

## Technical Errors in Using Inhalers among Patients with Asthma or COPD in Iraq

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### Abstract

<b>Background</b>	Inhaler is a device holding a medicine taking by breathing (inhalation). It is estimated that about 25 billion dollars spent for inhalers annually, 5-7 billion dollars are wasted because of inhaler misuse.
<b>Objective</b>	To evaluate inhaler use technique among Iraqi asthmatic and chronic obstructive pulmonary diseases (COPD) patients and identify the technical mistakes in using inhalers.
<b>Methods</b>	The study protocol consisted of interview session to answer the study questionnaire and assessment session to estimate the performance of using inhaler in three cities in the middle of Iraq during the interval between 1 <sup>st</sup> of August and 20 <sup>th</sup> of September 2015. Chi-square test and trend chi-square test were used for univariate association between potential determinants and correctness of inhalation technique. Relevant determinants were entered into a multivariate logistic regression model.
<b>Results</b>	A total of 364 patients participated in this study, 39.6% of patients were using their inhalers inadequately. Patients using turbuhaler, older patients (>60 years old) and patients with low level of education or shorter duration of use were significantly associated with more inhaler use mistakes.
<b>Conclusion</b>	This study showed that substantial proportion of patients with asthma or COPD using their inhaler inadequately. The worse performance was among patients using turbuhaler and best among those using diskus inhaler.
<b>Keywords</b>	Inhaler administration, asthma, COPD, pMDI, turbuhaler, diskus inhaler
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**List of abbreviation:** COPD = Chronic obstructive pulmonary diseases, DPI = Dry powder inhalers, pMDI = pressurized metered-dose inhaler, SPSS = Statistical package for the social science

### Introduction

More than 300 million people, worldwide have asthma with 250000 deaths each year, while chronic obstructive pulmonary diseases (COPD) affects 210 million people <sup>(1)</sup>. In Iraq, nearly 230000 asthmatics visited primary health care centers and asthmatic patients formed 16.4 per 1000 hospital outpatient visitors in 2013 <sup>(2)</sup>.

Inhaled therapy, introduced into clinical use 60 years ago, is a fundamental route of drug administration in modern management of asthma, and it might be difficult to think of a time when asthma was managed without <sup>(1)</sup>. Inhalers are also very important in the management of COPD, which makes inhaled drugs the cornerstone in the treatment of these diseases <sup>(1,3)</sup>. The inhaler is next to pills, the most common medication for asthma in the world, but the main problem is the incorrect use of inhaler devices, which may

have a major influence on the therapeutic efficiency of used drug<sup>(3,4)</sup>. Mistakes in inhaler use have been reported to occur in up to 85% of patients<sup>(3)</sup>. The most frequently used inhaler for treatment of asthma and COPD are the metered-dose inhaler (MDI) and dry powder inhalers (DPI) like turbuhaler and diskus inhaler<sup>(5,6)</sup>.

MDI have many advantages and disadvantages. MDI are usually small in size, portable, compact, convenient, relatively low cost, multi-dose capability, quick delivery, and their contents are protected from contamination by pathogens<sup>(7)</sup>. The disadvantages of MDIs include: drug delivery is highly dependent on inhaler use technique and misuse could result in a suboptimal (even zero) lung deposition as most of the dose is deposited in the oropharynx, failure to shake, have fixed drug concentration, and adverse reactions to propellants<sup>(7)</sup>. For DPI, a primary advantage is the need for coordination of actuation with inspiration, which depends on patient's inspiratory flow, while the main disadvantage is the time needed to load a dose for each use. For these reasons, large number of different types of inhalers were manufactured and introduced in the market<sup>(7)</sup>. The type of inhaler is an important determinant of mistakes in inhaler use and these were significantly more with users of the MDI use<sup>(3, 8-10)</sup>.

