

# Evaluating the Effectiveness of Written Dry Powder Inhaler Instructions and Health Literacy in Subjects Diagnosed with COPD

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**BACKGROUND:** Improper inhaler use results in decreased drug deposition in the lungs. The impact of health literacy and poor vision on the patient's ability to learn inhaler technique by reading instructions has not been confirmed. This study evaluated the effectiveness of learning inhaler technique from written instructions and the impact of health literacy for patients diagnosed with COPD who used a dry powder inhaler (DPI). **METHODS:** This pilot study recruited subjects diagnosed with COPD. A trained assessor scored subjects' inhaler technique before and after reading the appropriate American College of Chest Physicians handouts. Peak inspiratory flows (PIFs) were measured using an InCheck Dial. Health literacy was measured by the S-TOFHLA (Short Test of Functional Health Literacy in Adults), and visual acuity was measured by a Snellen chart. Associations between health literacy and visual acuity and changes in subjects' inhaler technique scores were assessed by Spearman's rho. Inhaler technique change scores were assessed by the Wilcoxon signed-rank test at  $P = .05$ . **RESULTS:** Of the 24 participants enrolled, 63% were female, mean age was 65.6 y, and 83% were Global Initiative for Chronic Obstructive Lung Disease air-flow limitation 2 or 3. Wilcoxon scores were significant for improved total scores for both the Diskus and HandiHaler, with medians improving from 6.5 to 7.0 (interquartile range 6.0–7.8) ( $P = .047$ ) and from 6.0 to 7.5 (interquartile range 7.0–9.0) ( $P = .002$ ), respectively. The minimum required PIF was achieved by 93.8% of the Diskus and 94.4% of the HandiHaler groups. There were no associations detected between the handout intervention (Diskus and HandiHaler) and health literacy level and vision. **CONCLUSIONS:** The educational handouts for DPIs helped participants already using a DPI to improve their inhaler technique. Stable participants diagnosed with COPD are able to generate appropriate PIFs to properly use DPIs. Neither vision nor health literacy was associated with the inability to learn inhaler technique from patient education inhaler device handouts. *Key words:* dry powder inhalers; patient education handout; health literacy; COPD; vision acuity; peak inspiratory flow. [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

## Introduction

Dry powder inhalers (DPIs) are commonly used in the management of patients with COPD. These breath-actuated devices have an advantage over metered-dose inhal-

ers because they do not require a patient's coordination with drug actuation. Therefore, DPIs are considered easier for patients to use.<sup>1</sup>

There are many reasons for incorrect inhaler technique, including inadequate inhaler education;<sup>2</sup> having several

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Ms Alsomali received a full educational scholarship from the University of Dammam, Saudi Arabia. The authors have disclosed no conflicts of interest.

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Ms Alsomali presented a version of this paper at the American Association for Respiratory Care Congress, held November 7-10, 2015, in Tampa, Florida.

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DOI: 10.4187/respcare.04686

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inhaler devices, each with different instructions for use;<sup>3</sup> and low health literacy.<sup>4,5</sup> Incorrect inhalation technique could result in decreased drug deposition in the lungs that can lead to poor disease management and eventually a higher cost of care.<sup>6-10</sup> Several studies report that there is a large variability in proper inhaler technique despite patients feeling confident about their performance.<sup>11-13</sup> Errors in at least one step of inhaler technique were found in 49–55% of subjects in a large observational study who had no inhaler instructions,<sup>14</sup> in 22–36% of subjects in a general audit (amount and type of instruction unknown),<sup>15</sup> and in 68–94% of subjects who had only written instructions.<sup>16</sup> Given the high frequency of poor inhaler technique, patients' inhaler technique should be reassessed at every opportunity.<sup>7-9</sup> There is also a need to standardize initial inhaler device education with evidence-based educational materials and instruction.

One potential cause of poor patient inhaler technique is that health-care providers may also lack knowledge about inhaler use. A 2013 review article that evaluated DPIs and metered-dose inhalers showed that only 15–69% of health-care providers were able to demonstrate correct inhaler technique for both types of inhalers. Health-care providers only demonstrated correct technique to a small proportion of patients, and an even smaller number of these patients had their inhaler technique reviewed by a health-care provider.<sup>7</sup>

More recently, the impact of health literacy on inhaler technique has been studied. Low health literacy is associated with having poorer inhaler technique, but it does not appear to hinder learning inhaler technique.<sup>4,5,17</sup> These findings were consistent for both metered-dose inhalers<sup>4,5,17</sup> and the Diskus<sup>5</sup> inhalers.

