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DEVELOPMENT AND INITIAL VALIDATION OF A TOOL TO CHECK COMPETENCY OF INHALER USE IN PATIENTS WITH OBSTRUCTIVE LUNG DISEASES

Sam Johnson Udaya Chander J.*[1], Santhakumar S.[2], Sam Solomon W.D.[3], Akelesh T.[4], Kandasamy C. S.[4], Arulraj P.[4] and Venkatanarayanan R.[5]

[1]Asst. Professor, Dept. of Pharmacy Practice, RVS College of Pharmaceutical Sciences, Coimbatore, Tamil Nadu, India.

[2]Consultant Pulmonologist, KG Hospital and Postgraduate Medical Institute, Coimbatore, Tamil Nadu, India.

[3]Professor, Dept. of Pharmaceutical Analysis, RVS College of Pharmaceutical Sciences, Coimbatore, Tamil Nadu, India.

[4]Professor, RVS College of Pharmaceutical Sciences, Coimbatore, Tamil Nadu, India.

***Corresponding Author: Sam Johnson Udaya Chander J.**

Asst. Professor, Dept. of Pharmacy Practice, RVS College of Pharmaceutical Sciences, Coimbatore, Tamil Nadu, India.

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ABSTRACT

Background: For obstructive lung diseases like COPD, delivering drugs directly to the airways through inhalers has become the primary modality of treatment. Errors during inhaler use accounts for decreased drug delivery to the lungs, leading to poor disease outcome. An impediment to assess proper inhaler technique has been lack of an accepted and validated scoring system. The objective of this study was to design, test, and validate a new scoring system to assess accuracy of inhaler use that can be used easily, is reproducible, and provides an accurate measurement system for clinical applications. **Methods/Design**: An expert panel of pulmonologists and clinical pharmacists were convened to design a simple, objective, and reproducible assessment tool to measure the accuracy of inhaler use. To test the validity, the developed scoring system was administered to a sample of 213 COPD patients prescribed with inhalers and scores were calculated. The construct validity and external criteria related validity was measured by correlating the checklist score with FEV_1% predicted and FEV_1/FVC ratio. **Results**: Inhaler use checklist and scoring sheet for five commonly used inhalers: pMDI, pMDI with spacer, Accuhaler, Handihaler, and Turbuhaler was developed. The mean percentage of steps correctly executed were correlated with FEV_1 % predicted (r^2 = -0.131, P<0.001) and FEV_1/FVC ratio (r^2 = -0.256, P<0.001). **Conclusion:** Results confirm homogeneity and validity of developed checklist and suggest usefulness of this tool in both clinical practice and research to assess the accuracy of inhaler use.

KEYWORDS: Inhaler Technique, COPD, Metered Dose Inhaler, Inhaler Checklist, Pharmacist.

1. INTRODUCTION

Chronic obstructive pulmonary disease (COPD) and asthma are the major cause of morbidity and mortality worldwide.[1-3] For effective management of these chronic diseases, inhalation therapy has become the primary treatment modality.[4] Many types of inhalers have been available in the market and the choice of inhaler is largely based on availability, cost, patient preference, physician preference, and the clinical setting.[5,6] Each inhaler device comes with specific usage instructions, failing those will result in poor treatment response.[7,8] Effectiveness of treatment may be diminished by various errors made during inhaler use.[9,10] Previous studies have reported that up to 94% of the patients use inhalers incorrectly.[11-15] Thus, the technique of inhaler use including device handling forms the integral part of effective drug delivery to the lungs.[16,17,18] Patients are often aware that they use their inhaler device incorrectly, but tend to overestimate their own abilities.[19] Therefore, education about proper inhaler use is the cornerstone of treating patients with obstructive lung diseases.[20,21] A thorough assessment of problems occurring during inhaler device use is essential to develop a full-fledged education strategy. Errors made during inhaler device use have been assessed in different ways in previous studies.[21-23] Although checklist and questionnaires were used predominantly to check the correctness of inhaler technique, these tools vary considerably. Moreover, different device needs different application procedure. A standardized tool to score the correctness of inhaler use applicable to all devices is literally non-existent.[24] Therefore, the aim of the present study is to develop a checklist for frequently used inhalers. This tool should be able to score the correctness

of inhaler use and also should allow patients using different inhaler devices to be included in a single study. The study also aims to standardize the developed tool for different parts of inhalation technique: 1) Assembling the inhaler, 2) Preparation of dose, 3) Administration of dose, 4) Retention of dose, and 5) Closure of inhaler. Finally, the developed tool should be easy to use in the clinical practice.