It is worth to mention that inhaler use technique is considered as dealing with a simple device, so it is often neglected in the general medical textbooks and literature<sup>(11)</sup>. A review of medical textbooks used in the education of physicians revealed that only two out of 40 books included a simple list of steps for proper pressurized metered-dose inhaler (pMDI) use<sup>(12)</sup>. As a result, 39-67% of nurses, doctors, and respiratory therapists were reported to be unable to adequately describe or perform critical steps for using inhalers<sup>(4)</sup>. This might be the reason behind the finding that between 28% and 68% of patients do not use pMDI or DPI well enough to benefit from the prescribed medication<sup>(4)</sup>.

The incorrect use of inhalers may lead to uncontrolled asthma and increased costs due to increased utilization for medication resulting from inefficient drug use<sup>(6)</sup>. It is estimated that out of 25 billion dollars spent for inhalers annually in the United States, 5-7 billion dollars were wasted because of inhaler misuse<sup>(4)</sup>.

In a recent study in Palestine, among 149 asthmatic patients showed that only 37.6% used inhalant properly and significant differences were found between types of inhaler device. Large number of published research had documented significant differences between different types of inhalers<sup>(8,9)</sup>. Additionally, significant relationship was found between correct score of handling inhaler device and educational level<sup>(10)</sup>. Similar significant differences were reported by many other studies. Training the patients and improving patient education about inhaler use technique could reduce these wasted resources and improve the effect of treatment<sup>(4,13-15)</sup>. All these issues make inhaler use evaluation and patient education, fundamental needed steps in respiratory diseases treatment with inhalation drugs<sup>(13,14)</sup>.

The objective of this study was to evaluate inhaler use technique among Iraqi asthmatic and COPD patients and to identify the technical mistakes in using inhalers.

## Methods

A cross sectional study conducted among asthmatic and COPD patients in the Medical City/Baghdad, Imam Hussein Medical City/Karbala and the Center of Asthma and Allergy/ Babylon between 1<sup>st</sup> of August and 20<sup>th</sup> of September 2015. A total of 364 outpatients (172 males and 192 females) were involved in the study. The study aimed to determine the main mistakes in inhaler use technique for the three main types of inhalers used (pMDIs, turbuhaler and diskus)<sup>(10)</sup>. The common investigated predictors of these technical mistakes were type of inhaler device and patient characteristics (gender, age, level of education and duration of disease). Inclusion

criteria: All patients with asthma or COPD using pMDI, turbuhaler or diskus inhaler who accepted to participate in the study. While exclusion criteria were: patients using other type of inhalers or those using additional spacer device beside the inhaler; patients below 6 year of age (because they need spacer devices); patient in acute attack of asthma or COPD (because they may have mistaken due to confusion). The study included two sessions for each participant: interview session to answer the study questionnaire and assessment session to evaluate his or her performance in using the inhaler. The interview session included information about the following four sections:

1. Demographic questions: age, gender, level of education, occupation and residency.

2. History of the present disease: type of the disease and its duration (asthma or COPD).
3. Inhaler use: Type of inhaler and the duration of inhaler use.
4. Who give the patients instructions to using their inhalers?

Assessment session included the demonstration of inhaler use according to standard steps for each inhaler type, ability to declared whether the inhaler contain drug and reading expiry date of the inhaler. The steps list was derived from the medication leaflet and from previous studies <sup>(16)</sup>, (Table 1). The practical assessment followed standardized steps checking which was followed strictly, as the interviewers were trained before conducting the study.

**Table 1: Standard steps for each inhaler type as included in the form of assessment**

Steps	pMDI inhaler	Diskus inhaler	Turbuhaler
1	Removing dust cap	Removing the dust cap	Removing dust cap
2	Shaking inhaler well	Loads inhaler with one dose	Loads inhaler with one dose
3	Exhaling before use	Exhaling before use	Exhaling before use
4	Inhaling through inhaler and releases a dose	Places mouthpiece in mouth and closes lips around it	Places mouthpiece in mouth and closes lips around it
5	Removing inhaler and holds breath	Inhaling forcefully and deeply	Inhaling forcefully and deeply
6	Observe that no leak	Removing inhaler and holds breath	Removing inhaler and holds breath
7	Wash mouth*	Wash mouth*	Wash mouth*
8	Replacing dust cap	Closing dust cap	Replacing dust cap

