



Dry Salt Therapy (Halotherapy) Reference & Resource Guide

Clinical Studies and Medical Research

DISCLAIMER: While there are many clinical and scientific studies conducted on dry salt therapy (halotherapy) throughout the world, the FDA has not evaluated the statements made throughout this document. Dry salt therapy is not intended to diagnose, treat, cure or prevent any disease.

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Table of Contents

Page

Click on the page name to go there directly

The Evolution of Halotherapy (Dry Salt Therapy)	5
The Halogenerator	6
Halotherapy in the United States	6
How Dry Salt Therapy Works (The 3 Fundamentals of Dry Salt Therapy)	7
Dry Salt Therapy and the Skin	7
Who Benefits from Dry Salt Therapy	8
How Dry Salt Therapy is Offered	9
Length of Session	9
Side Effects/Contraindications	10
Salt Concerns	10
Salt Type and Quality	10
Treatment Sessions	11
Dry Salt Therapy Treatment Protocols	11
Clinical Research and Medical Evidence	12



Table of Contents

Page

Clinical Studies: Click on the page name to go there directly

Pulmonary and Sleep Disorders.	13
Halotherapy in Patients with Cystic Fibrosis: A Pilot Study.	14-16
Halotherapy of Respiratory Diseases.	17-26
Halotherapy in Controlled Salt Chamber Microclimate for Recovering Medicine.	27-35
Halotherapy History and Experience of Clinical Application.	36-42
Prospects of Halotherapy in Sanatorium and Spa Dermatology and Cosmetology.	43-44
Halotherapy for Treatment of Respiratory Diseases.	45-56
Effect of Dry Sodium Chloride Aerosol on the Respiratory Tract of Tobacco Smokers	57-60
The scientific validation and outlook for the practical use of halo-aerosol therapy. Halotherapy for treatment of respiratory diseases.	61
The use of halotherapy for the health improvement in children at institutions of general education.	62
The use of halotherapy for the rehabilitation of patients with acute bronchitis and a protracted and recurrent course.	63
SALT-ED (salt therapy education) What All Types of Spas, Wellness Facilities, and Salt Therapy Providers Need to Know about Misconceptions Regarding Himalayan Salt.	64-69
Halotherapy in the combined treatment of chronic bronchitis patients.	70
The use of an artificial microclimate chamber in the treatment of patients with chronic obstructive lung diseases.	71
Effectiveness of halotherapy of chronic bronchitis patients.	72
Effects of halotherapy on free radical oxidation in patients with chronic bronchitis.	73
Efficacy of therapeutic use of ultrasound and sinusoidal modulated currents combed with halotherapy in patient with occupational toxic-dust bronchitis.	74
Salt caves as simulation of natural environment and significance of halotherapy.	75
Halotherapy as asthma treatment in children: A randomized, controlled, prospective pilot study.	76



Table of Contents

Page

Clinical Studies: Click on the page name to go there directly

Halotherapy in the combined treatment of chronic bronchitis patients.	77
The role of non-medicamental technologies in the rehabilitation of the children presenting with acute rhinosinusitis.	78
Theoretical basis and clinical benefits of dry salt inhalation therapy.	79
Bronchial hyperreactivity to the inhalation of hypo- and hyperosmolar aerosols and its correction by halotherapy.	80
The Effect of Salt Chamber Treatment on Bronchial Hyperresponsiveness in Asthmatics.	81-86
Salt Halo Therapy and Saline Inhalation Administered to Patients with Chronic Obstructive Pulmonary Disease: A Pilot Study.	87-91
Impact assessment of saline aerosols on exercise capacity of athletes.	92-96
Surveys on therapeutic effects of "halotherapy chamber with artificial salt-mine environment" on patients with certain chronic allergenic respiratory pathologies and infectious-inflammatory pathologies.	97-101
SALTMED: The Therapy with Sodium Chloride Dry Aerosols.	102-105
A Review of Halotherapy for Chronic Obstructive Pulmonary Disease.	106-113
Double-Blind Placebo-Controlled Randomized Clinical Trial on Efficacy of Aerosal® in the Treatment of Sub-Obstrucive Adenotonsillar Hypertrophy and Related Diseases.	114-120
Halotherapy and Buteyko Breathing Technique - a possible successful combination in relieving respiratory symptoms.	121-122
Halotherapy - An Alternative Method for the Treatment of Respiratory Diseases.	123-127
Halotherapy - Benefits and Risks	128-132
Dry Sodium Chloride Against Acute Respiratory Infections	133-138



The Evolution of Halotherapy (Dry Salt Therapy)

Modern dry salt therapy (halotherapy) can date its origins to the salt mines in Europe and Russia, where it was called speleotherapy, a respiratory therapy which involves the breathing of salt-infused air in a micro-climate of a salt mine. It was first officially recognized as a therapy in 1843 by Polish physician Dr. Feliks Boczkowski, who noticed that the salt mine workers rarely suffered from respiratory issues.

Miners, who chiseled, ground, and hammered the salt, produced micro-sized particles that were dispersed into the air and inhaled. Additionally, there were ideal conditions below the Earth's surface where air pressure and circulation, and humidity and temperature affected the quality of the environment. The air lacks airborne pollutants such as pollen and radon. In this environment, miners were receiving many natural health benefits by breathing in the salt particles.

Impressed with the positive health benefits he witnessed in the salt mines, Dr. Boczkowski founded and opened the first health resort facility at the Wieliczka Salt Mine in Poland.

Throughout Eastern Europe, others started using hollowed-out areas of salt mines, which were referred to as "caves", as underground health resorts and sanatoriums.

People would often spend days in the salt mines since speleotherapy was providing a significant positive impact on their health and wellbeing. Realizing that most people didn't have the time to spend in a salt mine or "cave", nor the financial resources to travel there, the Russians started to investigate developing the technology of how to recreate the microclimate of these micro-sized particles for inhalation.

In 1976, Russian doctors and scientists created the first halogenerator, which replicated the conditions of salt mines, and halotherapy, the above-ground alternative for speleotherapy, was born.



The Halogenerator

A halogenerator is a machine that intakes air and is comprised of a salt feeder, and a grinder or blade cutting mechanism that transforms pure grade sodium chloride into precise micro-sized salt particles and disperses the dry salt aerosol via a fan through an opening into a salt therapy room.

The depth of penetration into the airways is largely determined by particle size. In order to guarantee that the inhaled salt reaches not only the main respiratory tract and the bronchi but also the bronchiole and alveoli, the particle size should be between 0.1 and 5 microns, with 80% or greater smaller than 2 microns.

In Europe, halogenerator technology has evolved to the point that some medical device companies are now manufacturing halogenerators, which are being used by medical facilities and hospitals throughout Europe. When you can control the particle size and the concentration of how much salt is being inhaled; that's where the efficacy comes from this modality. Clinical studies have been done with halogenerators that have consistent particles sizes where concentration levels can be controlled, and dosing and protocols can be established.

Halotherapy in the United States

In the United States, dry salt therapy (halotherapy) started approximately 10 years ago with about a dozen facilities, and over the years, growing not as a trend but as an industry, over 1,000 salt therapy facilities are now expected by 2020. The restraints of the United States healthcare system, which includes FDA approval, pharmaceutical and insurance companies, medical lobbyists, and other restrictions are the only deterrents affecting its progress.

