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STUDY PROTOCOL TO ASSESS THE IMPACT OF "SEE AND DO" (SAD) TRIAL ON COMPETENCY OF INHALER USE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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ABSTRACT

Background: Inhaled medications are the primary modality of treatment for obstructive lung diseases like asthma and COPD. Poor inhaler technique leads to decreased drug delivery to the airways and poor disease outcome. Although intensive education improves inhaler skills, it deteriorates over time. Hence, a strategy ascertaining repeated education on proper inhaler use should be developed and implemented in inhaler mishandlers. This protocol aims to test the effectiveness of pharmacist-led "See-And-Do" (SAD) Trial on competency of inhaler use in patients with COPD. **Methods/Design**: A prospective, randomized, controlled trial is conducted at a 350-bedded tertiary care hospital in Coimbatore, India. Participants are randomly assigned to either intervention group or control group. The participants in intervention group receive three sessions of face-to-face, patient specific inhaler technique coaching, verbal instruction, and physical demonstration. The patients are provided with reminder flags highlighting the wrong steps they made at baseline check. The participants in control group receive device-specific instruction and pamphlets only. The primary outcome is change in inhaler technique score at 6 and 12 months compared to baseline. Secondary

outcome is COPD control measured by FEV1/FVC ratio. **Discussion**: This study will demonstrate the utilization of pharmacist-led intervention to improve inhaler technique and to better manager COPD, thereby minimizing the healthcare utilization cost in the country. This study also will assess the possibility of implementing such programs in all hospitals throughout the country. **Clinical Trial Registration**: The study was retrospectively registered in the Clinical Trial Registry of India (CTRI/2017/05/008526) dated May 9, 2017.

KEYWORDS: Inhaler technique, Chronic Obstructive Pulmonary Disease, Clinical Pharmacist, Reminder Flags.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the major cause of morbidity and mortality worldwide. It is estimated that COPD will become third leading cause of preventable death worldwide in 2030. In India, COPD is recognized as major health condition and it is estimated that there are about 30 million people suffering from COPD across the country.[1] Smoking cessation and inhalation therapy are the primary treatment modality of COPD.[2] Many types of inhalers have been developed and the selection of inhaler is largely based on cost, availability, patient preference, physician preference, and the clinical setting.[3,4] To ensure suitable drug delivery to the airways, each inhaler device has specific usage instructions, failing which the medication delivery will be poor at the airways which leads to poor disease control.[5,6] Correctness of inhaler use is an important aspect which should be taken into account when assessing the effectiveness of treatment in patients with COPD.[7] Improper inhaler use is the most important drug-related problem (DRP) in COPD patients and the effectiveness of treatment may be diminished by various errors committed by the patients during inhaler use.[8,9] Previous studies have published various errors encountered during inhaler use.[10,11] Several studies have also reported that up to 94% of the patients use inhalers incorrectly.[12-16] Although education about proper inhaler has proven to be effective[17,18], it deteriorates overtime.[19-21] This implies that the education provided on proper inhaler use should be repeated. Patients who receive repeated instruction on inhaler technique have better inhaler use technique than those who only received instruction at the time of inhaler prescription.[22] Many studies have demonstrated similar results in the community pharmacy setting also.[23,24]

Study Objectives

This proposal describes a study that is currently implemented in a 350-bedded tertiary care hospital in Coimbatore, India. The study hypothesis is that a structured, face-to-face, repeated, patient-specific inhaler technique coaching, verbal instruction, and physical demonstration by a clinical pharmacist and providing an inhaler technique checklist for self-appraisal will be more effective in improving inhaler techniques in patients with COPD. We also hypothesize that proper inhaler technique would lead to significant improvement in health-related quality of life. Hence, the objectives of this study are:

- Primary: To test the effectiveness of a structured, face-to-face, repeated, patient-specific inhaler technique coaching, verbal instruction, and physical demonstration by a clinical pharmacist on competency of inhaler technique in patients with COPD.
- Secondary: To develop and test a tool to check and score correctness of inhaler technique in patients with COPD.
- Secondary: To assess the change in health-related quality of life with regards to change in accuracy of inhaler use skills.

METHODOLOGY

Study design

The study is an open-label, prospective, randomized controlled trial comparing the effectiveness of pharmacist-led intervention in those identified as inhaler mishandlers on COPD control and health-related quality of life at follow up versus education provided by a practitioner/nurse on inhaler use. The study protocol was named “See and Do” (SAD), which is a part of a larger trial named Systematic Assessment and Monitoring Services (SAMS) which analyses the impact of pharmacist’s intervention on Health Outcomes in COPD patients.