In addition to using proper DPI technique, patients also need to have a sufficient inspiratory flow to disperse the medication dose into aerosol particles that will deposit in the lungs.<sup>18</sup> The inspiratory flow generated is dependent on the patient's effort and the internal resistance of the DPI.<sup>19,20</sup> Failure to breathe deeply and generate appropriate inspiratory flows through the DPI will prevent the therapeutic dose from being delivered.<sup>18</sup> COPD results in a gradual expiratory air-flow limitation; also, some patients might have a decreased inspiratory flow due to the effect of hyperinflation.<sup>2</sup> This might affect the deposition of the inhaled medication. It has been shown that COPD severity, inhaler resistance, sex, and age could affect the patient's capability to generate adequate inspiratory flows.<sup>18,19</sup>

Multiple factors influence whether patients can effectively use their inhalers. These factors include the accuracy of instructions provided by clinicians, the educational resources provided to patients, and patient variables related to learning and physical limitations. This study aimed to evaluate whether the content from the printed handouts

**QUICK LOOK****Current knowledge**

Incorrect inhalation technique results in decreased drug deposition in the lungs that can lead to poor disease management and eventually a higher cost of care. Patients diagnosed with COPD have expiratory air-flow limitation; they also might have decreased inspiratory flow due to the effect of hyperinflation. This may also affect the deposition of the inhaled medication.

**What this paper contributes to our knowledge**

Inhaler technique improved with the use of inhaler device handouts alone without any verbal instructions or demonstration. This study did not detect associations between insufficient vision and health literacy and the capability to learn inhaler technique using written educational handouts. Stable out-patient subjects diagnosed with COPD in a younger elderly population (46–82 y old) were able to generate appropriate peak inspiratory flows for dry powder inhalers.

alone was effective in teaching correct inhaler technique and whether subjects with COPD generated the appropriate peak inspiratory flows (PIFs) for their prescribed DPI. A secondary objective was to evaluate the role of health literacy and visual acuity in learning inhaler technique in the same population.

**Methods**

This study was conducted in a pulmonary function testing laboratory and pulmonary out-patient clinic at an urban academic medical center using a convenience sampling technique. Data for the study sample was collected between April 2014 and August 2014, based upon the availability of the investigator who attended the clinic on dates when greater numbers of patients with COPD were scheduled.

**Study Procedures**

Study participants were included if they had a diagnosis of COPD and were currently prescribed a DPI. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2014 guidelines were used to classify the COPD diagnosis, which requires a post-bronchodilator FEV<sub>1</sub>/FVC of <70%.<sup>2</sup> When no pulmonary function test results were available in the participant's chart or if results were older than 6 months, spirometry was performed to assess the presence of an obstructive lung disease using the EasyOne Plus spirom-

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eter (nidd Medical Technologies, Andover, Massachusetts). In those cases, a post-bronchodilator spirometry was not conducted because of the absence of a physician's order. Study participants were excluded if they were not diagnosed with COPD, spirometry did not show air-flow obstruction, a DPI was not prescribed or the DPI was not prescribed for the first time on the study day, the patient had an exacerbation of COPD or respiratory illness within the past 7 d, or the patient was hospitalized for a COPD exacerbation within the past 4 weeks. Individuals with the following comorbidities were also excluded from the study: acute neurological pathologies (cerebrovascular accident, craniocerebral trauma), dementia, and neuromuscular diseases. Patients who did not read, speak, or understand English were also excluded.

Informed consent was obtained from study participants using a form approved by a local institutional review board. A demographic data collection form was developed to collect the following variables: age, sex, weight, and height. Spirometry, vision, and health literacy information was also recorded, which included the FEV<sub>1</sub>/FVC, FEV<sub>1</sub> post-bronchodilator (% predicted), COPD air-flow limitation based on GOLD 2014 guidelines, FEV<sub>1</sub>/FVC pre-bronchodilator (if no spirometry post-bronchodilator was measured within the past 6 months), near vision score, and health literacy level.