More clinical studies need to be performed and validated in the United States in order to be more widely accepted by the medical community, but there is proven success, effectiveness, and results in using dry salt therapy as a complementary and alternative treatment in conjunction with respiratory issues, skin conditions, and overall general wellness.



How Dry Salt Therapy Works

The 3 Fundamentals of Dry Salt Therapy

There has been lots of science about hypertonic saline solutions in terms of nebulizer treatments, wet salt therapy solutions and saline, so utilizing salt and saline in medical environments is not something that is foreign. This is a dry salt application designed through a delivery mechanism of inhalation, and due to the particle size, it's able to penetrate the epidermis at the surface level.

Super Absorbent - Dry salt acts like a sponge attracting foreign substances along its path through the respiratory tract. The dry salt can be imagined behaving like a toothbrush that cleans the respiratory system removing the build-up of foreign elements that cause various respiratory ailments and conditions. Dry salt aerosol is also very hygroscopic. As quickly as it can, it attracts as much moisture as possible. When salt particles are inhaled and deposited on the mucus on the bronchial tree, the mucus is liquefied, which facilitates its easy expectoration. Sputum is loosened and can then be removed by coughing. The obvious advantage of this is that any blocking of the airways caused by the mucus is removed. Dry salt aerosol also works as a mucokinetic agent and can increase the effectiveness of a cough, either by increasing expiratory cough airflow or by unsticking highly adhesive secretions from the airway walls. Salt stimulates the bronchial self-cleaning mechanism and can, therefore, act as an expectorant. This slight stimulation removes the mucus faster.

Anti-Inflammatory - Inhaled dry salt particles may help to reduce inflammation in the entire respiratory tract and widen the airway passages. Clinical studies have found that the inhalation of dry salt aerosol results in decreased colonization of pathogenic bacteria flora. A clean respiratory system naturally results in higher oxygen intake, increased energy, and an improved immune system.

Anti-Bacterial - The dry salt particles act as an anti-bacterial agent, dissolving bacteria and pollutants lodged in the respiratory tract. These are then either coughed up or naturally expelled by the body.

Dry Salt Therapy and the Skin

The micro-particles of salt also have a beneficial influence to the integument system (skin protective layer) and hairs providing healing and cosmetic effects. This increases activity of skin cell ion channels and activates electrophysiological activity that determines the skin's protective properties. The dry salt impacts the skin microcirculation and assists cellular membrane activity used in dermatology and cosmetology and enhances their effectiveness.



Who Benefits from Dry Salt Therapy?

Halotherapy benefits adults and children alike, as well as athletes and animals. It is natural and safe and there are no known side effects. Many people who undergo halotherapy as a complementary treatment on a regular basis may find relief from a variety of respiratory conditions such as:

- Allergies
- Asthma
- Bronchitis
- Bronchial Infections
- Cold and Flu
- COPD
- Cystic Fibrosis
- Emphysema
- Pneumonia
- Rhinitis
- Sinus Infections
- Sinusitis
- Smoker's Cough
- Snoring & Sleep Apnea
- Stress & Fatigue
- Wheezing

Dry salt therapy is also extremely beneficial to your skin in treating:

- Acne
- Eczema
- Psoriasis
- Dermatitis
- Rosacea
- Itching
- Swelling & Inflammation
- Dry & Flaky Skin
- Rashes
- Skin Aging

In addition, dry salt therapy has been shown to reduce:

- Anxiety
- Fatigue
- Stress

The best thing about dry salt therapy, however, is that despite the fact that it can be used to help treat the respiratory issues and skin conditions listed above, it can be used by anyone to enhance their overall respiratory hygiene and combat the poor quality of today's indoor and outdoor air.



How Dry Salt Therapy is Being Offered

Typically, salt therapy is offered via salt therapy rooms in public environments such as standalone salt therapy facilities, day spas, fitness clubs, med spas and wellness centers, doctor offices, private country clubs, and destination resorts.

These rooms are specifically designed to control the proper salt concentration and air ventilation inside a room for people to be able to sit back, relax, breathe, and inhale in the micro-sized salt particles.

Salt therapy rooms are sometimes referred to as "salt caves" when such things as Himalayan salt are added to the floor, walls, and ceiling in an effort to make them look like the original salt caves and mines in Europe. This Himalayan salt, however, is just decor, and provides no therapeutic value.

Oftentimes, salt therapy is being offered along with yoga, massage, reiki, acupuncture, sound therapy, and meditation. Children's play rooms are beginning to incorporate salt therapy, and businesses are starting to hold company meetings in salt rooms.

Length of Session

The amount of salt aerosol inhalation is dependent on two factors:

1. The concentration of salt in the air
2. The length of salt aerosol inhalation

The duration of a salt therapy session is based on the size and cubic volume of air space in the environment and can be anywhere from 45 minutes in a salt therapy room down to 10 minutes in smaller, portable salt therapy units. Skin that is exposed will absorb the micro-sized salt particles that are not inhaled.



Side Effects/Contraindications

There have been a number of clinical studies and research on halotherapy, and, to date, there are no known contraindications otherwise than what has been recommended based on the properties of sodium chloride, as well as in health code situations in public environments, people with any type of:

- Active tuberculosis
- Contagious conditions
- Late stage lung cancer
- Acute issues & fever
- Open wounds & sores
- Cardiac insufficiency

We understand more studies are needed to understand if there are any further contraindications, but we can confidently say that thousands of individuals have experienced salt therapy throughout the decades, and none have suggested the contraindications were present. We also encourage individuals to consult their local physician before beginning any regiment of dry salt therapy.

Salt Concerns

Some people are concerned about the intake of salt because of issues relating to diet, high blood pressure, and hypertension. This type of salt intake is connected to the digestive tract. Dry salt therapy is different as it is associated with the respiratory system. When inhaled, the amount of micro salt particles entering your respiratory system is extremely low, so it doesn't present any risk to your health. It kills bacteria, reduces inflammation, and expands airways.

There have been no reports stating that inhaling the amount of salt being utilized in a salt therapy session can provide any type of disruption or elevation of high blood pressure or hypertension.

Salt Type and Quality

Halotherapy requires the highest-quality salt available, which means that the cleanest salt available should be used. All the clinical studies and research for halotherapy involve only using 99.99% pure grade sodium chloride. This salt comes from the earth and seas but goes through a process eliminating and removing all debris and contaminants. It is not processed with any additives or caking agents such as table salt.



Reference & Resource Guide

Treatment Sessions

Based on an individual's condition and symptoms, this can vary, since like many wellness and health regimens, individuals respond differently. Many individuals will notice a positive effect in just in one session, however, a series of sessions is recommended for optimal results.

Some people go two to three times a week for a three to four-week ritual during allergy and cold seasons, some people go twice a week for six to eight weeks for more chronic conditions. Those who go for general wellness, stress relief, and relaxation simply go as often as they like.

For best results, a series of treatments is recommended. The Salt Therapy Association additionally recommends using dry salt therapy as a continuous preventive measure to strengthen the immune system against colds, cough, allergies, and sinusitis. There are some people who have salt therapy in their homes and do a daily ritual. You cannot overdose from salt therapy.

