

ORIGINAL ARTICLE

Funhaler spacer: improving adherence without compromising delivery

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A novel asthma spacer device, the “Funhaler”, incorporates incentive toys which are isolated from the main inspiratory circuit by a valve. Here we show that its use does not compromise drug delivery. Improved adherence combined with satisfactory delivery characteristics suggest that the Funhaler may be useful for management of young asthmatics.

Poor adherence to prescribed frequency and technique remains a major problem for paediatric asthmatics on inhaled medication. Rates of compliance for offering medication regularly to asthmatic children range from 30% to 70%, while paediatric compliance rates for correct pressurised metered dose inhaler (pMDI) technique range from 39% to 67%.^{1–6} Unfortunately, adherence does not necessarily improve with rising severity of illness,^{7–9} and physicians do not always judge patient adherence accurately.¹⁰

Unfortunately drug deposition studies have shown that crying impedes drug delivery to children^{11 12} and poor technique frequently leads to reduced drug delivery to the patient. For example, a study of 55 moderate to severe asthmatic children found that only 73% had technique which would allow *any* drug delivery.⁵ Recent studies have confirmed these alarmingly low rates of adherence in children. A video based study found that only half of the children surveyed had appropriate pMDI technique.⁶

The consequences of poor adherence are serious. Irregular treatment and poor inhalation technique are linked to more hospitalisations and increased morbidity. For example, one study showed 14% compliance to offering medication to children with asthma exacerbations versus 68% of children without exacerbations.¹³

The reasons suggested for such poor compliance are varied, including ignorance, fear, boredom, forgetfulness, and apathy.^{9 14 15} Education can significantly improve adherence of asthmatic patients but is decreasingly effective in younger children, and a more holistic approach may be necessary to tackle this difficult age group.⁹ Especially in children it is likely that an interplay of adherence considerations with aerosol output factors can influence clinical outcomes (see Cole¹⁶ for review).

METHODS

Survey of adherence

A total of 32 children (10 male, 22 female; age range 1.5–6 years, mean age 3.2 years; average duration of asthma of 2.2 years) prescribed drugs delivered by pMDI and spacer were recruited into the study with informed consent. Matched questionnaires were completed with 27–32 valid responses to each pair of questions being collected after sequential use of the Breath-a-Tech (Scott-Dibben, Australia) and Funhaler (InfaMed, Australia, www.funhaler.com) spacer device for two weeks.

Aerosol output

Our standard methodology¹⁷ was used for comparison of the particle size distribution of salbutamol (100 µg/actuation; Ventolin, GSK) and beclomethasone dipropionate (BDP) (50 µg/actuation; Becotide, GSK) delivered via pMDI through two detergent coated small volume polycarbonate spacers (235 ml Breath-A-Tech; 225 ml Funhaler). Particle size distribution and total drug delivery was measured using a multistage liquid impinger (MSLI; Copley, Nottingham, UK) with a calibrated inhalation flow of 60 l/min. The pMDI was shaken vigorously for 30 seconds prior to actuations, and the first two actuations were wasted. Ten single actuations were introduced into the MSLI. The pMDI was shaken vigorously for five seconds between each actuation. The aerosol generated by the pMDI was drawn through the MSLI with the entraining air flow. Droplets were deposited on the actuator, “throat”, or one of four stages of the device. The location of particle deposition was determined by the aerodynamic size of the particle. The sizes of particles depositing on stages 1, 2, 3, and 4 (absolute filter) were >13 µm, 6.8–13 µm, 3.1–6.8 µm, and <3.1 µm, respectively. The actuator, spacer, throat, and stages of the MSLI were washed with HPLC grade methanol (BDP; 50 ml methanol; salbutamol, 45 ml methanol + 5 ml 0.1M NaOH). The absorbance (salbutamol 246 nm; BDP 238 nm) of each sample was measured in duplicate with a UV spectrophotometer. Data were taken from three experiments for each condition and standard errors (SE) were calculated.