The educational intervention in this study was a device-appropriate handout from the American College of Chest Physicians (ACCP). These handouts were developed based upon the manufacturer's instructions and expert review and thus had face validity. Participants were required to show their current inhaler technique to a trained assessor using a matching placebo DPI before receiving any inhaler education. The trained assessor recorded the participant's performance using a device-specific checklist derived from the ACCP handout to improve reliability. Each item in the checklist represented a step in the respective inhaler device handout. When there was more than one action in a single step, the actions were divided into 2 items on the performance checklist. Steps were scored as completed, not completed, or completed incorrectly. A total score was calculated by taking the sum of all correct steps. The Diskus (GlaxoSmithKline, Philadelphia, Pennsylvania) had a total of 9 possible points, and the HandiHaler (Boehringer Ingelheim, Pharmaceuticals, Ridgefield, Connecticut) had a total of 11 possible points. If the participant's technique of inhaler use was completely or partially incorrect, study participants were instructed to read the ACCP patient education handout for the specific inhaler that they were prescribed. Participants were given as much time as needed for reading. Study participants repeated their DPI inhalation technique with a placebo after reviewing the ACCP handout and were rescored using the same checklist. The difference between the total score after reading the ACCP

handout and the initial score comprised the inhaler technique change score. Coaching to correct any inhaler technique problems occurred after completing data collection.

Evaluation of an appropriate inspiratory flow for the prescribed DPI was conducted using an In-Check Dial (Clement Clark International Ltd, Harlow, United Kingdom). The PIF was measured 3 times for each participant. The highest PIF value was reported as well as whether the minimum PIF value for the prescribed device was achieved. The values for study participants who exceeded the threshold for the In-Check Dial (PIFs >120 L/min) or were less than the lower threshold (PIF <15 L/min) were documented as 120 and 15 L/min, respectively.

Near vision was assessed at the beginning of the study to determine the participant's ability to read instructions from the written handouts. A standardized Snellen chart was used to assess the smallest letters the participant could read. Participants were asked to wear their usual vision correction, eyeglasses or contacts if appropriate.<sup>21</sup> The Snellen chart was placed at the 14-inch point perpendicular to the plane of participant's face as measured by a ruler. Participants were asked to begin at the top left of the chart, read the line from left to right, and then move to the start of the next line below. They were coached to give a single reading for every letter and guess if they were not sure. Participants were instructed once to guess by the study examiner if they reached a line where they could not see the letters clearly. The assessment continued until participants reached a line where more than half of the letters were read incorrectly or they finished reading all of the letters on the chart.<sup>22,23</sup> Each line was assigned a visual acuity score. A score of 20/20 is considered normal vision acuity, and the visual acuity decreases as the denominator increases.

Health literacy level was assessed in this study through the S-TOFHLA (Short Test of Functional Health Literacy in Adults). The health literacy screening instrument should be a match between the tasks being studied and how the health literacy instrument operationalizes the construct.<sup>24</sup> Because participants were asked to read the ACCP patient education handouts and demonstrate their performance afterwards based on their understanding, the S-TOFHLA, which evaluates reading comprehension, was used. This instrument has a Cronbach's  $\alpha$  of .97.<sup>25</sup> Participants read 2 prose passages containing sentences with omitted words and need to select the appropriate word(s) to properly complete each sentence. Seven minutes are allowed to complete all 36 items, and one point is awarded for each correct answer. The total score is computed by taking the sum of all correct answers, which results in classifications of inadequate literacy (0–16), marginal literacy (17–22), and adequate literacy (23–36).<sup>5,26</sup>

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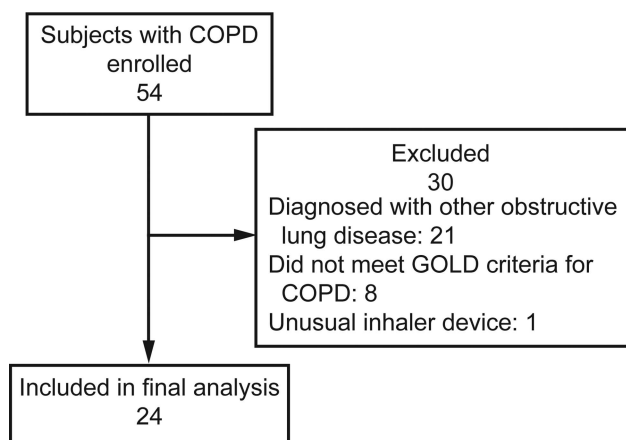


Fig. 1. Flow chart. GOLD = Global Initiative for Chronic Obstructive Lung Disease.

## Data Analysis

Descriptive statistics for continuous data were reported as means and SD. Medians and percentiles were reported for vision scores and health literacy level. Proportions were reported for sex, COPD air-flow limitation, meeting the minimum required PIF, and amount of change for each inhaler technique step.