*Dry Salt Therapy Treatment Protocols

Although the FDA has yet to establish official protocols for dry salt therapy in the United States, some European countries have incorporated the following duration of treatment:

- **Asthma (mild):** 12-14 days
- **Asthma (severe):** 18-21 days
- **Acute bronchitis:** 12-14 days
- **Recurrent bronchitis:** 12-14 days
- **Chronic simple bronchitis:** 18-21 days
- **Chronic obstructive bronchitis:** 18-21 days
- **Pneumonia after acute stage:** 12-14 days
- **Cystic fibrosis:** 20-25 days
- **Chronic sinusitis:** 14-18 days
- **Acute sinusitis:** 3-5 days
- **Hay fever:** 12-14 days
- **Smokers:** 12-14 days

*SOURCE:

MINISTRY OF PUBLIC HEALTH OF THE RUSSIAN FEDERATION, Halotherapy Application in Treatment and Rehabilitation of Respiratory Diseases, Methodical Recommendation No. 95/111, Moscow 1995

Methodical recommendation was discussed and approved by the Scientific Board of the Institute of Pulmonology of the Russian Federation.

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PLEASE NOTE:

For best results, during a course of therapy, chronic sufferers should try to complete sessions as consecutively as possible - daily is best, but at least 3 times a week are usually needed for challenging cases.

Back-to-back sessions - two in a row - can be greatly beneficial for sinus and skin conditions, though are not always recommended for chronic lung conditions.



Clinical Research and Medical Evidence

Salt has been used for its healing and therapeutic qualities for thousands of years from a variety of geographic regions and cultures. In modern times, dry salt therapy, also called Halotherapy, has been observed and researched with recorded studies that go as far back as the early 1800's from physicians and scientists throughout Europe and the Far East. In the past few decades, more recent and current clinical studies have been published showing the efficacy of dry salt therapy and its application to various conditions.

Most of the current research and clinical studies are based in the countries where dry salt therapy has been a health and wellness modality for the past few decades such as Russia, Hungary, Poland, Finland, Israel, Italy and other geographic locations. These studies have been conducted by licensed medical professionals, clinical researchers, and have been published in various medical journals and publications such as the US National Library of Medicine and the National Institutes of Health.

Some of the current research and published articles focus on how dry salt therapy impacts bronchitis, chronic obstructive lung diseases (COPD), asthmatics, dermatology, and other conditions.

The **Salt Therapy Association** is also leading the way with supporting additional medical and clinical studies here in the United States and abroad to further the research, development and efficacy of dry salt therapy/halotherapy.

The following are some of the published abstracts and clinical and medical studies conducted with dry salt therapy, halotherapy, dry salt aerosol, etc.

Dr. Alina Chervinskaya, one of the founding directors of the **STA**, conducted many of the studies you are about to read. Dr. Daniel T. Layish, who is also a founding director of the **STA**, was not only involved with an initial study but he also wrote an article, and has participated in other activities supporting salt therapy.

Halotherapy

By Daniel T. Layish, MD, FACP, FCCP, FAASM

The word Halotherapy comes from the Greek word "halos" meaning salt. While the potential benefits and therapeutic nature of salt has been known for centuries, it was not until the early 1800's that the underground salt mines throughout Eastern Europe were noted to benefit various respiratory conditions. As the workers were mining the salt in these climate-enriched chambers, dry salt particles would be inhaled into the respiratory system. The dry salt was discovered to be super absorbent, anti-bacterial and anti-inflammatory. Soon people with various conditions were spending time in these salt mines. In the mid-1900's the Russians began working on a technology to replicate the dry salt particles in the air and developed the first halogenerator, a device that grinds pure sodium chloride into precise particles (several microns in diameter) and disperses the dry salt into a climate controlled room or chamber. This was the start of modern Halotherapy, which has been utilized for several decades throughout Eastern Europe and has begun to expand into many other countries including the United States and Canada. The small particle size is felt to be important to allow penetration deep into the lungs, since larger particles will simply be deposited in the nose, throat or large airways. The air in a halotherapy chamber is also filtered to remove contaminants and the temperature and humidity are well controlled.

As a pulmonologist, I initially became familiar with halotherapy through my care of individuals with Cystic Fibrosis. Cystic Fibrosis is a genetic disorder characterized by dehydration of the respiratory epithelial surface, resulting in impaired mucociliary clearance. In this disorder, thick tenacious secretions obstruct the lower airway and sinuses and provide an environment for chronic infection. Nebulized hypertonic saline has been shown (in well done randomized clinical trials) to improve pulmonary function and respiratory symptoms as well as reduce pulmonary exacerbation rate in individuals with cystic fibrosis. This may be referred to as "wet" salt therapy as opposed to halotherapy which is "dry" salt therapy. Nebulized hypertonic saline can sometimes cause bronchospasm, and not all patients can tolerate this therapy even when premedicated with a bronchodilator. In cystic fibrosis, halotherapy has some theoretical advantages over nebulized hypertonic saline. The prolonged duration of therapy (typically a 45-minute session) appears to be associated with a much lower incidence of bronchospasm than is seen in the setting of nebulized hypertonic saline. In addition, in the halotherapy mode of administration the salt particles are delivered to both the sinuses and the lower respiratory tract. After seeing anecdotal benefit in our patients with cystic fibrosis, we performed a clinical study, which confirmed that this therapy was well tolerated and the patients derived symptomatic benefit in terms of their sinus complaints. Other studies are planned to study this therapy further in individuals with cystic fibrosis.

The fundamental defect in cystic fibrosis is related to chloride transport and therefore there is a strong rationale for halotherapy in this particular disease. Anecdotally, I have seen patients with other respiratory diseases derive significant benefit from Halo-

therapy including bronchiectasis, chronic bronchitis, chronic sinusitis and allergic rhinitis. The hypothesis is that Halotherapy may help with respiratory illnesses by liquefaction of airway secretions thereby enhancing expectoration. There seems to be very little risk to this therapy other than the financial and time investment. There is certainly a theoretical basis for the possible benefit of halotherapy, given the known antiinflammatory and anti-infective properties of salt. Currently, halotherapy is not covered by medical insurance companies. However, it is hoped that this may change as research is planned to try to prove the benefits that many patients have reported. Many halotherapy institutions offer a monthly pass that can make therapy more affordable than purchasing individual sessions. There is also an effort to develop systems that can deliver halotherapy in the home setting, avoiding the need to travel to a salt room. This is important since many people do not live close to a halotherapy center. It is worth noting that many patients have also noticed benefits in non-respiratory conditions, particularly dermatologic conditions such as acne and psoriasis and research is planned in this area as well.

References available upon request. I would like to thank Leo Tonkin and Ulle Pukk for reviewing this manuscript.

Daniel Layish, MD, graduated magna cum laude from Boston University Medical School in 1990. He then completed an Internal Medicine Residency at Barnes Hospital (Washington University) in St. Louis, Missouri and a Pulmonary/Critical Care/Sleep Medicine Fellowship at Duke University in Durham, North Carolina. Since 1997, he has been a member of the Central Florida Pulmonary Group in Orlando. He serves as Co-director of the Adult Cystic Fibrosis Program in Orlando. Dr. Layish serves as the medical advisor for the Salt Room Orlando and also sits on the board of the Salt Therapy Association. He may be contacted at 407-841-1100 or by visiting www.cfpulmonary.com. ■





Halotherapy in Patients with Cystic Fibrosis: A Pilot Study

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Abstract

Objectives: Cystic fibrosis (CF) is a complex genetic disorder involving the lower and upper respiratory tract. The purpose of this study is to evaluate the effect of Halotherapy on sinusitis symptoms, dyspnea, pulmonary function tests, and quality of life in CF patients.

Study design: This was a pilot open-label before-and-after-study.

