Title: Patient perception of metered-dose inhaler use and its implications in COPD management.

Authors:

Jin Sun Kim BS, Hannah Li BS, Nader Hashweh BS, Salik Choudhary MD, Sadashiv Santosh MD, Edward Charbek MD

Contact Details:

Jin Sun Kim: jinsun.kim@health.slu.edu

Hannah Li: hannah.li@health.slu.edu

Nader Hashweh: nadernael.hashweh@health.slu.edu

Salik Choudhary: salik.choudhary@health.slu.edu

Sadashiv Santosh: sadashiv.santosh@health.slu.edu

Edward Charbek: edward.charbek@health.slu.edu

Affiliation (for all authors):

Division of Pulmonary, Critical Care and Sleep Medicine, Saint Louis University School of Medicine, Saint Louis, USA.

Address:

3635 Vista Ave, Saint Louis, MO, 63110, USA

Corresponding author contact

Telephone: 408-858-2682

Email address: hannah.li@health.slu.edu

Conflicts of Interest Statement:

Based on ICMJE guidelines, there are no potential conflicts of interest to disclose.

Key Words:

COPD; Medical Error, Patient Safety, Quality of Care

Total Word Count:

2670

Abstract:

Objectives: Literature has shown a high prevalence of poor inhaler technique among COPD patients throughout the past several decades. We aim to study patient perspectives on inhaler use to understand how inhaler therapy can be better approached.

Methods: COPD patients who were regularly using pressurized metered-dose inhaler(s) (pMDI) with or without spacers were recruited to complete a survey regarding their perception of inhaler use. Each patient's inhaler technique was assessed using the American Thoracic Society (ATS)'s recommended steps on using pMDIs.

Results: One hundred and one patients participated in the study. 91 (90.1%) reported that they use their inhaler correctly and 80 (79.2%) indicated that using their inhaler is easy, however 47 (46.5%) demonstrated inhaler misuse. 35 (34.7%) indicated that they prefer to consolidate all of their inhalers into one. When asked about previous training, 25 (24.8%) reported that they have not been shown how to use inhalers before.

Conclusions: Despite the high prevalence of poor inhaler use, the majority of COPD patients are confident in their pMDI technique and find them easy to use. Increasing patient awareness of poor inhaler technique and providing more frequent coaching on how to correctly use pMDIs may be beneficial in improving overall COPD management.

Additional Questions:

What's already known about this topic?

- Inhaler misuse is prominent in asthma and COPD patients. Literature has shown that more than 30% of patients incorrectly use their inhalers.
- Despite this awareness and increased educational efforts, there has been no improvement in patients' inhaler technique for the past several decades.

What does this article add?

- Our study assessed the patient's perception of their inhaler technique, which has not been studied previously.
- Most patients reported that they use inhalers correctly and found them easy to use. The discrepancy in the patients' view of their inhaler technique and their actual assessed technique may explain the difficulty in improving patients' inhaler technique despite numerous efforts.

1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a chronic respiratory condition characterized by persistent airflow limitation leading to chronic symptoms including cough, dyspnea, and sputum production. COPD management aims to mitigate these symptoms and reduce acute exacerbations. Inhalation therapy is the preferred route of administration for COPD medications, since it evades potent adverse effects associated with systemic dosing (Broaddus et al. 2016). Long-acting beta agonists (LABAs), long-acting muscarinic antagonists (LAMAs), and inhaled corticosteroids (ICS) are the available maintenance inhaler classes. They are effective in providing symptomatic relief, improving quality of life, and reducing COPD exacerbations (Kew et al. 2013; Koch et al. 2014).

Since inhalers serve as the principal medium for medication administration among COPD patients, it is important that patients practice optimal inhaler technique to ensure adequate drug delivery. Unfortunately, there is a high prevalence of poor inhaler technique in COPD patients. The actual frequency of incorrect technique varies by population, and some studies have shown it to be as high as 94% (Rodriguez-Garcia et al. 2020). Correcting poor inhaler technique can improve FEV1 and COPD Assessment Test (CAT) outcomes, and thus overall quality of life among COPD patients (Khurana, 2019).

