Validation of scores of use of inhalation devices: valoration of errors*

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Abstract
Objective: To validate two scores quantifying the ability of patients to use metered dose inhalers (MDIs) or dry powder inhalers (DPIs); to identify the most common errors made during their use; and to identify the patients in need of an educational program for the use of these devices. Methods: This study was conducted in three phases: validation of the reliability of the inhaler technique scores; validation of the contents of the two scores using a convenience sample; and testing for criterion validation and discriminant validation of these instruments in patients who met the inclusion criteria. Results: The convenience sample comprised 16 patients. Interobserver disagreement was found in 19% and 25% of the DPI and MDI scores, respectively. After expert analysis on the subject, the scores were modified and were applied in 72 patients. The most relevant difficulty encountered during the use of both types of devices was the maintenance of total lung capacity after a deep inhalation. The degree of correlation of the scores by observer was 0.97 (p < 0.0001). There was good interobserver agreement in the classification of patients as able/not able to use a DPI (50%/50% and 52%/58%; p < 0.01) and an MDI (49%/51% and 54%/46%; p < 0.05). Conclusions: The validated scores allow the identification and correction of inhaler technique errors during consultations and, as a result, improvement in the management of inhalation devices.

Keywords: Asthma; Dry powder inhalers; Metered dose inhalers; Validation studies.

Introduction
Asthma is a chronic inflammatory disease that causes airflow limitation and affects the performance of activities of daily living.(¹) Pharmacological treatment is essential(²) and is aimed at achieving and maintaining clinical asthma control.(¹) Inhalation is the most widely used approach for the treatment of asthma because it allows drugs to reach the lungs in a selective manner, increasing drug concentration in the airways and reducing systemic adverse effects.(¹,³,⁴)

Only half of all asthma patients actually use the prescribed medication and do so correctly.(⁵) Low treatment adherence is related to the fact that patients do not know how to use or have difficulty in using inhaler devices correctly.(¹) Asthma education can remedy that, being a key component of asthma management.(⁶) Incorrect inhaler use can lead to treatment failure by reducing drug concentration in the airways(²,⁸) and contribute to treatment...
nonadherence, making clinical asthma control difficult.\(^9\)

The frequency of incorrect use of metered dose inhalers (MDIs) ranges from 14% to 90%, with an estimated mean of 50%.\(^10\) Incorrect MDI use reducing lung drug deposition to less than 20%. In a study of patients using inhaled or oral corticosteroids, increased bronchodilator use, nebulizer use, and hospitalizations were observed in more than 50% of the patients who did not adhere to treatment.\(^11\)

Methods

Instruments (or scoring systems) assessing the difficulties that patients face in using inhaled drugs might be useful to reduce those difficulties. By using such instruments, health professionals can devise an educational program targeting the most common errors made by patients, thus improving treatment adherence. There are some scoring systems that assess inhaler technique in patients with lung disease.\(^12\) Although some assess inhaler technique errors, there is no one system that is considered the gold standard for this purpose. Such an instrument could play an important role in the evaluation of patients using inhalers.\(^13\)

Leal\(^13\) developed a scoring system to assess the difficulties that patients face in using MDIs; the system scores correct and incorrect MDI use, assessing the errors made during MDI use. On the basis of that instrument, Santos et al.\(^3\) developed scoring systems for the assessment of dry powder inhaler (DPI) and MDI technique. Although the aforementioned instruments have yet to be validated for use, they are used in our hospital in order to assess inhaler technique in patients with asthma\(^3\) and in those with COPD.

Instrument validation allows determination of the congruence between the scoring system used and the reality being measured, thus increasing the reliability of the instrument.\(^14\) The use of validated instruments in order to assess inhaler technique in asthma patients will yield results that are more reliable and will ensure data quality.

The objectives of the present study were to validate two scores quantifying the ability of patients to use MDIs or DPIs; to identify the most common errors made during their use; and to identify the patients in need of an educational program for the use of these devices.

