Bronchial Asthma and Chronic Obstructive Lung Diseases:

Improvement of the 6-minute walking test and the lung function by inhaling activated air produced by the SOE-TIE therapeutic inhalation equipment

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Abstract

Background:

Atmospheric air activated by SOE-TIE therapeutic inhalation equipment leads to improved utilization of available oxygen in the atmospheric air and to improved peak flow. COPD patients often need oxygen therapy due to their increasing dyspnea and the resulting poor physical endurance. This study evaluates whether SOE-TIE can improve physical capacity and lung function parameters of COPD patients.

Patients and Methodology:

6 patients with bronchial asthma and 8 patients with COPD were subjected to daily 30-minute inhalation sessions using SOE-TIE over a period of 4 weeks. On days 0, 14, 28 and 56 the following tests were performed:

- 6-minute walking (m)
- Lung function test
- Serological determination (leukocytes, erythrocytes, Hb, Hct, thrombocytes, CRP, electrophoresis)

Results:

During the 4 week SOE-TIE therapy, the physical capacity in the 6-minute walking test increased threefold in both groups: from 93,3 to 352 meters ($p=0,0006$) in asthma patients and from 111 to 363,88 meters ($p<0,0001$) in COPD patients respectively. This effect continued during the following therapy-free period for a further 4 weeks. After three months without SOE-TIE therapy, the original status returned. FEV1%VC improved during the 4 week therapy by 3,25% in asthma patients (from 89,8% to 93% - $p=0,52$) and by 11,7% in COPD patients (from 75,6% to 88,14% - $p=0,07$) but fell to the original value during the post therapy observation phase. No changes were observed in the serological determinations. None of the patients experienced any exacerbation of their disease during the follow-up period.

Conclusion:

Asthma and COPD patients using SOE-TIE therapy experienced a significant improvement in their physical capacity (6-minute walking test) and an

improvement of their lung function. None of the patients experienced any exacerbation of their disease during the follow-up period.

These results will be further evaluated in a placebo-controlled, randomised, double-blind study during 2011.

Introduction

Asthma and especially COPD are the diseases with the highest rate of increase and, after malignant tumors and cardiovascular diseases, the highest rate of mortality[8,9]. Oxidative stress caused by smoking, respirable dust or infections are the most common causes for progressive symptoms (coughing, sputum), decreasing physical capacity and worsening lung function. Sustained broncho-dilatation also by a reduction of, or complete elimination of, oxidative stress can considerably reduce the rate at which the lung function deteriorates[1].

The innovative inhalation technology of the SOE-TIE could be a complementary form of treatment for COPD. Compared to oxygen therapies with high concentrations of oxygen, the SOE-TIE uses only the oxygen in the ambient air and transforms it into singlet oxygen - the physiologically active state - using a patented photosensitization process[6]. Due to its short lifespan (nanoseconds), singlet oxygen returns to the ground (triplet) state and releases singlet oxygen energy which is absorbed by water molecules in the air. The patient uses a light nasal cannula to inhale the activated air and water molecules acting as energy transmitters[2]. Hulten et al[4] were able to show a reduction of the oxidative radical stress by 30% using singlet oxygen energy. A further study with healthy test persons measured the effects of inhaling air activated with singlet oxygen energy on the utilization of oxygen by the organism and lung function parameters[5]. After the first 20-minute application the absorption of oxygen increased by 10% (inner respiration) and a 7% increase of the peak flow was measured, for which the reduction in oxidative stress is also responsible[5].

Can these reactions be induced in patients with irreversible lung diseases? The aim of this study was to evaluate the effects of the SOE-TIE on patients with asthma and COPD in relation to physical capacity, lung function, blood count, inflammation parameters and the exacerbation rate.

Patients and Methodology (Fig. 1)

Patients with bronchial asthma and a chronic obstructive lung disease were included in this study as long as COPD patients fulfilled the criteria according to GOLD 2010. Patients with malignant tumors were excluded from the study. All patients were administered a daily 30-minute inhalation therapy using the SOE-TIE equipment for 4 weeks. The therapy was not administered on Saturdays and Sundays. A wash-out phase of 4 weeks followed. Prior to therapy and after 2, 4 and 8 weeks, the following tests were performed:

- physical capacity (6-minute walking test in meters)
- lung function test (FEV_1, VC, FEV1%VC)
- serological test (erythrocytes, leukocytes, Hct, HB, thrombocytes, CRP)

The Forced Expiratory Volume 1-second capacity (FEV_1), the Forced Vital Capacity (FVC) and the Forced Expiratory Volume 1-second capacity as a percentage of the Vital Capacity (FEV1%VC) were calculated from the flow volume curve of a spirometer (CustoVit, CustoMed GmbH, Munich, Germany). All parameters were recorded as a percentage of the reference value (Standard=ECGs).

