# EFFECT OF THE WHISTLE WATCH DEVICE ON BRONCHODILATOR USE IN CHILDREN WITH ASTHMA

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*Objective.* To determine if the use of the whistle watch (WW), a simple device to monitor peak flow rate, affects the use of bronchodilators at home.

*Study design.* Prospective, randomised, crossover design.

*Setting.* The asthma outpatients' clinic at Coronation Hospital, a tertiary care centre in Johannesburg.

*Patients and methods.* Children between 6 and 18 years of age with moderate or severe asthma for more than a year were enrolled. They were randomised into two groups, with bronchodilator use determined either by the WW or solely by the patient's perceived symptomatology. The patients acted as their own controls, switching over to the other group after 30 days. Eighty patients were enrolled into the study.

*Results.* Forty-three patients completed the study (54%). There were no significant differences between these patients and those who did not complete the study in terms of sex, age and treatment characteristics. There was a significant reduction in the mean monthly number of bronchodilator doses used by the WW group (5.5 doses v. 16.81 doses, paired *t*-test, $t = 3.64$, $P < 0.001$, 95% confidence interval (CI) 6.1 - 16.55). The change in individual participants varied between 13 extra bronchodilator doses and 71 fewer doses per month with the use of the WW device.

*Conclusion.* The WW device is a cheap, easy-to-use and effective tool that reduces the number of bronchodilator doses used by asthmatic children at home.

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Effective management of childhood asthma consists of a combination of appropriate drug therapy, education of caregivers, and home monitoring of peak expiratory flow rate.[1] The latter is of special importance as asthma sufferers are often unaware of their need for bronchodilator therapy. Studies have shown that patients can monitor their own peak flow reliably by using portable peak flow meters.[2]

Peak flow meters, however, have some disadvantages. They can be inaccurate and they are based on an effort-dependent manoeuvre. The patient must be numeral literate to be able to measure the peak flow and to compare it with the best predicted value. In addition, the portable peak flow meters are relatively expensive (present cost approximately R90 - R200),[3] and are not child-friendly.

The whistle watch (WW), first introduced in 1998,[4] is an alternative device. It has many advantages. It is much cheaper (R21.50 — State hospital price), its accuracy has been established,[4] it is pocket-sized, and it is lighter than other peak flow meters. It is also a child-friendly device and its whistling tone encourages the co-operation of children, which results in greater expiratory effort by them. The device operates through a threshold-activated whistle to register peak flow. This threshold can be adjusted from 130 to 340 l/min, in steps of 10 l/min, by varying the size of the vent opening.[4] The lifespan of the device is at least 2 years.

As the WW appears to offer an objective way for the patient and the caregiver to monitor lung function at home, this study was undertaken to establish how the use of the WW would affect the frequency of bronchodilator use at home when compared with bronchodilator use based on symptomatology only.

## METHODS

### Subjects

Eighty asthmatic children were recruited from the paediatric asthma outpatient clinic at Coronation Hospital between February and September 1999. Coronation Hospital is a teaching hospital affiliated to the Department of Paediatrics of the University of the Witwatersrand and situated in Johannesburg, an urban environment.

### Inclusion criteria

Participants had to be between 6 and 18 years of age. They had to have a diagnosis of moderate asthma (symptoms such as cough, wheezing, etc. occurring up to once per week) or severe asthma (symptoms occurring more than once per week), requiring daily anti-inflammatory (inhaled steroid) therapy as well as the intermittent use of inhaled β-agonists. In addition, the children needed to be taller than 111 cm (a criterion for the effective use of the WW), not using conventional peak flow meters, and to have a history of good therapeutic compliance.

### Exclusion criteria

We excluded patients with newly diagnosed asthma (diagnosis made less than a year before the study), any case in which the

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diagnosis of asthma was uncertain, patients with other causes of wheezing (e.g. cardiac illness, known immune deficiency, known metabolic disease, confirmed gastro-oesophageal reflux), those with mental retardation, and cases where consent was refused.