**Methods**

This was an open prospective study conducted at a referral university hospital. The study was approved by the local research ethics committee. The inclusion criteria were as follows: having been diagnosed with asthma in accordance with the Global Initiative for Asthma criteria;\(^15\) having been in outpatient treatment for at least two years; being in the 15- to 65-year age bracket; having had at least four years of schooling; having no hearing impairment; and agreeing to participate in the study by giving written informed consent. Patients who had previously participated in educational programs regarding the use of asthma medications were excluded.

The study was conducted in three phases: validation of the reliability of the inhaler technique scores (phase 1); assessment of the content validity of the two scores (phase 2); and assessment of the criterion validity and discriminant validity of the instruments (phase 3).

In phase 1, two guest pharmacists (who were blinded to the study methodology) simultaneously evaluated inhaler technique. They used the inhaler technique scores developed by Santos et al.\(^3\) in order to identify the errors made during MDI and DPI use. The instruments provide step-by-step descriptions of MDI and DPI techniques. For each step that is performed correctly, patients receive a score of 1; for each step that is performed incorrectly, they receive a score of 0. For each serious inhaler technique error, points are deducted from those already scored. The final score determines whether a patient is able or unable to use an MDI or a DPI. The pharmacists were trained in the correct use of the aforementioned scoring systems, in accordance with the guidelines established in the Third Brazilian Consensus on Asthma Management.\(^16\)

The following drugs were used in the evaluation: for MDIs, 250 µg of beclomethasone dipropionate and 100 µg of albuterol; for DPIs, 200 µg of budesonide and formoterol + budesonide (6/200 or 12/400 µg; inhalation capsules); and 50 µg of salmeterol xinafoate (Diskus\(^\text{®}\)). The pharmacists proposed changes to facilitate and expedite instrument completion.

In phase 2, an expert panel evaluated the instruments from the previous phase in order to assess their contents. The expert panel comprised three pulmonologists, two pediatric pulmonologists, and two allergists, all of whom had extensive experience in the use of inhalers.

The proposed changes were judged in terms of the relevance of the items assessed by the
preliminary instruments, the need for additions, deletions, or changes to improve the accuracy of the modified inhaler technique scores being evaluated. After the changes had been systematized by consensus, new MDI and DPI technique scores were developed.

In phase 3, a new sample of patients using DPIs, MDIs, or both were randomly selected to participate in the study, the eligibility criteria being the same as those used in the previous phases. They were given placebo-containing inhalers and no instructions on how to use them, being asked to use them in the same manner as they did their own inhalers. Each patient was simultaneously evaluated by two other pharmacists, who were blinded to the changes that had been made. They used the instruments derived from phases 1 and 2 and were not allowed to communicate their decisions to one another. After the evaluation, all patients were instructed on how to use inhalers correctly.

The median and interquartile range of the scores obtained in phase 3 allowed us to establish cut-off values and divide the patients into two groups: the group of patients who were able to use inhalers and that of those who were not. The latter were then enrolled in our pharmaceutical care program.

In phases 1 and 2, we used a convenience sample based on previous validation studies, the sample size for phase 3 was calculated on the basis of the hypothesis of an association of at least 60% between the scores given by the pharmacists. Considering a power of 0.95 and a type I error of 0.05, we calculated that a sample size of 31 assessments was required for each inhaler type. The results obtained in phases 1 and 2 were described qualitatively. In phase 3, the mean scores were compared between the observers, agreements and disagreements being evaluated individually. The major errors made during inhaler use (as assessed by the observers) were described by frequency.

In phase 3, descriptive analysis of the absolute values of MDI and DPI technique scores by observer was performed with the Statistical Package for the Social Sciences, version 18 (SPSS Inc., Chicago, IL, USA). The degree of correlation between the scores by observer was assessed by Cronbach’s alpha coefficient. After assessment of data normality, the scores by observer were compared by means of the Mann-Whitney rank sum test, their correlation being determined by Spearman’s test, with SigmaStat software, version 3 (Systat Software Inc., San Jose, CA, USA). The chi-square test was used in order to determine interobserver agreement in the classification of patients as being able or unable to use MDIs and DPIs. Values of p < 0.05 were considered significant.

