Measured bronchodilator use in preschool children with asthma

Allison E Ferguson, Neil A Gibson, Thomas C Aitchison, James Y Paton

Abstract

***Objective*—To investigate how parents use bronchodilator treatment for relief of symptoms when treating their asthmatic preschool children.**

***Design*—A commercial electromechanical timer device was attached to a large volume spacer to record the time and date of each use of inhaled bronchodilator over two months. The recorded time and dates were compared with symptoms noted in an asthma diary card.**

***Setting*—Large paediatric teaching hospital in Glasgow.**

***Subjects*—29 preschool children with moderately severe asthma attending a specialist paediatric asthma clinic.**

***Main outcome measures*—Inhaler use measured by the timer device; symptoms and inhaler use recorded by parents in a daily asthma diary.**

***Results*—Satisfactory data were obtained in 22 of the 29 children; the median number of study days was 53 (range 18-77). Asthmatic symptoms were recorded on a median of 30 (3-77) days. Bronchodilator was used on a median of 19 (2-73) days, or on 63% (7-100%) of days when symptoms occurred. The median number of puffs used in a day was 1 (range 0-100) and was significantly related to symptom severity in only 14 of the 22 children. In only two of the 22 children was bronchodilator given more frequently than four hourly, and only five children ever used more than 12 puffs a day.**

***Conclusions*—The frequency of parental administration of bronchodilator treatment was variable and not closely related to the parent's record of symptom severity. Parents often recorded symptoms in their children but did not treat them.**

Introduction

The incidence and prevalence of asthma is increasing worldwide, particularly in young children.[1] Recently, there have been concerns that regular or excessive β_2 agonist bronchodilator use in asthmatic adults may be associated with deterioration in control of symptoms[2] and an increase in mortality.[3] As a result, the recommendation that bronchodilators should be used as required for symptom relief rather than regularly has been reinforced.[4]

With the development of electromechanical timer devices incorporating microprocessors, patterns of drug usage can be recorded objectively. For example, inhaler timer devices have been used successfully to monitor adherence to prophylactic inhaled treatment in asthmatic adults and older children.[5-7] Such devices record the time of each actuation and allow the observed pattern of inhaler use to be compared with reported use and with recorded symptoms. Such an approach avoids many of the errors encountered with other means of measuring the use of inhaled drugs. To our knowledge, there are no objective data in preschool asthmatic children comparing the prescribing doctor's advice on inhaled treatment with parents' administration of these treatments to their asthmatic children.

Increasingly, metered dose inhalers attached to large volume spacers are being used to administer both bronchodilators and preventive asthma treatment in young children. We used an electromechanical timer device fitted to a metered dose inhaler and spacer (*a*) to investigate parental administration of inhaled bronchodilators that had been prescribed to be used as required for symptom relief to preschool children with asthma and (*b*) to relate use to symptoms recorded by parents in an asthma diary card.

Subjects and methods

SUBJECTS

The parents of 29 preschool asthmatic children (median age 3 years 5 months (range 15 months to 5 years)) took part in the study. All children had moderately severe asthma that was treated with inhaled drugs through a large volume spacer device. All were attending a specialist paediatric respiratory clinic.

Initially, every parent received an oral explanation of the study and its aims. On a subsequent visit, inhaler timer devices and diary cards were issued. Their technique with the spacer device was checked and corrected if necessary. Each parent also completed a short questionnaire giving details of household members, number of siblings, arrangements for childcare during the day, and the person who usually gave the drugs.

DRUG TREATMENT

Our study was observational, and no changes were made to the child's prescribed treatment. All children who took part had been taking their treatment for at least one month before entry to the study. In each case treatment consisted of regular prophylactic treatment (beclomethasone dipropionate, budesonide, or sodium cromoglycate) and relief treatment (terbutaline or salbutamol). All were receiving their inhaled drugs through a large volume spacer device (Nebuhaler or Volumatic) and used a five breath technique.[8] Parents were advised to use the relief treatment as required. More specifically, they were advised to use bronchodilators when their child had symptoms of coughing or wheezing. In this group, we did not advise the parents to give bronchodilators prophylactically, before exercise, or routinely during an upper respiratory tract infection. None of the families in the study had nebulisers and none had additional bronchodilator treatment (oral or nebulised).

