

Salt Halo Therapy and Saline Inhalation Administered to Patients with Chronic Obstructive Pulmonary Disease: A Pilot Study

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Abstract

Introduction: Chronic Obstructive Pulmonary Disease (COPD) is characterised by progressive airflow limitation associated dyspnea and impaired quality of life. Halo therapy has been suggested to relieve respiratory discomfort in patients with COPD.

Aim: The aim of this study was to study the effect of halo therapy and isotonic saline inhalation, compared to controls, in COPD patients.

Material and methods: In this pilot cohort study 67 patients with COPD, GOLD stage 3 and 4, were included. Patients were assigned to 3 different groups; group 1 receiving 20 sessions of 45 minutes halo therapy with dry aerosols of salt, less than 5 µm over 5 weeks; group 2 inhaling 5 ml isotonic Saline over 5 minutes, 5 weeks, 3 times per day and group 3 as controls. Spirometry, 6 minute walking test, dyspnea-score (MRC) and Quality-of-life (SGRQ) score was investigated at inclusion and at termination of the study.

Results: Group 1 improved walking distance 75 meters ($p < 0.01$), SGRQ -6.66 points ($p < 0.05$) and FEV1 0.4 liters (2%), ($p > 0.05$), during the treatment period. Group 2 improved FEV1 0.7 litres (3%) ($p < 0.05$) and walking distance 90 metres ($p < 0.01$). There was a drop out of 28% (7/25) in this group due to discomfort. Group 3 reduced MRC 1 point ($p < 0.05$) and FEV1 0.6 litres (2%) ($p = 0.051$) during the observation period.

Conclusion: Both Halo therapy and saline inhalation improved walking distance and FEV1 in patients. SGRQ improved in patients treated with halo therapy. Halo therapy appeared to be better tolerated than saline therapy.

Keywords: Chronic obstructive pulmonary disease; Halo therapy; Saline inhalation; Quality of life; FEV1; MRC; 6 Minute walking test; Dyspnea

Introduction

Chronic obstructive pulmonary disease (COPD) has during the last centuries emerged to be the most important respiratory disease globally [1], with an estimated 210 million people suffering from COPD worldwide. It is characterised by progressive airflow limitation, often associated with dyspnea, reduced walking distance and hence impaired self-evaluated quality of life [1]. Treatment, in terms of smoking cessation [2], rehabilitation [3] and inhaled drug therapies [4] relieve symptoms. However dyspnoea remains a major complaint in COPD [5] and has, as well as impaired walking distance, a major impact on patients' perception of quality of life [6,7]. Therefore relief of symptoms and research in this field is of great importance.

In Central and Eastern Europe, natural salt caves have been used for centuries to relieve chest conditions [8]. The unique characteristics of

the microclimate within the caves are stable air temperature and humidity, the presence of fine aerosol elements (sodium, potassium, magnesium and calcium), and lack of airborne pollutants and pollens. This may be modeled above ground, in a so-called halo chamber. Halo therapy, inhalation of micronized salt in the controlled conditions of a halo chamber, has become increasingly popular in the general community worldwide. Although the claimed effects of halo therapy are plenty, i.e. bactericidal effect, improvement of immunity, improved rheological properties of secretion [9] only a single study has looked at immunological changes during halo therapy and suggested changes in T-lymphocyte activity [10]. However, halo therapy has been shown to relieve symptoms in smokers [11] and in patients with respiratory symptoms in general [12-14]. It has been argued that halotherapy is beneficial in treatment of COPD patients [15], but, as concluded in a recent review, further research is needed on the effect and impact on the quality of life of halo therapy in COPD [16].

Halo therapy chambers are not easily accessible; in Denmark the only established chamber is situated on the remote island called Laesoe.

Saline inhalation has previously been described to have possible effect on mucus clearance in COPD patients [17]. Still, this method may not be well tolerated as reported in a previous study; 1/3 of the study population had minor adverse events after inhalation due to discomfort [18].

Thus, we hypothesized that, in patients with COPD, halo therapy may relieve symptoms and improve quality of life. The same relief may be achieved by saline inhalation. Hence the specific aims of this pilot study were to investigate the possible effect of halo therapy and saline inhalation on lung function, in terms of spirometry, dyspnea, evaluated by the MRC score; ability, evaluated by 6 minute walking test and quality of life, measured by Saint George Respiratory Questionnaire (SGRQ).

Material and Methods

This Pilot cohort study was conducted in the Northern Region of Jutland in Denmark from September till November 2011.