The aim of our study was to assess perceptions of inhaler use among COPD patients. Specifically, we wanted to see if patient perceptions on their pressurized metered-dose inhaler(s) (pMDI) technique correlated with actual proficiency according to ATS guidelines. We also wanted to assess patient perceptions on inhaler consolidation, the ease of pMDI use, the need for more pMDI training, and the ability of pMDIs to provide symptom relief. We believe that understanding patient perceptions on the nuances of their inhaler use may help us improve COPD management.

2. Methods

Design and Participants

This study was a survey of patients with a diagnosis of COPD carried out at a single tertiary center in the outpatient pulmonary clinic. The manuscript authors developed the study design and survey questions after extensive literature review on inhaler use and patient perspectives on treatments in healthcare. The survey was not formally validated, however, was tested in three healthcare professionals. We enrolled patients from June 2018 and April 2019 and the survey was conducted in person by members of the research team. A clear explanation of the study was provided to each patient and informed consent was obtained. The Saint Louis University institutional review board approval was obtained prior to recruitment of participants. There was no funding for this study.

Adults aged $\geq$ 18 years and $\leq$ 90 years with a diagnosis of COPD who were regularly using pMDIs with or without spacers were recruited for this study. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria for airflow limitation (FEV1/FVC < 0.70) was utilized (Singh et al. 2019). Patient exclusion criteria included any patients with a concurrent diagnosis of asthma, a diagnosis of COPD but not meeting GOLD criteria, patients with COPD not using pMDIs, and

patients aged < 18 years and > 90 years. After the above screening, written informed consent was obtained for each participant.

Survey items development and analysis

The survey consisted of 7 close-ended questions investigating patients' views on their number of inhalers, correct use, difficulty of use, previous training, need of refresher training, and efficacy in symptom relief (Table 1). A member of the research team was always accompanying when completing the survey and was available to answer any clarifying questions regarding the survey. Survey answers were manually added into a data sheet using Microsoft Excel. Descriptive statistics were performed on each survey question.

Inhaler technique assessment

Each patient's inhaler technique was assessed utilizing the American Thoracic Society (ATS) recommended steps on using metered dose inhalers (MDIs) (Table 2). This was done in-person during each patient's office visit. One-on-one coaching was provided by a pulmonary critical care attending, fellow or medical student who were given training prior to the study for standardization. In evaluating the participant's technique, patients were asked to demonstrate how they would use their inhalers without actually taking a puff. Each step was graded as correct or error. Incorrect and omitted steps were pointed out and the full sequence of 12 steps were reviewed for all patients. The intervention took about 5 to 10 minutes. Patients were labeled as having incorrect technique if they had less than 75% (less than 9 out of 12) of the steps correct.

Table 1.

1.	With regards to inhalers, do you feel you need: (more, just right, less inhalers)
2.	Do you prefer to consolidate all of your inhalers in one inhaler? (agree, doesn't matter, disagree)
3.	Do you use your inhaler correctly? (yes or no)
4.	Difficulty using inhaler (difficult, doable, easy)
5.	Have you ever had someone show you how to use your inhaler? (yes or no)
6.	Do you need a refresher training for inhaler use? (yes or no)
7.	Do you think your inhalers provide symptom relief? (yes or no)

1

2 Table 2. ATS guidelines on correct MDI use.

1.	Put the metal canister into the "boot" making certain it is seated correctly.
2.	Shake the inhaler several times. This mixes the propellant and medicine.
3.	Remove the cap off from the mouthpiece.
4.	Breathe out to the end of a normal breath.
5.	Hold the inhaler in its upright position (with the mouthpiece at the bottom).