TIMER DEVICES

The Nebulizer Chronolog (model NC300, Forefront Technologies, Lakewood, Colorado) incorporates an electromechanical timer device which replaces the standard plastic metered dose inhaler holder and records the date and time of each actuation of the inhaler. The Nebulizer Chronolog was initialised by a

Department of Child Health, Royal Hospital for Sick Children, Glasgow G3 8SJ
Allison E Ferguson, *senior registrar*
Neil A Gibson, *senior registrar*
James Y Paton, *senior registrar*

Department of Statistics, University of Glasgow, Glasgow G12 8QQ
Thomas C Aitchison, *lecturer*

Correspondence to:
Dr Ferguson.

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special adaptor attached to an IBM computer with custom software. It was then loaded with the bronchodilator canister and fitted to a large volume spacer (fig 1).

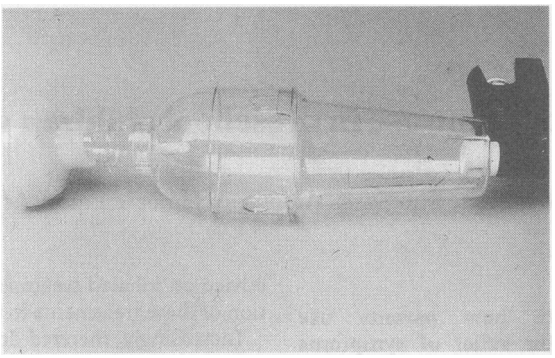

FIG 1—*Nebulizer Cronolog fitted to large volume spacer device*

DIARY CARDS

Children were studied over two months. At the initial visit the parents were supplied with diary cards to record the child's symptoms daily in each of four categories: daytime cough, daytime wheeze, night time cough or wheeze, and breathlessness. They were asked to give a score for each symptom category, no symptoms being scored 0, mild symptoms 1, moderate 2, and severe 3, with the maximum daily score being 12. They were also asked to record in the diary the number of times bronchodilator drugs were used each day and to note any actuations without inhalation—for example, from test firing a new canister before use or as the result of the child playing with the device. Each parent was contacted by telephone two weeks after the start of the study to check whether any problems had been encountered. The children were reviewed at a return visit two months later, at the end of the study, when the data were collected.

INFORMATION GIVEN TO PARENTS

We were concerned to ensure that the parents understood the purpose and nature of the study. At the time of issue the parents were informed of the accuracy of the timer device and made aware that it recorded the time and date of each actuation. When the devices were issued, each one was labelled with the name of the drug and its dosage instructions—for example, salbutamol, two puffs, for cough or wheeze. Each child's prescribed regimen was also written on a standard card (National Asthma Campaign, London). Lastly, the parents were given an information sheet explaining the nature of the timing device and the rationale of the study. This again explained that the device counted and timed the actuations of each inhaler.

DATA PRODUCTION

At the end of the study the data from the timer device were read into the computer; a printout of the times and dates of each actuation of the bronchodilator medication was obtained. A total symptom score for each day was calculated from the diaries.

STATISTICAL METHODS

The data on each individual subject were plotted both as two time series—that is, number of puffs and severity of symptoms against day number—and as a bivariate plot of number of puffs against symptom score ignoring the day number. Since the number of puffs is an integer, the potential dependence of the number of puffs on the severity score was modelled as a Poisson random variable whose average value was the exponential of a linear function of severity score (a standard model in the statistical regression analysis of counts data). For each subject a Poisson log-linear regression was carried out relating number of puffs as a response variable to the symptom score as an explanatory variable. The significance of the slope parameter was used to assess whether any relation between the number of puffs and symptom score existed for each subject. A time series analysis of the residuals from each subject's Poisson regression was then carried out to investigate whether the regression had removed the effect of autocorrelation between successive days on either of the variables.

ETHICS

The study protocol was approved by the Ethics Committee of the Royal Hospital for Sick Children, Glasgow. Written informed consent was obtained from each parent after the study had been fully explained to them.

Results

Twenty nine children were recruited over 13 months. For one child neither device nor diary card was returned despite numerous appointments and offers of home visits. Of the remaining 28 (table I), 25 had satisfactory data from the timer device and three did not. The parents of three other children did not keep or return the diary cards. Full comparison of symptoms and bronchodilator use was therefore possible in only 22 children.

