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A randomised controlled trial of the Buteyko technique as an adjunct to conventional management of asthma [☆]

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Summary

Objective: To assess the effectiveness of a non-pharmacological intervention in patients with asthma on conventional therapy including inhaled corticosteroid.

Design: A randomised controlled trial of the Buteyko technique in a group of adults with asthma. The control group was trained by a physiotherapist in breathing and relaxation techniques.

Setting: A single centre associated with a University-based asthma programme.

Main outcome measure: Asthma control, defined by a composite score based on the Canadian asthma consensus report 6 months after completion of the intervention.

Results: Both groups showed substantial and similar improvement and a high proportion with asthma control 6 months after completion of the intervention. In the Buteyko group the proportion with asthma control increased from 40% to 79% and in the control group from 44% to 72%. In addition the Buteyko group had significantly reduced their inhaled corticosteroid therapy compared with the control group ($p = 0.02$). None of the other differences between the groups at 6 months were significant.

Conclusions: Six months after completion of the interventions, a large majority of subjects in each group displayed control of their asthma with the additional benefit of reduction in inhaled corticosteroid use in the Buteyko group. The Buteyko technique, an established and widely recognised intervention, or an intensive programme delivered by a

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chest physiotherapist appear to provide additional benefit for adult patients with asthma who are being treated with inhaled corticosteroid.

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Introduction

Asthma is a chronic disease, which affects up to 10% of the population of Canada.¹ The disease cannot be cured, but randomised clinical trials have shown that with efficacious medication approximately 70% of those with asthma can enjoy disease control.²⁻⁵ Control of asthma has been defined as not having any restriction in activities, not waking at night with asthma, not needing β_2 agonist therapy to relieve symptoms more than 3 times per week, not missing school or work because of asthma and not having severe exacerbations of asthma.⁶ Data from several studies in Canada have shown that only one in three to four people with the disease enjoy control of their asthma.⁷⁻¹⁰ It has been stated that some of the failure to control asthma relates to a widespread fear or dislike of medications, notably inhaled corticosteroid, which are used to manage asthma.¹¹ This apprehension has stimulated the development of several non-pharmaceutical approaches to the management of asthma. Many of these have been embraced without objective evidence for their efficacy. The assessment of many modalities of treatment of asthma has been impeded by the striking impact of the placebo effect in this disease.^{12,13} Improvement in asthma control has often been attributed to an intervention, which was coincidentally applied when asthma was improving because of the variable nature of the disease and the phenomenon of regression to the mean. In other words, those with asthma will often seek assistance during periods of very poor disease control. With time their disease will improve (back to its average state) and any new treatment which was applied is credited with the improvement. This concern is true also for the Buteyko breathing technique, which has a dedicated following, but to date, no rigorous data to support its efficacy.

The Buteyko breathing technique was developed by Dr. Konstantin Buteyko, a Russian physician who postulated that asthma was caused by hyperventilation. He proposed that all of the manifestations of asthma could be explained on the basis of low tension of CO₂. The Buteyko technique was developed to train those with asthma to reduce their ventilation.

There have been several studies, which claim success using the Buteyko technique,¹⁴⁻¹⁶ but these were either uncontrolled or showed only a trend towards improvement. Others have studied the technique and concluded that any benefit is not related to changes in ventilation.¹⁷ Three randomised controlled trials have been published recently: one comparing the Buteyko method with placebo and with the Pink City Lung Exerciser,¹⁸ one with education and relaxation classes¹⁹ and the third used video instruction in Buteyko and upper body exercises.²⁰ The first two presented data favouring the Buteyko technique while the third showed that both interventions produced an equivalent benefit. The present study is the first which was designed to

demonstrate in a randomised controlled trial setting whether the Buteyko technique improved global asthma control and a reduction in inhaled corticosteroid usage.

Methods

Subjects for the study were between 18 and 50 years of age and had asthma, which had been confirmed by a physician's diagnosis and current use of asthma medications or by a current or previous demonstration of reversibility of their FEV₁ with β_2 agonist of at least 12% and no less than 200 ml. They were currently using inhaled corticosteroid for management of their disease. Their dose of inhaled corticosteroid should have been stable for at least 6 weeks prior to entry to the study. They should not have suffered from an exacerbation of their disease requiring oral corticosteroid and or a visit to an emergency department within 2 months of their entry to the study. Smokers and ex-smokers were not excluded. Subjects with a diagnosis of another respiratory disease including chronic obstructive pulmonary disease were excluded.