RESULTS AND DISCUSSION

The Funhaler toy circuit design: harnessing play for drug delivery

In an attempt to address the adherence problem from a new perspective (that of the child), a novel low volume spacer device, the “Funhaler” was designed. This device incorporates a number of features to distract the attention of children from the drug delivery event itself and to provide a means of self reinforcing the use of effective technique. Figure 1 shows the design of the Funhaler, with an inset showing a 4 year old child using the device. The Funhaler design differs from previous efforts to make spacers appealing to children in several major respects. Firstly, it isolates incentive toys (spinner and whistle) in a separate branch to the standard inhalation circuit, placing them outside the expiratory valve of the spacer to avoid problems of contamination and interference of drug delivery. Secondly, the design of the toys themselves ensures sufficient inspiratory resistance to minimise entrainment of inspired air through the toy circuit. Thirdly, the design attempts to link the optimal function of the toys to deep tidal breathing pattern conducive to effective medication. Finally,

Abbreviations: BDP, beclomethasone dipropionate; MSLI, multistage liquid impinger; pMDI, paediatric metered dose inhaler; SE, standard error



Figure 1 The Funhaler device.

the design of the Funhaler anticipates the potential for boredom of children with particular incentive toys in its modular arrangement which would allow the replacement of the incentive toy module with a range of different toys.

Funhaler use associated with improved measures of adherence

We have recently completed a study of the effect of the Funhaler on measures of paediatric adherence in the home setting. In this survey, the details of which are to be reported elsewhere, use of the Funhaler was associated with improved parental and child compliance. For example, when surveyed at random, 38% more parents were found to have medicated their children the previous day when using the Funhaler, compared to their existing small volume spacer device (22/27 versus 16/27, respectively; $p = 0.016$), and 60% more children took the recommended four or more cycles per aerosol delivery (24/30 versus 15/30; $p = 0.02$) when using the Funhaler compared with the standard spacer.

No significant difference in aerosol output from Funhaler and conventional spacer device

Here we describe a complementary comparison of the performance of the Funhaler (InfaMed Ltd, Australia) with the most prevalent small volume spacer device in Australia, the Breath-a-tech (Scott-Dibben, Australia; analogous in design to the Optichamber device, Respironics, USA) to assess whether the aerosol delivery characteristics of the Funhaler

are comparable to conventional devices. In addition to helping with problems of breath coordination, spacer devices can help to minimise oropharyngeal deposition by releasing a higher proportion of fine aerosol droplets ($<6.8 \mu\text{m}$), particles which we refer to here as the “respirable dose”. For this study we used prototypes of the Funhaler which were made of polycarbonate, the material intended for the production units of the device.

Overall no significant differences were observed between the Funhaler and the Breath-a-tech spacer for delivery of the respirable particle fractions (compare percentage delivered dose of $3.1\text{--}6.8 \mu\text{m}$ and $<3.1 \mu\text{m}$ between the two devices; see table 1). The apparently slightly higher ex-spacer output of particles of the smaller size range (particularly $<3.1 \mu\text{m}$) observed with the Funhaler was compensated by lower losses overall from within the conventional spacer device itself (data not shown), resulting in a comparable percentage of the ex-actuator dose being delivered from both devices.

Given the large variance in compliance of children to the prescribed frequency and technique for asthma medication, it is likely that compliance to prescribed use may be more influential than minor variations in the delivery characteristics of the spacer per se. Indeed in two recent studies, the variation in delivery from spacer devices in daily life is considerably greater than that predicted from in vitro studies,^{6, 18} and some of this variability may be attributed to problems of adherence.

Based on the results presented here and proven effects of spacer use on morbidity of children,¹⁹ we hypothesise that use

Table 1 Spacer aerosol output

	Salbutamol		BDP	
	Funhaler	Breath-A-Tech	Funhaler	Breath-A-Tech
Mean (SE) percentage ex-actuator dose				
Extrafine particle fraction ($<3.1 \mu\text{m}$)	20.25 (0.97)	20.65 (0.56)	12.69 (0.46)	14.95 (1.11)
Particles $<6.8 \mu\text{m}$	32.98 (1.28)	36.30 (0.67)	25.60 (1.14)	31.21 (2.01)
Mean (SE) percentage ex-spacer dose				
Extrafine particle fraction ($<3.1 \mu\text{m}$)	49.62 (1.95)	43.97 (0.90)	28.23 (1.00)	29.39 (0.69)
Particles $<6.8 \mu\text{m}$	80.74 (0.89)	77.31 (0.88)	56.90 (1.93)	61.41 (0.95)

No significant differences between spacers for either salbutamol or BDP ($p > 0.05$).

of the Funhaler could be translated to improved measures of clinical outcome. Therefore the work presented here provides a basis for future efficacy studies to test the hypothesis that use of functional incentive devices such as the Funhaler may improve the health of children.

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