2. METHODOLOGY

2.1 Development of the tool

An expert panel comprising of pulmonologists and clinical pharmacists was formed. The aim of the panel was to develop an inhaler technique checklist which has the following characteristics:

1. It should provide summary scores amenable to statistical analysis.
2. The checklist should be valid, reliable, and reproducible.
3. The checklist should be capable of being administered by an interviewer or being self-administered.
4. It should take less time to assess a patient's inhaler technique.

Item formulation was primarily based on previous studies showing common mistakes patients make during inhaler use.[18,22,23,25-28] The steps were categorized under five domains: 1) Assembling the inhaler, 2) Preparation of dose, 3) Administration of dose, 4) Retention of dose, and 5) Closure of inhaler. A checklist (SAMS Inhaler Checklist) consisting of steps specific to each device was developed using NAC checklist for each device.[29] The number of required steps varied from 11 to 15 depending on the device. This checklist was used to score the inhalation technique. Each correct step fetches a score of one. The score sheet also calculates the percentage of steps executed correctly.

2.2 Scoring Hypothesis

The scoring is based on the hypothesis that a score of zero indicates that no medication is delivered to the airways and incremental scores increases the likelihood of drug delivery. The patients may be categorized as "mishandlers" of a device even if one step in the checklist is made incorrectly.

2.3 Testing the developed tool

Participants were recruited from the Pulmonology Clinic of a tertiary care hospital in Coimbatore, India, after they expressed their willingness to participate in the study. Eligible participants were (1) Patients aged >18 years and diagnosed with either asthma or COPD in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD),[1,2] (2) Patients using one of the five inhaler devices under study for more than three months, (3) Patients able to communicate in either English or Tamil, (4) Patients who are considered cognitively competent to understand instructions. Exclusion criteria include patients who are pregnant and patients having psychiatric condition or other major medical issues that would not allow them to participate in the study. As a prerequisite of enrollment, each participant was asked to sign an informed consent form, which was printed in both English and Tamil. After signing the informed consent form, the inhaler technique was assessed by the study pharmacist with the help of a trained pulmonary nurse specialist. Each patient was asked to demonstrate the inhaler technique with placebo devices of the type of inhalers they use. The patients were asked to use the inhalers like they do normally at their home. Percentage of steps correctly executed by each patient was measured using the developed checklist. The mean percentage of steps executed correctly was correlated with FEV_1 % predicted and FEV_1/FVC to analyze construct validity and external criteria related validity.

2.4 Ethical Concerns

The study was approved by Institutional Ethics Committee of KG Hospital and Postgraduate Medical Institute, Coimbatore, India. The study has been registered in the Clinical Trial Registry – India (CTRI) and the registration number is CTRI/2017/05/008526.

2.5 Data analysis

Data were analyzed using SPSS (Statistical Package for Social Sciences) Version 19. Data were presented as mean±standard deviation for continuous variables and percentages for categorical. Correlations between mean percentage of steps executed correctly, FEV_1 % predicted, and FEV_1/FVC ratio were performed and the R^2 values were also noted. Statistical significance was accepted at $P<0.05$.

3. RESULTS

3.1 Patient Characteristics

A total of 213 participants were enrolled into the study. The patients were predominantly males (77%) with a mean age of 61.5±8.2 years. Almost 65% had low educational level (28.2% had no studies, 16.4% had elementary education, and 20.2% had high/higher secondary education). The participants had mean FEV1% predicted at 46.3±20.5 with moderate-to-severe COPD at baseline. Approximately 42% of the participants used more than one type of inhalers. pMDI users (n=129, 60.6%) were the highest among the enrolled patients followed by pMDI with spacer users (n=78, 36.6%), and Accuhaler users (n=6, 2.8%). The mean duration of inhaler use was 5.6±8.7 years. The baseline characteristics of the participants are shown in Table 1.

