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The use of a new breath-actuated inhaler by patients with severe airflow obstruction

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The use of a new breath-actuated inhaler by patients with severe airflow obstruction. R.J. Fergusson, J. Lenney, G.J.R. McHardy, G.K. Crompton.
ABSTRACT: The ability of patients with severe airflow limitation (forced expiratory volume in one second <1.0 *l* or peak expiratory flow rate <200 *l*·min^{-1}) to use a new breath-actuated inhaler (BAI) was assessed. One hundred and fifty six patients attending two respiratory units entered and completed the study. Subjects were instructed how to use the device and after attempting to trigger the BAI had flow-volume loops measured. One hundred and fifty one (97%) were able to actuate the inhaler on their first (146) or second (5) attempt. The five unsuccessful patients did not have the most severe airways obstruction. It is concluded that this new device, which is actuated at low inspiratory flow rates, can be used by patients with severe airflow limitation and represents an important advance in inhaler technology.
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Since the metered-dose inhaler (MDI) was introduced into clinical practice in 1956 it has become a widely used and effective method of administering treatment in patients with airflow obstruction [1, 2]. Although the device is small and simple in design, many patients have difficulty in using it and obtain less than maximum therapeutic benefit [3, 4]. Patients can make many mistakes using an MDI [5], the most common being an inability to co-ordinate actuation of the inhaler with inspiration [3]. Attempts to overcome co-ordination problems have included the introduction of "spacer" chambers [6, 7] and dry powder inhalers [8].

The development of a breath-actuated device, which is triggered at a low inspiratory flow rate, has been a fundamental approach to improve drug delivery using an MDI. Early versions were bulky, generated a loud "click" when the valve mechanism was triggered and required generous inspiratory flow rates for actuation. A new breath-actuated inhaler [BAI] has been developed which is only slightly larger than a conventional MDI (fig. 1), has a quiet triggering mechanism and is actuated by inspiratory flow rates of approximately 30 *l*·min^{-1} [9]. Untrained subjects have been reported to find it easier to use and preferable to a standard MDI [10].

This study was undertaken to assess whether adult patients with severe chronic airflow obstruction were

Fig. 1. – The new breath-actuated inhaler.

capable of using this BAI and to document the inspiratory and expiratory flow rates generated at the time of testing.

Patients

Patients with chronic airflow limitation attending the Respiratory Unit, Northern General Hospital, Edinburgh and the Chest Unit, City Hospital, Edinburgh were enrolled. All had chronic bronchitis, emphysema or chronic asthma. To be eligible for study they required either a forced expiratory volume in one second (FEV_1) <1 *l* or a peak expiratory flow rate (PEFR) <200 $l \cdot min^{-1}$. The study protocol was approved by the Lothian Ethics of Medical Research Committee.

Methods

Pulmonary function tests were performed using a Vitalograph Compact Spirometer (Vitalograph Ltd, Maid's Moreton, Bucks, UK). The inhaler units used (Aerolin Autohaler, 3M Riker Laboratories, Loughborough, UK) contained no active drug but were filled with a propellant and a surfactant only.

The study was of an open design to evaluate the inhaler as a device only. No attempt was made to assess what proportion of the administered dose entered the airways. All patients were studied after a 15 min resting period. An initial FEV_1 and PEFR was performed to ensure that patients satisfied the entry criteria. They were instructed both verbally and by demonstration how to use the inhaler and then asked to inhale through the device in the presence of an investigator.

The BAI was "primed" for the patient by raising a small lever in the top of the unit. A triggering mechanism prevents dose release until a low flow inspiratory effort moves a blocking vane to allow the device to be fired. Successful operation was easy to assess by the investigators since a very slight "click" together with the noise of the propellant release was audible as the inhaler fired. When a patient failed to trigger the BAI the blocking vane could be seen to be still occluding the mouthpiece.

Immediately after inhaler use, flow-volume loops (the best of three attempts) were recorded. FEV_1, PEFR, forced inspiratory flow at 50% of vital capacity (FIF_{50}) and maximum inspiratory flow rate (MIFR) were measured. Patients who failed to operate the inhaler at their first attempt were re-studied on a separate occasion.

Results

A total of 156 patients entered and completed the study, 91 were hospital in-patients and 65 out-patients. There were 74 men, mean age 68.8 yrs (range 34–90 yrs) and 82 women, mean age 65.4 yrs (range 30–80 yrs). The pulmonary function values obtained for all subjects are shown in table 1. The patients were subdivided into three subgroups according to their pre-test FEV_1 on entry into the study. Group 1: FEV_1 0.75–1.0 *l*; Group 2: FEV_1 0.5–0.75 *l* and Group 3: FEV_1<0.5 *l*. There was a wide scatter of results for other measurements within each of these subgroups.