Eligible subjects were then asked to provide consent prior to allocation to the Buteyko or the control group. The consent form informed them that they would be participating in an asthma breathing techniques study. Their allocation to the Buteyko or control groups was determined by opening the next of 200 sequentially numbered sealed envelopes. Randomisation was achieved by using two equal lists of random numbers, one for each limb of the study. These two lists were then combined in a database and indexed in ascending order. The study number allocated to each random number and recorded on the sealed envelope was the random number's rank in the indexed list. This process provided approximately equal numbers in each treatment limb and an unpredictable sequence of allocation. No adjustment of allocation could be made after the subject had been enrolled. The two groups had no contact with each other after randomisation as the two interventions were provided at the same time by different personnel at different and widely separated venues.

Each patient completed a questionnaire, which contained questions about their asthma control, asthma medications and a self-assessment of the extent to which asthma restricted their lifestyle. We have used this questionnaire in our centre to assess over 6000 individuals with the disease. The questions we asked included the following direct questions about asthma control:

β_2 agonist use: "On average how many doses of your bronchodilator (reliever medication) (Ventolin, Bricanyl, salbutamol, Berotec) do you use per day?"

Waking at night: "In the past week how many nights has your sleep been disturbed by asthma?"

Emergency department visits: "Have you been to an emergency room or to a physician for urgent treatment of

your asthma (for example, nebulized Ventolin) in the last 12 months?"

Missed work/school: "Have you missed school or work because of asthma in the last 3 months?"

Additional questions were asked in relation to the patient's medication including their use of inhaled and oral corticosteroid, asthma monitoring, use of action plans, hospital admissions and asthma trigger exposure.

The data obtained from the questionnaire appear to correlate well with other findings related to asthma severity and control.²¹ The subjects also completed a brief quality of life questionnaire (Juniper Mini Asthma Quality of Life Questionnaire).²² Subjects then performed spirometry before and ≥ 10 min after salbutamol 200 μg by inhalation.

Each subject was provided with information concerning the management of their asthma during the study. They were given an 'action plan' designed to help them adjust their medication in the face of increasing asthma symptoms. In addition, they received a sheet, which advised them not to withdraw or reduce their asthma controller medications without a discussion with their family physician and a letter to give to their family physician which carried clear indications for assessing control as defined in this study and for considering a decrease in controller medication. The family physicians each received a letter informing them that their patient was participating in the study and that they should not alter the standard of medical care that they ordinarily provided for their patient.

Interventions

The Buteyko and the control subjects received instruction, which was provided to groups of 10–12 subjects in the early evening on 5 consecutive days. The Buteyko group received instruction from a trained and internationally accredited Buteyko practitioner. They were instructed in techniques designed to reduce ('normalise') their ventilation. These included training to hold their breath at functional residual capacity (FRC) and instruction to avoid breathing through the mouth including mouth-taping at night. They were given a series of exercises, which they were encouraged to practice repeatedly throughout the day.

The control group was instructed by a registered physiotherapist with a series of exercises designed to develop a slow, controlled exhalation, down into FRC toward their residual volume. Paced breathing was taught during exercise. In addition, in both groups there was an opportunity to receive information about asthma from the instructor and for participants to discuss aspects of asthma.

Follow-up

Subjects were contacted at 3 months and at 6 months after completion of their intervention. They were asked to complete diary cards for the week before their 3- and 6-month review. The diary cards were used to support the questionnaire data regarding asthma control.

Both groups were reassessed 3 and 6 months after the completion of the intervention to determine whether their asthma was controlled, their usual daily dose of inhaled

corticosteroid and their quality of life. Spirometry was repeated within 1 month of the 6-month questionnaire.

Asthma control was defined as achieving all of the following:

- Not waking at night with asthma in the week prior to the assessment.
- Not needing to use β_2 agonist to relieve asthma symptoms more than 3 times in the week prior to the assessment.
- Not having any restriction of their daytime activities because of asthma in the week prior to their assessment.
- Not having needed urgent treatment for their asthma (in an emergency department or a walk-in clinic) since the previous assessment.
- Not having missed work/school because of asthma in the period since their previous assessment.