TABLE I—*Details of children participating in study*

Variable	
No of children	28
Sex:	
No of boys	15
No of girls	13
Age:	
Median	3 years 5 months
Range	15 months to 5 years
Time receiving inhaled treatment (months):	
<3	5
3-12	17
>12	6

The median number of study days was 53 (range 18 to 77). The median individual number of symptom days was 30 (3-77) and the median individual number of days that bronchodilator was used was 19 (2-73)), or 63% (7-100%) of days when symptoms occurred.

GENERAL OBSERVATIONS

The total number of puffs given on each symptom day was low (median 1, range 0-100), even on days when high symptom scores were recorded.

Only five out of 22 children ever received more than 12 puffs daily (equivalent to two puffs four hourly). In two children this occurred on days with high symptom scores, the number of puffs used each day being 14, 14, 23, 22, and 33. In the three others 20-100 puffs were recorded within four minutes. This was consistent with repeated actuation of the metered dose inhaler over a short time but the parents did not report any symptoms or record an explanation. (A similar finding of repeated actuations over a short time has been noted in other studies using inhaler timers and has been termed canister dumping.[5,7]) When this discrepancy was pointed out to parents, no explanation was offered. To ensure that the finding was not due to the mechanical microswitch of the device sticking, we tested several devices by keeping the aerosol depressed for 20 minutes at a time. In each case such a test produced only one time entry on the computer printout, this being the time when the aerosol was first depressed.

The pattern of use throughout the day was fairly consistent for all children. Most bronchodilator doses

were given in the morning and evening, with only a few being given in the middle part of the day. Doses were rarely given overnight (despite frequent recording of nocturnal symptoms). Interestingly, we found that on 80% (478/598) of occasions bronchodilator was given within five minutes of the prophylactic treatment.

Diary card recording of bronchodilator use was inaccurate when compared with the data from the timer device. There were discrepancies between reported and recorded inhaler use in all patients, eight patients differing from recorded data on more than 10 study days. The tendency was always to underreport bronchodilator use.

RELATION BETWEEN SYMPTOM SEVERITY AND BRONCHODILATOR USE

Data plots—Plots of the number of puffs against severity score for each of the 22 subjects for each day were studied. In most cases the pattern for the number of puffs and that for symptom score were similar. In other cases there was little evidence of a relation. A representative sample of these plots is shown in figure 2.

Poisson regression showed that in 14 out of 22 children the number of puffs depended in a log-linear fashion on the severity of symptoms ($P < 0{\cdot}05$). A time series of analysis of the residuals showed that in most subjects there was no significant autocorrelation with respect to any previous day. Accordingly, the Poisson regression model ignoring a day effect substantially removed any day effect and therefore had adequately allowed for the fact that the data were observed on consecutive days. From the 95% confidence intervals for the individual slopes 14 of the 22 subjects had a significant positive relation between the number of puffs and the severity of symptoms (fig 3). Three of the intervals (cases 7, 12, and 22) were extremely wide because they showed, if anything, a negative relation with a restricted range of symptom scores.

