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ORIGINAL ARTICLE

A new asthma spacer device to improve compliance in children: a pilot study

GERVASE CHANEY,[1,5] BARRY CLEMENTS,[1] LOU LANDAU,[2] MAX BULSARA[1,3] AND PAUL WATT[4,5]

[1]*Princess Margaret Hospital for Children,* [2]*Faculty of Medicine and Dentistry,* [3]*Department of Biostatistics/ Public Health,* [4]*TVW Telethon Institute for Child Health Research and Centre for Child Health,* [5]*School of Paediatrics and Child Health, The University of Western Australia, Perth, Western Australia, Australia*

A new asthma spacer device to improve compliance in children: a pilot study
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Objective: This pilot study was designed to compare the acceptance, ease of use, and effects on compliance between currently used spacer devices and the Funhaler—a new small volume spacer device designed to improve adherence to asthma medication in children.

Methodology: A matched questionnaire-based survey was conducted by two interviews of each caregiver by the same person. A total of 32 children were randomly recruited from seven clinics spanning widely differing socioeconomic and geographical areas of Perth, Western Australia. Preschool children taking regular inhaled asthma medication using an existing low volume spacer device and aged between 1.5 and 6 years, took part in the pilot study. Parents completed two matched questionnaires. The first questionnaire was completed at the beginning of the study and the second after 2 weeks' use of the Funhaler spacer. Data collected related primarily to ease of use of the devices, child and parental compliance, and treatment attitudes. During the study, parents were also called at random on one occasion to ascertain whether they had attempted to medicate their child the previous day.

Results: Using the Funhaler incentive spacer device, parents reported significantly more success at medicating their children (22/30 always successful) in comparison to using their existing spacer device (3/30). Parental adherence to prescribed frequency and the delivery technique of children were also improved. The children also showed improved satisfaction and willingness to use the device and parents' attitude towards medicating their children was improved with the Funhaler spacer device.

Conclusions: Use of a novel, incentive spacer device (Funhaler) appeared to be associated with increased success and fewer problems in medicating children, improved child and parental adherence, and a more positive attitude towards treatment, suggesting that more extensive long-term efficacy trials with the device are warranted.

Key words: adherence, asthma, children, compliance, incentive, spacer.

INTRODUCTION

The treatment of children has been recognised as a major unmet need in the management of asthma.[1] The incidences of asthma and atopy have been increasing over the past 20 years, particularly in children.[2] While asthma mortality rates have been declining since the mid 1990s in some countries, there are still many preventable deaths[3–5] which extensive education programmes and the availability of new asthma therapies have failed to address completely. In Australia, where approximately one in four children have asthma symptoms, asthma attacks are the second most common cause of paediatric hospital admissions,[6,7] and are a major cause of school absenteeism.

Several factors have been identified as influencing or possibly preventing admission of children to hospital with an attack of asthma, including early management,[8,9] regular review,[10,11] and provision of an asthma management plan.[12,13] However, there is

Correspondence: Dr Paul Watt, TVW Telethon Institute for Child Health Research and Centre for Child Health, University of Western Australia, 100 Roberts Road, Subiaco, WA 6008, Australia. Email: paulw@ichr.uwa.edu.au; www.funhaler.com

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mounting evidence that poor adherence to prescribed treatment (referred to here as compliance) with prophylactic medication is a major cause of apparent treatment failure.[14–16]

Patient compliance with inhaled asthma medication is notoriously low in all age groups with reported non-compliance rates of 30–70%.[17–20] In young children, evidence points to at least two kinds of non-compliance: the non-compliance of the children to recommended inhalation technique and the non-compliance of their care-givers, who frequently cite medication episodes as being stressful and often fail to offer medication regularly.[21]

National and international guidelines are now recommending the metered dose inhaler plus spacer device as the most effective system in children up to the age of 5 years.[22,23] The guidelines recommend that the child inhales the drug through the spacer using tidal breathing with either a face mask (0–3 years) or mouthpiece (3–5 years). However, existing spacer devices are reduced versions of those designed for adults and there has been no attempt to make them appealing to young children.[24] Moreover, despite the long held belief that crying and screaming results in increased drug inhalation due to the deep inhalations taken by the child, measurements of drug delivery[25] and lung deposition[26] indicate that the amount of drug inhaled by the child decreases markedly while the child is crying or in distress.