Settings: The study was performed at the Salt Room® Orlando. Participants were from a single CF care center, and were enrolled in the study between January and June, 2012.

Subjects and methods: Patients with clinically stable CF were included in the study. Participants received 9 sessions of HT, 45 minutes each, completed over a 3-week period. Study endpoints include: FEV1 and FVC, Borg dyspnea index test, Cystic Fibrosis Questionnaire-Revised (CFQ-R), and the Sino-Nasal Outcome Test (SNOT-20).

Results: Twelve patients completed the study protocol. FEV1 and FVC did not change significantly ($p=0.49$ and 0.87 , respectively). SNOT-20 score improved by 0.62 points (95% CI -1.03 to -0.2, $P=0.007$). There was a trend for improvement in Borg Dyspnea index; the mean score decreased by 0.79 (95% CI -1.64 to 0.05, $P=0.065$). There was significant improvement in the physical domain, the health perception domain, and the digestive domain.

Conclusion: HT is associated with improvement in symptoms of sinus disease in CF, and should be explored as an adjunct treatment for CF patients.

Introduction

Cystic fibrosis (CF) is a complex genetic disorder characterized by dehydration of the respiratory epithelial surface resulting in impaired mucociliary clearance [1,2]. Thick, sticky secretions obstruct the lower airways and sinuses, providing an environment for chronic infection. A significant proportion of CF patients experience sinus symptoms and almost all have radiographic findings of chronic sinusitis. Increasing the volume of airway surface liquid improves mucus clearance in patients with CF [2,3]. Inhaled hypertonic saline is one method used in patients older than 6 years to rehydrate the

airways [3]. In clinical trials hypertonic saline inhalation improved pulmonary function [2,4], and respiratory symptoms, reduced pulmonary exacerbations [4,5] and reduced absenteeism from school or work [5]. Halotherapy (HT; “halos” means salt in Greek) aims to deliver salt particles into the upper and lower airways, and appears to be a promising alternative method.

For centuries, especially in Eastern Europe, people have visited natural salt caves for the healing properties of the air. Halotherapy (HT) simulates conditions in a natural salt cave by dispersing salt particles in a controlled air medium. While similar in principles to hypertonic saline, HT differs in that it delivers dry aerosol microparticles (1-5 μ m) of salt rather than a wet solution [6]. Typically, a person visits a facility that provides HT services for a period of 30-60 minutes, where they read or perform relaxing activities while undergoing halotherapy. Breathing through the nose and mouth allows treatment effect to target the upper and lower airways.

While considered spa treatment, Halotherapy’s effectiveness was evaluated in multiple clinical trials. HT was studied in 139 patients with respiratory diseases, among whom 5 had CF. Improvements in flow-volume loop parameters and decreased bronchial resistance measured by plethysmography were reported after 10-20 sessions. The CF patients were reported to have similar response with the treatment [7]. Another recent study showed an increase in lung function and sputum production in 6 CF subjects after only 5 halotherapy sessions [7].

As a pilot work to assess feasibility, evaluate effectiveness, and gather clinical data to better estimate sample size for an experimental study, we used a pre- and post- test study design to assess the effect of HT on the pulmonary and sinus symptoms, dyspnea, and quality of life in CF patients.

Methods

This open-label study was performed at the Salt Room® Orlando, which provided the facilities for HT. Patients from a single CF care center (Central Florida Pulmonary Group, Orlando, FL, USA) were enrolled in the study between January and June of 2012. Study endpoints were measured twice: before the first and after the last HT

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Table 1: Baseline Characteristics of the 12 Patients

Age	35.11
Female	8 (66.7%)
FEV1 (L)(% predicted)	1.841.7 +/- 0.75 (56.17)
FVC (L)	2.8183 +/- 0.98
FEV1/FVC	65.3% +/-12.73%
SNOT 20	1.48 +/-0.65
Borg Dyspnea Score	2.17 +/- 1.09
CFQ-R	
The physical domain	57.6+/-23.0
The Vitality Domain	56.9 +/- 15.8
The Emotion Domain	83.3 +/- 14.6
The eating domain	96.3 +/- 9.9
The treatment burden	55.5 +/- 20.6
Health perception	63.9 +/- 12.6
The Social Domain	65.7 +/- 12.3
Body Image	84.2 +/-23.4
Role Domain	85.4 +/- 13.4
Weight domain	66.7 +/- 37.6
Respiratory domain	54.6 +/- 18.9
The digest domain	81.5 +/- 13.8

All values except gender are stated +/- SD

Table 2: Effect of Halotherapy on Lung Function, SNOT, and Borg Score

FEV1	-0.0192 (95% CI -0.0781 to 0.0398, P=0.49)
FVC	-0.010(95% CI -0.1202 to 0.1402, P=0.87).
SNOT 20	-0.62(95% CI -1.03 to -0.2, P=0.007)*.
Borg Score	-0.79(95% CI -1.64 to 0.05, P=0.065).

session. The ethics committee at Quorum Review Board approved the study. Each participant provided written informed consent or assent. The trial was designed and executed by the academic investigators. The Salt Room® Orlando provided the HT sessions and information on participants attendance but otherwise did not participate in the design and conduct of the study, in the analysis and interpretation of the data, or in the writing or review of the manuscript.

The inclusions criteria were the following: History of CF and the following, age 15 years and older, clinically stable on their medical regimen for at least a month prior to enrollment, forced vital capacity (FVC)>40% of predicted value, forced expiratory volume in one second (FEV1) between 30% and 85% of predicted value, and a score of 10 or above on the rhinologic domain of the Sino-Nasal-Outcome Test-20 (SNOT 20), which is a validated patient-outcome reported measure with four sub-domain: psychological function, rhinological symptoms, sleep function, and ear and/or facial symptoms [8]. Participants who had received antibiotics or corticosteroids for the treatment of a pulmonary exacerbation within 30 days, had taken hypertonic saline within two weeks, or had used HT previously were all excluded from the study. Patients were screened for eligibility in the clinic, prior to enrollment. Eligible participants, based on the available clinical information, returned for a baseline visit within one week of screening. At the baseline visit patients provided written consent, had a medical history and physical exam, performed spirometry, and answered questionnaires, including the Borg dyspnea index test, Cystic Fibrosis Questionnaire-Revised (CFQ-R), and the Sino-Nasal Outcome Test (SNOT-20).

Results

Between January and June of 2012, twelve participants completed the study protocol, including all 9 sessions of HT. Two additional patients met the inclusion criteria but they developed respiratory exacerbations before starting the treatment and were excluded from the analysis. Every participant completed medical history and physical exam, spirometry test, and sets of questionnaires (Borg, CFQ-R, SNOT-20). During the course of the study the participants continued on their standard regimen of treatment for CF.

The baseline characteristics of the participants are shown in Table 1. The average duration of follow up was 3 weeks. FEV1 and FVC did not change significantly (p value of 0.49 and 0.87, respectively).