Study sites

The study is currently implemented in the Pulmonology Clinic of a tertiary care hospital in Coimbatore, India. This is a 350-bedded hospital that serves a large population in and around the district of Coimbatore. To prevent cross contamination with the study, the hospital pharmacy of this hospital has not established the inhaler education program. The study is taking place in a semiprivate area in the Pulmonology department. This area is secluded enough to ensure adequate patient confidentiality.

Development of the tool

The Need: 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.[25] One of the objectives of SAD Trial 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 Development: An expert team was formed consisting of following experts apart from the study pharmacist: 1) Head, Pulmonology Clinic (KG Hospital and Postgraduate Medical Institute, Coimbatore); 2) Consultant Pulmonologist (KG Hospital and Postgraduate Medical Institute, Coimbatore), 3) Academic Dean (KG Hospital and Postgraduate Medical Institute, Coimbatore); 4) Head, Dept. of Pharmacy Practice (RVS College of Pharmaceutical Sciences, Coimbatore); 5) Professor, Dept. of Pharmacy Practice (RVS College of Pharmaceutical Sciences, Coimbatore), and 6) Professor, Dept. of Pharmacy Practice (PSG College of Pharmacy, Coimbatore). The tool to be developed should possess the following characteristics:

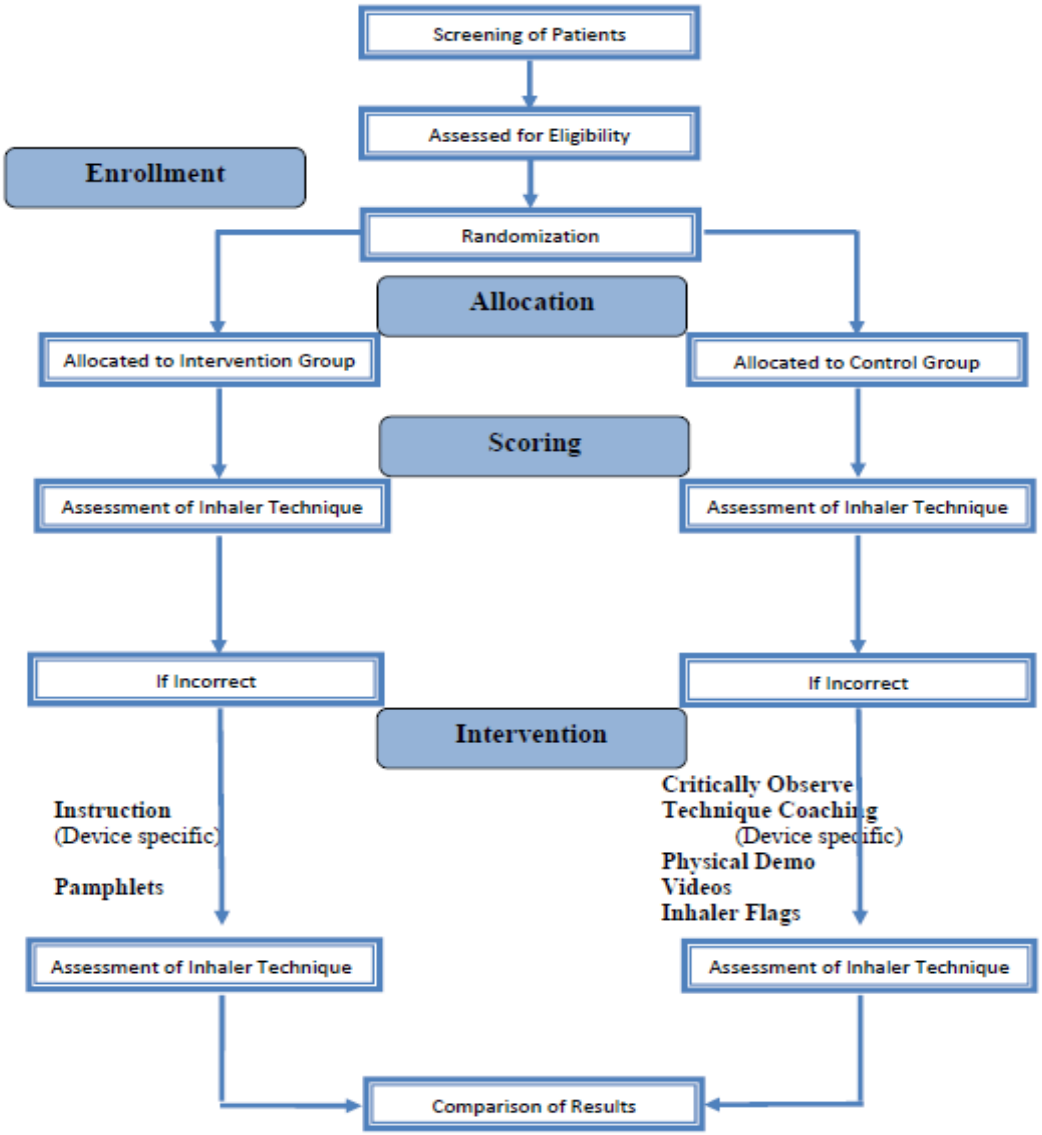
1. It should provide summary scores amenable to statistical analysis.
2. The checklist should be valid, reliable, and reproducible.
3. The checklist should be capable of being administered by an interviewer or being self-administered.
4. It should take less time to assess a patient's inhaler technique.