6.	Put the mouthpiece in your mouth, past your teeth and above your tongue. Close your lips around the mouthpiece so that the medication does not go in your eyes.
7.	While breathing in slowly and deeply through your mouth, fully press down once on the top of the metal canister of your inhaler.
8.	Hold your breath for 5 to 10 seconds.
9.	Breathe out slowly
10.	If you take more than one spray, wait 15 to 30 seconds (or as directed in the package insert) before taking the next puff. Then repeat steps 3-9.
11.	Replace the cap on the mouthpiece after you are finished.
12.	If you are inhaling a steroid, rinse your mouth out with water, swish, gargle and spit.

3. Results

One hundred and one patients (mean age 64.74 years) met the study criteria and participated in the study (Figure 1). The majority of participants were female (61.4%), however there were no significant differences in mean age, race, mean number of inhalers, and most common inhaler combination between male and female patients (Figure 2). Patients utilized a range of 1 to 4 different inhalers, with 58 (57.4%) patients utilizing 3 inhalers. The majority of patients were prescribed a combination of tiotropium bromide, budesonide-formoterol, and albuterol sulfate (Figure 2).

All recruited patients succeeded in completing the survey. 17 (16.8%) said that they need more inhalers, 75 (74.3%) said that the number of inhalers they have are just right, and 9 (8.9%) said that they need less inhalers (Graph 1). 35 (34.7%) indicated that they would prefer to consolidate all of their inhalers into one, 55 (54.5%) said that it doesn't matter, and 11 (10.9%) said that they do not prefer to consolidate all of their inhalers into one (Graph 2).

When asked about inhaler use, the majority of patients believed that their inhalers are easy to use and that they use it correctly. 91 (90.1%) reported that they use their inhaler correctly while 10 (9.9%) said that they use it incorrectly (Graph 3). 80 (79.2%) indicated that using their inhaler is easy, 18 (17.8%) indicated that it is doable, and only 3 (3.0%) indicated that they have difficulty using their inhaler (Graph 4).

When asked about training, 76 (75.3%) reported that they have had someone show them how to use their inhaler before, while 25 (24.8%) reported that they have not. 24 (23.8%) reported that they need a refresher course, while 77 (76.2%) reported that they do not (Graph 5). Finally 92 (91.1%) reported that they think their inhalers provide symptom relief, while 9 (8.9%) reported that they do not (Graph 6).

Upon assessment of inhaler technique using the ATS guidelines and scoring system, 47 (46.5%) of patients demonstrated inhaler misuse (Graph 7).

Figure 1. Patient Recruitment

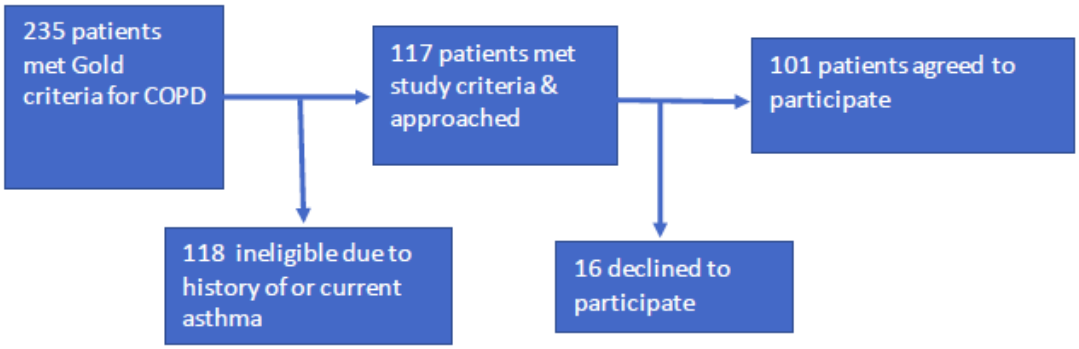
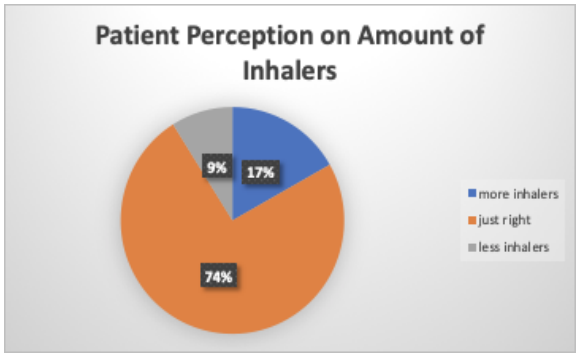