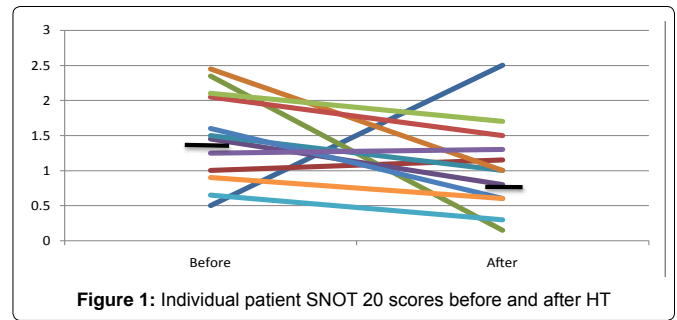


Figure 1: Individual patient SNOT 20 scores before and after HT

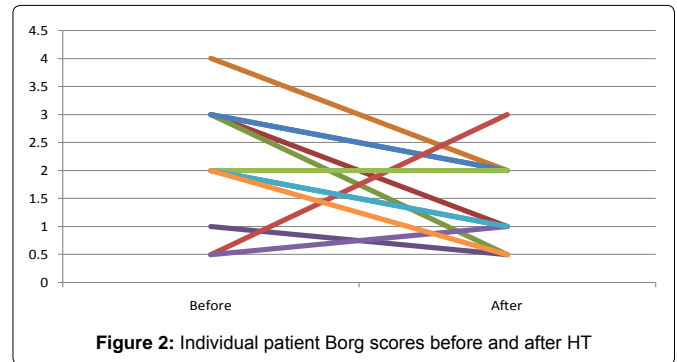


Figure 2: Individual patient Borg scores before and after HT

Table 3: Effect of Halotherapy on CFQ-R**

Physical domain	8.33 (95% CI 4.09 to 12.57, P = 0.001)*
Vitality Domain	6.25 (95% CI -2.97 to 15.47, P = 0.16)
Emotion Domain	3.95 (95% CI -1.98 to 9.90, P = 0.176)
Eating domain	0 (correlation and t test can't be computed since values were unchanged)
Treatment Burden	1.85 (95% CI -9.72 to 13.42, P = 0.73)
Health perception	10.18 (95% CI 3.19 to 17.15, P = 0.008)*
Social Domain	5.092 (95% CI 1.95 to 12.14, P = 0.14)
Body Image	-4.62 (95% CI -11.03 to 1.77, P = 0.14)
Role Domain	0.00 (95% CI -6.81 to 6.81, P = 1.0)
Weight domain	5.55 (95% CI -10.54 to 21.65, P = 0.46)
Respiratory domain	9.25 (95% CI -2.94 to 21.46, P = 0.124)
Digestive domain	10.18 (95% CI 4.39 to 15.97, P = 0.002)*

* Statistically significant difference

** For each domain in the CFQ-R a higher score indicated improvement. Highest possible =100.

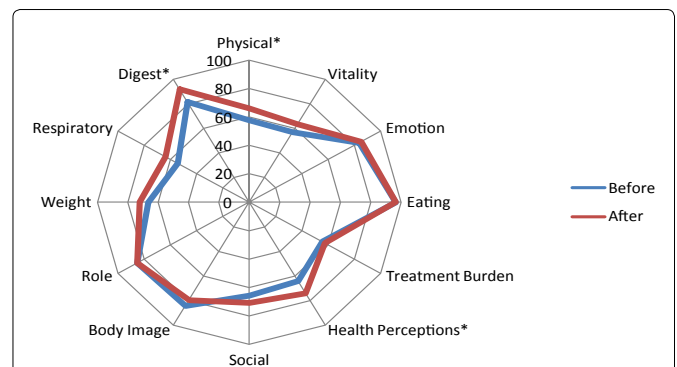


Figure 3: CFQR domains

The score on the CFQ-R domains ranges from 0, the worst score (poor health), to 100, the best score (good health). Asterisks indicate P<0.05 for the comparison between before- and after- treatment.

SNOT-20 Table 2 score (Figure 1) improved by 0.62 points (95% CI -1.03 to -0.2, P=0.007). There was a trend for improvement in Borg Dyspnea index (Figure 2); the mean score decreased by 0.79 (95% CI -1.64 to 0.05, P=0.065). Among the CFQ-R Table 3 domains there was significant improvement in the physical domain, the health perception domain, and the digestive domain. The respiratory domain improved by an average of 9.25 points, and while this is well above the recognized clinically important difference of 4 points, the

change did not reach significance ($p=0.124$). All the other domains showed no significant change (Figure 3). There were no reports of chest tightness or wheezing as a direct result of the HT.

Discussion

This pilot study of HT is the first to include assessment of pulmonary function, dyspnea scores, sinus symptoms, and quality of life exclusively in patients with CF. Hypertonic saline has long been used successfully in CF, and HT is thought to work similarly in clearing the thick mucus secretions. A potential advantage of HT is the osmotic effects of salt particles both in the nose and sinuses as well as the lower airways. Hypertonic saline inhalation functions mainly in the lower airways, and may also be used via lavage or nebulization to the sinuses, but this is a separate procedure. Hypertonic saline can provoke bronchospasm in susceptible individuals; none of the participants in our study reported such symptoms.

The symptomatic improvement in the sinus symptoms may relate to the ability of the salt particles from HT to reach a target in the sinuses and stimulate mucus clearance. In this study, we enrolled only participants with significant baseline sinus symptoms (score >10 on the SNOT-20 rhinosinusitis domain). HT may not have similar effects on patients with absent or minimal sinus symptoms.

The improvement in some of the CFQ-R domains must be interpreted with caution as the study population was relatively small. The improvement in physical activity score may infer improved exercise capacity, which helps preserve pulmonary function [10]. The improvement was also significant in the health perception and digestive domains. One could speculate that the digestive domain may be influenced by better sinus function by improving olfactory sensation, and therefore appetite.

Our study had some limitations. Since this was an open-label study, we could not evaluate whether the improvement in the reported symptoms were due to subjective effects or objective physical benefits. While there were clear trends toward improvement in dyspnea perception, our pilot study was not powered enough to detect the change. The improvement in sinus symptoms was based on patient report, but was not validated by objective measures like sinus imaging. While the study was too short to evaluate outcomes like reduction in antibiotics or surgery, our initial findings suggest that a more detailed and longer-term study may be worthwhile to evaluate those important outcomes. Longer-term studies are also necessary to evaluate the effect of HT on pulmonary exacerbations and lung function. Examining the quantity or rheologic characteristics of sputum might also be considered in further studies, as well as the effects of HT on bacterial colonization.

In conclusion, this exploratory study has demonstrated that HT may have some benefit in CF patients with symptomatic sinus disease. Longer studies, using particularly a randomized controlled study design, are necessary to better evaluate the effects of HT on other outcomes and on patients with asymptomatic sinus disease.

Acknowledgment

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Conflict of interest

Daniel Layish MD sits on the Board of Directors of the Salt Therapy Association and serves as Medical Advisor for the Salt Room® Orlando. Dr. Geller is currently employed by AbbVie, Inc in North Chicago, IL.

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HALOTHERAPY OF RESPIRATORY DISEASES

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The physical methods aimed to correct and support the protective properties of organism and the optimization of medication load, have a significant impact on the prevention and rehabilitation treatment stages. In patients with respiratory tract pathology the aerosol therapy methods with application of natural factors, which effect the respiratory system have been proved to be especially perspective.

Halotherapy present-day development of speleotherapy method

Among the methods of the artificially replicable climatic factors halotherapy (HT) has held increasingly stable positions. HT originates from speleotherapy (ST). ST (&om Greek *speleon* =cave) is a therapeutic method based on prolonged staying under the specific microclimate of karst caves, grottoes, salt mines and etc.