Non-compliance with prophylactic asthma therapy can have serious consequences, resulting in increased emergency department attendance and hospitalisation.[27] A significant difference in compliance (recorded with electronic monitors) has been noted between children who experience asthma exacerbations (compliance 13.7%) and those who do not experience exacerbations (68.2%).[27]

The aim of this pilot study was to establish the acceptance, ease of use, and compliance of the Funhaler spacer compared with currently used spacer devices, in a group of young asthmatic children on regular inhaled therapy, to determine the basis for further clinical trials. Two findings from this adherence study have been reported in brief elsewhere,[28] in an article which concentrated on the aerosol delivery characteristics of the Funhaler. Here we present the complete results of the compliance survey, focussing on the design rationale and analysing the attitudinal and behavioural response to the device.

METHODS

Participants

Children aged between 1.5 and 6 years (median and mean of 3 years) with known asthma, and currently on regular asthma treatment using a leading low volume spacer device (AeroChamber or Breath-a-tech), were randomly recruited through seven local paediatrician or general practitioner clinics spanning a wide area with a radius of 51 km. Parents were initially contacted by the study coordinator by telephone before being visited at home. Written, informed consent was obtained from parents before they were interviewed, using a questionnaire, about the asthma device they were currently using. This questionnaire was completed without the Funhaler ever having been shown or described to the participants, to minimise the influence of recruitment effects. They were then given a Funhaler device to use instead of their current device for a period of 2 weeks with instructions that the device should only be used with adult supervision. Parents were contacted once by telephone on an ad hoc basis during the study, to ascertain whether or not they had medicated their child the previous day. They were then visited once more at the end of the 2-week trial period and a second questionnaire regarding use of the Funhaler spacer was completed, by interview with the same parent who responded to the first questionnaire.

A placebo spacer was not included, as all patients had previously used spacer devices. The potential for conducting valid placebo and cross-over studies is further limited due to the obvious differences between the Funhaler and conventional spacer devices (see Discussion).

The spacer device

To address the compliance problem when medicating young asthmatics, a new inhaler attachment device (Funhaler; InfaMed, Australia) for use with metered dose inhalers (pMDI) has been developed that incorporates an incentive toy module (including a spinning disk and whistle), which is activated by the child's breathing pattern, to allow for less stressful and more effective use of inhaler therapy. A low volume spacer chamber has been developed, which incorporates the most optimal delivery characteristics of other low volume spacers (i.e. valve, volume and shape). This spacer has been specifically designed using attractive polycarbonate components so that the whole appearance of the unit resembles a toy, from the perspective of the child. The face-mask attachment facilitates drug delivery for the preschool age group.

The Funhaler incentive toy module can be attached to the Funhaler-spacer to allow the use of the 'toy' when using a pMDI-spacer for aerosol therapy. Because the toy is attached to an expiratory valve on the Funhaler attachment, it does not increase the inspiratory resistance when inhaling through either the dry powder inhaler or the pMDI-spacer, nor does it interfere with drug delivery to the patient since the standard inspiratory drug circuit is not altered (Fig. 1). The rationale behind the device is to ensure that while children focus on making the toys function optimally, they are medicated effectively. Good technique (i.e. a steady tidal breathing pattern) is thereby rewarded by optimal toy performance. In contrast, shallow hyperventilation does not result in effective toy function. The Funhaler has been designed such that the toy module can be replaced with alternative toys in the future. However, this pilot study focuses on the effect of a single toy on compliance. Preliminary *in vitro* output and particle

