted education because they did not receive interactive education and that this was a negative aspect of video education.

In our study, there was a more favorable benefit in correct usage scores in patients who were given both MAT and VEWPD together for Ellipta and Levered Diskus inhaler devices, compared to either VEWPD or MAT alone. It may be that the mechanisms of both devices were more complicated and difficult for the patients. Therefore, the patients may have benefited from receiving two consecutive trainings with different methods for these two devices. In the training of these two devices, we believe that it would be more useful if MAT was given together with VEWPD rather than VEWPD alone. VEWPD score was statistically significantly higher in dry powder inhalers and Turbuhaler devices. We were surprised that only VEWPD was more effective than two trainings in a row on these two devices. In the end, patients received both oral and video training, but reinforced training did not help them learn better. This may be explained by the fact that this method causes confusion for the patient.

Although our study does not allow face-toface conversations or question-answer activities as part of VEWPD education, such possibilities will arise in verbal education, which may be more beneficial for the patient. As a remarkable finding from the same study<sup>20</sup>, patients who used Ellipta and Diskus after training perceived that they used them in the correct way, and the results indeed showed this was the device type that was operated the most accurately<sup>20</sup>. The correct usage scores for Ellipta and the non-levered Diskus inhaler devices were also higher in our study. We believe that the similar results of the two studies<sup>8,9</sup> are due to the fact that these two types of devices are less complex to use. Similar to our study, Lavorini et al<sup>9</sup> emphasized the benefits of VEWPD on the proper use of inhaler devices, especially in dry powder and metered dose inhalers.

For Ellipta, there was a statistically significant increase in the proportion of patients with no errors among those who received the two educations together (p = 0.009) (Table V). This finding suggests that the proportion of patients making no errors will increase if the two educations are given together for Ellipta. For other devices, the proportion did not differ statistically. In a study by Van der Palen et al<sup>21</sup>, 567 patients were trained with the patient information leaflet (PIL). Device usage was checked after the training. Ellipta, Diskus, Turbuhaler, dry powder inhaler, Handihaler and Levered Diskus inhaler devices were included in the study. According to the results of the study, the proportion of patients making no errors and at least one critical error after the training in Ellipta inhaler device was significantly lower.

## Limitations

The most important limitation of our study was the inadequate number of subjects to compare the effect of educational status on the proper use of inhaler devices, although a power of 0.85 was achieved for a population of 75 with power analysis. There were not enough patients to analyze different age groups (over 65 and under). A third limitation was not having attained sample homogeneity regarding educational status, due to the absence of a control group. However, we observed that the patients were able to comprehend the training well when they were perceptive, regardless of educational status. We have occasionally seen that a patient with an associate degree could perform more poorly than a primary school graduate. Another limitation was that we measured the patients' short-term memory. More conclusive results could be obtained if the same patients were called back and re-evaluated at longer intervals (3 months, 6 months, etc.). However, the study was designed according to the assumption that the more effective the initial training is, the more properly the patients will use the device in the long run.

# Conclusions

It is important to educate patients so they can use their inhalers correctly. Verbal education, which is done by using the traditional method of demonstrating the use of the device, still seems to be the most effective method. We also think that in some devices, MAT, besides VEWPD, will increase patients' perception regarding device usage. Nevertheless, we believe that the best method to offer education on these devices can be evaluated more accurately with studies performed with larger populations.

### **Informed Consent**

All subjects in the study gave consent to participate in the study.

### Authors' Contributions

Sule Cilekar: Planning, designing, literature survey, interpretation of the results, active intellectual support, submission. Ibrahim Guven Cosgun: Planning, designing, literature survey, interpretation of the results, active intellectual support. Nalan Ogan: Planning, designing, literature survey, interpretation of the results, active intellectual support, writing. Sibel Gunay: Planning, designing, data collection, literature survey, interpretation of the results, active intellectual support. Volkan Taskın: Planning, designing, data collection, performing the study, literature survey, interpretation of the results, active intellectual support, writing. Aydin Balci: Planning, designing, literature survey, interpretation of the results, active intellectual support. Sebnem Emine Parspur: Planning, designing, literature survey, performing the study, interpretation of the results, active intellectual support, English editing. Ersin Gunay; Designing, literature survey, interpretation of the results, active intellectual support.

#### **Data Availability**

The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

#### Funding

None.

## **Conflict of Interest**

The authors declare no conflict of interest.

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#### Ethics Approval

This study was approved by the Afyonkarahisar Health Science University local Ethics Committee (07.02.2020- number 77).

#### **Informed Consent**

Informed written consent was obtained from the patients.

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