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.[26] 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. 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.

Development of Educational Strategy

Based on previous studies[27,28], the expert panel developed a study plan and strategy to impart effective education on inhaler use. Counseling and interviewing techniques were discussed in detail. A counseling manual was also developed to be used as an on-site resource during the study. A data collection form was also framed to document the patient's demographic and inhaler use history. The score obtained by using the inhaler checklist was also documented in the data collection form. The flow of study plan is shown in figure 1.

Furthermore, it was determined to measure the patient's health-related quality of life using St. George's Respiratory Questionnaire for COPD (SGRQ-C), which is a validated questionnaire to assess health-related quality of life in COPD patients.[29] The SGRQ was scored according to the developer's guidelines and recommended method for handling missed items.[30]



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.

Study Site

The SAD protocol is implemented in the Pulmonology Clinic of a tertiary care hospitalin Coimbatore, India, a 350-bedded teaching hospital.

Screening for Eligibility

Participants were recruited after they expressed their willingness to participate in the study. The study pharmacist administered a structured data collection form specially prepared for this study in order to assess for their eligibility to take part in the study. The demographic information like name, age, sex, educational background, residence, smoking history, duration of disease, comorbidities, number of inhalers used, type of inhaler used, telephone number, and address were collected using the data collection form. Eligible participants were (1) Patients aged >18 years and diagnosed with COPD in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD)[7], (2) Patients using one of the three inhaler devices under study for more than three months, (3) Patients able to communicate in either English or Tamil, (4) Patients who are willing and capable of attending all the scheduled sessions and (5) Patients who are considered cognitively competent to understand instructions. Exclusion criteria include (1) Patients receiving any structured education for inhaler use technique, (2) Patients planning to leave India in the next 12 months, (3) Patients admitted with acute exacerbation of COPD within the past six weeks of study (4) pregnancy, and (5) psychiatric condition or other major medical issues that would not allow the patient to participate in the program.

Study Enrolment

After the screening procedure was completed, the study pharmacist explained the eligible participants about the study including potential benefits, inconveniences, risks, and other discomforts, and his/her right to confidentiality. As a prerequisite of enrollment, each participant was asked to sign an informed consent form, which was printed in both English and Tamil.

Inhaler technique

After signing the informed consent form, the inhaler technique was assessed at baseline by the study pharmacist with the help of a trained pulmonary nurse specialist without prior notification. This assessment was done in a separate room prior to meeting the physician. 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. The developed checklist was used to check the correctness of inhaler technique. The critical steps in each device category were highlighted in that checklist with bold letters in the checklist.

Intervention Group

The patients assigned to intervention group will receive three sessions of "See and Do" (SAD) inhaler technique counseling service. This includes one-on-one education either in Tamil or English. The study pharmacist will go through each step on the device-specific checklist and the score they got at baseline check. The study pharmacist will also critically observe the inhaler use skills, physically demonstrate the correct inhaler use technique, give verbal instructions on how to improve inhaler use technique, and motivate the patients. A device-specific video demonstrating correct use of the type of inhaler will be loaded on to the patient's mobile device, which can be viewed at their leisure time. The patients will also receive pictorial device information pamphlets.

First session

After the baseline assessment of inhalation technique and initial intervention as per the SAD protocol, the study pharmacist, with the help of a highlighter pen, will highlight the incorrect steps from the patient's baseline assessment in the "Inhaler Technique Flag," which was preprinted in Tamil and English. The Inhaler Technique Flag consists of device specific steps for correct use of inhalers. The study pharmacist will glue the device-specific flag to inhaler the patient had, taking care not to cover the important information on the inhaler canister. The patients will be provided with three additional flags specific to their device.