Study population

Patients were recruited by public announcement in writing, from an out patients' clinic, a rehabilitation centre and at the island of Laesoe, (1860 inhabitants), situated 29 kilometres of the coast of Jutland, where the only halo therapy chamber in Denmark was located. Patients with COPD GOLD stage 3 according to the 2007 GOLD guidelines (FEV1 30-50%) and 4 (FEV1<30%) were included [1]. Only patients treated according to GOLD guidelines recommended at the time of inclusion participated in the study [19]. Patients were in stable state i.e. none of the study participants had exacerbations of COPD or major changes in medication treating co morbidities, such as diabetes, cardiac disease and mental disorders within three months of study start. Patients were not allowed to use other types of halo therapy and were asked not to change smoking habits during the study period. Patients with end stage malignant diseases were excluded.

No more than one hour's transportation time to treatment was accepted. As such patients were referred to three groups; patients from Laesoe received halotherapy (group 1), patients in contact with the outpatient clinic received saline inhalation (group 2). A third group of patients, all in contact with a rehabilitation centre were included to elucidate possible changes in a population of COPD patients treated after general recommendations over the same time period (group 3). Eighty-five patients were tried for inclusion by primary interview. Of those 67 met the inclusion criteria; 17 were included in group 1, and 25 in each of groups 2 and 3.

A maximum of 3 days before study start an interview was performed and demographic data; age, sex, smoking status, BMI, number of exacerbations one year prior to inclusion, were recorded. A spirometry was performed (EasyOne Spirometer®, Medizintechnik AG, Zürich, Switzerland), MRC-score was recorded [20], a 6-minute walking test was performed [21,22], and quality of life was evaluated by the Saint George Respiratory Questionnaire (SGRQ) [23]. A similar examination was performed a maximum of 3 days after the end of the study; patients were handed out the SGRQ on the day of the final examination and asked to return it by mail.

During the study period the number of exacerbations was recorded.

Treatment

During the study period patients were treated as follows:

Group 1: Seventeen patients received 20 sessions of 45 minutes halo therapy with medical salt (Sanal®, Azco Nobel Salt, Mariager, Denmark), composed of 92% **Natriumchloride**, 3% **Calciumsulfate**, 2% **Magnesiumsulfate** and **Magnesiumchloride** and 0,3% Potassiumchloride, over a 5 week period. The inhalation took place in a salt chamber with regulated micro-climate; temperature 25° Celcius, humidity<40%, and a salt generator (Micronizer SaltPro 3®, Microsalt Medical Schwäbisch Hall, Germany) distributing dry aerosols of salt, size less than 5 µm, to an even concentration of 10 mg/m³ throughout the chamber. Patients were resting during the sessions.

Group 2: Twenty-five patients received inhalations of 5 ml isotonic Saline, 5 minutes, 3 times per day evenly distributed over the day, in 5 weeks. The inhalations took place in the patients' home on a nebulizer, using a face mask. Patients were instructed to rest during the sessions.

Group 3: Twenty-five control patients. These patients had all recently completed a rehabilitation programme. No further actions were taken on this group.

The study was approved by the Local Ethical Committee (N-20110012) and data were registered and kept according to the legislation of the Danish Data Protection Agency. Patients were informed according to the Helsinki declaration.

Statistical analysis

Demographic data are described in means and ranges. A paired t-test was applied to test differences in means on gender, age, BMI, smoking status and exacerbations. Furthermore subgroup analyses of responders versus non-responders of the SGRQ were performed in the three groups, applying a paired t-test. Possible differences in means on gender, age, smoking status and exacerbations as well as walking distance, lung function and MRC at the end of the study were investigated.

Results

Of those included in group 1 all 17 completed the study. Of the 25 patients included in group 2 18 patients completed the study. Drop outs were due to exacerbation (2) and side effects in terms of severe dyspnea in relation to inhalations (5). Of the 25 patients included in group 3, 24 patients completed the study.

Baseline characteristics of the study groups are demonstrated in Table 1. The table shows that the majority of the study population were female although there was no statistical difference in gender within the groups (p=0.07); the three groups were comparable in age (67-71 years old) and BMI (27-28). Group 2 had more, but not statistically significant more exacerbations (1.36) than groups 1(0.76) and 3(0.96) (p=0.08). There were significantly more current smokers in group 1 (10/17) than in 2 (6/25) (p=0.04) and 3(2/25) (p=0.002). There was no significant difference in the number of smokers in group 2 and 3 (p=0.08).