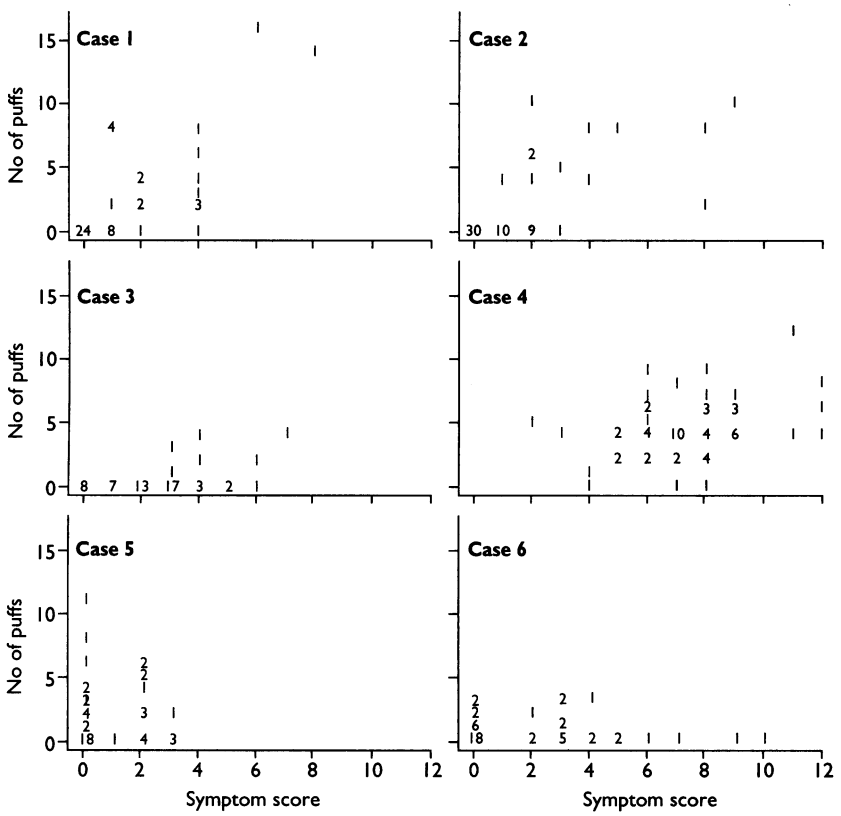

FIG 2—*Representative plots showing numbers of measured puffs administered against symptom scores for six children. Numbers refer to number of days when each treatment-symptom profile was obtained. Cases 1-4 show evidence of significant positive relation between symptom score and measured puffs. In case 5 there are few recorded symptoms but frequent bronchodilator use, and in case 6 there are symptoms but infrequent bronchodilator use*

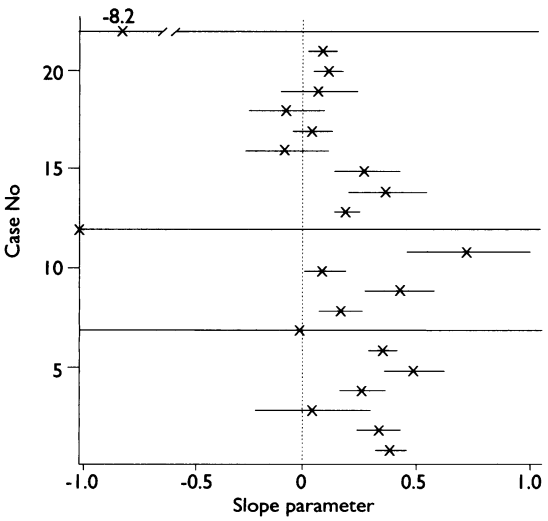

FIG 3—*Approximate 95% confidence intervals for individual slope parameters in Poisson regression equation. In 14 children the interval did not include 0, indicating a significant positive relation between number of puffs and severity of symptoms*

RELATIONSHIP BETWEEN SIBLINGS, CARE DURING THE DAY, AND BRONCHODILATOR USE

We also compared bronchodilator use in children according to the number of siblings and whether they were looked after during the day in a nursery on a part time or full time basis. Neither the number of children in the family nor whether children were cared for at home or in nursery during the day seemed to make a significant difference to bronchodilator administration (table II).

TABLE II—*Bronchodilator use related to number of siblings in the family and day care provision*

Home circumstances	Proportion (%) of symptom days with bronchodilator use
No of siblings:	
0 (n=10)	98/286 (34)
1 (n=6)	175/254 (69)
≥2 (n=6)	120/202 (59)
Day care use:	
None (n=10)	157/303 (52)
Part time (n=11)	234/423 (55)
Full time (n=1)	2/16 (13)

Discussion

To our knowledge, our study is the first to investigate parental use of bronchodilators in preschool children with asthma, and the results provide several interesting insights.

Firstly, parents do not rely excessively on bronchodilator drugs when treating their child's asthma. With the exception of three cases in which the canister was actuated between 20 and 100 times in four minutes (possible canister dumping[5]), the maximum amount of bronchodilator used in a single day was 33 puffs of terbutaline. This is roughly equivalent to only four administrations of the age appropriate nebulised dose of terbutaline (2 mg) in a day. In general, even when the child had symptoms of asthma parents tended to give infrequent doses on only a few days. We also noted that, despite instructions to use the bronchodilator as required, most doses of bronchodilator were given within five minutes after the children inhaled prophylactic drugs.

Secondly, the number of puffs administered did not seem to be related to the severity of symptoms. In only 14 of the 22 children studied was there evidence of a significant positive relation between recorded symptom severity and measured bronchodilator use, with parents increasing the amount of bronchodilator

administered in the presence of higher symptom scores. More surprising was the fact that in eight of the 22 children the number of bronchodilator puffs administered showed no dependence on the severity of symptoms. Overall, there was no evidence that the number of puffs administered was strongly dependent on the severity of the symptoms in this group of asthmatic children.