Separate line of ST proved to be the treatment under the salt cave microclimate (generally the old salt mines). Extensive treatment experience in patients with different respiratory diseases (RD) confirmed a high efficiency of ST under the conditions of salt mines Velichka, Solotvino, Nakhichevany, Chon- Tuz and others. Researches have shown that within the process of treatment human organism adapts to the specific particularities of microclimate and as a result the reorganization of the all functional systems activity of the body occurs [13]. Air of such caves saturated with fine salt aerosol of certain concentration that varies within 1. to 20 mg/m³ (generally from 2 to 5mg/m¹ provides the main therapeutic effect.

Since mid 80's there have been initiated attempts to simulate the microclimate of salt medical clinics under the ground-base conditions. Parameters of artificial aerodisperse environment to be created in rooms should have certain characteristics that are similar to natural conditions and adapted to the curative room environment.

At present time the curative microclimate simulation methods are focused as follows. The first proposed and the most primitive one is the covering of the walls with salt blocks. It was found that it has been impossible to create a dry fine salt aerosol environment under the conditions of rooms when applying only the passive means as the wall salt covering with sodium chloride (halite) or sylvinite [6]. This method is ineffective to produce aerosol and air sanitation and can be used only as room decoration.

In rooms where the prospective salt aerosol source is represented by, so called, saturating filters, labyrinth partitions, ventilation systems together with the salt blocks, the aerosol particles concentration, as a rule, is inappreciable or they are absent; the necessary dispersibility (respirable fraction content) is not replicated, controlled and considerably dependent on premises characteristics. In buildings, which are not equipped with the facilities to produce aerosol with necessary characteristics (concentration, size of particles) and to monitor the microclimate environment parameters there is no possibility to dose procedures.

Significance of dosing and monitoring the curative air parameters is even greater when applying microclimate of artificial sylvinite speleoclimatic chambers, where increased aeroionization, generated by radioactive γ - and f_3 - decay ^{40}K contained in sylvinite [7] is one of the acting factors. Potassium content in sylvinite formations varies significantly (17 to 43%) and moreover, there are differences in the salt block thickness, premises dimensions, ventilation and filters work rate, present patient number and etc. As a result aeroion production may vary from therapeutically minor to significantly major values.

HT technical realization with ultrasonic generators or other salt solution spraying devices is incorrect as resultant physicochemical characteristics of aerosol are very different with the dry salt aerosol. Aerodisperse environment of humid aerosol in room is almost impossible to control and dose. Sodium chloride aerosol produced in this manner does not have any curative effects in comparison with dry haloaerosol. Furthermore, high humidity in rooms considerably limits the indications for this method.

Исследования в области
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Thus, it is necessary to take in account that using of artificial microclimate of salt caves as a preventive or curative method requires the corresponding facilities including technical equipment that provides dosing and monitoring of the procedures to be taken under the according documentary permission.

Among the different names of facilities to replicate the salt cave microclimate the name "halochamber" is the most commonly accepted and this method has come to be called as halotherapy ("*hals*" - is a "salt" in Greek). Use of the terms "speleoclimatic chambers", "speleotherapy" is probably less acceptable as underground (cave) conditions are not simulated there.

Thus, halotherapy (HT) is the mode of treatment in a controlled air medium which simulates a natural salt cave microclimate. Medical requirements to this method combined with technical solutions allowed to develop a new medical technology, i.e. a controlled curative microclimate of halochamber [15].

The main curative factors of halotherapy under conditions of a controlled microclimate:

Fine dry salt aerosol within the range (0.5 mg/m³ to 10 mg/m³) with the controlled curative concentrations (modes) in accordance with the method of Ministry of Health of Russian Federation [18].

The basic mass of aerodisperse environment particles (more than 97%) is composed of respirable fraction (1-5 μm) which allows such aerosol effectively influence everywhere including the deepest parts of respiratory passages.

Physicochemical properties of dry aerosol determine specific character of HT method, which feature proved to be the multicomponent curative effect of extremely small doses of substance.

Hypobacterial and allergen-free air environment. Depending on the operational mode the quantity of salt aerosol particles in one liter of air totals from 0,4x10⁵ particles/l to 4,6x10⁷ particles/l. Availability of salt aerosol forms in curative room environment free from microorganisms and allergens.

Aeroionization. When powdering in halogenerators the salt particles due to a heavy mechanical action acquire a negative charge and high surface energy. When interacting with air molecules its aeroionization occurs (6 - 10 nK/m³). Light negative ions are the additional factors of therapeutic effect on organism and room environment clearance. Such natural way of aeroionization is the most physiological and safe.

Optimal density of aerosol and aerosols generated with such technology gives the maximal therapeutic effect.

Stability of optimum microclimatic parameters. Air curative environment has a stable humidity (40-60%) and constant temperature (18-24°C) that are the most beneficial and comfort for respiratory system.

Application of rock-salt of natural deposits (Solotvino, Sol-Iletska, Artemovska and others). This salt has natural physical properties and is composed of the lowest impurity content (Russian State Standard 51574-2000 "Table salt").

Special development of this kind of salt is not required. Extremely small doses of sodium chloride neither cause irritation nor increase bronchial mucosa reactivity that are observed when applying the hypersmolar solutions in a number of patients with bronchial asthma (BA) and other pulmonary pathology.

Design of natural salt cave and aesthetic appeal. They have positive effect on psycho-emotional field and create comfort conditions to take this procedure.

Pathophysiologic foundations of curative action of halotherapy

Experimental and clinical data allowed expressing the vision about preventive and curative effect of the main operative factor of HT [15, 17]. Dry fine sodium chloride aerosol (haloaerosol) when improving the rheological properties of bronchial mucus and contributing to mucociliary activity has a mucoregulatory effect and improve the drainage function of respiratory system. Due to the physicochemical properties this action is effectively provided in the deep hard-to-reach parts of respiratory tract. When acting as a rehydratant haloaerosol decreases bronchial walls edema and contributes to improvement of microcirculation. Dry fine sodium chloride aerosol takes inhibitive effect

Chervinskaya A. V. Halotherapy of respiratory diseases. - Physiotherapy, balneology and rehabilitation. - 2003. - N6. - P.8-15. (Rus.;

on bacterial growth and activity followed by the degradation pathogenic properties. Natural antimicrobial effect comparing to sodium chloride does not have any negative influence on the local protection and contributes to improvement of respiratory tract biocenosis. Furthermore, haloaerosol when acting as a physiological osmolar stimulus increases phagocytal activity, takes positive effect on other local immune and metabolic processes.

Local sanogenic and anti-inflammatory action of dry fine sodium chloride aerosol have an indirect positive influence on the status of systemic humoral and cellular immunity, general nonspecific organism resistance, contributes to reduction of hyper sensitization level.

As a result of action of dry superfine sodium chloride aerosol on various mechanisms of patho- and sanogenesis of respiratory passages its mucolytic, bronchodrainage and anti-inflammatory effect is taken.

HT application improves bronchial passage in patients with different respiratory tract pathologies. Effect on bronchial patency is taken gradually on account of influence on its dyscrinic and edematous-inflammatory components. Improvement of drainage function and reduction of respiratory passages inflammation contributes to indirect decrease of hyperreactivity and reduction of bronchospasmodic component of obstruction.

Present light negative aeroions activate metabolism and local protection of biological tissues; beneficially influence the cardiovascular and endocrine systems, gastrointestinal tract and respiratory mucosae, take adaptogenic effect on the organism central and peripheral stress-limiting systems. While staying in halochamber autonomic nervous system is stabilized and positive psycho-emotional effect is taken.