### Study design

The study used a randomised, crossover design with subjects acting as their own controls. Block randomisation was used. Patients were randomised to either group A, who used the WW to determine their need for bronchodilators (therapeutic regimen 1), or to group B, who used bronchodilators at their own discretion (therapeutic regimen 2). After a 30-day period, the patients switched over from regimen 1 to regimen 2 for another 30 days.

### Description of the study groups

In group A, the WW group (therapeutic regimen 1), the children received instructions regarding the use of the WW. The threshold was set by the investigators at 80% of the patient's best peak expiratory flow rate. They were instructed to use the WW twice daily (morning and evening) and to record on charts whether they succeeded or failed to obtain an audible whistle. If a whistle was elicited there was no need for bronchodilators, and vice versa. Use of bronchodilators was also allowed in the event of asthma symptoms developing, or pre-exercise. Participants had to keep records of this.

In group B (therapeutic regimen 2), participants were instructed to use bronchodilators as needed. This is usually based on the occurrence of asthma symptoms (breathlessness, wheezing, cough, etc.). They, too, kept records of their use of bronchodilators.

### Study visits

The study period lasted for 60 days and the children were seen monthly.

During visit 1 (randomisation), eligible subjects were identified and randomised. Appropriate charts along with the WW (for therapeutic regimen 1) and user instructions were provided.

During visit 2, 30 days later, patient charts were checked. If the patients had followed the instructions correctly (100% recording on charts of bronchodilators and/or WW use), they switched from therapeutic regimen 1 to therapeutic regimen 2, and vice versa. The next appointment was booked for 30 days later. In cases where the patients had failed to follow instructions they were asked to continue with the same therapeutic regimen for another 30 days. Participants who failed to comply with the study instructions after two attempts were excluded from the study.

During visit 3 participant charts were reviewed. Those who had incorrectly/incompletely filled in charts were asked to repeat the same process for another 30 days.

Visit 4 was a final visit for chart retrieval.

### Sample size calculation

In calculating the sample size, a difference in the frequency of the use of bronchodilators of 10% between the two groups was considered to be clinically significant. Assuming that the frequency of bronchodilator use would vary from zero to three times a day, a minimum sample size of 32 patients in each group was required for statistical significance at a 5% level of significance and a power of 90%.

### Statistical analysis

Statistical significance testing for the effect of the WW on the number of doses of bronchodilators was done using the paired *t*-test. Groups were compared using the Z-test. A *P*-value of $< 0.05$ was considered to be statistically significant.

This was an investigator-initiated study. The WWs were provided free by HarMed and Boehringer Ingelheim. No other funds were obtained from these companies or other sources. Ethical clearance for the study was obtained from the Committee for Research on Human Subjects of the University of the Witwatersrand.

## RESULTS

### Dropouts

Thirty-seven patients (46%) were excluded from the analysis of the study; of these, 18 (49%) had incomplete charts. Eight patients were excluded after the first review of the charts (22%), and the remaining 10 after a second review (27%). Nineteen patients failed to return after enrolment in the study (24%). There was no significant difference between these 37 patients and those in the final analysis with regard to age, sex, parental education level, race, usual mode of transport, type of bronchodilator used, steroid use and randomisation groups.

### Subjects

Forty-three children were included in the final analysis of the study. The mean age was 10.7 years (range 6.8 - 16.4 years, standard deviation (SD) ± 2.44). Twenty-three of the children (53%) were male. The mean height was 141 cm (range 118.5 - 168.0). Twenty-one patients were on budesonide (Inflammide), 19 on fluticasone (Flixotide) and 3 on beclometasone (Becotide). Fenoterol (Berotec) was used by 28 participants, and 15 used salbutamol (Ventolin) as their bronchodilators. Twenty-two subjects (51%) were initially allocated to group B and the rest (49%) to group A. Information regarding ethnicity was available in 42 cases: 33 were coloured, 5 black and 3 Indian and 1 was white. The primary caregiver's level of education

was available in 34 cases: 1 parent had tertiary education, the educational level of 28 varied from Grade 9 to Grade 10, and in 5 others it was Grade 8 or less. Three subjects walked to the clinic, 9 children used family transport and 29 relied on public transport (information was unavailable in 2 cases).