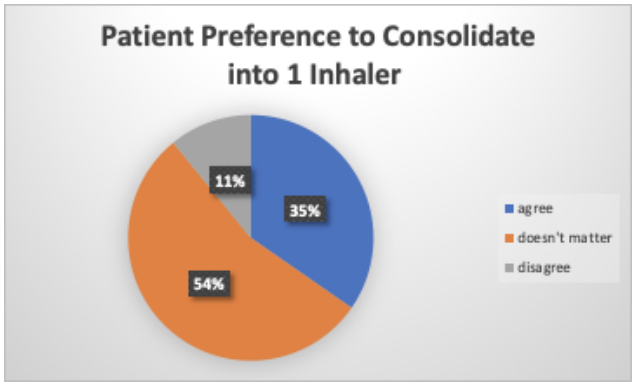
Figure 2: Demographics

		Male (n = 40)	Female (n = 61)
Mean age		64.2	63.5
Race	African American	21 (52.5%)	34 (55.7%)
	Caucasian	16 (40.0%)	22 (41.0%)
	Other	3 (7.5%)	5 (3.3%)
Smoking		16 (42.1%) *2 patients declined to answer	18 (30.5%) *2 patients declined to answer
Mean number of inhalers		2.6	2.6
Most common inhaler combination		Tiotropium bromide, Budesonide-formoterol, and Albuterol sulfate	Tiotropium bromide, Budesonide-formoterol, and Albuterol sulfate

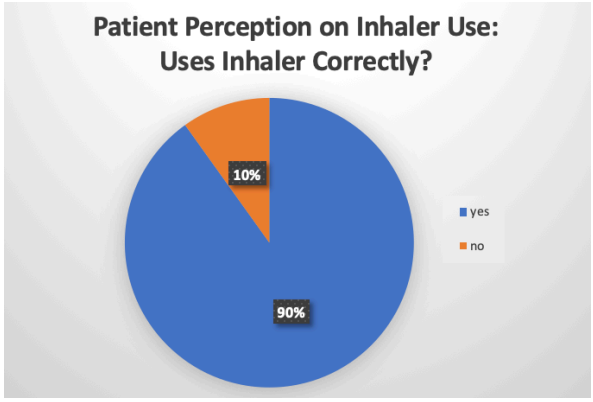
Graph 1.



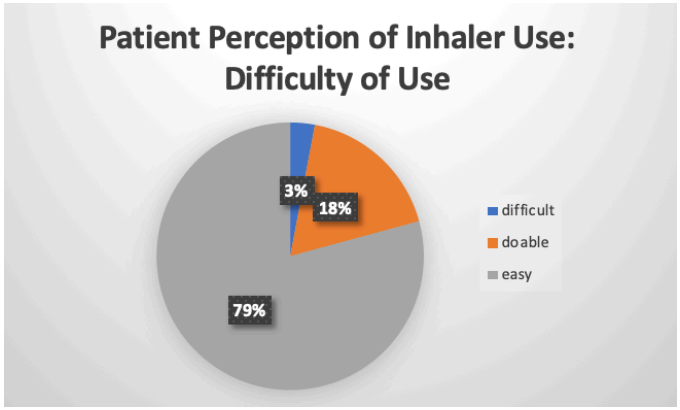
Graph 2.