Of the 156 patients studied, 151 (97%) were able to actuate the inhaler on their first (146) or second (5) attempt. Five patients failed to trigger the device. Their pulmonary function data are shown in table 2. Two patients unable to trigger the inhaler were in group 2 and three in group 1. Two patients were re-studied and were still unable to trigger the device and the remaining three patients were not available for a second study day.

Table 1. – Pulmonary function values of all patients

	Group 1 n=52	Group 2 n=66	Group 3 n=38
FEV_1 *l*	0.88±0.19 (0.76–1.22)	0.63±0.07 (0.51–0.75)	0.43±0.06 (0.31–0.5)
PEFR $l \cdot min^{-1}$	168.3±49 (68–263)	130.3±38 (46–227)	117.6±49 (50–253)
FIF_{50} $l \cdot min^{-1}$	119±59 (34–286)	105.6±48 (27–245)	105.6±47 (40–257)
MIFR $l \cdot min^{-1}$	134.4±63 (45–302)	119.4±47 (45–257)	116.7±48 (47–262)

Mean±SD (range). FEV_1: forced expiratory volume in one second; PEFR: peak expiratory flow rate; FIF_{50}: forced inspiratory flow at 50% of vital capacity; MIFR: maximum inspiratory flow rate.

Table 2. – Pulmonary function values of the 5 patients unable to trigger the inhaler

Patient no.	Attempt no.	FEV_1 *l*	PEFR $l \cdot min^{-1}$	FIF_{50} $l \cdot min^{-1}$	MIFR $l \cdot min^{-1}$
20	1	0.6	97	60.6	67
	2	0.5	70	39.0	43
44	1	0.73	98	70.2	89
	2	0.72	83	79.2	82
72	1	0.78	119	81.6	85
77	1	0.78	139	72.0	88
79	1	0.79	167	105.6	183

For abbreviations see legend to table 1.

Discussion

Although inhalation therapy is widely prescribed in patients with obstructive airways disease it is well known that many have a faulty inhaler technique and therefore will not receive the maximum benefit from treatment [3, 8]. Developments which simplify inhaled drug delivery are to be welcomed. In this

study we have assessed the ability of a large group of patients with severe airflow limitation to use a new breath-actuated inhaler. The vast majority (97%) were able to actuate the device after a brief instruction period, a figure which far exceeds the published success rates for both normal subjects (including doctors) and patients using a standard MDI for the first time [3, 5, 10–12].

All the subjects tested had severe airways obstruction as assessed by measurement of FEV_1 and PEFR at the time of study, although there was a wide variation in measurements of inspiratory flow rates and in particular a poor correlation between PEFR and MIFR (table 1). This observation, which has been noted previously [13, 14], may be explained by expiratory airways collapse in patients with emphysema and by the fact that forced inspiratory flow, unlike forced expiratory flow, is predominantly effort-dependent [15]. Five patients out of 156 failed to actuate the device, with two failing on two separate occasions. The reasons for failure are unclear. None had particularly low expiratory flow rates (table 2) and all were capable of generating sufficient inspiratory flow to trigger the device. Indeed we found no correlation between the degree of airflow limitation and the ability to "fire" the inhaler. Presumably the unsuccessful patients performed quite different inspiratory manoeuvres when breathing through the spirometer and when using the BAI.

This new BAI has been shown in the laboratory to be triggered by flow rates of approximately 30 $l \cdot min^{-1}$ [9]. In clinical practice the device should therefore fire early in the inspiratory cycle which may increase drug delivery to peripheral airways [16]. A previous study [10] has shown that a group of 70 adults with no experience of inhalers found this BAI easier to use and preferable to the standard MDI. The study reported here confirms that this BAI can be actuated by patients with severe airways obstruction.

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L'emploi d'un nouvel inhalateur déclenché par la respiration chez les sujets atteints d'obstruction sévère du courant aérien.
R.J. Fergusson, J. Lenney, G.J.R. McHardy, G.K. Crompton.
RÉSUMÉ: L'aptitude des patients qui présentent une limitation sévère du courant aérien (VEMS <1.0 *l* ou DEP <200 $l \cdot min^{-1}$) à utiliser un nouvel inhalateur actionné par la respiration (BAI) a été évaluée. Cent-cinquante-six patients, examinés dans deux services de maladies respiratoires, ont pris part à cette étude et l'ont complétée. Le fonctionnement du dispositif a été démontré aux sujets et, après qu'ils aient essayé de déclencher le BAI, leur courbe débit-volume a été mesurée. Sur cent-cinquante-six sujets, 151 (97%) ont été capables d'actionner l'inhalateur, dès le premier essai (146) ou le second essai (5). Les cinq patients ayant échoué au premier essai ne présentaient pas d'obstruction respiratoire particulièrement grave. Il a été conclu que ce nouveau dispositif, déclenché par un débit inspiratoire faible, peut être utilisé par des patients présentant une limitation sévère des débits aériens, et qu'il représente un progrès important dans la technologie des inhalateurs.
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