\* If the inhaler contains corticosteroids

**Scoring system**

A Likert scale was followed in the assessment of each step according to its importance in the treatment as reported in many similar studies <sup>(4)</sup>, and a final score was calculated accordingly. The steps of inhaler use were divided into:

1. Essential step that is critical to ensure the drug delivery to the lung and mistake in this step cause failure in the treatment. These steps included “inhaling properly through inhaler with active the canister to releases

the dose and” Observe that no leak ”, for pMDI inhaler; and “loads inhaler with one dose” and “inhaling forcefully and deeply” for both diskus and turbuhaler inhalers. This type of classifying the steps into essential and minor steps was followed in many published studies <sup>(8-10)</sup>. Each step was assessed by the interviewer and then a score was given consisting of three grades, 0: if the patient did not conduct the process

at all, 2: if the step was done partially and 4: if the step was properly done.

2. Minor step that have minor effect on drug delivery, which included shaking inhaler well before use, exhaling gently as much as comfortable, removing inhaler, holds breath and wash mouth for steroid containing inhalers. Here scoring was similar to the essential steps but a lower score was given consisting of three grades, 0: if the patient did not conduct the process at all, 1: if the step was done partially and 2: if the step was properly done.
3. Routine steps included other steps not affecting drug delivery and these were not scored.

The total score for each patient was found by summation of the scores got for all the steps. A range of 11-14 was considered as 'Adequate' while a score of 10 or less was categorized as 'Inadequate score'. The data was entered into a database using the Statistical Package for Social Science (SPSS) version 22. Chi-square test was used for bivariate associations between inhaler use performance and potential determinants. Relevant determinants were entered into a multivariate logistic

regression model and correlation analysis. Effect sizes were expressed in odds ratios (OR) with their 95% confidence intervals (95% CIs). Moreover, inhalation technique errors were examined for three inhalers and all were assessed at a significance level of  $<0.05$ .

## Results

A total of 364 patients, 172 male (47.3%) and 192 female patients (52.7%) participated in this study. The age ranged between 11 and 78 year with a mean of  $47.8 \pm 14.6$  year. The majority of patients had asthma (332 patient, 91.2%) and the remaining had COPD (32 patient, 8.8%). About two thirds (220 patients, 60.4%) got an adequate score of performance in the assessment session indicating acceptable inhaler use (Table 2). A highly significant difference in performance was observed between the different types of inhaler used. The best performance was observed among patients using diskus inhaler, where 88.2% of the patients got adequate score while the lowest proportion was among patients using turbuhaler (48.5%), while pMDI was in the middle (72.5%, Figure 1 and Table 2).

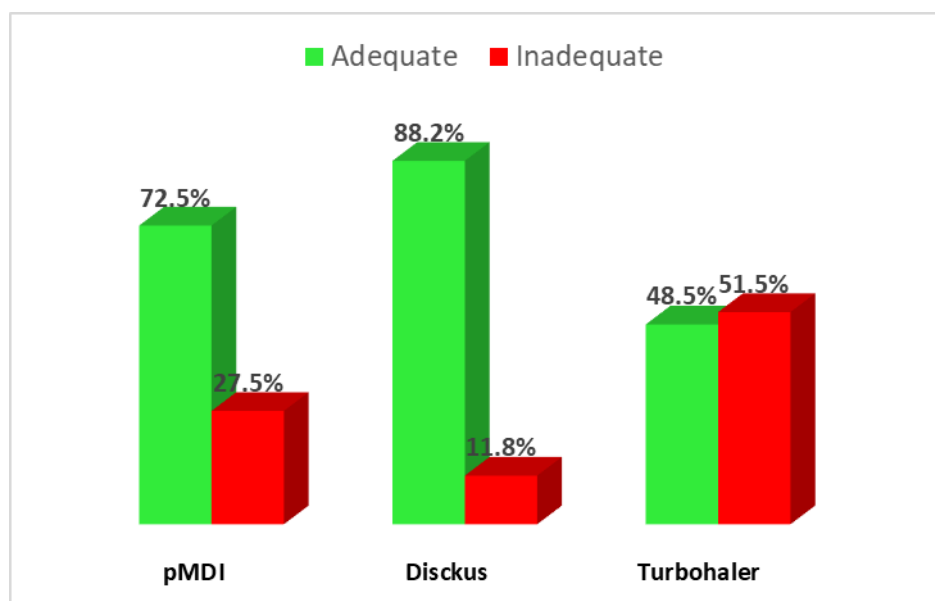


Figure 1. Inhaler use performance by type of inhaler among 364 Iraqi patients.