In the context of all the curative factors specified that a controlled halochamber microclimate has influence on:

- respiratory tract
- immune system;
- cutaneous covering;
- cardiovascular system;
- autonomic nervous system
- mental-emotional state.

Method of halotherapy

Modern halochamber represents two specially equipped rooms (Halocomplex of ZAG Aeromed, Russia). Patients are mainly placed in the principal (treatment) room in the comfortable armchairs. Aerodisperse environment is produced by halogenerator - special device for the dry salt aerosol therapy ACA-OI.3. Halogenerator is positioned in the operator's room and feeds a flow of dehydrated and filtered air saturated with fine particles of salt aerosol to the treatment room. In order to maintain the predetermined optimal parameters of microclimate in the treatment room the sensors for continuous measurement of sodium chloride aerosol mass concentration are positioned. Microprocessor built in ASA-OI.3 device handles the sensor signals and maintains the specified parameters of curative environment as referenced. Walls are covered with salt, which is the buffer capacity for atmospheric moisture and contributes to stabilization of aseptic environment. Salt covering serves as aesthetical appeal when creating a comfort perception while staying in cave. However, halochambers can adequately function without salt covering. Salt covering is not covered on the walls for economic reasons as well as in preschool institutions where playing situation and interior is created. Halocomplex without salt covering is usually called as haloroom.

HT course consists of 10-25 daily procedures for 30 minutes (for children) and 60 minutes (for adults). It is expedient to repeat HT courses 1-2 times a year for the patients with chronic pathology. During the session the patients (as a rule, 4-6 persons) are staying in armchairs. Generally, HT procedures are accompanied by quiet music; during the session quiet musical entertainment events or fairy tales are demonstrated for children. Within a day several (on average 6-8) HT sessions can be conducted. Between the sessions a room is ventilated.

There is a simpler and easier way to use dry salt aerosol in a dry environment for the curative purpose - Haloinhalation Therapy Method (HIT). Dry aerosol environment is created by the table set and aerosol gets directly to respiratory passages. HIT is conducted with halo inhalator "Haloneb" (series-produced by ZAG Aeromed, Russia). Distinctive feature of halo inhalator is proved to be ability to feed mainly respirable (1-5 mkm) dry salt aerosol fraction to the patient's respiratory system - more than 90 % of fraction composition. Special salt treatment for this device is not required.

HT and HIT methods provide for differential application of certain concentrations (modes) of dry fine sodium chloride aerosol depending on clinical features of RD and indices of respiratory function (RF) [16,18].

Dynamics of disease clinical symptoms under the influence of dry fine sodium chloride aerosol is connected with its action on different pathogenetic mechanisms of bronchopulmonary pathology and primarily with its effect on dyscrinic obstruction component. During the treatment process the overwhelming majority of patients with different forms of chronic obstructive pulmonary diseases (COPD) demonstrate positive dynamics of symptoms that proved the disorders of respiratory drainage; decrease in cough frequency and intensity, easier expectoration of sputum, which becomes less viscous and changes in its nature. Such a dynamic of clinical symptoms is an evidence of mucociliary transport activation and intensification of respiratory drainage. The results of the factor analysis showed that dyscrinia syndrome influences HT efficiency in patients with COPD [1, IS]. In patients with broncho-obstructive syndrome of different stage accompanied by respiratory drainage disorders, HT is especially effective.

As a result of HT application cough is considerably reduced as well as the symptoms of day and nocturnal expiratory dyspnea. Against this fact demand for reduction of inhaled β_2 -agonists is recorded; decrease of extrapulmonary allergy manifestations is observed. Significant differences in dynamics of the main respiratory symptoms in patients when applying both HT and HIT are not generally observed. These facts support that the dry fine sodium chloride aerosol proved to be a key factor in curative action and its application is possible both with halo chamber and halo inhalator. Change in clinical symptoms and syndromes are produced within certain terms of procedure course. In this connection the main dynamics profiles are noted. The 1st profile is "Gradual improvement". This type of changes is the most common (40% cases). Dyscrinia and expiratory dyspnea manifestations in patients reduce gradually with the first week of treatment. Improvement of clinical symptomatology is confirmed by the positive dynamics of peak expiratory flow rate (PEFR) measurement. The 2nd profile "Dyscrinia intensification" (23%) demonstrates growth and intensification of dyscrinia syndrome during the first week of treatment with its subsequent positive dynamics. Minor transient decrease in the PEFR is fixed almost concurrently. The 3rd profile of the main clinical syndrome dynamics (22%) demonstrates gradual intensification of dyscrinia (for the first week of treatment) and expiratory dyspnea followed in 1-2 days. Upon overcoming the temporary deterioration the positive dynamics of cough, dyspnea and sputum nature is observed. Indices of PEFR demonstrate the clinical symptom dynamics: initial temporary decrease precedes the expiratory dyspnea symptom intensification and lasts 2-3 days longer. When this treatment is continued the positive dynamics is observed. Such shifts are the evidence of local reaction of bronchial passage and change in the total organism reactivity in response to application of the physical curative factor. In-process changes are treated as "haloreaction", which positively influences the destruction of stable pathological process. Within these days it is necessary to add abundant drink to the treatment including fresh mineral waters. Depending on the health state and in accordance with the indications the chest massage, kinesiotherapy, drainage respiratory gymnastics, resistive breathing exercises, nebulized therapy and etc. can be used. The 4th profile of clinical presentation dynamics while undertaking HT course by patients "Dyspnea intensification" demonstrates the transient intensification of expiratory dyspnea symptoms and PEFR reduction against practically constant clinical presentation. Bronchial drainage and change in clinical pattern as compared with the initial one is not improved subsequently. Similar reaction to treatment is found in patients with bronchial asthma (BA) with clinical signs of primarily changed bronchial reactivity.

It was revealed that different nosological forms of COPO are characterized by the specific factors of clinical syndrome dynamics in response to HT. In patients with mild BA and chronic nonobstructive bronchitis (CNB) the gradual improvement of clinical presentation is generally observed. The factor "Oyscrinia and dyspnea intensification" is extremely incident to patients with serious case of BA. The factors "Oyscrinia intensification" and "Oyscrinia and dyspnea intensification" are mostly specific for chronic obstructive bronchitis (COB). "Oyscrinia intensification" type is more frequently found in patients with bronchiectases (BE). Nature of response to treatment depends on the initial level of bronchial patency. In patients with more massive obstruction disorders HT process may be accompanied by reaction "Oyscrinia and dyspnea intensification" it can be fully explained based upon haloaerosol mechanism.

HT may be applied as a main or adjunct to the drug therapy. When the clinical pattern and functional parameters are changed the recommendations to change doses of the baseline pathogenetic and symptomatic therapy (correct the administration of cromoglycates and nedocromils, corticosteroids, methylxanthines, β_3 -agonist and others) are provided. HT prescription for patients with chronic bronchopulmonary pathology within a decline period and remission contributes to achievement of maximum clinical effect with the optimum doses of drug therapy. Within a phase of incomplete remission HT primary purposes are proved to be the symptoms relief, which is insufficiently corrected with the baseline therapy, drug load reduction or drug cancellation. HT courses contribute to remission prolongation; its timely prescription prevents development of recurrent exacerbation in chronic patients. HT accelerates the process of full recovery at acute pathology especially in chronic cases. Within rehabilitation period, when drug application is frequently inexpedient and in some cases unnecessary, the application of this method is of current interest.