Analysis and sample size

The primary outcome measurement was asthma control 6 months after completion of the intervention. It was estimated from data which we have developed in Calgary and from Canadian statistics that less than 30% of those with asthma who are taking inhaled corticosteroid will fulfill the criteria for asthma control. It was estimated that 107 subjects in each group would be needed to show with 95% confidence and 80% power that a threefold greater increase in the proportion with disease control could be attributed to the Buteyko intervention. In this model, the percentage in the control group with disease control would increase from 30% to 40% and in the Buteyko group from 30% to 60% measured 6 months after the intervention. Secondary outcome measures would include indices of improved control, quality of life measurement and reduction in the dose of inhaled corticosteroid following the intervention. Although spirometric criteria for control have also been stipulated, the spirometric data were used only to compare the change in FEV_1 between the two groups as one of the secondary outcomes.

Statistical analysis was performed by χ^2 analysis of categorical data and by paired Student's *t*-test for continuous data.

All subjects provided written informed consent prior to entering the study, which was approved by the Conjoint Health Research Ethics Board of the University of Calgary.

Results

A total of 182 subjects were screened for the study (Figure 1). Fifty-three subjects were excluded: 17 failed to attend for their randomisation visit; 15 withdrew after being told about the study structure and time commitment; 10 subjects were not using inhaled corticosteroid; 4 subjects had unstable asthma or were, for reasons not stated, considered unsuitable for the study; one subject was deaf and thus considered unable to participate fully in the study and 6 subjects were inappropriately removed from the study because of a smoking history of greater than 10 pack years. The remaining 129 subjects were randomised, 65 to the

