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Spirometric Improvements with Two Commonly Used Spacers in Asthmatic Patients

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ABSTRACT

Background: *Pressurized metered dose inhalers (pMDIs) are commonly used in patients with asthma. However, the need to coordinate inhalation with inhaler actuation means that they are not suitable for use per se. Spacer devices were developed to overcome some of the problems of pMDIs. Several types of holding chambers of different sizes are available in Iran. This study was designed to compare spirometric parameters between Asmyar® and Damyar® spacers in asthmatic patients.*

Materials and Methods: *This was an observational comparative study. Patients with mild to moderate asthma were entered in this study. The ease of use, convenience, and portability of the mentioned spacers were evaluated using a visual analogue scale (VAS). Lung function was assessed by using a portable spirometer (Spirolab® Italy) and spirometric parameters of $FEF_{50\%}$, $FEF_{25-75\%}$, PEF, FEV_1, FVC and FEV_1/FVC were measured.*

Results: *Forty patients (25 females, 15 males) with a mean age of 43.10± 12.99 years were studied. Mean ± SD changes of FVC , FEV_1 , PEF , $FEF_{25-75\%}$, $FEF_{50\%}$ and FEV_1/FVC (as percentage of the predicted values) before and after using Asmyar® were not significantly different from those of Damyar®. However, patient satisfaction was significantly higher with Damyar® (P<0.0001).*

Conclusion: *Lung response after using salbutamol with either Damyar® or Asmyar® spacers was not significantly different.*

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Key words: *Asthma, Asmyar , Damyar , Spacer, Spirometry*

INTRODUCTION

The majority of asthmatic patients continue to use pressurized aerosol metered-dose inhalers (pMDIs) (1-3). The need to coordinate inhalation and actuation of inhalers is an important issue (4). Spacers are introduced to overcome this problem. It has been shown that inhalation therapy using a pMDI with a spacer plays a crucial role in treatment of asthmatic patients (4-6). Drug delivery in asthmatic patients is due to their simplicity of use compared with pMDIs without spacers (7). They allow the

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patient to breathe tidally from a pool of the drug. Also, spacers decrease the amount of medication deposited in the oropharynx and thus, reduces steroid-induced side effects (e.g. candidiasis) (4). Finally, spacers increase the delivery of drug to its target (i.e. lungs) while minimizing oral absorption (8).

Several types and different sizes of holding chamber are available in the market (e.g., Aerochamber, Babyhaler and Volumatic). Asmyar® and Damyar® are two commonly used spacers in Iran. There is no evidence regarding improved compliance by using the small and portable spacer (Damyar®), or increased satisfaction of patients. Besides, there is no conclusive study on the efficacy of spacers of different sizes. The main objective of this study was to compare the clinical efficacy of these two devices in terms of spirometric parameters. Patient preference for each spacer was also evaluated.

MATERIALS AND METHODS

Study subjects and setting

Patients referred to the pulmonary clinic of NRITLD, Masih Daneshvari Hospital in the age range of 18-60 years were assessed for eligibility to enter the study. Diagnosis of mild-to-moderate persistent asthma was confirmed by clinical examination and spirometry. Patients were excluded if they were smokers, pregnant or noncompliant. All medications except inhalers were discontinued for at least 24 hours prior to the study.

Study Design

This was an experimental, observational study approved by the drug and therapeutic committee of the hospital and the ethics committee of Shahid Beheshti University of Medical Sciences. Written consent was obtained from each patient.

The spacer devices used in the study consisted of a polycarbonate volumatic (750ml; Asmyar®, Iran) and a polycarbonate nonvolumatic (140ml; Damyar®, Iran) salbutamol 100 mcg/dose pMDIs (Ventalex® ; Sina Daru, Iran) was used with each spacer.

The first few actuations from each pMDIs were fired (primed) prior to use. The pMDIs were pressed firmly into the spacers.

Before beginning, patients were educated and they practiced the correct inhalation technique from the spacer used at each step. Four doses of Salbutamol (Ventalex®; Sina daru, Iran) were then inhaled via the spacer (volumatic or nonvolumatic). The times between actuation of the pMDI and inhalation was kept less than 3 seconds. Spirometry was performed 10 minutes after the puffs. Each patient was trained to inhale via Asmyar® and Damyar® separately. The subjects used Damyar® on the first week and then crossed over to Asmyar® on the second week.