Fasting blood samples (EDTA, Serum) were taken from the patients between 8.00 and 10.00 in the morning and tested by the laboratory MVZ für Labordiagnostik, Cologne, Germany.

The parameters of leukocytes, thrombocytes, erythrocytes, haemoglobin and haematocrit were measured using flow cytometry (Pentra DX 120, Axonlab, Montpelier, France)[7]. The limit values using this method of determination were:

Leukocytes:	4-11.000/nL
Erythrocytes:	4,6-6,2/pL (male), 4,0-5,4/pL (female)
Thrombocytes:	140-400.000/nL
Haemoglobin:	14-18g/dl (male), 12-16g/dl (female)
Haematocrit:	40-50% (male), 37-47% (female)

The C-Reactive Protein (CRP) was measured using turbidimetry (Modular D, Roche Pharma GmbH, Grenzach-Wyhlen, Germany)[8]. The limit value was <5mg/L.

For statistics the t-test for paired samples was used.

Results

8 patients with COPD with an average age of 68 (60 to 82) and 6 patients with bronchial asthma with an average age of 72 (59 to 91) were included in this study. COPD patients had been suffering from their disease for an average of 12 years (4 to 16) whereby 3 patients were GOLD stage 1, one patient was GOLD stage 2, and 4 patients were GOLD stage 3. During this period none could be included with GOLD stage 4. The patients were taking the following medication: 8 ß2-sympathicomimetic inhalations, 4 corticosteroids inhalations, and for one patient orally: theophylline. Patients with bronchial asthma had been suffering from their disease for an average of 8 years (2 to 15). The patients were taking the following medication: all a combined ß2-sympathicomimetic and corticosteroids inhalation.

In asthma patients the average walking distance for the 6-minute walking test before the therapy was 93,3m (52-198m). After 2 weeks of the SOE-TIE therapy, the average physical capacity rose to 198m (138-298m) and after 4 weeks to 352m (298-428m). Without continuing the SOE-TIE therapy, the physical capacity sank to an average of 259,6m (128-398m) during the 4 week wash out phase (Fig. 2). Compared to the reference value these values were significantly improved at all times: after 2 weeks by 102,6m (70-152m - p=0,0002), after 4 weeks by 258,6m (126-260m - p=0,0006) and 4 weeks after wash-out still by 166,3m (70-330m - p=0,009).

In COPD patients the average walking distance for the 6-minute walking test before the therapy was111m (28-284m). After 2 weeks of the SOE-TIE therapy, the average physical capacity rose to 238,6m (98-402m) and after 4 weeks to 363,8m (198-582m). Without continuing the SOE-TIE therapy, the physical capacity sank to an average of 267,5m (102-428m) during the 4 week wash out phase (Fig. 2). Compared to the reference value these values were significantly improved at all times: after 2 weeks by 127,6m (66-200m - p=0,0006), after 4 weeks by 252,9m (166-400m - p=0,0001) and 4 weeks after wash-out still by 156,5m (70-244m - p=0,003).

The progress of the lung function and laboratory parameters is compiled in Fig. 3. The vital capacity in patients with bronchial asthma did not change. Before the SOE-TIE therapy it lay at an average 86,8% (46-128%) of the reference value and, using the SOE-TIE, after two weeks it remained at 85,2% (59-128%) and at 79,8% (43-127%) after four weeks, and finally at 81,8% (45-131%) during the wash-out phase. Compared to the reference value these values are statistically not significant.

The vital capacity in patients with COPD before the SOE-TIE therapy lay at an average 88,5% (37-108%) of the reference value and, using the SOE-TIE, after two weeks it fell to at 78,4% (43-111%) and to 80,1% (35-106%) after four weeks, and finally to 72,3% (34-106%) during the wash-out phase. Compared to the reference value these values are statistically not significant.