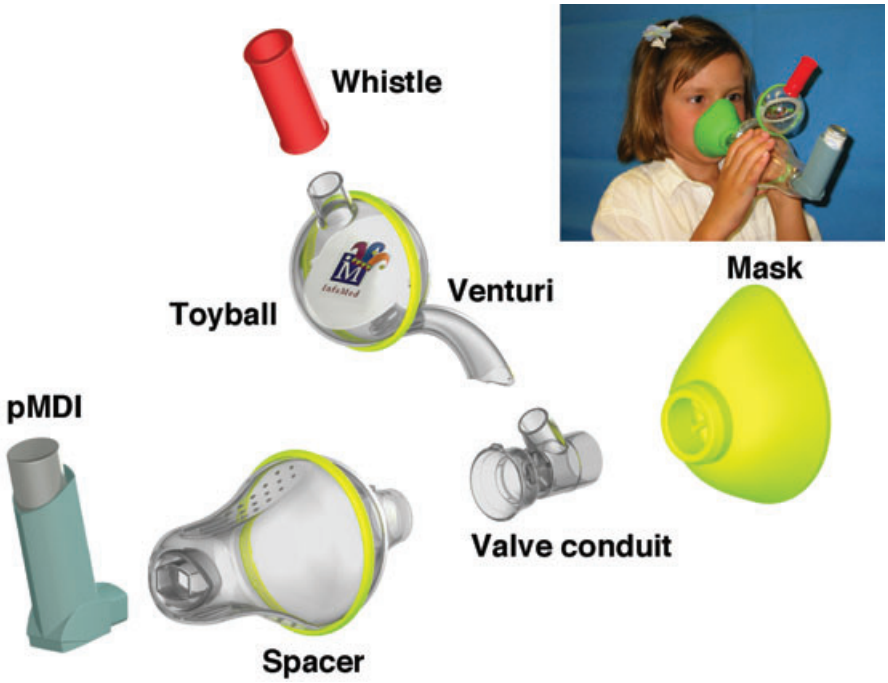

Figure 1 The Funhaler Device.

size measurements on the Funhaler spacer prototype showed the output of 'respirable' particles to be comparable to that of a leading commercial small volume spacer.

Questionnaires and statistical analysis

The two matched questionnaires were specifically designed for the study by the investigators to monitor a range of measures of attitude and adherence to recommended technique and frequency of medication. The questionnaires were validated by a biostatistician and a psychologist. Information collected related to the child's baseline characteristics, problems associated with the delivery of medication, parental and child compliance in using the device, the treatment attitude of the child as well as the parents' approach to medicating using the device. Parents could answer most questions only by indicating 'yes' or 'no', or by selecting the most appropriate answer from a predetermined list of responses. The two sets of results were compared using McNemar χ^2 tests.

RESULTS

Baseline characteristics

A total of 32 children, prescribed drugs delivered by pMDI and spacer, were recruited into the study and matched questionnaires were completed, with 27–32 valid responses to each pair of questions being collected. The baseline results are displayed in Table 1. In total, 22 children were male and 10 were female and the age range was 1.5–6 years with a mean age of 3.2 years and an average duration of asthma of 2.2

Table 1 Age, gender, duration of asthma, and asthma medication devices used at the start of the study. Percentage of valid cases is indicated in brackets

Total no. cases	No. responses 32 (100)
Age	
< 1 year	0 (0)
1 year	1 (3)
2 years	7 (22)
3 years	13 (41)
> 4 years	11 (34)
Total no. of valid cases	32 (100)
Gender	
Male	22 (69)
Female	10 (31)
Total no. valid cases	32 (100)
Duration of asthma	
< 1 year	7 (22)
1–2 years	6 (19)
2–3 years	10 (31)
3–4 years	6 (19)
> 4 years	3 (9)
Total no. valid cases	32 (100)
Devices used	
Spacer with face mask	25 (81)
Spacer without face mask	14 (45)
Turbuhaler	1 (3)
Nebuliser	25 (81)
MDI without spacer device	7 (23)
Total no. valid cases*	31 (100)

*Some subjects gave more than one response.

years. A total of 75% of children in the study were 3 years of age or older. A history of previous asthma device use was also taken. In total, 25 children had used a spacer device with face mask, 14 had used a spacer without a mask, 25 had used a nebuliser at some time, seven had used a metered dose inhaler with no spacer, and only one child had used a Turbuhaler (Astra-Zeneca).