Results

A total of 16 patients participated in phases 1 and 2 of the study. Pharmacists together identified the need for changes in the scoring systems and proposed two preliminary changes: removal of the overall score; and removal of the suggestions section in order to reduce the number of sheets. This resulted in a scoring system consisting of a single table for assessment of inhaler technique, including examples of correct/incorrect inhaler use. Interobserver disagreement in phase 1 was found in 19% and 25% of the DPI and MDI scores, respectively, indicating not only inhaler technique errors made by the patients but also interpretation errors made by the observers (the pharmacists). That level of disagreement was considered acceptable and was of relatively little significance, being clarified and resolved in the subsequent phase.

The expert panel suggested that two changes be made to the DPI technique score, and both suggestions were accepted: the inclusion of an item regarding patient head position (at an angle of more than 90° or less than 90°), patients receiving 1 point for “an angle of less than 90°” and 0 points for “an angle of more than 90°”; and the definition of TLC, which was included at the bottom of the page.

With regard to the MDI technique score, the expert panel suggested that eight changes be made, and all of their suggestions were accepted: the item “shaking the inhaler” was changed from “3 times” to “twice or more”; the item “mode of use” was changed to “inhaler use”; the score for the item “in the mouth, with a spacer” was changed to 1 because it provides a correct example of MDI use, as does the item “out of the mouth, without a spacer”; the item “time point” was changed to “time point (rapid inhalation)”; the items “upon actuation” and “immediately after actuation” have the same weight and were therefore merged; the item “only sprays it into the mouth and does not inhale” was changed to “the device is actuated...
scores were 4.5 and 5.0 for observers 1 and 2, respectively.

The degree of correlation of the scores by observer was 0.97, as assessed by Cronbach’s alpha coefficient. The correlation was statistically significant (p < 0.0001), as assessed by Spearman’s correlation coefficient (Figure 1). There were no significant differences between the scores given by each observer, as assessed by the Mann-Whitney test. The scores were quite similar, indicating criterion validity.

All patients whose MDI and DPI technique scores were < 4 were enrolled in an educational program. A median score of 4 was the lowest whole number showing interobserver agreement.

With regard to discriminant validity, there was good interobserver agreement in the classification of patients as being able/unable to use a DPI (50%/50% and 52%/58%; p < 0.01) and an MDI (49%/51% and 54%/46%; p < 0.05).

Discussion

The present study allowed assessment of the content validity, criterion validity, and discriminant validity of the DPI and MDI scores. It also allowed identification of the major difficulties that patients encounter when using inhaler devices for the treatment of asthma. Finally, it allowed determination of cut-off scores to classify patients as being able or unable to use their inhalers, the latter patients being enrolled in an educational program.

To the best of our knowledge, there is only one validation study of MDI technique scores (in patients with asthma)\(^\text{12}\) and one of DPI technique scores (in patients with COPD).\(^\text{21}\) In addition, according to Basheti et al.,\(^\text{22}\) although the use of device-specific checklists is the most feasible method for assessing inhaler technique, little evidence is available to assess the relative importance of different criteria. Divergence between the scoring systems for the same inhaler device in different studies makes direct comparison of results difficult. In our study, MDI and DPI technique scores were validated in asthma patients, and the results allowed us to identify MDI and DPI technique errors and address them in a personalized manner, meaning that the instructions provided to patients were based on their own inhaler technique errors.