The result is in an improvement of the 1-second capacity related to the vital capacity (FEV1%VC) within the four week inhalation therapy using the SOE-TIE for asthma patients from 89,5% (61-112%) before the therapy to 93% (73-116%) after two weeks and 86,8% (50-118%) after four weeks, increasing to 91% (74-110%) during the wash-out phase. Compared to the reference value these values are statistically not significant.

The result is in an improvement of the 1-second capacity related to the vital capacity (FEV1%VC) within the four week inhalation therapy using the SOE-TIE for COPD patients from 75,6% (44-96%) before the therapy to 88,2% (56-109%) after two weeks and 78,6% (31-97%) after four weeks, increasing to 89,6% (35-128%) during the wash-out phase. Compared to the reference value the values after weeks of SOE-TIE inhalation were significantly improved by 11,7% (from -6 to 27% - p=0,07); all other values were not significant (Figs. 4 and 5).

The inflammatory parameter (CRP) before the inhalation therapy with SOE-TIE was only pathological in 3 COPD patients. None of these 3 patients had signs of a clinical infection or were being treated with antibiotics. The CRP of these three patients showed no changes under therapy. There were no changes

observed in parameters related to leukocytes, erythrocytes, thrombocytes, haemoglobin and haematocrit throughout the duration of the study either.

Four of the 8 COPD patients began the inhalation therapy in a phase of bacterial exacerbation which, with an antibiotic therapy complimented by the SOE-TIE therapy, was completely cured within 7 days. During the total therapy phase and wash-out phase, none of the patients suffered any exacerbation despite a seasonal wave of infection (bordetella pertussis, haemophilus influenza, chlamydia pneumonia, staphylococcus aureus). This condition remained for a further 3 months. Only after the fourth month after the therapy ended did an exacerbation of the COPD occur in two of the 8 patients.

Discussion

The objective of this study was to evaluate the effects of activated air from the SOE-TIE on the physical capacity, the lung function and inflammatory parameters of asthma and COPD patients. Primarily, the physical capacity (6-minute walking test) of all the asthma and COPD patients improved 3-fold. This can be explained, secondly, by the deflation of the lung (VC reduced by 11,8% in COPD and 7% in asthma patients, FEV1%VC increased by 11,6% in COPD and 3,25% in asthma patients) (Fig. 2).

Publications in respect of SOE-TIE therapy of patients with chronic diseases do not yet exist. The results of Schöllmann[6] showed a 7% improvement in the peak flow and a 10% improvement in oxygen absorption with healthy test persons using singlet oxygen energy therapy, confirm our results respective the changes in lung function parameters of asthma and COPD patients using the SOE-TIE. The 30% reduction of oxidative stress in patients using a singlet oxygen energy therapy, as proven by Hulten et al[4], probably led to a reduction of the obstruction - caused by a reduction of the inflammation - and a deflation of the lung (improved FEV1%VC). Sustained broncho-dilatation, also by reduction or complete elimination of oxidative stress, can dramatically impede the depletion of lung function[1] and thereby increase the physical capacity of the patient. The reduction in oxidative stress is not only the result of the, as proven by Briviba[2], generated singlet oxygen; it would appear that inhalation of activated atmospheric air also effects the neurotransmitters (adrenalin, noradrenalin, serotonin) and other stress hormones (TSH, ACTH, Cortisol)[5]. Further studies will clarify these assumptions. The extended absence of exacerbation of all COPD patients of this study for four months following after the inhalation of activated air implies influences on the immune system. Positive influences on the interleukins as well as the T-cell-implied immune defense are highly probable[5] and should be scrutinized in future studies.

Proof of the improvement in the physical capacity of asthma and COPD patients combined with an improved lung function and inflammation parameter as a result of the SOE-TIE therapy has encouraged a double-blind, randomized,

placebo controlled study on asthma and COPD patients, to prove the effects according to GCP-ICH.