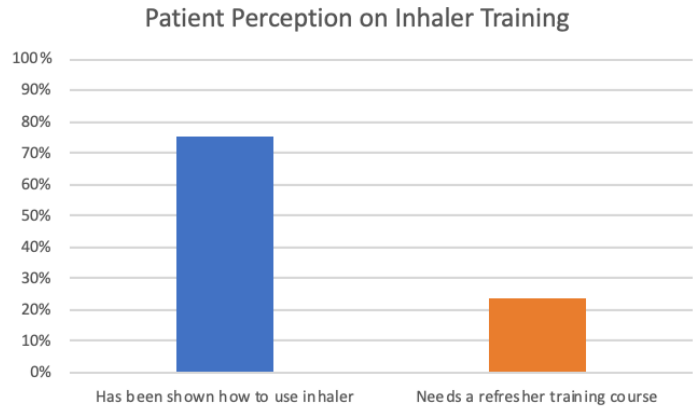
Graph 3.



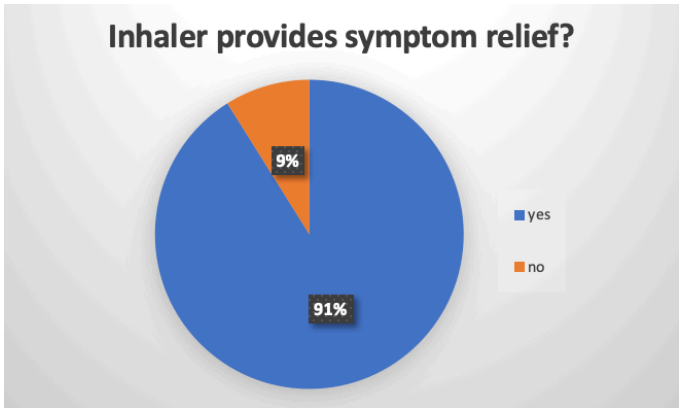
Graph 4.



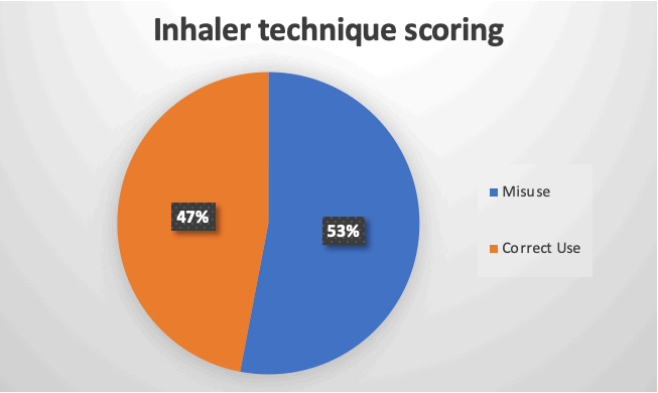
Graph 5.



Graph 6.



Graph 7.



4. Discussion and Conclusion

4.1. Discussion

A key finding in this study is that most (90.1%) patients believed that they used their pMDI correctly, however about half of them demonstrated poor inhaler technique based on ATS guidelines. As aforementioned, the extent of incorrect inhaler technique varies by population (Rodriguez-Garcia et al. 2020). For example, a systematic review of articles from 1975 to 2014 revealed that only 31% of inhaler users demonstrate proper technique (Sanchis et al., 2016). The discrepancy between perceived versus actual pMDI technique suggests that patients are not aware of their incorrect pMDI use. This can be partially explained by perceived symptom relief. Most patients in our study reported symptom relief with inhaler use, indicating the subjective effectiveness of inhaler therapy even among those with poor technique. However this was assessed with a simple yes-or-no question rather than a more scalable measure such as FEV1 or CAT score. Other studies have shown improved FEV1 and CAT scores after correcting pMDI technique (Khurana, 2019). It would be interesting to investigate how pMDI use among the patients in our study affects the degree, rather than just the presence or absence, of symptom relief. We anticipate

even greater satisfaction with symptom relief when optimizing medication delivery via correct pMDI technique.