Table 1: Demographics and clinical characteristics of COPD patients at baseline.

Variable	Value (n=213)
Age, mean (SD)	61.5 (8.2)
Gender, n (%)	
• Males	164 (77.0)
• Females	49 (23.0)
Residence, n (%)	
• Town	89 (41.8)
• Village	124 (58.2)
Educational Background, n (%)	
• Illiterate	60 (28.2)
• Elementary Education	35 (16.4)
• High/Higher Secondary	43 (20.2)
• Graduation/PG	75 (35.2)
Smoking Status, n (%)	
• Non-smoker	49 (23.0)
• Current smoker	98 (46.0)
• Ex-smoker	66 (31.0)
Number of Inhalers Used, n (%)	
• One	122 (57.3)
• Two	67 (31.5)
• Three	24 (11.2)
Type of Inhalers Used, n (%)	
• pMDI	129 (60.6)
• pMDI with Spacer	78 (36.6)
• Accuhaler	6 (2.8)
Years of Inhaler Use, n (SD)	5.6 (8.7)
FEV1% Predicted, % (SD)	46.3 (20.5)
GOLD stage	
• I-Mild	17 (7.9)
• II-Moderate	81 (38.1)
• III-Severe	84 (39.4)
• IV-Very Severe	31 (14.6)
• Inhaler Technique Score, mean (SD)	5.3 (2.0)

SD – Standard Deviation; PG – Post Graduation; GOLD – Global Initiative for Chronic Obstructive Lung Disease; pMDI – Pressurized metered dose inhaler

Based on developed checklist, all patients made at least one mistake in their inhalation technique and the mean inhaler technique score was 5.3±2.0. The mean percentage of steps executed correctly in 213 enrolled patients was 68.2±12.3. Number of participants making errors in the steps needed for dose inhalation in each device category is listed in Table 2.

Table 2: Common errors made in steps needed for dose inhalation.

Device Used/Steps Failed	N (%)
pMDI (n=129)	
3. Hold inhaler upright and shake well	11 (8.5)
6. Start to breathe in slowly through mouth and, at the same time, press down firmly on canister	38 (29.5)
7. Continue to breathe in slowly and deeply	31 (24.0)
pMDI Plus Spacer (n=78)	
4. Hold inhaler upright and shake well	4 (5.1)
5. Insert inhaler upright into spacer	0 (0)
6. Put mouthpiece between teeth (without biting) and close lips to form a good seal	15 (19.2)
8. Keep spacer horizontal and press down firmly on inhaler canister once	1 (1.3)
9. Breathe in slowly and deeply	12 (15.4)
Accuhaler (n=6)	
2. Open cover (use thumb grip)	2 (33.3)
3. Load dose: keep device horizontal while sliding lever until it clicks (Do not shake)	1 (16.6)
5. Put mouthpiece in mouth (without biting) and close lips to form a good seal (Keep inhaler horizontal)	1 (16.6)
6. Breathe in steadily and deeply	1 (16.6)

The number assigned to each step here corresponds to the step number in the SAMS inhaler technique checklist.

3.2 Reliability

The internal consistency reliability for the developed checklist was determined using the alpha coefficient and Kuder-Richardson analyses.[30,31] The checklist's reliability coefficients were 0.72 and 0.67 respectively. Reliability values equal to or greater than 0.70 indicate an adequate level of internal consistency with this group of patients in this setting.[30-33]

3.3 Convergent and divergent validity

Convergent validity is the strength of an association between knowledge of proper inhaler use and inhaler use skill for the same individual at one point in time.[32,33] Knowledge of proper inhaler use was by assessed by patient response to the question "Do we need to hold our breath at least five seconds after dose inhalation?" This question was asked by the study pharmacist during interview. Table 3 indicates that patients who correctly responded "yes" performed significantly better (P=0.006) on the inhaler checklist than the patient who responded "no." This supports the convergent validity of the instrument.

Table 3: Analysis of score on developed inhaler checklist by response to knowledge-related question on inhaler use.