Tables

Fig. 1

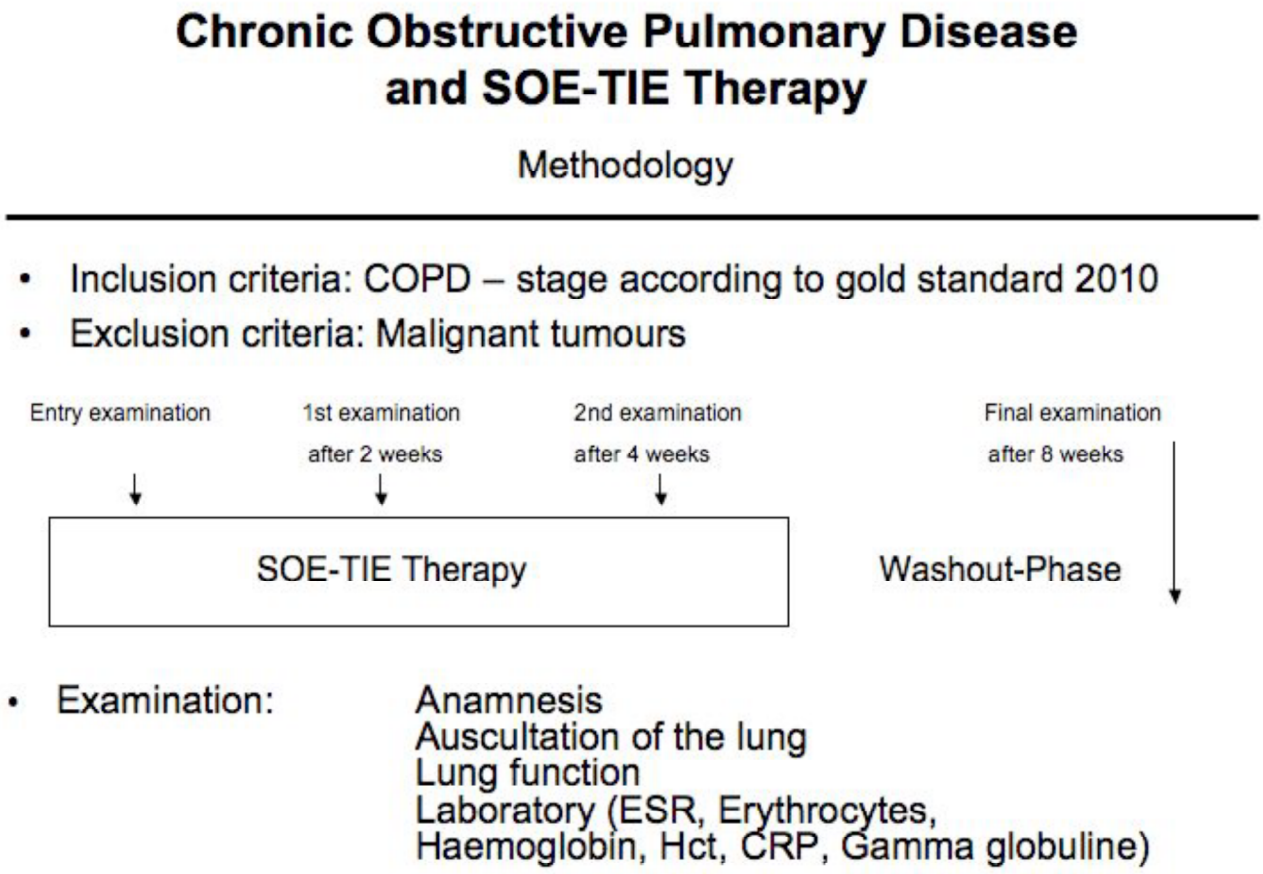
Chronic Obstructive Pulmonary Disease
and SOE-TIE Therapy
Methodology
• Inclusion criteria: COPD – stage according to gold standard 2010
• Exclusion criteria: Malignant tumours
Entry examination
1st examination
after 2 weeks
2nd examination
after 4 weeks
Final examination
after 8 weeks
SOE-TIE Therapy
Washout-Phase
• Examination:
Anamnesis
Auscultation of the lung
Lung function
Laboratory (ESR, Erythrocytes,
Haemoglobin, Hct, CRP, Gamma globuline)

Fig. 2

Chronic Obstructive Pulmonary Disease, Bronchial Asthma and SOE-TIE Therapy

Primary endpoint: Improvements of physical fitness -> 6-minute walking distance

	Prior to therapy	2 weeks	4 weeks	8 weeks
COPD				
Walking distance (m)	**111** (28-284)	**238,6** (98-402)	**363,8** (198-582)	**267,5** (102-428)
Bronchial Asthma				
Walking distance (m)	**93,3** (52-198)	**196** (138-298)	**352** (298-428)	**259,6** (128-398)