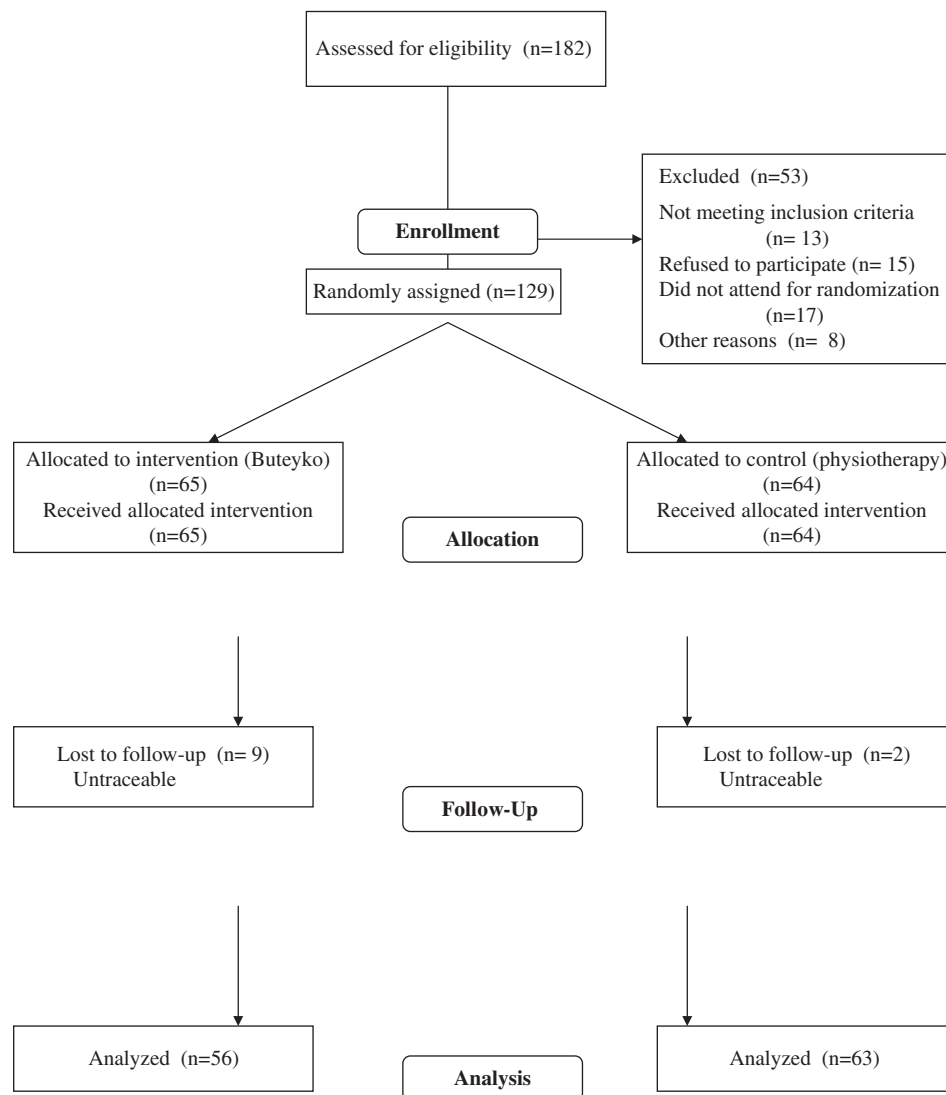


Figure 1

Buteyko and 64 to the control group. They received their education in groups of approximately 12 subjects for 5 consecutive evenings and the interventions were completed during a 6-week period in September and October 2004. The characteristics of these subjects are presented in Table 1. There were no significant differences in these characteristics between the two groups. The initial level of disease control was higher than expected with 40% of the Buteyko and 44% of the control group showing disease control ($p = 0.7$). There was no difference in the average daily dose of inhaled corticosteroid between the groups and all were, as required by the study protocol, using inhaled corticosteroid. The initial quality of life measurement using the Juniper Mini Asthma Quality of Life questionnaire²² was similar in the two groups, 4.6 in the Buteyko and 4.7 in the control group ($p = 0.8$). There were no differences between the groups with regard to spirometry expressed as percentage predicted FEV₁,²³ 83% in the Buteyko and 79% in the control group ($p = 0.3$).

For the 6-month follow-up 10 subjects could not be traced leaving 119 subjects, 56 in the Buteyko and 63 in the control

groups. Repeated attempts were made by letter and telephone to reach the missing subjects. Subjects in both groups enjoyed a significant improvement in their asthma status 6 months after the end of the intervention (Table 2). The percentage of those with asthma control improved from 40% to 79% (95% CI 68%, 89%) in the Buteyko group and from 44% to 72% (95% CI 60%, 83%) in the control group with no difference between the groups ($p = 0.4$). If it was assumed that all of those not included in the 6-month review had uncontrolled asthma, the percentage controlled at 6 months would be 68% for Buteyko and 70% for controls, again, with no difference between the groups ($p = 0.7$). Subjects in both groups showed a clinically and statistically significant ($p < 0.0001$) improvement in their quality of life scores (0.96 in the Buteyko and 0.95 in the control group), but there was no difference between the groups in the degree of improvement or in their overall quality of life scores.

While both groups had been using similar daily doses of inhaled corticosteroid on entry to the study, the Buteyko group who remained for assessment at 6 months had reduced their average daily dose from 865 to 548 μg of

Table 1 Characteristics of subjects on entry to study.

	Buteyko (n = 65)	Control (n = 64)	P
Age (years) (SD)	47 (12.5)	48 (12.5)	0.9
Gender (F:M)	49:16	50:14	0.7
Duration of asthma (years) (SD)	22 (15.4)	21 (18.1)	0.8
Non-smokers (%)	46 (71)	46 (72)	0.9
Packyears for smokers and ex-smokers (mean)	6	7	0.6
Asthma controlled (% subjects)	40	44	0.7
Average dose inhaled corticosteroid in beclomethasone equivalent (μg) (SD)	863 (527)	817 (595)	0.6
Subjects with emergency visits in past year	13	10	0.5
FEV ₁ % predicted ²³ (SD)	83 (19.2)	79 (21.6)	0.3
QOL ²²	4.6	4.7	0.8

Table 2 Status at 6 months after completion of the intervention.

	Buteyko (n = 56)	Control (n = 63)	P
Asthma controlled (% subjects)	79	71	0.4
Average change in daily inhaled corticosteroid (beclomethasone equivalent (μg) (SD))	-317 (588)	-56 (575)	0.02
Subjects with Emergency visits in past 6 months	1	4	0.2
Change in FEV ₁ % predicted ²³ (SD)	-0.05 (0.472)	-0.01 (0.372)	0.6
Change in QOL ²²	0.96 (1.044)	0.95 (1.154)	1.0

beclomethasone equivalent at 6 months after completion of the intervention ($p = 0.0002$) compared with 818 μg down to 762 μg for the control group ($p = 0.4$). A reduction of beclomethasone equivalent of 100 μg or more was achieved by 23 of the Buteyko and 13 of the control group ($p = 0.02$). A total of 10 subjects in the Buteyko group and only one in the control group stopped using a long-acting β_2 agonist in the 6 months after their intervention ($p = 0.005$) and in the same period three Buteyko and five control subjects starting using a long-acting β_2 agonist (NS). No adverse effects were reported by subjects in the Buteyko or control groups.

