Saline inhalation has previously been described to have possible

		Gender	Age	Body Mass Index	current/prior smokers	Exacerbations
	N	(male/female)	Mean (range)	Mean(range)		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

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 questionaire 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 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 mili Liters (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.

Acknowledgement

Thanks to the Opel family foundation for financial support.

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