THE EFFECT OF SALT ROOM TREATMENT ON BRONCHIAL HYPERRESPONSIVENESS IN ASTHMATICS: A RANDOMISED CONTROLLED TRIAL

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AIMS

Complementary and alternative medicine is widely used in asthma. However, data on the efficacy of these treatments are usually lacking. This study assessed the effect of salt room treatment as an add-on therapy to low to moderate inhaled steroid in asthma patients with bronchial hyperresponsiveness (BHR).

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METHODS

A parallel group, double blind, randomised placebo controlled trial was conducted. After a 2 week baseline period, patients were randomised to 2 week active salt room treatment or placebo. Treatment, lasting 40 minutes, was given once a day and 5 times a week in the salt room of The Baths of Lappeenranta.

Patients continued their original asthma medication throughout the study and salt room treatment acted as an add-on therapy. If there was a need for increasing the steroid dose because of worsening of asthma the patient was excluded from the study. The study was conducted outside the pollen season.

The main outcome parameter was BHR. Patients were submitted to a histamine inhalation challenge three times: at the baseline, at the end of the two week treatment and two months after the treatment. The flow of the subjects through the study is shown in **Fig. 1**. Baseline characteristics of study subjects are given in **Table 1**. There were no significant differences between the groups.

Treatments were given in a salt room, 12,5 m^2 and 27,5 m^3 in size. The roof, walls and partly floor were covered with 20-50 mm thick salt coat (rock salt, NaCl 98,5 %). Both active and placebo treatments were given in the same salt room. During the active treatment three grams of salt was fed into the salt generator (Polar and Iris salt generator, PolarHealth Oy, Finland, IndiumTop LLC, Estonia) at intervals of four minutes, first pulverised and then blown into on the room through the feed channel. During the placebo treatment salt was not fed into the salt generator. The generator was, however, on and patients could hear its sound.

During the active treatment mean salt concentrations in indoor air of the salt room fluctuated from 7,1 to 7.6 mg/m^3 (range 0–31,5 mg/m^3; n = 7). During the placebo treatment the mean salt concentration was 0,3 mg/m^3 (n = 3). Salt concentrations were restored to zero level (0–1 mg/m^3, n = 7) during the 20 minutes of enhanced ventilation after each treatment period. Measurement of conditions were carried out by the Lappeenranta Regional Institute of Occupational Health, a local unit of the Finnish Institute of Occupational Health.

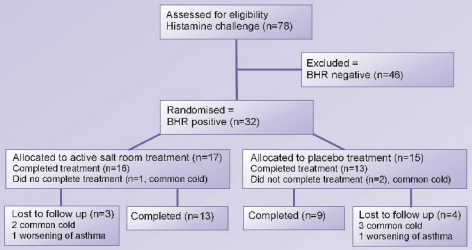

Fig. 1. Flow of subjects through study.

Table 1. Baseline characteristics of the study subjects. The values are means (ranges) and patient numbers

	Active N=17	Placebo N=15
Age, yrs	53.2 (32-67)	52.1 (26-70)
Female	15	14
Duration of asthma, yrs	10.6 (1-30)	8.9 (0.5-25)
Atopy*	10	9
Inhaled steroid dose, mg	0.635 (0.2-1.2)	0.567 (0.25-0.8)
Long acting beta-2 agonist	9	6
FEV_1 ,litres	2.61 (1.80-4.67)	2.54 (1.88-3.30)
FEV_1 ,% predicted**	89.5 (72-138)	91.9 (73-106)
FVC, litres	3.25 (2.19-5.45)	3.21 (2.45-4.14)
FVC, % predicted**	90.4 (69-136)	95.6 (80-103)
Morning PEF, litres/minute	441 (332-632)	438 (362-562)
Evening PEF, litres/minute	455 (325-726)	448 (361-569)
PD_{15} FEV_1 ,mg	0.488 (20-1570)	0.588 (16-1420)

* allergic rhinitis or atopic eczema reported by the subject
** Viljanen AA, Haittunen PK, Kreus KE, Viljanen BC. Spirometric studies in non-smoking, healthy adults. *Scan J Clin Lab Invest* 1982; 42 (Suppl. 159): 5-20.

