J Int Med Res (1980) **8**, 217

Clinical Trial of Two Inhalation Techniques for Pressurized Aerosols

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The clinical effects of a bronchodilator, terbutaline sulphate, were compared after administration in the beginning of the inhalation by means of a standard inhaler and administration by actuating 2 seconds before starting the inhalation by means of an inhaler furnished with a 32 × 100 mm tube. No differences could be seen in the parameters measured – forced vital capacity (FVC), 1-second forced expiratory volume (FEV_1), forced mid-expiratory flow (FMF), and oscillatory resistance (R_{os}). The results indicate that when attaching a tube to the standard inhaler co-ordination of inhalation and actuation of the aerosol is not of vital importance.

Introduction

Many surveys have been published estimating the number of asthmatic patients who cannot handle their metered aerosols properly. Lack of synchronizing the actuation of the aerosol and the inhalation, which Munt (1979) called hand-lung dyscoordination, is one of the main errors. This error was present in 42% (Langaker 1976), 34% (Dahl 1977), and 38% (Epstein *et al* 1979) of the patients investigated. Despite careful tuition, 14% out of 321 asthmatic patients used their inhalers inefficiently (Paterson & Crompton 1976).

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Poor co-ordination in self-administration has been shown to give significantly lower clinical effects compared to administration by the physician (Orehek *et al* 1976).

Morén (1978) showed that, when attaching a tube (32 × 100 mm) to the actuator and setting off the aerosol 5 seconds before inhalation was started, the same amount of drug was deposited before reaching the pharynx as when using the common actuator and setting off the dose in the beginning of the inhalation.

This indicates that the same amount of drug is available to the lungs.

This trial was carried out in order to compare the two inhalation techniques and devices assessed as clinical effects in asthmatic patients.

Materials and Methods

The following criteria had to be fulfilled if the patient was to take part in the trial:

(i) reversibility of the airway obstruction by > 20% 30 minutes after 2 puffs of 0·1 mg salbutamol sulphate aerosol measured in 1-second forced expiratory volume (FEV_1),

(ii) FEV_1 > 1·0 L before salbutamol sulphate aerosol,

(iii) the variation in the obstruction on the two test days should be < 15% in FEV_1.

Thirteen patients fulfilled the criteria – nine men, mean age 58 years, (range 36–69), and four women, mean age 50 years, (range 12–68).

A terbutaline sulphate aerosol* delivering 0·25 mg per actuation was used, administering two actuations 1 minute apart. Two different inhalation techniques were used. When using the ordinary actuator, the actuation of the aerosol took place at the beginning of a deep inhalation. When the tube (32 × 100 mm) was attached to the actuator, the setting off of the dose took place 2 seconds before the deep inhalation started.

Registration of forced vital capacity (FVC), FEV_1, and of forced mid-expiratory flow (FMF) was made on a dry wedge spirometer (Vitalograph®). Oscillatory resistance (R_{os}) was assessed with Siemens Siregnost FD5. Measurements were made before and 5, 15, 30, and 60 minutes after the puffs were inhaled.

The trial was of the open, crossover, and randomized type. Statistical evaluations were made using Student's paired t-test.

Results

The results of the measurements using the two inhalation techniques are presented in Figures 1, 2 and 3 and Table 1.

Using either technique, the response is immediate and a significant improvement is registered after 5 minutes and throughout the trial in all parameters.

The pre-values of the two test days do not differ significantly, FEV_1 ($p < 0·05$) excepted. Looking at the figures it can be seen that the difference is only 0·06 L which cannot be considered clinically significant.

For any parameter measured the increases from the pre-values do not differ significantly between the two administration techniques for any of the times 5, 15, 30, and 60 minutes. No side-effects were reported. Remarks on taste and effect of the aerosol were made by six subjects in the trial. When the tube was attached four subjects found the taste better, and three subjects experienced a subjectively better effect. Only one patient found the ordinary aerosol actuator to be best; he felt that he inhaled more with the ordinary actuator than with the tube.

Discussion

It is of vital importance to make the aerosol as easy to use as possible, the reason being that the effect of medical aerosols, to a very great extent, depends on the patients' own efforts. One of the hardest phases is the pressing of the actuator at the beginning of the inhalation. In a previous study (Bloomfield, Crompton & Winsey 1979) it was found that attaching a tube spacer to the actuator could at least partly compensate for poor co-ordination. A dry powder insufflator was tried in order to deliver bronchodilators locally to the lungs. However, this showed no advantages as 50% of the patients still had a faulty technique (Hartley, Nogrady & Seaton 1979). In none of the patients tested was the dry powder insufflator superior to the aerosol in the dose used and 66% of the patients preferred the aerosol. Using a technical device attached to the ordinary actuator, we have shown that you can alter the inhalation technique with regard to co-ordination. The patient now exhales through the tube, releases the aerosol, and after this inhales with no strict demands for co-ordination. This new inhalation technique can be of vital importance to patients having difficulties in using their aerosols according to the earlier instruction.