Discussion

This study, which we believe to be the largest randomised controlled trial and the first to use a global assessment of asthma control as a primary outcome in a non-pharmacological intervention in asthma, failed to show a difference between the intervention (Buteyko) and control (physiotherapy) groups. These data suggest that both interventions can be considered to have been active with a remarkably high level of disease control in both groups 6 months after completion of the intervention. The level of disease control achieved is equivalent to that noted in trials of optimal asthma medication.² The Buteyko group differed from the control group only in their reduction of their daily dose of inhaled corticosteroid and in the number who stopped using long-acting β_2 agonists. Fourteen of the Buteyko and only four of the control group had managed to completely withdraw their inhaled corticosteroid and of these 12 and four, respectively, enjoyed asthma control.

It is difficult to know how to attribute the results of this study. As with any studies of complementary intervention, development of a suitable control group intervention was difficult. In general, physiotherapy is not considered to contribute to the chronic management of asthma.²⁴ It was chosen as it was thought important to provide an apparently credible intervention of similar intensity and duration to that received by the Buteyko group. The control intervention was disadvantaged by the knowledge, which became available during the publicity for the study, that one of the intervention arms involved the Buteyko technique about which there is considerable awareness from entries on the World Wide Web. Indeed the entire process of recruiting subjects to this study was hampered by the acknowledgement to all of those who responded that they would be randomly allocated to either the Buteyko or the control groups. Most of those who called did so because of interest in the Buteyko technique. This initial disadvantage makes the results in the control group even more remarkable. It should be noted that the predetermined result from the intervention was exceeded by both the Buteyko and the control groups.

It is quite possible that the favourable results reflect aspects other than the interventions which we were testing and which might include the additional opportunity to acquire asthma information during approximately 10 h of contact with the group instructors and with others with asthma. Nevertheless, whatever the explanation, these interventions proved to be extremely effective adjuncts to conventional asthma management. In this context, the Buteyko method can be recommended given that it is structured, well-developed and in the

public domain and because there is no evidence that it has any adverse effects. Similarly, in centres where there are expert chest physiotherapy services by physiotherapists trained in asthma education, a programme of similar intensity to that provided here could be considered for patients with asthma, who remain poorly controlled while taking inhaled corticosteroids.

The frequent explanation of a prolonged benefit from a control or placebo intervention in asthma studies is that subjects are recruited when their asthma is poorly controlled and that there is natural regression to the mean. That explanation seems unlikely in this study; those with recent asthma exacerbations were excluded and recruitment occurred over several months prior to the onset of the interventions which were scheduled to occur in a very short period during which the Australian Buteyko practitioner was available to provide instruction at our Canadian site. Furthermore, the method of recruitment and inclusion criteria were designed to enroll subjects with asthma which was stable and reflected their usual baseline.

Although Buteyko believed that the results from his technique reflected a decrease in ventilation this was not assessed in this study and has not been demonstrated in other studies. However, taking the Buteyko theory to its logical conclusion, any increase in PaCO₂ should produce a demonstrable improvement in spirometry. We were not able to demonstrate any spirometric response in the Buteyko group. After 6 months, the post-bronchodilator FEV₁ showed no significant change nor any difference between the groups with a decrease of 80 ml in the Buteyko and of 40 ml in the control group.

The Buteyko group did gain the additional benefit of a reduction of 317 µg beclomethasone equivalent in their average daily dose of inhaled corticosteroid therapy compared with a reduction of 56 µg in the control group ($p < 0.02$). This does appear to be a real effect: the Buteyko instructor was asked not to directly advise her subjects to adjust their therapy on the grounds that this would interfere with our ability to assess this important secondary study outcome. Nevertheless, advice to reduce medications is given on several Buteyko websites that our subjects in either of the groups might have accessed.

Conclusion

This randomised clinical trial showed that both the Buteyko and control (physiotherapy) interventions produced a favourable outcome in that over 70% of the participants enjoyed asthma control 6 months after completing the intervention. In addition, the subjects in the Buteyko group were able to significantly reduce their daily doses of inhaled corticosteroid. The Buteyko technique or an intensive programme delivered by a chest physiotherapist appear to provide additional benefit for adult patients with asthma who are being treated with inhaled corticosteroid.

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