RESULTS

After two week treatment the median $PD_{15}FEV_1$ increased significantly in the active group but not in the placebo group compared to baseline. In the active group median (range) $PD_{15}FEV_1$ before and after treatment were 0.445 mg (0.020–1.57) and 0.595 mg (0.022– >1.6) (p=0.047); and 0.720 mg (0.016–1.42) and 0.630 mg (0.085–1.25) in the placebo group (p>0.05). The difference in change during the treatment between the active and placebo groups was significant (p=0.02).

In nine patients (56%) in the active group and in two patients (17%) in the placebo group BHR decreased at least one doubling dose (Fischer`s exact, p=0.040). Six patients (38%) in the active group and none in the placebo group became non-responsive to histamine (Fischer`s exact, p=0.017). Changes in individual BHR in active and placebo groups are given in **Fig 2**. The duration of the effects on BHR and asthma control cannot be reliably estimated as the sample size became too small during the two month follow-up.

Spirometric indices, PEF values, rescue bronchodilator use and nocturnal awakenings before and after salt room treatment are given in **Table 2**. A significant reduction of nocturnal awakenings (p=0.012) and a trend of reduction of broncho-dilator use (p=0.062) were detected in the intragroup analysis of active treatment group. No other significant changes were found in active or placebo groups.

CONCLUSIONS

This is the first controlled trial to study the effect of salt room treatment on BHR Two week salt room treatment reduced BHR as an add-on therapy on low to moderate dose of inhaled steroids. It also had a positive effect on asthma control measured by reduction of nocturnal awakenings.

We believe that the subjective benefit that patients get from salt room treatment is connected to the reduction of BHR. The possible treatment effect of salt room is, however, unclear. No side-effects were observed but salt room treatment is neither simple or cost free. The optimum duration or interval of treatments are not known. Health economic aspects should be evaluated, too. In future studies, the cost benefit should be compared with other treatment modalities including improving of existing drug treatment.

Table 2. PD_{15} FEV_1 results (median values); spirometric indices, PEF values, bronchodilator use and nocturnal awekenings (mean values) before and after two week salt room treatment.

	Active Before N=17	Active After N=16	Placebo Before N=15	Placebo After N=13
PD_{15} FEV_1, mg	0.445	0.595*	0.720	0.630*
FEV_1, litres	2.61	2.67	2.54	2.43
FVC ,litres	3.25	3.24	3.21	3.09
Morning PEF, litres/minute	441	446	438	448
Evening PEF ,litres/minute	455	462	443	451
Treatment PEF, litres/minute**	477	478	464	467
Short acting bronchodilator use, n / 2 weeks	2.8	1.4	1.2	0.5
Nocturnal awakenings, n / 2 weeks	2.9	0.8	0.4	0.1

* difference in changes between active and placebo, p=0.02
** measured just before and after the salt room treatment

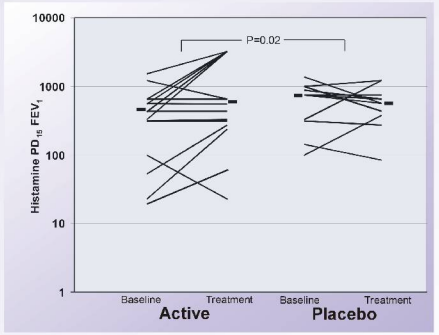

Fig. 2. Changes in airway responsiveness to histamine in the active and placebo salt room treatment groups. $PD_{15}FEV_1$ (µg histamine) at baseline and after the two week treatment. An arbitrary value of 3200µg was used in subjects who were challenge negative. Thick lines represent median values.