	N	Gender (male/female)	Age Mean (range)	Body Mass Index Mean(range)	current/prior smokers	Exacerbations Mean(range)
Group 1 (halo therapy)	17	7/10	70 (49-88)	28 (20-38)	10/7	0,76 (0-3)
Group 2 (saline inhalation)	18	7/11	70 (52-84)	28 (20-35)	4/14	1,39 (0-5)
Group 3 (control)	24	14/10	67 (58-80)	27 (23-40)	2/23	0,96 (0-3)

Table 1: Demographic data: Age, Body Mass index and Exacerbations. There was no significant difference between the groups

Table 2 shows data on FEV1, FEV1%, MRC-score and 6-minute walking test in the groups at the time of inclusion and at the end of the study period. Only data from participants who completed both examinations are presented in the table. Group 2 had significantly lower FEV1% (31%) at the time of inclusion than groups 1(49%) and

3(51%), ($p < 0.05$). Group 2 also had significantly lower MRC score (4) at the time of inclusion than groups 1(3) and 3(3) ($p < 0.05$). Group 1 and 2 had a significantly shorter walking distance (336 and 301 metres respectively) in the 6 minute walking test than group 3 (458 metres) ($p < 0.01$).

		At inclusion		End of study	
		N	Mean (range)	N	Mean (range)
Group 1 (Halo therapy)	FEV1 (liter)	17	1.28 (0.48-2.29)	17	1.32 (0.54-2.55)
	FEV1%	17	49 (27-78)	17	51 (21-86)
	MRC	17	3 (2-4)	17	3 (2-4)*
	6 minute walking test (meters)**	14	329 (167-526)	14	367 (198-543)**
Group 2 (Saline inhalations)	FEV1 (liter)*	18	0.84 (0.61-1.51)	18	0.91 (0.62-1.90)*
	FEV1%*	18	31 (21-53)*	18	34 (23-54)*
	MRC	20	4 (2-4)	20	3 (2-4)
	6 minute walking test (meters)**	17	341 (142-513)	17	374 (180-528)**
Group 3 (Controls)	FEV1 (liter)	24	1.42 (0.7-2.2)	24	1.36 (0.7-2.3)
	FEV1%	24	54 (26-77)	24	52 (29-82)
	MRC	24	3 (1-4)	24	3 (2-4)*
	6 minute walking test (meters)	24	457 (286-602)	24	454 (260-614)

Table 2: Comparison of FEV1, MRC, 6-minutes walking test and SGRQ within the groups 1 (halo therapy), 2 (saline inhalations) and 3 (controls) and number of patients performing the tests. Only patients with complete dataset are reported in this table. *= $p < 0.05$ (paired t-test). **= $p < 0.01$ (paired t-test).

At the end of the study patients in group 1 had improved 6 minutes walking test with 75 metres ($p < 0.01$). There was a statistically insignificant increase in FEV1% of 2% (0.04 litres) – however, sample size calculations showed that, given a normal distribution, a 2% change in FEV1% would have been significant in a study population of 65.

At the end of the study, patients in group 2 had a statistically significantly improved FEV1% with 3% (0.07 litres) ($p < 0.05$) and 6 minute walking test with 90 metres ($p < 0.01$). Demographic data of the 7 patients dropping out of group 2 were equally distributed compared to the 18 patients in group 2 that completed the study period.

At the end of the study period group 3 had a significant decrease in the MRC-score of 1 point ($p < 0.05$). The decrease was due to 3 participants, of which two had had major exacerbations during the inter-observational period.

Table 3 shows the results of the SGRQ at inclusion and study end. Sixty-five % (11/17) of patients in group 1; 50% (9/18) of patients in group 2 and 58% (14/24) of patients in group 3 completed the SGRQ questionnaire both at study start and study end. Group 1 improved significantly with -6.66 points ($p = 0.03$) and group 2 and 3 showed no improvement in SGRQ. Within the individual groups there were no statistical difference in age ($p = 0.8$), gender ($0.7 < p > 0.8$), 6 minute

walking test ($0.3 < p < 0.7$), MRC-score ($0.4 < p < 0.7$), FEV1% ($0.2 < p < 0.6$), smoking status ($p = 0.6$) and number of exacerbations ($0.4 < p < 0.7$) between responders and non-responders to the SGRQ.