Our findings corroborate those of other studies.\(^\text{9,23,24}\) The inability to hold their breath...
for more than 10 s after inhalation was the major
difficulty that our patients encountered during
MDI and DPI use (83% and 75%, respectively). Manzella et al.\textsuperscript{12} assessed inhaler technique and
reported that 69% of the patients studied did
not hold their breath for at least 10 s. A review
compiling the results of 12 studies (including
955 patients) identified the most common errors
made by patients using inhaler devices, less than
10 s of breath-holding after inhalation having

\begin{center}
\textbf{Chart 1 -} Scoring systems modified and approved by an expert panel (phase 2) and validated for use in
Brazil (phase 3).
\end{center}

\begin{center}
\begin{tabular}{|l|l|}
\hline
\textbf{METERED DOSE INHALER (MDI) TECHNIQUE SCORE} \\
Name of the patient \___________ & ID \___________ & Date \___________ \\
Place your hand on the chest of the patient \\
Ask him or her to inhale and exhale deeply \\
Use your findings in order to assess depth \\
\hline
\textbf{Criteria} & \textbf{Score} \\
\hline
Shaking the inhaler (twice or more) & \\
No & 0 \\
Yes & 1 \\
Errors & Not shaking the inhaler & -4 \\
& Removing the canister from the inhaler & -1 \\
\hline
Position & \\
Incorrect & 0 \\
Correct & 1 \\
Error & Removing the spacer & -4 \\
\hline
Exhalation (inhale deeply and then exhale deeply) & \\
Yes & 1 \\
No & 0 \\
Error & Exhaling into the spacer & -2 \\
\hline
Inhaler use & \\
In the mouth, without a spacer & 0 \\
Out of the mouth, without a spacer & 1 \\
In the mouth, with a spacer & 1 \\
Out of the mouth, with a spacer & 0 \\
Errors & Using the space irregularly & -2 \\
& Keeping the mouth open when using the inhaler in the mouth & -2 \\
\hline
Time point (rapid inhalation) & \\
Before MDI actuation & 0 \\
Upon or immediately after MDI actuation & 1 \\
Errors & Nasal breathing & -8 \\
& Inhaling too early (inhaling before MDI actuation) & -4 \\
& The device is actuated directly into the mouth, and the patient does not inhale & -4 \\
& Inhaling too late (inhaling long after MDI actuation) & -4 \\
& Inhaling irregularly & -2 \\
& Breathing shallowly into the spacer & -1 \\
\hline
Speed & \\
High or < 3 s & 0 \\
Low or \geq 3 s & 1 \\
\hline
Depth & \\
Insufficient & 0 \\
Sufficient & 1 \\
\hline
Maintenance of TLC & \\
For < 10 s & 0 \\
For 10 s or more & 1 \\
\hline
Time between MDI actuations & \\
2x \text{ < 60 s} & 0 \\
\geq 60 s & 1 \\
Spraying two or more jets & -4 \\
\hline
\textbf{Total} & \\
\hline
\end{tabular}
\end{center}

TLC: total lung capacity.
In our study, less than 10 s of breath-holding after inhalation was the most common error made during MDI use, having been made by 89% of those who used MDIs. A period of 10 s of breath-holding is important to ensure that a greater quantity of drug reaches the airways. (12)

been observed in 26%. A period of 10 s of breath-holding increases drug deposition in the lungs by allowing more time for the particles to settle. (26) The author of the aforementioned review reported that 50% of the patients were able to hold their breath for 10 s between doses.

In our study, less than 10 s of breath-holding after inhalation was the most common error made during MDI use, having been made by 89% of those who used MDIs. A period of 10 s of breath-holding is important to ensure that a greater quantity of drug reaches the airways. (12)