The most common errors among patients using pMDI inhaler were missing exhalation before use (36.6%) and missing to shake the inhaler before use (21.5%). Among patients using turbuhaler and diskus inhaler, the most common errors were missing mouth washing

after use (51%) and (29.4), respectively. Other common missed steps for turbuhaler patients were failure to load inhaler with one dose properly (49.5% - both partial done and not do at all-) and not exhaling before use (44.8%, Table 3).

**Table 2. The distribution of patient's inhaler use performance according to inhaler type, disease, demographic characteristics and duration of disease among 364 Iraqi patients**

Variable	Categories	Adequate No. (%)	Inadequate No. (%)	X <sup>2</sup>	Significance
Inhaler type	pMDI	111 (72.5%)	42 (27.5%)	26.533	<0.001
	Turbuhaler	94 (48.5%)	100 (51.5%)		
	Diskus inhaler	15 (88.2%)	2 (11.8%)		
Disease	Asthma	199 (59.9%)	133 (40.1%)	0.395	0.530
	COBD	21 (65.6%)	11 (34.4%)		
Gender	Male	105 (61.0%)	67 (39.0%)	0.050	0.823
	Female	115 (59.9%)	77(40.1%)		
Residency	Urban	196 (60.1%)	130 (39.9)	0.131	0.717
	Rural	24 (63.2%)	14 (36.8%)		
Age group (year)	21-30	25 (65.8%)	13 (34.2%)	3.43	0.047*
	31-39	31 (56.4%)	24 (43.6%)		
	40-49	64 (66.6%)	32 (33.3%)		
	50-59	51 (68%)	24 (32%)		
	60-69	40 (54.8%)	33 (45.2%)		
Educational level	70-80	9 (33.3%)	18 (66.3%)	21.11	<0.001*
	Illiterates	48 (44.9%)	59 (55.1%)		
	Primary school	67 (60.4%)	44 (39.6%)		
	Intermediate school	33 (61.1%)	21 (38.9%)		
	Secondary school	31 (77.5%)	9 (22.5%)		
Duration of disease	College graduates	41 (78.8%)	11 (21.2%)	2.71	<0.001*
	< 1 year	18 (50.0%)	18 (50.0%)		
	1-20 year	154 (60.2%)	102 (39.8%)		
	>20 year	48 (66.7%)	24 (33.3%)		
Total		220 (60.4%)	144 (39.6%)		

\* Trend chi square test (trend chi-square test) used for ordinal variables

Patients with COPD did better than patients with asthma in inhaler use performance (65.6% and 59.9%, respectively) but the difference was not significant. There was slight non-significant difference in adequate score between patients living in rural and urban areas (63.2% and 60.1%, respectively, Table 2).

Negative significant association was found between performance score and age distribution ( $r=-0.132$ ,  $p=0.012$ ). The highest proportion of patients with adequate score was among those aged 50-59 year (68%), while the lowest (33.3%) was among those aged 71-80 year and the difference was significant (table

2). Additionally, a highly significant positive association was found between performance score and patient educational level ( $r=0.254$ ,  $p<0.001$ ). The highest proportion of adequate scores was among patient having education level 4 (college graduates, 78.8%), while the least (44.9%) was among patients having education level 0 (illiterates, Table 2).

There was no gender difference in performance although males showed better performance (Table 2). A positive significant association was found between performance score and duration of disease ( $r=0.1162$ ,  $p=0.028$ ). The best performance was among

patients having the disease for >20 years (66.7%), while the least was among patients having the disease for less than 1 year (50%) (Table 2).