Adherence to prescribed frequency and technique of medication

With the device they currently used, 59% of children (16/27) were found to have been medicated the previous day on random questioning of parents, compared to 81% (22/27) when using the Funhaler ($P = 0.016$, Table 2). Furthermore, the recommended four or more breath cycles per aerosol delivery were achieved regularly while medicating using the currently used device in only half (15/30) of patients. In contrast, 80% (24/30) of children using the Funhaler achieved the recommended four or more breath cycles. Of the remaining 15 patients achieving less than four breaths with the conventional spacer, 11 achieved four or more breaths regularly with the Funhaler ($P = 0.022$, Table 3).

Problems associated with delivery of medication by spacers

When using their existing spacer device, only 3/30 parents reported being always successful in medicating their children, compared to 22/30 when using the Funhaler ($P < 0.001$, Table 4). Of the parents who were unsuccessful with the conventional spacer, 19 became always successful in medicating when switching to the Funhaler.

Of the parents who were not always successful in delivering medication to their children using the existing device, 17 became successful with time and practice, leaving 11 who never succeeded. When these 11 were changed to the Funhaler, seven were successful immediately, one became successful with time, and only three continued to have problems. In general, parents who could not overcome their problems with medicating their children usually resorted to using a nebuliser, explaining the large overlap in nebuliser and pMDI usage (Table 3).

Table 2 Cross-tabulation for the question 'Did you medicate your child yesterday?'

	Did you medicate your child yesterday? (Funhaler)			
	No	Yes	Total	Significance (Binomial distribution used)
Did you medicate your child yesterday? (existing spacer device):				
No	5	6	11	
Yes	0	16	16	$P = 0.016$
Total	5	22	27	

Table 3 Cross-tabulation for the number of breaths usually inhaled by child through the device

	No. breaths usually inhaled by child through the device (Funhaler)			
	< 4	≥ 4	Total	Significance (Binomial distribution used)
No. of breaths usually inhaled by child through existing spacer device				
< 4	4	11	15	
≥ 4	2	13	15	$P = 0.022$
Total	6	24	30	

Table 4 Cross-tabulation of parental reporting of success in medicating their child using the device. Numbers refer to the number of valid responses

	Success in medicating child (Funhaler)			
	Not always	Always	Total	Significance (Binomial distribution used)
Success in medicating child (existing spacer device)				
Not always	8	19	27	
Always	0	3	3	$P < 0.001$
Total	8	22	30	

Table 5 Problems associated with the delivery of medication using the Funhaler compared to the existing spacer device. Percentage of valid cases is indicated in brackets

	No valid responses*	
	Existing spacer	Funhaler
If not always successful in using device, parent's general experience in delivering medication to child:		
No problems (i.e."always successful")	3 (10)	23 (74)
Experienced problems at first but eventually managed to use device successfully	17 (55)	4 (13)
Experienced problems at first and did not manage to overcome them	9 (29)	3 (10)
Experienced problems at first which got worse with each use	2 (6)	1 (3)
Total no. valid cases	31 (100)	31 (100)
If not always successful in using device, parent:		
Experienced no problems (i.e."always successful")	3 (10)	23 (74)
Persisted in using device	16 (52)	5 (16)
Resorted to another delivery method	12 (39)	3 (10)
Total no. valid cases	31 (100)	31 (100)
If not always successful in using device, problem(s) experienced by child when using the device:		
No problems (i.e."always successful")	3 (10)	23 (74)
Unwilling to use the mask	18 (58)	1 (3)
Unwilling to breathe through the device at all	19 (61)	2 (7)
Breathes through the device, but not deeply	21 (68)	6 (19)
Unwilling to breathe for very long through the device (e.g. for a period to the count of 1 s)	19 (61)	4 (13)
Struggles a little	10 (32)	3 (10)
Struggles a lot	11 (35)	1 (3)
Screams when device is brought close to face	15 (48)	1 (3)
Total no. valid cases	31 (100)	31 (100)

*Some subjects gave more than one response.