**Table 1 -** Proportion of inhaler technique errors as assessed by the metered dose inhaler score.

| Evaluation criteria                                                                                      | Errors, % |
|----------------------------------------------------------------------------------------------------------|-----------|
| Interval of < 60 s between doses (patients are instructed to allow 60 s between doses)                    | 89        |
| Maintenance of TLC for < 10 s after inhalation (patients are instructed to hold their breath for 10 s after inhalation) | 83        |
| Inadequate inspiratory flow rate (patients inhaled too quickly, shallowly, or both)                      | 81        |
| Incorrect MDI use without a spacer (for patients who used a spacer)                                     | 73        |
| Not exhaling prior to inhalation (patients did not exhale before using their MDIs)                       | 59        |
| Shaking the inhaler only once (patients are instructed to shake their MDIs at least twice)               | 32        |
| Not shaking the inhaler (patients are instructed to shake their MDIs at least twice)                     | 31        |
| Incomplete inhalation (patients did not perform a deep inhalation maneuver)                            | 18        |
| Incorrect MDI position (patients are instructed to sit down in such a way that their legs and the floor form a 90° angle) | 10        |
| Lack of synchronization between MDI actuation and inhalation (the device was actuated before the beginning of inhalation) | 8         |
| Nasal breathing (patients breathed through their nose during inhalation)                                 | 5         |
| The device is actuated directly into the mouth, and patients do not inhale (patients are instructed to place their MDIs at a distance of three fingers’ breadth from their mouth and inhale after actuation) | 5         |
| Others                                                                                                  | 9.5       |

MDI: metered dose inhaler.
inspiratory flow rates having been observed in
19% of the total of patients. This is a serious
error, given that a slower inspiratory flow rate
translates to higher lung drug deposition with
the use of MDIs. (25)
Not exhaling prior to inhalation was an error
made by 62% of the patients using DPIs, being
the second most common DPI technique error.
The lung volume at the beginning of inhalation
interferes with drug deposition, which is why
patients should exhale before inhaling. (26)
Incorrect speed of inhalation was the third
most common DPI technique error (57%). In order
to deliver medication, DPIs depend on patient
inspiratory flow. If the flow rate (volume/time)
is lower than required, the inhaled doses will be
lower, and this contributes to treatment failure. (8,27)
Sandrini et al. (28) analyzed MDI use in a sample
of patients, classifying inhaler technique as correct,
slightly incorrect, moderately incorrect, or clearly
incorrect. Inhaler technique was classified as
incorrect in 48% of the patients. The most
common errors were placing the inhaler in
the mouth (68.0%), inhaling before actuation
(15.5%), inhaling too quickly (11.0%), and inhaling
through the nose (9.0%). Although our method
of evaluation differed from that used in the
aforementioned study, our patients made the
same errors as did those in that study.
Dalcin et al. (24) and Souza et al. (29) used
checklists or forms in order to determine whether
patients were using their inhalers correctly at
work. Souza et al. (29) found that 54.5% of the
patients who used DPIs did not exhale properly
before inhaling the medication. This finding
is consistent with those of the present study,
because that was the second most common error

- **Table 2** - Proportion of inhaler technique errors as assessed by the dry powder inhaler score.

| Evaluation criteria                                                                 | Errors, % |
|-------------------------------------------------------------------------------------|-----------|
| Maintenance of TLC for < 10 s after inhalation (patients are instructed to hold their breath for 10 s after inhalation) | 75        |
| Not exhaling prior to inhalation (patients did not exhale before using their DPIs) | 62        |
| Inadequate inspiratory flow rate (patients inhaled too quickly, shallowly, or both) | 57        |
| Incomplete inhalation (patients did not perform a deep inhalation maneuver)         | 21        |
| Incorrect dose preparation (patients did not place the capsule inside their DPIs, did not puncture the capsule before inhalation, or both)* | 18        |
| Inhaling shallowly (patients did not perform a deep inhalation maneuver)            | 5         |
| Exhaling into the device (patients exhaled while their DPIs were in their mouth)     | 3         |
| Nasal breathing (patients breathed through their nose during inhalation)            | 2         |
| Inhaling irregularly (patients were unable to inhale continuously)                  | 2         |

DPI: dry powder inhaler. *For the DPI type used in the present study (adaptation).

- **Figure 1** - Interobserver agreement. In A, metered dose inhaler (MDI) scores. In B, dry powder inhaler (DPI) scores.