The majority of patients (84.3%) reported that they were able to decide whether inhaler contain drug or is empty, whilst, more than one-half of the patients (56.6 %) reported that they read the expiry date. Regarded the instructor for using inhaler, the majority (85.4%) learned using inhaler by their treating physician and most of the patients (76.9%) declared that they prefer being taught by their treating physician.

**Table 3. The distribution inhaler use performance assessment by type of inhaler type among 364 Iraqi patients**

Inhaler type	Steps of inhaler use	Done properly No. (%)	Done partially No. (%)	Not done No. (%)
pMDI	Shaking inhaler well	115 (75.2%)	5 (3.3%)	33 (21.5%)
	Exhaling before use	92 (60.1%)	5 (3.3%)	56 (36.6%)
	Removing inhaler and holds breath	128 (83.7%)	0 (0%)	25 (16.3%)
Turbuhaler	Loads inhaler with one dose	98 (50.5%)	93 (48%)	3 (1.5%)
	Exhaling before use	102 (52.6%)	5 (2.6%)	87 (44.8%)
	Wash mouth	95 (49%)	0 (0%)	99 (51%)s
Diskus inhaler	Exhaling before use	13 (76.5%)	0 (0%)	4 (23.5%)
	Removing inhaler and holds breath	14 (82.4%)	0 (0%)	3 (17.6%)
	Wash mouth	12 (70.6%)	0 (0%)	5 (29.4%)

A multivariate regression model for inhaler use performance was built including all variables and the results showed that the significant predictors for performance were: Educational level (odds ratio=0.60); the duration of disease (odds ratio=0.69) and Inhaler type (odds ratio=1.71) while governorate where the study was conducted (odds ratio=0.78) (Table 4). The goodness of fit for the model was acceptable (0.750) (Table 4).

## Discussion

Inadequate use of inhalers is a significant problem for both asthma and COPD

management because it may result in diminished therapeutic effect, resulting in poor control of symptoms and thereby insufficient disease management<sup>(3,16)</sup>. In Iraq, a previous published study tried to explore inhaler use technique mistakes among 150 asthmatic patients in Baghdad reported that two-third (66%) of participant used inhaler incorrectly<sup>(17)</sup>. However, the study did not observe the patients using inhaler, but depend on self-administered questionnaire. A study in the Netherland reported that about one quarter (24.2%) of the asthmatic and COPD patients (N=558) made at least one essential mistake in their inhalation technique<sup>(8)</sup>.

**Table 4. Inhaler use performance logistic regression model with predictors results among 364 Iraqi patients**

Variable	Odd ratio and 95% confidence interval	Significance
Medical department (Governorate) Ref. category: Kerbala governorate	0.78 (0.58-1.04)	0.082
Inhaler type Ref. category: Ventolin inhaler	1.71 (1.34-2.17)	< 0.001
Duration of disease Ref. category: one year or less	0.69 (0.59-0.82)	< 0.001
Educational level Ref. category: Illiterate patients	0.60 (0.40-0.90)	0.012

The scoring system used in this study was better than assessment in a previous study conducted in Baghdad <sup>(17)</sup>, where only self-administered questionnaire with no assessment of inhaler use was tried. Scoring is thought to be better than the scoring system reported in the study in the Netherland <sup>(8)</sup>, where one or more negative scores on preparation or breathing maneuvers indicated incorrect technique while the Likert scale scoring used in the present study allowed a quantitative assessment rather than only ‘all or none’ scoring indicating presence or absence of the step.

In the present study, patients having asthma were much more than those having COPD because one of the study premises was a specialized center for asthmatics. Additional reason might be related to wide range of participants’ age as COPD is not common among Youngers.

