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Evaluation of dry powder inhalers with a focus on ease of use and user preference in inhaler-naïve individuals

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ABSTRACT

Inhaler errors are common amongst inhaler users. Therefore, in the development work of new inhalation devices, it is important to characterize the ease of use of the inhalers. In this study four dry powder inhalers, Diskus, Easyhaler, Ellipta and Turbuhaler, were evaluated, focusing on ease of use and patient preference. The study used a triangular methodology. The sample consisted of 31 inhaler naïve individuals. Educational videos for all inhalers were watched, and afterwards, the use of all four inhalers was demonstrated in a random order. The demonstrations were videotaped. Thereafter they were checked against a predefined checklist and all mistakes were recorded. Only 33% of inhaler demonstrations were completed without the participants making any mistakes. The proportions of subjects who used the devices correctly were as follows: Diskus 48%, Easyhaler 19%, Ellipta 55% and Turbuhaler 16%. When comparing correct and incorrect inhaler technique for each inhaler pair the following differences were statistically significant: Diskus vs. Easyhaler ($p < 0.05$), Ellipta vs. Easyhaler ($p < 0.01$), Diskus vs. Turbuhaler ($p < 0.01$), Ellipta vs. Turbuhaler ($p < 0.01$). In the participants' ranking, the inhalers Ellipta, followed by Turbuhaler, were most often ranked as most preferred. Participants' preference of Ellipta over Easyhaler ($p < 0.01$) and over Diskus ($p < 0.001$) were statistically significant.

1. Introduction

Asthma is a chronic disease that affects 235–300 million individuals worldwide (Accordini et al., 2008; Masoli et al., 2004). It has become a major public health problem, especially among inner city populations (Moorman et al., 2007; Gupta et al., 2006; Wisnivesky et al., 2005). Despite the fact that asthma treatment guidelines have been both extensively published and are easily available, there appears to be a significant gap between the aims of treatment and the actual level of asthma control among patients (Gillissen 2004). Incorrect inhaler use has been suggested as a contributing factor to this problem.

Inhaler errors among asthma patients are common and it has been stated that a majority of asthma patients make mistakes while using their inhalers (Onyedum et al., 2014). The frequency of error varies between different studies, but it is estimated that between 50 and 94% of asthma and COPD patients make at least one mistake when using their inhalers (Crompton et al., 2006). It is estimated that out of an assessed 25 billion USD spent on asthma inhalers per year, 5–7 billion is wasted due to inhaler misuse (Fink and Rubin, 2005). The incidence of errors in inhaler use is highly dependent on which inhaler is used, since they have different modes of operation. Thus, the frequency of error may vary greatly between different studies. The knowledge of proper inhaler use is often incomplete, not only amongst patients, but also amongst healthcare professionals (Price et al., 2012; Self et al., 2007).

In the development work of new inhalation devices, it is, therefore, in addition to the physicochemical and mechanical evaluation, important to characterize the ease of use of the inhalers. One of the requirements for inhalers used for inhalation therapy is user-friendliness during the attack and during long-term treatment (Lavorini et al., 2008). Price et al. (2012) states that one of the factors for an ideal inhaler is that it is easy both to teach and to learn how to use. Other important properties of asthma inhalers that have been considered key factors are minimal requirements for cooperation and coordination, minimal cleaning and high patient preference (Lavorini et al., 2008). Research by Small et al. (2011) suggests that the level of satisfaction patients have with their inhaler device is observed to have a positive influence on the treatment goals for asthma through its association with preferences and perception of the inhalers they try.

The most essential criterion to consider when selecting inhalers for patients is ease of use. For patients, ease of use has been shown

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to be the most important feature of an ideal inhaler (Serra-Battles et al., 2002). Chrystyn (2007) argues that the three main points that affect the ease of use are: the number of steps needed in order to actuate the device, low requirements on inhaler training and the amount of manual dexterity needed to operate the device. Of course, in addition to ease of use, patient satisfaction and the patient's abilities are important factors that influence the use of the inhaler. Much of the research available on inhaler technique has been done under clinical conditions where good inhaler technique is a prerequisite for participation in the study (Chrystyn, 2005). Real-life studies may be more relevant when evaluating the ease of use of DPIs. Well-documented comparisons between devices are few. Another problem arises from the fact that many of the available studies have been sponsored by pharmaceutical companies. The results of the studies may, therefore, have to be examined critically. One study has compared three of the four inhalers used in this study (Diskus, Easyhaler and Turbuhaler) and in that study no statistically significant difference was found between the acceptability and correct use amongst 326 inhaler-naïve asthmatics/symptomatic individuals (Rönmark et al., 2005). Ellipta is a new inhaler and, therefore, not many studies including that inhaler exist. In one study (sponsored by GSK) it has been compared with Diskus and Turbuhaler inhalers in a clinical environment (Sharma et al., 2014).