Inhaler technique change scores were assessed with a Wilcoxon signed-rank test. Spearman's rho was used to assess for associations between inhaler technique change scores and both vision acuity and health literacy levels. All tests were conducted with  $\alpha = .05$  using SPSS 18 (IBM, Armonk, New York).

## Results

Fifty-four participants with obstructive lung disease were enrolled in the study. Thirty participants were excluded because they did not meet GOLD COPD guidelines or used a DPI that did not yield sufficient data for analysis. A total of 24 participants were included in the final analysis (Fig. 1).

Descriptive statistics revealed that the mean  $\pm$  SD age was  $66 \pm 10.0$  y and that the sample was 63% female, 83% GOLD 2 or 3 air-flow limitation severity, 63% 20/20 vision, and 67% adequate health literacy (see Table 1). The median health literacy and vision scores were 31 (interquartile range 20–36) and 20/20 (interquartile range 20/20 to 20/30), respectively.

## Inhaler Technique

The Wilcoxon signed-rank test showed a significant difference for the Diskus between the total number of correctly performed steps pre-intervention and post-intervention with median scores of 6.5–7.0 (interquartile range

Table 1. Demographics

Characteristics	Values
Age, mean $\pm$ SD y	65.6 $\pm$ 10.0
Weight, mean $\pm$ SD kg	78.7 $\pm$ 19.4
Height, mean $\pm$ SD cm	163.8 $\pm$ 13.0
Sex, <i>n</i> (%)	
Female	15 (62.5)
Male	9 (37.5)
FEV <sub>1</sub> /FVC pre-bronchodilator, mean $\pm$ SD	46.5 $\pm$ 14.7
FEV <sub>1</sub> /FVC post-bronchodilator, mean $\pm$ SD	48.5 $\pm$ 12.1
FEV <sub>1</sub> pre-bronchodilator, mean $\pm$ SD % predicted	41.5 $\pm$ 19.5
FEV <sub>1</sub> post-bronchodilator, mean $\pm$ SD % predicted	55.8 $\pm$ 18.3
COPD air-flow limitation, <i>n</i> (%)	
Mild	1 (4.2)
Moderate	12 (50.0)
Severe	8 (33.3)
Very severe	3 (12.5)
Vision score, <i>n</i> (%)	
20/20	15 (62.5)
20/25	2 (8.3)
20/30	5 (20.8)
20/50	2 (8.3)
Functional health literacy level, <i>n</i> (%)	
Adequate functional health literacy	16 (66.7)
Marginal functional health literacy	4 (16.7)
Inadequate functional health literacy	3 (12.5)

6.0–7.8) ( $P = .047$ ), yielding a medium effect size,  $r = .35$ . A larger change occurred in the HandiHaler group, which had median scores improve from 6.0 to 7.5 (interquartile range 7.0–9.0) ( $P = .002$ );  $r = .53$ . One participant was prescribed the Diskus Serevent instead of Diskus Advair, and because the handout described the Diskus device, that participant was included. The only difference was that, unlike with the Diskus Advair, rinsing the mouth after taking the medication is not required when using the Diskus Serevent. Therefore, for the purpose of analysis, that step was considered completed correctly for the Diskus Serevent if the participant did not rinse his/her mouth.

## Peak Inspiratory Flow

The minimum required PIF in the Diskus group was achieved by 15 of 16 participants (93.8%). For the HandiHaler, 17 of 18 participants (94.4%) achieved the minimum required PIF.

## Visual Acuity

A Spearman's rho was used to evaluate the correlation between vision scores and changes in inhaler technique pre- and post-intervention. The correlation coefficient and the significance (in parentheses) for the Diskus were

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Table 2. Diskus Number of Correct Inhaler Steps

Steps	Diskus ( <i>n</i> = 16)	Baseline	After Reading Handout
1	Hold Diskus in one hand, and put the thumb of your other hand on the thumb grip.	16	16
2	Hold Diskus level with mouthpiece facing you.	16	16
3	Slide lever away from you.	16	16
4	Turn your head, breathe out normally.	1	5
5	Breathe in fast and deep.	12	13
6	Remove from mouth, hold breath for 10 s.	6	8
7	Put your thumb on the thumb grip and slide it back toward you.	15	15
8	Rinse mouth, spit, do not swallow.	8	11
9	Check dose counter.	16	16

$r_s = 0.37$  ( $P = .16$ ), and the values for the HandiHaler were  $r_s = -0.013$  ( $P = .96$ ). No significant correlations were found between visual acuity and changes in inhaler technique for either device.