Table 6 Child's attitude to using their device and parental approach to medicating their child. Percentage of valid cases is indicated in brackets

	No. valid responses*	
	Existing spacer device	Funhaler
Child's attitude to using their device:		
Pleasure	3 (10)	21 (68)
Acceptance	18 (58)	6 (19)
No interest in device	1 (3)	1 (3)
Suspicion	0 (0)	3 (10)
Mild fear or dislike	4 (13)	0 (0)
Strong fear or dislike	6 (19)	0 (0)
Panic or phobia	2 (6)	0 (0)
Total no. valid cases	31 (100)	31 (100)
Parent's approach to medicating their child:		
Completely happy	3 (10)	19 (61)
Confident	10 (32)	5 (16)
Acceptance	12 (39)	6 (19)
Mild concern	2 (7)	1 (3)
Strong concern	4 (13)	0 (0)
Dislike	5 (16)	0 (0)
Total no. valid cases	31 (100)	31 (100)

*Some subjects gave more than one response.

Use of the Funhaler was associated with fewer problems for children (Table 5). Most children experienced one or more problems when using their existing device, including screaming when the device was brought close to the face ($n = 15$), unwillingness to breathe through the device ($n = 19$) or use the face mask ($n = 18$), unwillingness to breathe for long ($n = 19$), unable to breathe deeply ($n = 21$), and struggling a little ($n = 10$) or struggling a lot ($n = 11$). However, when children switched to the Funhaler, the incidence of these problems was much lower (Table 5).

Treatment attitude and approach

The attitudes of the children towards the Funhaler device were very positive (Table 6). When using their existing device, many children showed fear, ranging from mild fear/dislike to panic or phobia ($n = 13$, overall), and in only three cases was the attitude one of pleasure. In contrast, when switched to the Funhaler there was a dramatic turnaround in the numbers of children displaying attitudes of pleasure ($n = 21$). Furthermore, no children showed any signs of fear or dislike when using the Funhaler.

Parents' attitude to medicating their children was also much improved with the Funhaler (Table 6). Using the Funhaler, around 60% of parents felt they had a 'completely happy' approach and no parents indicated strong concerns or dislike. In contrast, when using the existing device, parents reported their approach to be completely happy in only 10% of cases, while an attitude of strong concern or dislike was reported in 13% and 16% of cases, respectively. As a negative, the Funhaler apparently elicited more 'suspicion' (10% of cases) than the conventional spacer device, for which no instances of suspicion were recorded.

DISCUSSION

In this study, use of a novel, incentive spacer device—the Funhaler spacer—was associated with increased success in medicating children, based on parental assessment. When using the Funhaler device, 73% of parents indicated they were always successful, compared to a success rate of only 10% when using the existing device ($P < 0.001$ on cross-tabulation). Interestingly, of the parents who were not always successful in using a conventional spacer device, approximately half persisted with the device while the remainder turned to another delivery system — usually a nebuliser. Parents resorted to using a nebuliser in only three out of 31 children using the Funhaler. The Funhaler may have the potential to reduce unnecessary use of nebulised therapy in young children. When using the Funhaler spacer, children also experienced fewer problems. There was a lower incidence of unwillingness to breathe through the device or to use the face mask, when using the Funhaler compared to the existing device and there was also significantly less screaming and struggling when using the Funhaler. Use of the Funhaler was associated with improved parental and child compliance. When called at random, more parents were found to have medicated their children the previous day when using the Funhaler, compared to their existing device and many more children inhaled the recommended four or more cycles per aerosol delivery when using the Funhaler. These striking effects are unlikely to be simply due to a recruitment effect, since the reported compliance levels with the conventional spacer matched levels measured by electronic recorders. Moreover, any postulated recruitment effect would need to have been greatly more pronounced with the Funhaler, regardless of the fact that the group using the standard spacer were completely unaware of the Funhaler while being tested.