Outcome Measures

The change in FEV_1 after salbutamol was the primary outcome measure. Measurements were performed by means of Spiro lab II (Medical International Research, Via del Maggiolino, Italy). Individual predicted FEV_1 values were recorded according to patient characteristics. All measurements were performed by a trained investigator. The change in FEV_1 10 minutes after administration of salbutamol was the primary endpoint. We calculated the absolute change in values from initial pre-bronchodilator value.

Subjects were also asked to score their degree of satisfaction in terms of the ease of use, convenience, and portability with the spacer device on a visual analogue scale from 0-10 (0, not satisfied; 10, very satisfied) at the end of all inhalations. This part of the study was performed by an investigator blind to the spirometry results.

Statistical analysis

The analysis of data was performed using

Statistical Package for Social Sciences (SPSS 11.0, SPSS Inc., Chicago, IL, USA). The results were expressed as mean ± SD. P values of <0.05 were regarded as significant.

RESULTS

Forty patients (25 females and 15 males) with a mean±SD age of 43.10±12.99 years were recruited. The correct spirometry maneuver was assured by a trained investigator throughout the study period. There was a significant improvement in mean spirometric parameters after using each spacer ($p<0.05$). Data for each parameter is shown in Table 1 and Figure 1. No significant difference was observed between the two spacers. Patient satisfaction was significantly ($P<0.0001$) higher with Damyar® (Table 1).

Table 1. Spirometric improvements and patient satisfaction after using the two spacers.

Spirometry parameters	Asmyar®	Damyar®	P value
FVC	4.75±6.99*	5.93±7.94	0.35
FEV_1	7.68±5.08	7.10±5.91	0.53
PEF	7.10±13.64	1.25±12.91	0.05
$FEF_{25-75\%}$	16.30±12.05	16.10±13.06	0.92
$FEF_{50\%}$	13.45±11.78	14.42±11.44	0.64
FEV_1/FVC	0.04±0.05	0.02±0.08	0.21
Preference	4.82±2.38	7.17±2.23	<0.0001

* Figures are the difference between pre and post spacer usage.

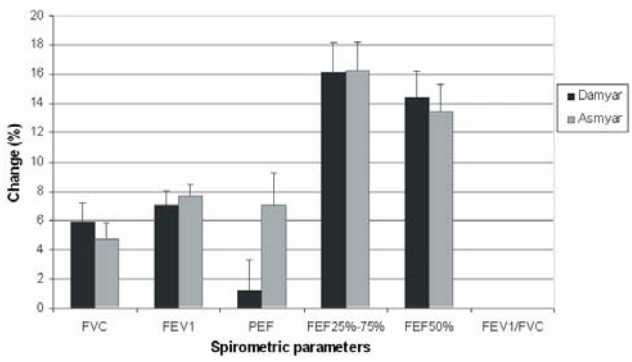

Figure 1. Mean percentile changes in spirometric parameters after using spacers.

DISCUSSION

The usage of pMDI with both spacers caused significant improvements in FEV1. We could not find any significant difference between the two spacers in terms of improvement in FEV_1. Previous studies documented that large-volume spacers are able to increase the delivery of fine particles and hence better drug deposition (9,10). It is important that the pMDI with spacers are useful and acceptable by patients. As described earlier the two commonly available spacer devices in Iran are Asmyar® and Darnyar®. Asmyar® is more bulky compared to Damyar® which has a smaller volume, thus, is inconvenient to use and carry around. This factor may compromise compliance. There are reports on better drug delivery by higher volume spacers (11).

In performing inhaler studies, it is essential to realize that a large number of variables are involved, including age of subjects, the exact technique of inhalation, and the type of drug (12,13).

The influence of inhalation technique as another variable was omitted by the crossover fashion of this study. Patients were required to undergo assessment at the same time of the day during two consecutive weeks. They were assigned to use Damyar® on the first week and changed over on the second week. The two devices also had similar inhalation features. We studied the efficacy of the spacer device by assessing the changes in lung function as our main outcome measure. We demonstrated that Damyar® was not significantly different in terms of bronchodilator response compared to Asmyar®.

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