### Health Literacy

The Spearman rho was used to assess the correlation between health literacy level and the difference in the participant's performance pre- and post-intervention. The correlation coefficient and the significance (in parentheses) for the Diskus were  $r_s = 0.127$  ( $P = .64$ ), and for the HandiHaler, they were  $r_s = 0.048$  ( $P = .85$ ). Again, no correlations were detected.

### Discussion

This study included 24 stable participants with COPD. The participants' mean age was 66 y, and 63% of participants were female. The severity of air-flow limitation in the majority of participants was moderate or severe. Approximately two thirds of participants had perfect 20/20 vision and adequate health literacy.

The inhaler device handouts for DPIs were effective in improving inhaler performance in this study even when no verbal instructions were provided. The total number of correctly completed steps showed a statistically significant improvement for both inhalers. For the Diskus, the steps that state, "Turn your head and breathe out normally," "Rinse your mouth with water," "Remove Diskus from mouth. Hold your breath for 10 s," and "Breathe in fast and deep" improved post-intervention (Table 2). For the HandiHaler, the steps that state, "Breathe out all the way," "Wash your hands," "Dump capsule in a trash can. Do not touch the capsule," "Remove the HandiHaler from your

Table 3. HandiHaler Number of Correct Inhaler Steps

Steps	HandiHaler ( <i>n</i> = 18)	Baseline	After Reading Handout
1	Open the HandiHaler.	18	18
2	Remove one capsule.	18	18
3	Place the capsule in the center chamber.	17	18
4	Press the button on the side of the HandiHaler just once.	14	15
5	Sit up straight or stand.	18	18
6	Breathe out all the way. Make sure you never breathe out into the HandiHaler.	1	5
7	Close your lips and make a tight seal. Breathe in fast and deep.	16	16
8	Remove the HandiHaler from your mouth, and hold your breath for 10 s.	8	11
9	Repeat steps.	4	4
10	Dump capsule in a trash can. Do not touch the capsule.	5	10
11	Wash your hands after using this device.	1	4

mouth and hold your breath for 10 s," and "Press the button on the side of the HandiHaler just once" also improved post-intervention (Table 3). Some DPI steps might be more important than other steps. Press et al<sup>27</sup> defines "mission critical" steps as those steps that prevent any medication from reaching the lungs if missed. For example, loading the HandiHaler and piercing the capsule or charging the Diskus are considered mission-critical steps. Chapman et al<sup>6</sup> considered 2 steps as critical steps for appropriate drug delivery: loading the inhaler device with full release of the piercing button for the HandiHaler and breathing out away from the inhaler before inhalation. The critical step of breathing out away from the inhaler showed the most improvement in both devices.

The written handouts for the inhalers did not help participants to correct all steps. Others reported similar findings that providing only written instructions was inadequate for the correct use of inhalers.<sup>6,16</sup> Wilson et al<sup>17</sup> measured whether providing subjects with print materials to take home after receiving inhaler technique education from a health-care provider might further advance their long-term retention of the new information, but their findings did not achieve significance.

Clinicians may improve inhaler technique by combining written instructions with verbal instruction or video resources. Press et al<sup>5</sup> and Verver et al<sup>28</sup> found that providing subjects with verbal instructions improved their inhaler technique significantly. The use of verbal instructions also benefited subjects with COPD who needed to learn the proper PIFs to use with DPIs.<sup>18</sup> When both verbal and written instructions were used, subjects' PIFs through their DPIs were improved and maintained for at least 5 weeks.<sup>20</sup>

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Comparisons among the effectiveness of video and written training resources for inhaler instruction were also made. Video outperformed print when measured immediately after training. However, 1 week after the training, the retention was similar among video and print.<sup>17</sup>

An advantage of written materials is that patients can easily access them at any time and place.<sup>17</sup> In middle-age and older adults, written materials improved long-term retention of new inhaler information.<sup>17</sup> Written materials may be the only instruction on inhaler use that patients receive. Thus, validating the effectiveness of written inhaler instructions is important for patients that are prescribed DPIs.