### Bronchodilator usage

Bronchodilators were used significantly less in the WW group. The mean number of bronchodilator doses used per month was 5.46 ± 8.13 for group A, versus 16.81 ± 19.99 for group B (difference in mean = 11.33, $t = 3.64$, $P < 0.001$, df = 42) (Table I, Fig. 1). Ten cases showed an increase in bronchodilator doses used during the WW-usage period, and 33 cases (77%) used bronchodilators more during the phase of self-monitoring of symptoms (group B). Of the 43 patients, only 4 were using bronchodilators before exercise. No data were collected on how often participants were exercising.

**Table I. Frequency of the use of short-acting bronchodilators per month**

| Group | Mean[§] | Median | Range | SD | Paired *t*-test | *P*-value |
|---|---|---|---|---|---|---|
| Group A* | 5.46 | 1 | 0 - 31 | 8.13 | | |
| Group B† | 16.8 | 11 | 0 - 80 | 19.99 | | |
| A - B‡ | 11.33 | | | 20.38 | 3.64 | < 0.001 |

* Group A = whistle watch group.
† Group B = self-monitoring.
‡ Difference in the number of bronchodilator doses used between the two groups.
§ Mean number of bronchodilator doses used per month.

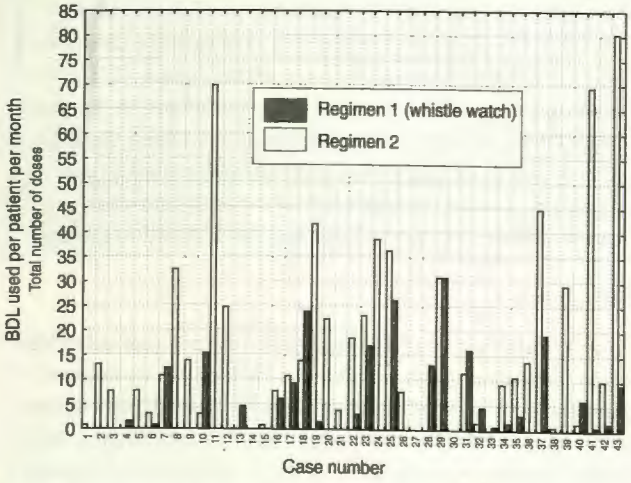


*Fig. 1. Differences in the use of short-acting bronchodilators by paediatric subjects. Therapeutic regimen 1: use of the whistle watch, therapeutic regimen 2: self-monitoring group.*

## Discussion

An accurate assessment of the severity of asthma is crucial for optimal management. This study found that paediatric subjects with moderate to severe asthma required 67% less bronchodilator use with the aid of the WW device compared with the amount used during self-monitoring, confirming the usefulness of the WW device. However, does less bronchodilator use by WW users correspond with better asthma management? The study cannot clearly answer this question. There were no acute asthma exacerbations requiring emergency care visits in either group. Therefore, the inference is that many asthmatic children and their parents/caregivers attribute many symptoms unnecessarily to asthma exacerbation and ignore other considerations or diagnoses (such as coryza, allergic rhinitis, sinusitis, etc.).

It is well established that children and/or their caregivers demonstrate considerable variation in the extent to which their subjective evaluations correspond with objective measures of airway obstruction.[5-10] Peak expiratory flow rate meters offer one such objective measure of pulmonary function which can enhance home self-management of asthma, including the more appropriate use of bronchodilators. Unfortunately, they are relatively expensive and may be inaccurate.[11-15] Studies have also shown that there is poor utilisation of these devices by families with asthmatic children (as few as 30% of families in one study).[16,17]

The WW offers an attractive alternative. It is much cheaper (costing R21.50), its accuracy has been established,[4] it is pocket-sized, and it is lighter than other peak flow meters. It is also a child-friendly device and its whistling tone encourages the co-operation of children, which results in greater expiratory effort by them.[4]

The cost savings that may be attained by the use of the device may also be substantial. Considering that use of the WW may save a mean of 11.3 bronchodilator doses monthly, this extrapolates to a saving of about R4.20 - R48.50 (depending on the bronchodilator used — State hospital prices) annually. This should be contrasted with the once-off cost of the WW device (R21.50). The lifespan of the device is at least 2 years.

