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Study protocol

Efficacy of an Educational Action in the Sustained Improvement of Inhalation Technique

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ABSTRACT

Study methodology: This is an institutional, prospective and observational study on COPD out-patients. An inadequate inhaler technique remains a major cause of insufficient disease management. Face-to-face demonstration of inhalation devices are effective methods of teaching the correct inhalation technique. However, if some improvement is sustained over time, is not yet determined. This is the primary aim of this study. Secondary objective is to evaluate the factors that can predict a sustained improvement of inhalation technique. In a previous visit, COPD out-patients diagnosed according to GOLD criteria, were recruited consecutively. Participants were asked to demonstrate the use of their prescribed ID, just as they does it at home. For each inhaler device we defined a checklist of steps for a correct inhalation technique, and critical errors, which are likely to make therapy useless. After this evaluation, demonstrations and training with placebo inhalers were given to all participants, until a correct use is achieved. Patients will be invited for a second medical visit, 10 to 12 months after the first visit, and they will be asked again to demonstrate the use of their inhalers. It will be used the same check-list of the first visit, and the reevaluation will be done by the same healthcare professional.
Impact of the research: To the best of our knowledge this will be the first study carried out in Portuguese population of COPD patients, concerning the sustained improvement of the inhalation technique after a single educational intervention. The characteristics of both the patients and inhalation devices related to a sustained maintenance of a correct inhalation technique can be useful for planning education interventions on COPD patients. This can be the added value of this study.

Keywords: COPD, Inhalation Technique, Educational Action.

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BACKGROUND

Chronic Obstructive Pulmonary Disease is the 4th leading cause of death and the most common chronic respiratory disease worldwide. COPD currently represents the most significant health problem at international level, and its economic and social impact still is constantly increasing[1]. COPD is a chronic and incurable disease, but symptoms significantly improve with therapy. Inhalers are the vehicles used for effective administration of medication. A correct treatment, based on the best medical evidence, and a correct inhalation technique are well-known factors of therapeutic success[2]. However, inhaler misuse remains unacceptably high[3], and a major cause of insufficient disease management[4]. Many factors, related to the inhaler devices or to patients' characteristics, can influence the effectiveness of the medication. Choosing the right device for a given patient and education on inhaler technique are important factors of COPD management[5].

In clinical practice, inhalation technique can be measured using check-lists, counting the number of correct steps, defining critical errors or essential steps[6-7], grading the inhaler use, or classifying the quality of the inhaler technique[8]. However, the evaluation of inhalation technique remains difficult and somewhat subjective. In a country where the patients' access to health-care services and to efficacious therapies is good, any improvement in treatment outcomes must address the improvement of the inhalation technique.

Face-to-face demonstration of inhalation devices (IDs) with verbal instructions and multi-media tools are probably the most effective methods of teaching the correct inhalation technique for each ID. A successful maintenance of an effective use depends on correct instructions and demonstrations, but training the correct inhaler use is of paramount importance. Because inhaler technique can deteriorates over time, periodic re-training is also recommended[9]. However, beyond training and education, other domains, related to the patient and device, must be met in order for optimum inhaler technique maintenance[10].

In a previous study with 282 COPD out-patients performing 467 inhalation maneuvers, ten types of IDs were examined. We found that 48% of inhalations had at least one step incorrectly performed, and in 29.6% of demonstrations critical errors were observed[11]. A significant relationship between a correct inhalation technique and both the type of ID and some patients' characteristics like age, gender, education level and socioeconomic status was observed.

Study methodology

This is an institutional, prospective, observational study, enrolling COPD out-patients on the Respiratory Department of hospital de Guimarães. The primary objective is to evaluate if the application of an educational action in COPD patients, regarding the correct use of the IDs, can improve inhalation technique is a sustained way. Secondary objective is to evaluate if the type of ID or some demographic, clinical or functional characteristics of patients can predict a sustained improvement of inhalation technique. The study was

approved by the hospital de Guimarães Ethics Committee, the Research Ethics Committee of Minho' University and by the Portuguese Data Protection Agency (record 5778/2016).

In a previous visit[12], COPD out-patients over 40 years old, diagnosed according to GOLD criteria, were recruited consecutively, after giving their written informed consent. The inability to understand and respond to simple questionnaires was the exclusion criterion. A survey of demographic and clinical data was applied. Evaluation of symptoms was done using the Portuguese versions of the COPD Assessment Test (CAT) and the Medical Research Council Dyspnea Questionnaire (mMRC). The number of COPD exacerbation in the last year was recorded. For each inhaler device, in accordance with the international recommendations, we defined a checklist with five steps for a correct inhalation technique, and two essential steps and critical errors, related to priming/loading and the inhalation manoeuver, which are likely to make therapy useless[13]. Participants were asked to demonstrate the use of their prescribed ID, and all inhalation maneuvers were evaluated. After this assessment, instructions, face-to--face demonstration and a training with placebo inhalers were given to all participants, until a correct use is achieved, or until the patient becomes tired.

Participants will be invited for a second medical visit, 10 to 12 months after the first visit. Exclusion criteria will be refuse to participate, quitting medication, and the use of different IDs from the first visit. Patients will be asked again to demonstrate the use of their inhalers. It will be used the same check-list of the first visit, and the reevaluation will be done by the same healthcare professional, to avoid inter-observer variability. A statistical analysis will be performed using the IBM SPSS Statistics for Windows software, version 22.0. Armonk, NY: IBM Corp.

Strengths and limitations of the study

To the best of our knowledge this will be the first study carried out in Portuguese population of COPD patients, concerning the sustained improvement of the inhalation technique after a single educational intervention. However this study has some strengths and limitations. It will be conducted in a single care institution, where patients are being treated by pulmonologists. This may limit the generalization of the results to other populations. As patients were enrolled consecutively in the first medical visit we cannot exclude selection bias. Inspiratory flow will be not objectively evaluated, and the assessment of inhalation technique is always difficult and somewhat subjective, especially the inhalation manoeuver[14]. However, this is how, in real-life setting, clinical data are judged and decisions are done. Although our choice of critical errors and number of steps was based on previous literature, it is subjective, deserving discussion. To minimise subjectivity, our check-lists were constructed full of steps and possible errors for each ID. All IDs in use by COPD patients will be evaluated. Inhalation technique was assessed in the first visit by a single trained pulmonologist, and the same pulmonologist will done the second evaluation, to avoid inter-observer variability.

Impact of the research

The misuse of IDs in COPD patients remains a topic of outstanding relevance. Verbal instructions and a face-to-face demonstration of the inhalation devices, patient' teach-back, and training the correct inhaler use are well-known factors for a correct inhalation technique. But inhaler technique can deteriorates over time. If some improvement, after a single education intervention, is sustained over time, is not yet determined[14]. This can be the added value of this study. Discussion will be focused on the comparison of the inhalation technique between the two medical visits, centered on critical errors and steps correctly performed. The role played by the education intervention, the maintenance of training by the daily use and the over-time deterioration of inhalation technique will be also discussed. Discussion will be also focused on the characteristics of patients and on the type of IDs that can predict a sustained improvement in the inhalation technique. This knowledge should be able to motivate physicians in teaching the correct inhalation technique for all IDs, and reinforce the need for a periodic re-training. It should also help the choice of the ID in which a better inhalation technique is expected to be maintained over-time. The knowledge of some demographic and clinical characteristics of patients related to the sustained maintenance of a correct inhalation technique can be useful for planning education interventions on COPD patients.

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