Follow-up sessions

Each month, the study pharmacist will make a telephone call to the participants asking them if they had purchased a new inhaler. If new inhaler was purchased, the participants will be reminded to attach the "Inhaler Technique Flag" to their new device. At 6- and 12-month visits, the participants will be asked to demonstrate their inhaler technique as they do at home

and technique will be directly observed by the study pharmacist and scored again. Additional technique coaching will be provided where errors were observed in critical steps.

Control Group

The participants in the control group will receive the pictorial device information pamphlets at first visit and receive device specific instruction and usual care by the practitioner/nurse at each visit. At the end of the study, participants of both groups will be re-trained in inhaler use technique.

Study Piloting

The study was piloted by recruiting around eight patients and implementing the SAD protocol. Feedback was provided on quality of patient counseling and patient education. Minor adjustments were made to the consent form, data collection form, and inhaler check list as indicated by the expert panel.

Educational Material

The placebo device was provided by Cipla Respiratory. The device specific information pamphlets were supplied by Astra-Zeneca and Glaxo Smith Kline. Videos demonstrating correct inhaler use technique were downloaded from YouTube. Counseling aids were prepared by the study pharmacist using internet resource.

Continuous Quality Improvement and Evaluation

The study pharmacist will receive constructive feedback from the panel of pulmonologists and others in the expert panel. In addition, ad-hoc meeting will be held to address any irregular issues that might arise during the study.

Outcome measures

Primary outcome is change in inhaler technique score between baseline, 6- and 12-month visits, which is measured using Inhaler Technique Checklist developed for this study. Secondary outcomes are (1) COPD control measured by the symptoms recalled by the patients at each visit, (2) FEV1/FVC ratio measured at each visit using spirometry, and (3) Mean change in health-related quality of life score between baseline, 6- and 12-month visits.

Data analysis

Data will be analyzed using SPSS (Statistical Package for Social Sciences) Version 21. Data are presented as mean±standard deviation unless stated otherwise. Device checklist steps and

scores were converted to percentages for comparison between devices. Comparison of percentage of correct inhalation technique between visits within groups was analyzed using general linear models. Comparisons of change in FEV1/FVC ratio between intervention and control groups at different visits were made using general linear models. To assess the patient's health-related quality of life, a total health-related quality of life score and a domain specific score will be calculated at baseline, 6 months, and 12 months for each participant in the intervention and control groups. The change in the total and domain-specific quality of life score from baseline will be calculated for each participant at 6 and 12 months and will be analyzed using linear mixed models. Statistical significance was accepted at $P<0.05$.

Sample Size Calculation

The recruitment period is 12 months. Around 35 COPD patients visit the pulmonology clinic each day out of which approximately 25 will be using the inhaler under study. Expecting that the study will recruit around six to eight patients every week and expecting a 2% drop out rate, a minimum sample size of 100 participants was estimated for each group. An extra eight weeks of recruitment time will be considered to account for holidays and sickness.

DISCUSSION

This study investigates the impact of pharmacist-led educational intervention on competency of inhaler use in COPD patients. To our knowledge, this is the first randomized controlled trial conducted in India to test the role of pharmacists in improving the inhaler use techniques in COPD patients and to establish the relation between appropriate inhaler technique and improved quality of life. This "See And Do" (SAD) trial is a novel program where the study pharmacist follows the patients for one year and their inhaler technique score was measured pre- and post-education. The novel inhaler technique flags provided to the intervention group participants ensures personalized inhaler education to every participant. The flags along with highlighted wrong steps will visually prompt the patients to adhere to the inhaler use recommendations.[31] Within one year, the study will analyze the participants' inhaler use technique three times. Previous studies have stated that correctness of inhaler technique can deteriorate after single face-to-face education and regular reinforcement is needed to maintain correct inhalation technique.[32] Previous studies have also shown that patients who demonstrate their inhaler technique to a healthcare professional were found to have better disease control.[33] Moreover, the flags fixed on the inhaler canister may help other healthcare providers too, as studies have demonstrated that healthcare providers themselves show poor

inhaler use technique.[33-36] In a country like India where literacy level is still below the benchmark, face-to-face education and demonstration is crucial to attain good inhaler use technique. If the study holds good, it will prove that simply providing the patients with pictorial pamphlets regarding inhaler use technique is not enough and a novel educational strategy has to be developed and implemented similar to SAD protocol all over the country to effectively manage COPD patients. This study will also expand the role of pharmacists in India where the term clinical pharmacy and pharmaceutical care are still in the developing stage.

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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 study, study design, and drafted the study protocol. SS and SSWD participated in study design. SJUC assessed the effect of the intervention. All authors read and approved the final manuscript.

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