Fig. 3

Chronic Obstructive Pulmonary Disease, Bronchial Asthma and SOE-TIE Therapy

Secondary endpoints: Lung function + laboratory parameters

	Prior to therapy	2 weeks	4 weeks	8 weeks
	COPD			
Lung function				
FVC (%)	88,5 (37-108)	78,4 (43-111)	80,1 (35-106)	72,3 (34-106)
FEV1%VC	75,6 (44-96)	88,2 (56-109)	78,6 (31-97)	89,6 (35-128)
	Bronchial Asthma			
Lung function				
FVC (%)	86,8 (46-128)	85,2 (59-128)	79,8 (43-127)	81,8 (45-131)
FEV1%VC	89,5 (61-112)	93 (73-116)	86,8 (50-118)	91 (74-110)

Fig 4.

COPD: T-TEST - COMPARISON TO REFERENCE VALUE

Variable	N	Minimum	Maximum	Average	Variance	StdDev	StdError	Coeff of Variation	t Value	Pr > [t]
6-minute walking test										
after 2 weeks	8	66	200	127.62	3683.41	60.69	21.45	47.55	5.95	0.0006
after 4 weeks	8	166	400	252.87	8172.41	90.4	31.96	35.74	7.91	<0,0001
after 8 weeks	8	70	244	156.5	4391.71	66.27	23.42	42.34	6.68	0.0003
FEV1%										
after 2 weeks	6	-30	6	-135	235.5	15.34	6.26	-113.67	-2.15	0.0837
after 4 weeks	6	-30	0	-16.5	107.1	10.34	4.22	-62.72	-3.91	0.0113
after 8 weeks	6	-25	28	-8.66	403.06	20.07	8.19	-231.65	-1.06	0.3387
VC%										
after 2 weeks	6	-47	6	-11.8	376.56	19.4	7.92	-163.98	-1.49	0.1955
after 4 weeks	6	-32	3	-10.5	177.5	13.32	5.43	-126.88	-1.93	0.1114
after 8 weeks	6	-24	6	-9.83	174.56	13.21	5.39	-134.36	-18.2	0.1279
FEV1/VC										
after 2 weeks	6	-6	27	11.66	158.66	12.59	5.14	107.96	2.27	0.0726
after 4 weeks	6	-13	12	-0.16	107.36	10.36	4.23	-6217.07	-0.04	0.9701
after 8 weeks	6	-14	66	15.5	898.3	29.97	12.23	193.36	1.27	0.2610

Fig. 5

BRONCHIAL ASTHMA: T-TEST - COMPARISON TO REFERENCE VALUE

Variable	N	Minimum	Maximum	Average	Variance	StdDev	StdError	Coeff of Variation	t Value	Pr > [t]
6-minute walking test										
after 2 weeks	6	70	152	102.66	719.46	26.82	10.95	26.12	9.38	0.0002
after 4 weeks	6	126	360	258.66	6881.01	82.95	33.86	32.06	7.64	0.0006
after 8 weeks	6	70	330	166.33	9691.87	98.44	40.19	59.186	4.14	0.009
FEV1%										
after 2 weeks	5	-12	8	0.6	75.8	8.7	3.89	1451.05	0.15	0.885
after 4 weeks	5	-16	7	-2.6	110.3	10.5	4.69	-403.93	-0.55	0.6094
after 8 weeks	5	-12	2	-3.4	31.3	5.59	2.5	-164.54	-1.36	0.2457
VC%										
after 2 weeks	5	-15	13	-1.6	171.8	13.1	5.86	-819.2	-0.27	0.7984
after 4 weeks	5	-29	15	-7	280	16.73	7.48	-239.04	-0.94	0.4025
after 8 weeks	5	-19	8	-5	141.5	11.89	5.31	-237.9	-0.94	0.4005
FEV1/VC										
after 2 weeks	4	-3	12	3.25	42.25	6.5	3.25	200	1	0.391
after 4 weeks	4	-11	6	-3	68.66	8.28	4.14	-276.21	-0.72	0.5214
after 8 weeks	4	-16	13	1.25	174.25	13.2	6.6	1056.03	0.19	0.8619

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