Regarding the use of DPIs in patients with COPD, participants in this study with severe or very severe air-flow limitation were able to generate appropriate PIFs. This might be attributed to the fact that this study was conducted on stable out-patients. Only one participant with moderate air-flow limitation and prescribed both the Diskus and the HandiHaler did not achieve the minimum required PIFs. However, that participant was able to generate the appropriate PIF after receiving verbal instructions. Similarly, other studies found that subjects could achieve appropriate PIFs with verbal instructions and training.<sup>18,20</sup>

Many of the participants in this study inhaled at flows greater than the maximum flows of 90 L/min for the Diskus and 45 L/min for the HandiHaler as stated on the In-Check Dial (<http://alliantechmedical.com/products/check-dial-training-device/>. Accessed December 6, 2015). A study conducted in the United Kingdom in 2007 evaluated whether subjects with stable COPD could generate PIFs of >30 L/min through their DPIs. They concluded that subjects with moderate to severe air-flow limitation had trouble attaining the target PIF.<sup>18</sup> The difference in our findings might be attributed to the COPD population studied and the sample size. The study conducted in the United Kingdom enrolled 163 participants and did not use the GOLD guidelines to classify the COPD air-flow limitation. The United Kingdom's moderate severity group (40%) and severe group (38%) correspond with GOLD's severe and very severe air-flow limitation groups, respectively. The current study's population was composed of 24 participants with mainly moderate (50%) and severe (33.3%) participants and only a limited number of very severe participants (12.5%). The United Kingdom study's larger sample size and greater number of subjects with very severe air-flow limitation may also contribute to these differences.

Other studies suggest that age, sex, and cognitive impairment affect PIFs more than COPD air-flow limitation severity. Age was associated with decreased PIF in 3 different studies.<sup>19,29,30</sup> The mean ages of participants in those studies were 65 y,<sup>29</sup> 73.5 y,<sup>30</sup> and 76 y.<sup>19</sup> The par-

ticipants in the current study had a mean age of 65.6 y and were relatively younger, which may have allowed them to generate appropriate PIFs. Also, there may not have been adequate power in the current study to detect this difference. Furthermore, there is a need to expand the assessment of PIF to the in-patient population who are experiencing respiratory illness or COPD exacerbations.

No correlation was found between visual acuity and inhaler technique in the present study. Study participants' visual acuity ranged between 20/20 and 20/50. Others reported that participants with insufficient vision had a higher rate of Diskus misuse than participants with adequate vision (95% vs 61%,  $P = .004$ ). However, there was no significant association between the ability to learn the Diskus inhaler steps after coaching and inadequate vision. They also reported that more than one in every 4 study participants had inadequate vision ranging between 20/50 and 20/100.<sup>5</sup> The lowest vision score in the present study was 20/50. An association between vision and learning inhaler technique may have been found if the current study had more participants who had worse vision.

Similarly, no correlation was found between health literacy and inhaler technique in the present study. Other authors who used the S-TOFHLA reported similar findings,<sup>4,5,26</sup> of which one study was a randomized controlled trial.<sup>26</sup> However, a study that utilized the Rapid Estimate of Adult Literacy assessment showed a positive relationship between better inhaler performance after either print or video educational intervention.<sup>17</sup> Further study is needed to evaluate the effects of health literacy on learning inhaler technique and which literacy instrument is most appropriate to make this assessment.

This study had a number of limitations. The convenience sampling technique limited the generalizability of the study results. Four study participants had no post-bronchodilator pulmonary function test performed within the past 6 months, and a simple spirometry was conducted instead. This limited the ability to accurately assess the COPD air-flow limitation based on the GOLD guidelines. Furthermore, this study evaluated only 2 DPIs. The findings may differ if other types of inhalers are included. The study participants' relatively good vision and high levels of adequate health literacy limited an assessment of how these variables contributed to inhaler misuse. Education level was not assessed because functional health literacy was used. The impact of education level on inhaler technique may be a more sensitive indicator. Another limitation is that prior inhaler education (verbal instructions, online videos, written handouts, or others) was not assessed. Instead, a pretest assessment was performed to establish a baseline inhaler performance level. Also, the long-term retention of improved inhaler technique and the clinical importance of improved inhaler technique were

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not evaluated. To address all of these issues, larger multi-center studies are needed.

### Conclusions

Use of inhaler device handouts alone without any verbal instructions or demonstration improved inhaler technique. Importantly, this study did not measure the clinical importance of this improvement. Further, the study demonstrated that stable out-patients diagnosed with COPD in a younger elderly population ranging from 46 to 82 y old are able to generate appropriate PIFs for DPIs. This study did not detect associations between vision and health literacy and the capability to learn inhaler technique using written educational handouts.

### ACKNOWLEDGMENTS

We thank Ellen Moran, Renee Kiourkas, Roisin McLaughlin, and Ryn-dell Magbalon for assistance in recruitment.

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