	N	SGRQ at inclusion	N	SGRQ at end of study
Group 1 *	14	50,67	14	44,01
Group 2	10	52,04	12	51,65
Group 3	19	39,98	17	41,65

Table 3: Number of patients completing (N) the SGRQ and the results of the questionnaire at inclusion and end of study in groups 1 (halo therapy), 2 (saline inhalations) and 3 (controls). * $p = 0.03$ (paired t-test).

Discussion

This study indicates that salt inhalation, whether administered as saline therapy or halo therapy, has a beneficial effect on FEV1% and 6 minute walking test in COPD patients. Furthermore it indicates that quality of life, measured by SGRQ, may improve in patients receiving halo therapy.

All patients receiving halo therapy completed the study despite that fact that they had to go to the salt chamber 4 times a week, 45 minutes per session, in 5 weeks. No patients experienced side effects which indicate that the treatment is safe and well tolerated. In contrast, a large drop out occurred in the saline group despite the fact that treatment was fast and easy accessible as it was carried out in the patients' homes. The drop out was mainly due to side effects. A possible explanation could be that the patients in the saline group had more severe COPD judged by FEV1% and MRC score; however, there was no difference in these characteristics in those completing the treatment and those who dropped out.

It is interesting to notice that even though patients in group 1 had better lung function than those in group 2, the walking distance of patients in group 2 was better than those in group 1 at all times. Also patients in group 1 had better lung function than group 3 at the end of the study period, still the walking distance of patients in group 3 was better compared to group 1. It has previously been shown that FEV1 and walking distance does not decline at the same rate [24]. However, the interesting figure in this context must be the intra-group variation over time; inter-group differences have not been considered.

As such both patients in groups 1 and 2 improved walking distance significantly. Not only was this statistically significant, but also clinically significant according to the Wise et al; the minimal clinical important improvement is considered to be 54-80 meters dependent on initial distance [25].

The existing literature on halo therapy is sparse. Chervinskaya et al. has investigated a group of patients with various respiratory diseases and found a 3% improvement in lung function, judged by FEV1 [12]. Hedman et al. has investigated the effect of halo therapy on FEV1 in asthma patients and found no improvement in FEV1 during treatment [26,27]. However, none of these studies are directly comparable to this study as none of the studies have investigated verified COPD patients only; neither was the duration of the study period nor the concentration of salt in the halo chamber comparable to this study. Furthermore none of the existing literature has included patient evaluated parameters such as MRC and SGRQ scores. As such this

study is the first to investigate the effect of halo therapy in COPD patients and to evaluate the influence on patient evaluated parameters.

A statistically significant improvement in FEV1 was found after 5 weeks of isotonic saline treatment. However, a clinically significant difference in FEV1, which is considered to be 100 mL [28] was not seen, as FEV1 improved by 70 mL. Hypertonic saline inhalation has previously been studied in patients with chronic bronchitis by the group of Clarke and Pavia who showed improved mucociliary clearance, yet no improvement in FEV1 was found [17]. The inconsistency of the findings may be explained by the duration of treatment; in the studies of Clarke and Pavia patients were only treated for 3 days. As such the optimal duration of treatment still needs to be established, both in saline- and halo therapy.

A decline in MRC score was seen in group 3. As these patients had completed rehabilitation just prior to inclusion one could expect a decrease in physical abilities; however previously this has not been proved this to be statistically significant till after 12 months [29]. As stated previously patients with declining parameters had had exacerbations, which may explain the finding.

This pilot study has several limitations. As the location of the salt chamber was very isolated geographically patients were stratified to group 1 when living in an acceptable distance from the salt chamber. This was chosen to enable the study population to complete the study despite physical impairment. This disposition may of course have biased the results. Although all patients met the inclusion criteria they turned out to differ in certain parameters which resulted in skewed data on FEV1% and MRC. This calls for caution in interpretation of the data, even though patients were evaluated within the groups, before and after intervention, which validates the inter-group results.

Patients were asked to forward the SGRQ per mail correspondence; a number of study participants did not complete the questionnaire. This is a weakness of the study design and calls for caution in the interpretation of data.

This study has not evaluated long term effects of the therapies; a follow up of the patients could have been wished for.

All in all larger randomised studies in this field are needed; not only to establish the effect but also to seek the optimal inhalation concentration, duration of treatment and investigation of possible long term effect of treatment.

Conclusion

The results of this study indicate that both saline and salt halo therapy has a positive effect on walking distance. An improvement in FEV1% is registered in both groups although only statistically significant in saline inhalation. Patients receiving halo therapy had significant improvement of SGRQ. Halo therapy appears to be better tolerated than saline inhalation. However, further randomised studies are needed in this area.

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