UNDERUSE OF BRONCHODILATORS

Parents may underuse bronchodilators for several reasons. Firstly, parents underreport bronchodilator use. They may also have underreported symptoms but administered treatment appropriate to the symptoms that were present. Against this, the overall finding was of infrequent bronchodilator use rather than frequent unexplained use.

Secondly, preschool children depend on their parent or guardian noting that they have symptoms and then giving the treament. Parents may be comparatively unaware of their child's need for relief treatment. Alternatively, a parent may notice the symptoms but be concerned about possible side effects of bronchodilators. It may also be relevant that parents, unlike adult asthmatic patients, do not experience the rapid relief of symptoms brought about by β_2 agonists. Unfortunately, we did not ask the parents if they were themselves currently using bronchodilators for asthma and cannot therefore comment on whether asthmatic parents administer bronchodilators more readily.

Finally, it may be that our educational efforts to emphasise the difference between regular or preventive treatment and emergency or relief treatment may have discouraged the use of bronchodilators except for quite severe symptoms. Whatever the reasons, the effect was that the young children in this study received bronchodilators comparatively infrequently for mild to moderate reported asthma symptoms.

OTHER FACTORS AFFECTING USE OF BRONCHODILATORS

Neither the number of siblings nor whether children were looked after in a nursery during the day seemed to influence frequency of bronchodilator use.

Perhaps most surprisingly, in view of the information given to the parents, we found occasional evidence of canister dumping. This behaviour has also been recorded in studies using inhaler timers in adults and older children.[5,7] In canister dumping, patients actuate the inhaler repetitively but are thought not to inhale the drug. In adults the reasons for this behaviour are not known and seem to be unrelated to asthma symptoms.

In studies of adherence to an inhaled prophylactic regimen adult patients and older children have tended to overestimate their use of regular inhaled drug treatment.[5-7] In contrast, the parents underestimated bronchodilator use in our study. One possible explanation is that a target exists for prophylactic treatment (the prescribed dose). Patients may overreport to approach this, whereas there is no such target for bronchodilator use. The discrepancy noted between observed and reported bronchodilator use again emphasised that diary cards are not a reliable source of information about asthma, either for accurate assessment of symptoms or for the use of drugs.[6,9]

The fact that parents seemed to administer bronchodilator rather erratically and tended to report symptoms without treating them suggests that there is scope for improvements in educating parents. At the very least, the prescription of bronchodilators for relief of symptoms as required needs to be defined more clearly.

Although studies have suggested that a better understanding of asthma and its treatment improves the use of drugs, such assessments have been based on patient questionnaires alone. The correlation requires to be reassessed using more objective measures of drug use. In the future, obtaining information on when inhaled medicines are used in young children may result in prescribing strategies more in keeping with parental practice. Such an empirical approach may encourage better use of drugs. For example, if parents tend to use bronchodilators mainly in the morning and evening, twice daily, long acting bronchodilators might be a more appropriate therapeutic strategy than bronchodilator as required. Another example is the recent revival of interest in the use of combined prophylactic-bronchodilator inhalers in adults, in the hope that prophylactic treatment would then be used more frequently.[10] Our study suggests that such a strategy is not likely to be useful in young children in whom inhaled bronchodilators are at present used infrequently when symptoms are mild to moderate.

In conclusion, we have found that parents of young asthmatic children tend to administer inhaled bronchodilators infrequently even when they report clinically significant symptoms and that the number of doses given does not always relate to the severity of symptoms.

Key messages

- Parents of young asthmatic children tend to give bronchodilators infrequently, even when they record clinically significant symptoms; they do not administer bronchodilators excessively
- Bronchodilators, if given, tend to be administered at the same time as prophylactic inhaled drugs
- The role of bronchodilator treatment in relieving the child's symptoms and guidelines about appropriate use must be emphasised to parents

We thank the parents who took part in the study. The Chronolog inhaler timers were funded by the Faculty of Medicine, University of Glasgow.

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Correction

Pressor reactions to psychological stress and prediction of future blood pressure: data from the Whitehall II study

An editorial error ocurred in this paper by Professor Douglas Carroll and others (25 March, pp 771-6). In table III the correlation coefficients between follow up systolic blood pressure and laboratory baseline systolic blood pressure and baseline diastolic blood pressure should have read 0·58** and 0·39** respectively rather than −0·58** and −0·39** as published (**$P<0·01$).