*Bricanyl,® AB Draco, Subsidiary of AB Astra, Sweden.

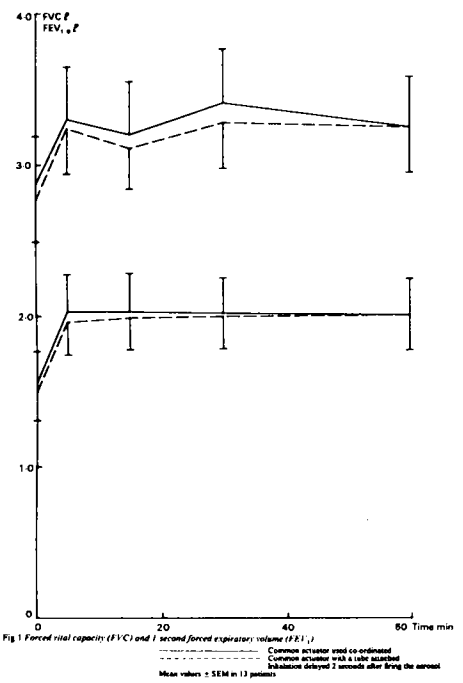

Fig 1 *Forced vital capacity (FVC) and 1 second forced expiratory volume (FEV_1)*

Common actuator used co-ordinated
Common actuator with a tube attached
Inhalation delayed 2 seconds after firing the aerosol

Mean values ± SEM in 13 patients

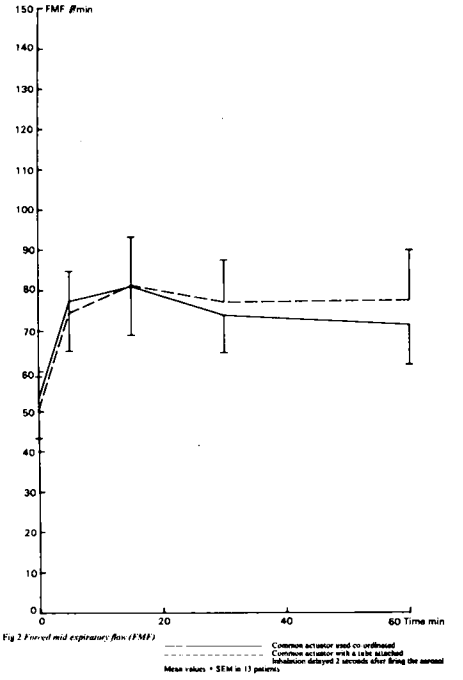

Fig 2 *Forced mid expiratory flow (FMF)*

Common actuator used co-ordinated
Common actuator with a tube attached
Inhalation delayed 2 seconds after firing the aerosol

Mean values ± SEM in 13 patients

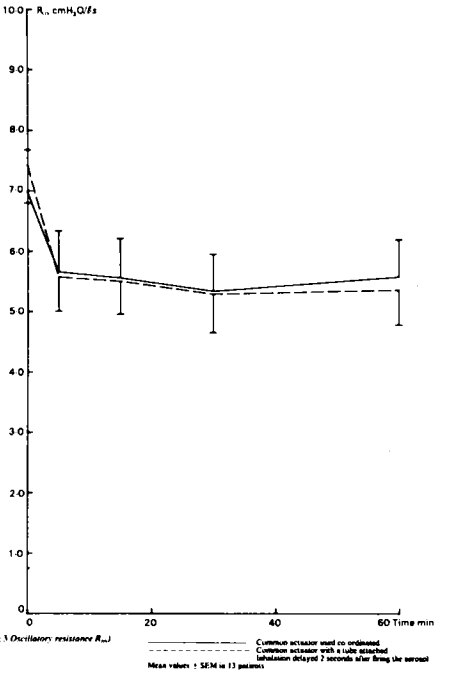

Fig 3 *Oscillatory resistance*

Common actuator used co-ordinated
Common actuator with a tube attached
Inhalation delayed 2 seconds after firing the aerosol

Mean values ± SEM in 13 patients

Table 1

Mean ± SEM of the increase, averaged over the times 5, 15, 30, and 60 minutes after 2 actuations of terbutaline sulphate aerosol

	FVC (l)	*FEV_1 (l)*	*FMF (l/min)*	*R_{os} (cmH_2O/ls)*
Standard inhaler, co-ordinated inhalation – actuation of aerosol	*** 0·42 ± 0·07	*** 0·46 ± 0·09	** 22·80 ± 5·84	** −1·45 ± 0·39
Standard inhaler with tube attached, unco-ordinated inhalation – actuation of aerosol	*** 0·46 ± 0·08	*** 0·49 ± 0·08	** 27·29 ± 6·89	*** −2·00 ± 0·34

*** $p < 0·001$ Denote significant differences
** $p < 0·01$ compared to pre-values

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