	Frequency (n=213)	Mean Score±SD	T-value	P-Value
Correct Response	148	6.2±1.7	-2.63	0.006
Incorrect Response	65	4.4±2.3		

The divergent validity assesses the degree to which score on the instrument is predictive of a variable of the patient population or score on another instrument. The divergent validity of the developed checklist was established by testing the hypothesis that patients with high mean percentage of correctness of inhaler use will have improved COPD control indicated by high FEV_1 % predicted and FEV_1/FVC. As indicated in table 4, the mean percentage of correctness of inhaler score was well correlated with FEV_1% predicted (r^2 = -0.131, P<0.001) and FEV_1/FVC ratio (r^2 = -0.256, P<0.001).

Table 4: Correlations between developed tool, FEV_1 % predicted, and FEV_1/FVC in patients with COPD.

	Mean % of Score	FEV_1 % predicted	FEV_1/FVC
Mean % of Score	1	-0.131*	-0.256
FEV_1 % predicted	-0.131*	1	0.328**
FEV_1/FVC	-0.256	0.328**	1

*P<0.05; **P<0.001

4. DISCUSSION

The quest for an effective intervention in COPD patients necessitates the use of an assessment tool that measures the correctness of inhaler technique. The tool tested in this study was designed to provide a simple, reliable, and quantitative measurement of competency of inhaler use in COPD patients. Ease of use by the tool administrators and time to complete the assessment are the two requirements for an effective checklist. In this study, the tool took only 10 to 15 minutes to assess a patient's inhaler technique and the tool was easy to use. Up to 33% of our study population made errors in critical steps needed for drug delivery. The patients with mild COPD will have better respiratory function (FEV_1 % predicted and FEV_1/FVC) than the patient with moderate or severe COPD[34,35] and this association is also reinforced through our study results. In our study, a statistically significant decrease in FEV_1 % predicted and FEV_1/FVC ratio with decreased score and mean percentage of correct steps executed indicates the construct validity and external criteria related validity of the tool.

5. LIMITATIONS

The checklist has following limitations:

- Weighing each skill equally does not reflect its relative importance in maximizing drug delivery.[36]
- There are no available data on the checklist's inter-rater reliability.
- The observers were not trained in its use.
- The sensitiveness of the tool towards children is not known since children are not included in the study and a pediatrician is not consulted during item formulation.
- The scoring hypothesis should be assessed by measuring drug delivery to the lower airways.
- A comment section to mention why the patient failed a step is lacking.

6. CONCLUSION

The developed checklist has many potential benefits: 1) The use of inhaler use checklist may reduce confusion among providers regarding correct inhaler technique. 2) It provides a consistent way of measuring the correctness of inhaler use technique. 3) The well-framed steps makes the checklist an excellent teaching tool for healthcare providers. 4) The score helps in analyzing the

effectiveness of an intervention. 5) It helps in monitoring the patient's inhaler technique at each visit, ensuring continuity of care. 6) It is easy to use and takes less time to complete. 7) The checklist also helps in clinical decision making. Inadequate inhaler use technique indicates insufficient drug delivery to the airways even though the patient is 100% adherent to the treatment. The developed checklist would possess acceptable level of reliability and validity. The data collected in this study can be used to analyze interventions and improve patient's inhaler use skills.

LIST OF ABBREVIATIONS

COPD – Chronic Obstructive Pulmonary Disease
CTRI – Clinical Trial Registry of India
FEV – Forced Expiratory Volume
FVC – Forced Vital Capacity
GOLD - Global Initiative for Chronic Obstructive Lung Disease
pMDI – Pressurized Metered Dose Inhaler
SAMS – Systematic Assessment and Monitoring Services
SPSS - Statistical Package for Social Sciences

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AVAILABILITY OF DATA AND MATERIALS

The datasets analyzed during the current study will be available from the corresponding author on reasonable request.

AUTHORS' CONTRIBUTION

SJUC participated in conception of the tool development. SS, SJUC and SSWD participated in tool design and item selection. SJUC assessed the utility of the developed tool. All authors read and approved the final manuscript.

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