Both patient concern for proper device technique and the lack of coaching by providers may contribute to this problem. According to GOLD guidelines, patients should be coached on how to use their pMDI when it is first prescribed and technique should be assessed regularly (Singh et al. 2019). However, a study by Hanania et al. showed that when prescribing inhalers to newly-diagnosed COPD patients, only 45% of providers assess their patients for proper technique (2018). In this same study, 64% of patients were unconcerned about correct inhaler technique and reported receiving inconsistent education on how to use their inhalers. In our study, most patients perceived their pMDI technique to be adequate, but we did not ask if they believed correct technique to be important to COPD management. A fourth of patients said that they never had someone show them how to use a pMDI before, suggesting a potential gap in education on the provider's end. A fourth of patients also said that they could use a refresher course on pMDI use, highlighting the need for more frequent follow-up to assess and reinforce proper inhaler technique. For instance, it would be useful for providers to reinforce key steps of pMDI use (e.g. remembering to exhale to clear out the lungs before inhaler administration) that patients often omit. Overall these results emphasize the need to coordinate educational efforts so that patients understand the importance of good pMDI technique and providers are able to provide consistent training for it.

Combined inhaler treatment is another important factor to consider from the patient's perspective. Studies have shown that fixed triple therapy and once-a-day dosing is preferred by patients and leads to improved medication adherence (Molino, 2018; Bogart et. al, 2019). One study conducted via patient surveys showed that patients believe they would have an easier time using their inhaler(s) if there were fewer operational steps, easier coordination of breathing maneuver, and confirmation of dose delivery (Molimard and Colthorpe, 2015). In our study, the majority of

patients (57.4%) utilized a total of 3 inhalers including both pMDIs and dry powder inhalers (DPIs). The most common inhaler therapy was a LAMA and LABA/ICS combination with tiotropium bromide and budesonide-formoterol. All patients had an albuterol sulfate rescue inhaler. While most patients reported having just the right number of inhalers, a significant proportion (34.7%) preferred to consolidate their inhalers into one. As discussed above, utilizing multiple inhalers that require different administration techniques may be difficult, contribute to poor compliance, and worsen patient outcomes. Patients may benefit from consolidating their inhalers into one.

Study Limitations:

One limitation of the study was the close-ended nature of the questions. Most of the questions were simple yes or no questions or had three answer choices to pick from. Although this format of questions provided the benefit of quantitative analysis, it limited the investigation of patients' specific opinions on their use of inhalers. It did not allow patients to elaborate on their responses. For example, it was difficult to determine what patients meant when they found the use of inhalers easy. Different patients may have referred to different degrees of ease. Having the opportunity to subjectively explain their answers may have provided further insight.

Regarding combined inhaler therapy, our study only assessed if patients wished to have less inhalers. We did not assess patient preferences on the different types of combination maintenance inhalers (e.g. budesonide/ formoterol vs. fluticasone propionate/ salmeterol). A study by Tervonen et al. among COPD patients on dual-combination inhalers showed that current practice may not allow patients to identify their preferred inhaler combination (2019). It showed a discrepancy between patients' preference of inhaler combination versus what was actually prescribed to them. However, this study only included patients on dual inhaler therapy. Since most of the patients in our

study were on triple inhaler therapy, it would be interesting to investigate if there is a difference between patient preferences and actual prescriptions within our specific patient population.

Another limitation of the study was the limited variety of the study population. The study was performed in one urban academic outpatient clinic. The majority of the study population were Caucasian or Black and the vast majority of patients used 3 inhalers. The lack of heterogeneity of the study population may limit the generalizability of results.

4.2. Conclusion

Despite the high prevalence of poor inhaler technique, COPD patients may not be aware of their incorrect use. Patients are generally satisfied with their inhaler therapy and confident in their use of inhalers. There may be a benefit of consolidating inhalers into one, however most patients do not have a strong preference in their number of inhalers and further investigation on patient preferences is required. Most importantly, this study highlights the need for ensuring that COPD patients practice adequate technique when using pMDIs. Proper and consistent inhaler technique should be taught at the initiation of therapy and reinforced during subsequent office visits.

5. Acknowledgements

We thank our Pulmonology office and all physicians, nurses, and staff in the office for allowing us to proceed with this study. We disclose no external funding for this study.

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