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ORIGINAL ARTICLE

The Clinical Evaluation of the Acceptance of Fluticasone Propionate Diskus® by Older Japanese Patients with Bronchial Asthma

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ABSTRACT

Background: Fluticasone propionate (FP) Diskus® is generally regarded as an easy to use and efficacious inhaled device. This study clinically evaluated whether its easy handling and inhalation process were affected by the aging factor or not, compared with those of the FP Diskhaler® and Beclomethasone dipropionate (BDP).

Methods: Twenty-four elderly patients with stable moderate asthma (12 aged 65−74 years and 12 aged 75 years or older) who were accustomed to using the Diskhaler® were evaluated by measuring the required time for finishing one-time inhalation with the device, compared with 7 patients aged less than 65. Ten elderly patients (5 aged 65−74 years, and 5 aged 75 years or older), who used the BDP, were also similarly evaluated and compared with 8 patients aged less than 65. All subjects then switched to use with the Diskus® and the required time for finishing one-time inhalation was measured soon after and 2 weeks after the change. The patients' usage impressions were also questioned.

Results: The mean required times (seconds) were significantly different between patients aged 75 years or older, and with patients less than 65 years of age ; 45.8 ± 8.1 *vs.* 31.8 ± 12.3 ($p = 0.046$) in the BDP group, and 56.8 ± 25.3 *vs.* 33.3 ± 18.5 ($p = 0.047$) in the Diskhaler®, respectively. Soon after changing to the Diskus®, those times became insignificant in both groups. After 2 weeks, the required time for using the Diskus® was significantly shortened in all age groups. 50.0% patients in the BDP group and 79.2% in the Diskhaler® group finally chose the Diskus®.

Conclusions: The FP Diskus® inhalation was not affected by the aging factor and all patients could quickly get accustomed to using it, suggesting its clinical efficacy for older patients.

KEY WORDS

asthma, drug compliance, Fluticasone propionate Diskus ®, older patients

INTRODUCTION

Steroid inhalation, as recommended in the Japanese guideline for bronchial asthma[1] and the Global Initiative for asthma (GINA) 2002,[2] currently plays a pivotal role in daily asthma therapy. Early and effective therapy with inhaled corticosteroids results in long-term remission in the majority of asthmatic patients.[3] Many effective inhaled corticosteroids and associated specialized delivery device systems have been developed and are clinically distributed world-wide at present. There has been an abundant accumulation of clinical evidence showing the therapeutic efficacy of the new dry powder type inhaled corticosteroids.[4-7] However, I think, the clinical evaluation of the patients' view of usage has been insufficient ; in particular for aged patients. The most distinguishing clinical factor in elderly patients compared to young and middle-aged patients is aging itself. This factor often strongly affects the introduction and continuation of inhaled corticosteroids for older patients. The aging changes, such as the decline of understanding, eye-

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Table 1 Patients Characteristics

	the BDP group				the FP Diskhaler group			
Age range	older patients			young and middle-aged patients	older patients			young and middle-aged patients
	Total	65–74	75–	20–64	Total	65–74	75–	20–64
Numbers of Patients	10	5	5	8	24	12	12	7
Mean age (yr)	74.2 ± 6.3	69.1 ± 3.2	79.3 ± 3.8	43.1 ± 16.3	74.8 ± 4.4	71.3 ± 2.3	78.3 ± 2.8	46.9 ± 16.0
Gender (M/F)	7/3	3/2	4/1	6/2	18/6	9/3	9/3	3/4
Type of asthma (Atopic/Non-atopic)	2/8	2/3	0/5	7/1	8/16	4/8	4/8	6/1

sight and finger movement, often make it difficult for older patients to handle the inhalation devices smoothly and naturally. And the most troublesome clinical problem is that some aged patients are not aware of their own aging decline. The author has been interested in the relationship between the aging factor and the acceptance of inhaled corticosteroids device systems, and has already investigated and reported on the acceptance of a dry powder type of inhaled corticosteroid and device system, the Budesonide Turbuhaler ™ (BUD-TH), by older asthmatic patients who were changed to BUD-TH from Beclomethasone dipropionate (BDP) with a spacer device InspirEase® (Schering-Plough K.K., Osaka, Japan) or Fluticasone Propionate (FP) Diskhaler®.[8] In that study, we showed that what was generally considered to be easy for young and middle-aged patients was not always easy to handle for aged patients, suggesting the major influence of the aging factor upon the daily use of an inhalation device.

FP Diskus®, another new type of dry powder inhaled corticosteroid and a device which is generally regarded as easy and efficacious, has frequently been used in recent daily clinical fields. In addition to the changing of BUD-TH, the change to the FP Diskus® from other types of inhaled corticosteroids also often occurs for various therapeutic reasons, requiring the same kind of clinical evaluation. This study clinically investigated whether the easy handling of the FP Diskus® will be affected by the aging factor or not, and also evaluated the acceptance of the FP Diskus® by older Japanese patients with bronchial asthma, when changed from the previously distributed inhaled corticosteroids, BDP with a spacer device InspirEase® and the FP Diskhaler®.

METHODS

PATIENT CHARACTERISTICS

Before enrollment in the study, the clinical meaning, purpose of this study, and the possible disadvantages including side effects caused by changing to the new inhaled corticosteroids, were explained in detail to each patient. Subsequently, 34 elderly Japanese patients aged 65 or older and 15 aged less than 65 with stable moderate bronchial asthma (Step 2–3 according to Japanese guidelines for the diagnosis and management of bronchial asthma),[1] who could fully understand this study and who showed their intention to join this study, were the subject of this study. They consisted of 24 older asthmatic patients (12 aged 65–74 years and 12 aged 75 years or older) and 7 patients aged less than 65 who had become accustomed to using the Diskhaler®, and 10 older patients (5 aged 65–74 years and 5 aged 75 years or older) and 8 patients aged less than 65 who had become accustomed to inhaling the BDP with InspirEase®. All subjects had used their inhaled corticosteroids daily for at least more than 6 months with a stable asthmatic condition. Patient characteristics are shown in Table 1. This study was carried out in accordance with the principles embodied in the Helsinki Declaration of 1995 (as revised in Edinburgh 2000). Before starting this study, written informed consent for study participation was obtained from all the enrolled patients.

PROTOCOL

All of the patients in the BDP group used 800 μg/day of BDP daily and were changed to a half dose of FP Diskus® in this study. All patients in the FP Diskhaler® group used 400 μg/day of FP Diskhaler® daily and were changed to the same dose as above of FP Diskus® in this study. Finally, both groups were evaluated according to the following terms.

Measurement of Frequency of Explanation Required at the Introduction of This Device

Before changing to the new device, FP Diskus®, each patient was carefully instructed on how to use the device and we investigated the frequency of explanation needed at the time of the introduction until each of them could fully understand this inhalation method and perfectly independently perform the successive inhalation process. After 2 weeks we confirmed whether all of subjects in this study could perform inhalation correctly. Each subject was checked on the detailed inhalation process of the FP Diskus®.