The present study showed that about two fifths of the patients (39.6%) were using the inhaler inadequately, which was similar to the findings in Jordon (43%) reported by Khassawneh and his colleague in 2008 <sup>(9)</sup>. A lower prevalence (24.2%) was reported in a study in by Hesselink and his colleague in the Netherland in 2001 <sup>(8)</sup>, and the reason might be related to methodology as the measurement checklist used in this study included only essential steps in inhaler use technique <sup>(8)</sup>. However, variation in the results is common and is accepted and was estimated to be between 4% and 94% in a systematic literature review by Lavorini and his colleague in 2008 <sup>(3,8,9)</sup>. The wide range in the

prevalence of incorrect technique reported may largely be explained by differences in scoring systems <sup>(3,10)</sup>. Significant large difference between the different types of inhalers was expected because of the difference in the techniques and the date of introduction in the market <sup>(3,6,8,9)</sup>. DPI available since the 1970s, have been developed to make inhalation simpler compared with pMDIs, without the need to coordinate inhalation and actuation, this should be made DPIs easier to use <sup>(3)</sup>. However, Turbuhaler got the highest percentage of inadequate use (52%) in the present study. A possible explanation might be related to the free distribution of Turbuhaler inhaler in the visited hospitals, leading to possible increased patients neglect to learn instruction use. Additionally, in some studies, it was also observed that many doctors and staff teach the patients incorrectly regarding the loading inhaler with one dose <sup>(9,10)</sup>, a finding reported by other studies <sup>(18,19)</sup>. Next possible reason might be due to the fact that pMDI inhaler was available long before Turbuhaler and this is supported by high percentage of adequate grade among patients using inhaler for longer duration in the present study.

The majority (85.4%) of patients in the present study was taught to use inhaler by their treating physician and this was similar to those reported in other studies <sup>(10)</sup>, but this was not a source for significant improvement in performance which was reported by the study in Palestine <sup>(10)</sup>.

The three most frequent missed steps were mouth wash after use, exhalation before use

and shaking inhaler before use (table 3). Poor training by medical staff might be an additional reason for these common mistakes <sup>(18,19)</sup>. Additional reasons behind these common mistakes might be related patients neglect or they consider these not important steps. Besides, the low educational level of the participants where about two thirds (59.9%, table 2) were illiterate or primary school graduates might be a contributing factor. The increasing in the adequate performance of using inhalers with increase in education level may due to access to information on the internet and other sources and easy to understanding the correct instruction.

The highest inadequate grade (66.6%) was among those aged 71-80 years old and also about one half of the patients in the 61-70 years group do inadequately and a similar finding was reported by the study in Baghdad <sup>(17)</sup>, This might be related to their medical problem such as arthritis, weakness or impaired dexterity or vision and needs further study.

The positive significant correlation between the duration of disease and the total score of the patient can contributed to the experience of the patients over the time and was reported in some reviewed studies <sup>(3,8,9)</sup>.

The highest percentage of patients not know expiratory date it might because large proportion of patients in the present study were illiterate or at low level of education, similar results was reported by the study in Baghdad <sup>(17)</sup>.

The COPD patients and patients living in rural area did better than other patients in this study but the difference was not significant and this might be due to small number of COPD and rural patients, so these findings need to be explored further in future studies.

The multivariate regression model findings demonstrated that inhaler type and medical premises were the significant predictors of mistakes in inhaler use. Rootmensen and his colleagues <sup>(15)</sup>, reported that inhaler type was a significant predictor of mistakes (OR between 1.5 and 25.7).

Conclusion: Our study showed that substantial proportion of patients with asthma or COPD

using their inhaler inadequately. Adequate performance was more in patients of younger age groups and high level of education. The worse performance was among patients using turbuhaler and best among those using diskus inhaler.

Recommendation: Education system about their inhalers should be introduced alongside with regular assessment of patient with asthma and COPD. Special attention should be paid for elderly patients using tubuhaler and pMDI.

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### Author contribution

Aboud: study design, questionnaire preparation and training of interviewer. Al-Mousawi: literature review. Al-Mousawi and Abutiheen: preparation of the questionnaire, statistical analysis and interpretation. Khudhair, AL-Khatib and AL-Obaidi: data collection (interview and practical assessment). Khudhair: data entry to the SPSS program, interpretation and preparing the article.

All authors were involved in final approval of the version to be published as group.

### Conflict of interest

Authors declare no conflict of interest.

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