Use of the Funhaler device was associated with a more positive attitude towards treatment in children, and an improved approach to medicating by parents when using this device. When using the Funhaler, around 68% of children were reported to show an attitude of pleasure compared to only 10% when using their existing device, while about 60% of parents designated their attitude as 'completely happy' when medicating their children using the Funhaler spacer, compared to only 10% when using their existing conventional spacers.

Importantly, non-compliant parents who had failed to medicate with the conventional device could be converted to compliance. More than half of the parents who on random questioning had not medicated with the conventional device were converted to compliance (in offering medication) when the Funhaler was used.

The design of this pilot study did not involve a cross-over component. Functional and aesthetic differences between the Funhaler and standard spacer devices are so obvious to children and care-givers as to make their comparison by blinded cross-over studies unintelligible. Indeed, we have frequently observed apparent disappointment in children who were involved in the Funhaler study, upon returning to use of standard spacer devices. The effect of such a switch would significantly confound any cross-over approach and, given the data reported here, might be expected to create a bias of the results in favour of the Funhaler and was, therefore, avoided. It is formally possible that the apparent improvements in adherence associated with the Funhaler device were simply a function of novelty. However, such a recruitment effect would not explain the unusually high levels of adherence to appropriate technique with the new device in a short period of time, which suggest that it may function naturally as a teaching-aid for children. This possibility would best be investigated further by analysis of video footage of children learning techniques with the two kinds of spacer device. Moreover, since the completion of this pilot study, many parents have reported anecdotally that their children had continued to derive pleasure from the device after many months of use. The opposite effect of increased suspicion of the new device is a concern with the Funhaler. It will be important to assess whether this effect is apparent in longer-term studies. The important issue of the duration of the apparent compliance effect we observed should be addressed in future studies. In such studies it would also be interesting to address the effect of exchanging toy modules on the Funhaler in an attempt to reduce the likelihood that the child will tire of playing with a single device. Another possibility which should be investigated in studies with spacer-naïve children, is whether even short-term interest in a device such as the Funhaler can be a useful tool in overcoming long-term negative associations resulting from an initial fearful exposure to spacers, which is prohibitive for some children.

Several features of devices such as the Funhaler may have contributed to its apparent success in this pilot study: first, the presence of audible and visual incentive toys; second, the linkage of toy function to a tidal breathing technique; third, the ability to incrementally reward improved effort with corresponding improvement in toy function (i.e. acceleration of disk, improved whistle tone); and finally, the use of bright colours to distract attention from the medication purpose of the device, identifying it to the child as a toy. The question of which of these features contribute most to the acceptability of the Funhaler could be addressed through a comparative study in which these incentive components are sequentially eliminated.

Published studies assessing the impact of intervention on medical compliance in asthmatic children have demonstrated a 1.3-fold improvement in compliance with the introduction of an educational programme,[29] and a 1.8-fold improvement with a combination of educational and behavioural strategies.[30] The 1.6-fold improvement in compliance with technique (with the recommended four or more breath cycles per aerosol delivery), achieved with the introduction of the Funhaler device was comparable with these interventions. The observed 1.4-fold improvement in the rate of offering medication with the Funhaler is also encouraging.

Based on the preliminary data from the pilot study, the Funhaler has the potential to have a significant impact on the management of paediatric asthma. However, it needs to be established whether the observed increase in compliance using the Funhaler is translated into better outcomes for children. There is much evidence linking poor compliance to morbidity in asthmatic children, and data showing that compliance with recommended medication regimes is translated into reduced unscheduled asthma admissions to hospital.[31] Hence, with the improvement in compliance the Funhaler spacer offers, it has the potential to decrease the burden of preventable hospitalisation in preschool-age children. Given that the Funhaler has recently been shown not to compromise the delivery of appropriately-sized aerosol drug particles when tested with a standard instrument *in vitro*,[28] the likelihood that its use may be associated with improvements in efficacy of treatment is increased. These encouraging findings need to be confirmed in a multicentre-controlled trial of young spacer-naïve children, randomised for Funhaler or standard spacer use, with an extended follow-up period, and allowing for a greater number of children under 3 years of age.

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