The major limitation of this study is the high dropout rate. This is explained by two main factors. First, the requirement for absolute compliance with the study protocol (i.e. recording all bronchodilator use and/or WW readings), which should be an integral part of routine asthma monitoring and care, resulted in almost half of all dropouts. This highlights the fact that asthmatic patients often have poor understanding of their condition and fail to pay attention to detail in the management of this condition. Second, the poor socio-economic situation of patients (as evidenced by reliance on public transport, poor caregiver education levels, etc.) was the other major reason for dropouts. In these circumstances it is expected that the level of therapeutic inconstancy will also be high, and that perhaps the WW may motivate better compliance, particularly if combined with more appropriate and better-directed education. The results reaffirm the importance of more time being spent on

educating the children and their families about optimal asthma management.

Use of pre-exercise prophylaxis was low in this cohort. Only 4 patients (9%) were using bronchodilators before exercising. None of them was on a long-acting bronchodilator (Serevent), which may eliminate the need for exercise prophylaxis. Of the remaining 39 participants, 8 were on Serevent. While this pattern of pre-exercise bronchodilator use suggests a prevalence of 9 - 28% of exercise-induced asthma in this cohort, this figure is low compared with figures from other studies in which exercise-induced asthma was found to occur in up to 90% of asthmatics.[18] Indeed, on reviewing the records of 69 of the 80 patients enrolled in the study, as many as 52 cases (75%) had reported exercise-induced cough or/and wheezing.

In conclusion, the use of the WW decreased the utilisation of bronchodilators and offered a more rational approach to asthma management. It also provides cost benefits to a health service that is chronically underfunded. Furthermore, the study underlies the need for doctors to improve their communication skills with both asthmatic children and their parents.

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# ALLERGENICITY AND CROSS-REACTIVITY OF BUFFALO GRASS (*STENOTAPHRUM SECUNDATUM*)

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*Background.* In the subtropical climate of South Africa, grasses of the subfamily Panicoideae are predominant. Bermuda grass has previously been shown to be an important local allergen, and immunoglobulin E (IgE) epitopes of Bermuda grass extracts are known to be distinct from those of the Pooid pollen extracts. Following our demonstration of sensitivity in 43% of patients grass-allergic to the Panicoid, Kikuyu grass, we have studied the closely related buffalo grass, *Stenotaphrum secundatum*, indigenous to the Western Cape region, the east coast of Africa and the oceanic islands such as Mauritius; and *Eragrostis*, another common indigenous grass with a wide distribution.

*Objective.* To partially characterise the allergens of buffalo pollen, and examine its immunological relationships with local common grasses such as *Eragrostis* and Kikuyu.

*Methods.* Grass-allergic patients were evaluated clinically, and skin prick tests (SPTs) and radio-allergosorbent tests (RASTs) to Bermuda and grass mix were performed. Sera of timothy grass-sensitive patients from Belgium were also included in this study. Pollen extract from buffalo grass was characterised by specific IgE binding by means of immunoblotting and enzyme-linked immunosorbent assay (ELISA). Cross-reactivity between the grasses was studied by means of inhibition of IgE binding.

*Results.* More than 90% of grass-sensitive patients were found to have IgE antibodies to Buffalo and *Eragrostis* pollen. Inhibition of ELISA and immunoblots revealed that extracts of these grass pollens could significant inhibit IgE binding to the local grass pollens, Kikuyu, buffalo, *Eragrostis* and Bermuda on solid phase, but 100% inhibition was never achieved, indicating that cross-reactive but also unique epitopes are present. We also identified a subset of patients with negative RASTs to Bermuda, and minimal inhibition by Bermuda pollen extract.

*Conclusion.* Buffalo and *Eragrostis* are important aero-allergens in the Cape, dispersed during the long dry, windy summer. Our data suggest that the local grasses are major sensitisers, and that South African diagnostic panels should include extracts of buffalo and *Eragrostis* grasses.

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