The aim of this study is to examine how a naïve subject without inhaler experience finds learning and using an inhaler (Diskus, Easyhaler, Ellipta, Turbuhaler) after receiving a short video education. This study measures the frequency and nature of inhaler errors for each inhaler type after this form of demonstration. By measuring these factors, the aim was to gain a better understanding of which elements affect the ease of use of an inhaler and how different aspects of an inhaler are perceived by users. By investigating which errors appear to be common for each inhaler type and the frequency of errors for the compared inhalers, it is hoped that this information could be used by prescribers and healthcare professionals to gain an understanding of common difficulties facing patients when using a new inhaler.

2. Material and methods

2.1. Overview

The study was designed to examine the frequency of error, frequency of different error types and preference among four placebo dry powder inhalers (Diskus (GSK), Easyhaler (Orion), Ellipta (GSK) and Turbuhaler (AstraZeneca)). These were chosen as they represented the three most sold dry powder inhalers on the Finnish market as well as the most recent newcomer (most sold: Diskus, Turbuhaler and Easyhaler, and newcomer: Ellipta). All material distributed to participants was reviewed and approved by the Ethical Review Board in the Humanities, Social and Behavioral Sciences at the University of Helsinki (Statement 4/2015).

Most of the studies on the matter have measured the technique of asthma or COPD patients with prior inhaler experience. This study targets healthy inhaler-naïve individuals and aims to compare how easily they learn to use the four DPIs. The study measures the frequency of inhaler errors after receiving a video demonstration of the correct inhaler technique.

2.2. Subjects

Inhaler-naïve individuals were recruited from the general public. The chosen population consisted of 25–34-year-olds since statistics from the National Institute for Health and Welfare (THL) indicated that asthma is most prevalent for this age group in the adult population in Finland (Borodulin et al., 2013). Subjects were considered inhaler-naïve, if they did not have asthma or any experience in using any type of inhaler device. Subjects who indicated that they had worked within the pharmaceutical industry, at a pharmacy, or had family members who suffered from asthma, were excluded. It was considered that their prior experience could lead to a bias. A total of 31 people participated in the study. When examining similar studies, 30 participants appeared to be the minimum number of participants encountered (Giner et al., 2004). The average age of participants was 28 years, 17 (55%) participants were men and 14 (45%) were women. The 31 participants demonstrated the use of all four inhalers. The individuals who belonged to the selected population were made aware of the study through fliers posted in a number of relevant locations, such as educational institutions, libraries, grocery stores and public places. The requirements for participation were listed on the fliers. The chosen participants were all individuals living or working in the Helsinki metropolitan area, as research has shown that asthma is more prevalent in larger city populations (Wisnivesky et al., 2005). The study used self-selection sampling and purposive sampling (Saunders et al., 2012). The number of participants who volunteered was 33. The volunteers contacted the first author after seeing the fliers. Two participants had to be excluded from the study as knowledge regarding previous inhaler use for other purposes than asthma emerged. The data was collected in the spring of 2015 over 1.5 months.

2.3. Procedure

It was decided to use a triangular method for data collection. Quantitative data was collected through semi-structured interviews. In addition, observational qualitative data was collected through videotaping of the participants and note-taking during the inhalation demonstrations. The data collection process took place in quiet rooms at the University of Helsinki or Hanken School of Economics. All data collection sessions were carried out without interruptions. The first author was present during the data collection process. This researcher filmed the inhaler performances, and answered any questions the participants had regarding the questionnaires. The researcher did not answer any questions regarding the inhalers until after all demonstrations were filmed and all questionnaires were completed. The time required for data collection varied between participants. The approximate time per participant was between 45 and 60 min. Overall, the material analyzed for this study included 155 questionnaires and 124 videotaped inhaler demonstrations.

Participants were asked to fill in a total of 5 questionnaires. The questions will be explained in detail further on. Before being introduced to the inhalers, participants were asked to fill in a general questionnaire determining control variables and ensuring inhaler naïvety. Later on in the process participants were asked to fill in one questionnaire for each device. The questionnaires used for this study were built up as a structured interview and contained both open-ended and closed questions. The participants were able to ask clarifying questions while filling in the questionnaires. This was considered to eliminate the risk of possible misunderstandings among participants. The process will be described in more detail below. In addition to the questionnaires, observational qualitative data was collected through videotaping of the participants' inhaler performances and note-taking during the inhalation process.

After filling in the first questionnaire, participants were shown a demonstrational video of one of the inhalers produced by the Association of Finnish Pharmacies (Apteekkariliitto). Each inhaler-specific instruction video was under 2 min long. All videos had been created in cooperation with representatives from the pharmaceutical companies representing the devices. In the videos,