Incorrect speed of inhalation was the third most common MDI technique error in our study and was reported by McFadden as the third most common error in 12 studies, inappropriately rapid
One of the limitations of the present study is the lack of follow-up. A follow-up evaluation might have allowed us to determine whether there were improvements in inhaler technique. The present study was biased by the fact that the proportion of MDI technique errors was high, with median scores of 4 and 5 for observers 1 and 2, respectively; these scores are significantly different from the score of 7.2 suggested in the literature. Given that interobserver agreement was high when a cut-off score of less than 4 was used—a finding that suggests that the MDI score has good accuracy—it can be inferred that many patients were classified as being able to use an MDI despite the fact that they did not obtain the minimum score predicted in theory, i.e., 20% of a maximum total score of 9. This underscores the need for reassessing inhaler technique at each visit and for sequential use of the MDI score in a large population sample.

In the aforementioned studies, the instruments used allowed the authors to quantify and classify the errors made by patients. We found no technical differences between the MDI and DPI techniques used at our institution and those described in the Third Brazilian Consensus on Asthma Management or in the 2012 Brazilian Thoracic Association Guidelines for Asthma Management. However, in addition to providing a step-by-step description of inhaler technique, the scoring systems used in the present study are tools that health professionals can use in order to assess objectively and mathematically the errors that patients make when using inhaler devices. In addition, patients can be classified as able or unable to use their inhalers on the basis of their cut-off scores. This allows health professionals to monitor improvements in inhaler technique in an objective manner.

Our results show that the proportion of MDI technique errors was higher than that of DPI technique errors. This difference might be related to the fact that the correct DPI technique is more easily understandable to patients than is the correct MDI technique. Lavorini et al. conducted a literature review of 47 articles analyzing DPI technique. The results showed that incorrect inhaler use affects drug efficacy, and the authors reported that assessment of inhaler technique is still considered irrelevant by many health professionals.

In a study conducted in 2011 in the state of Bahia, Brazil, inhaler technique errors were assessed, and the proportion of errors was found to be low. This was attributed to the fact that the patients in that study were monitored at an asthma referral center; they periodically received instructions and refresher training on inhaler technique from a multidisciplinary team.

One of the limitations of the present study is the lack of follow-up. A follow-up evaluation might have allowed us to determine whether there were improvements in inhaler technique. The present study was biased by the fact that the proportion of MDI technique errors was high, with median scores of 4 and 5 for observers 1 and 2, respectively; these scores are significantly different from the score of 7.2 suggested in the literature. Given that interobserver agreement was high when a cut-off score of less than 4 was used—a finding that suggests that the MDI score has good accuracy—it can be inferred that many patients were classified as being able to use an MDI despite the fact that they did not obtain the minimum score predicted in theory, i.e., 20% of a maximum total score of 9. This underscores the need for reassessing inhaler technique at each visit and for sequential use of the MDI score in a large population sample.

The new MDI and DPI scores will allow the implementation of educational programs proposed in asthma management guidelines and strategies, which recommend that patients receive ongoing training in inhaler technique to ensure correct inhaler use. By providing pharmaceutical care, pharmacists can instruct patients on how to use their inhaler devices correctly. By using our inhaler technique scores, pharmacists can assess inhaler technique errors and determine whether patients are able to achieve an ideal level of technical correctness (of 80%) and maintain it throughout the educational program. The present study showed that our inhaler technique scores can reveal exactly what it is that patients are doing incorrectly when using MDIs or DPIs so that the educational program during follow-up can focus on their errors rather than repeating what they already know.

Inhalation is the most widely used approach for the treatment of asthma, and correct inhaler technique is directly related to the therapeutic efficacy of the drug. Therefore, correct inhaler technique is essential for the efficacy of pharmacological treatment. We believe that
the present study is clinically relevant because it validated objective MDI and DPI technique scores that can reveal the major difficulties encountered by patients using MDIs or DPIs and provided cut-off scores that can be used in order to classify patients as being able or unable to use their inhalers. By using the validated scores, health professionals will be able to identify and correct inhaler technique errors during visits and, as a result, improve inhaler use.

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