Indications for HT prescription proved to be practically all the most common respiratory diseases. As a rehabilitation method HT is prescribed to the patients with acute bronchitis (AB) and prolonged pneumonia, chronic nonobstructive (CNB) and obstructive bronchitis (COB), bronchial asthma (BA) of different severity and various clinical-pathogenetic treatment types including hormone-dependent forms, multiple bronchiectasis (MB), cystic fibrosis (CF).

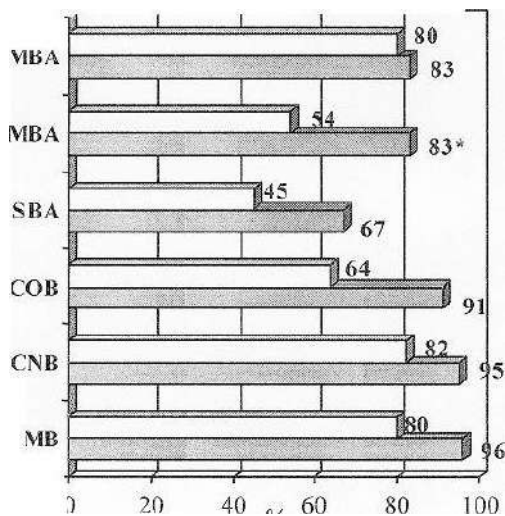
Halocomplexes (halochambers and halorooms) may be organized in outpatient hospitals, physiotherapeutic, therapeutic, pulmonologic, rehabilitation departments of in-patient hospitals and sanatoria, medical units and sanatoria-preventoria of industrial plants, resorts and preschool institutions. Under conditions of outpatient clinics and hospitals the day patient facility is the most acceptable structural unit to undertake HT. Advantages of HT method with a controlled microclimate allows to recommend it for rehabilitation and recovery treatment of patients in sanatorium-resort institutions, SPA and rehabilitation centers.

Efficiency of halotherapy within rehabilitation treatment in patients with bronchopulmonary diseases

Adding of this method to the complex of recovery treatment and rehabilitation of patients with chronic bronchopulmonary pathology in recovery and stabilization phase allows to achieve the maximum clinical effect in 82 - 96% patients with optimum doses of drug therapy, contributes to improvement of the quality of life. Results of the controlled research showed that HT prescription enabled to achieve good results of treatment in a proved number of patients that demonstrate complete cessation of respiratory symptoms and respiratory function normalization or in patients with more severe cases - stabilization of clinical and functional parameters and bringing them to the individually optimum values (Fig. 1). Data analysis of the long-term follow-up showed that upon taking the complex therapy with HT application in BA patients, remission is prolonged. At that, the stable remission within 6 months was observed in HT group in 62% and in control group - in 43% patients. In 83 % patients with mild BA remission persisted within a year and longer. In control group such a result was observed only in 67 % patients. In patients with moderate BA the average remission duration before treatment totaled 4.9 \pm 0.8 months and upon taking HT course it totaled 6.4 \pm 0.7 months ($p < 0.05$). Differences were reliable according to the symptom score as compared to the control group ($p < 0.01$). Upon taking HT the number

of urgent hospitalizations in BA patients decreased in 1.7 times. State stability in BA patients allowed reducing the range of baseline drug therapy in 3-5 months upon terminating HT course in the main group. More than a half (56%) of patients with moderate BA could reduce the maintenance dose of inhalation corticosteroids. Curative effects of HT in BA patients are realized completely against the adequate drug therapy. Application of dry superfine sodium chloride aerosol exponentiates the drug action. It allows suggesting improvement of quality administration in BA patients when applying the complex therapy with HT.

Positive treatment effect



Good treatment effect

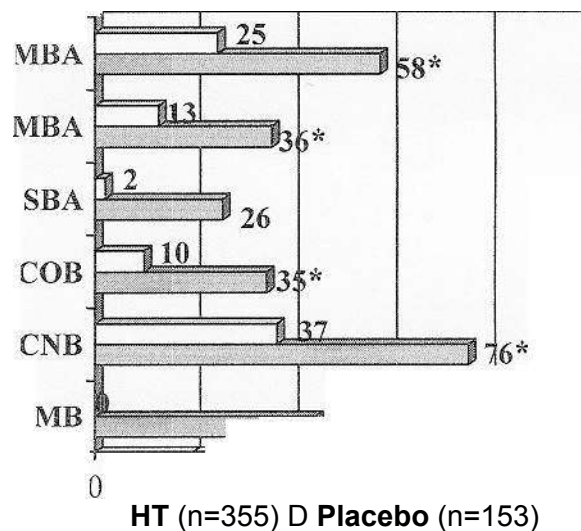


Fig. 1. Efficiency of halotherapy in patients with chronic obstructive lung diseases.

Note: MBA - mild bronchial asthma, MBA - moderate bronchial asthma, SBA - severe bronchial asthma, COB - chronic obstructive bronchitis, CNB - chronic nonobstructive bronchitis, MB - multiple bronchiectasis.

The long-term follow-up of patients with CB and MB showed that upon taking HT remission in this category of patients was prolonged as well. If the average remission duration within a period preceding HT application in this category totaled 5.0 ± 1.0 months then remission duration within a period following HT totaled 8.2 ± 1.1 months ($p < 0.05$). In CNB patients the average remission duration before treatment totaled 5.7 ± 1.1 months and upon taking HT course it totaled 9.2 ± 1.2 months ($p < 0.05$); in COB patients it totaled 5.5 ± 1.0 and 8.6 ± 0.9 ($p < 0.05$) accordingly; in MB patients it totaled 3.8 ± 0.93 and 6.7 ± 1.1 ($p < 0.05$) accordingly.

Thus, when analyzing the long-term follow-up upon treatment it was revealed that HT application in complex treatment in *capo* patients allowed prolonging the disease remission and reducing the range of baseline therapy, improving the systemic condition and emotional status of patients. Good result of HT was achieved in 85% patients with prolonged and recurrent forms of AB and residual pneumonia, which demonstrates symptomolytic condition and normalization of functional parameters. The most part of patients (53%) with the diagnosed infectious agents upon taking HT as monotherapy demonstrated reduction of antibody level to pneumococcus and hemophilic bacillus that is evidence of pathogen elimination. In addition to the mild anti-inflammatory action this method takes stimulatory effect on local

and general nocifensors suffered within exacerbation period, contributes to recovery of respiratory biocenosis. HT was prescribed as an adjunct for the group of CF patients, which was compared with the control group taken only baseline therapy. Application of both HT and HIT resulted in elimination of clinical course monotonicity, contributed to cough reduction, easier sputum discharge and its better consistency, pyogenesis reduction, upward trend of bronchial patency function that is evidence of improvement of bronchial drainage and influence on respiratory infectious and inflammatory process. Regimen and duration of HT and HIT application was developed both in hospital environment and domiciliary, tolerance was positively confirmed. In order to prognosticate response to HIT the functions (spirometry results and bronchial hyperreactivity level) were used. Form of disease, particularities of microorganisms in sputum had not any influence on efficiency.

In pediatrics HT is mostly applied for treatment and rehabilitation of BA children within postattack and interattack period (efficiency - 75-85%), high efficiency was achieved when treating children with recurrent bronchitis especially in obstruction cases. Prospects of HT therapeutic action allow reducing the antibacterial agent prescription to a considerable extent that contributes to prevention of dysbacterioses and hypersensitive reactions in children. Preventive courses for infirm children reduce risk of recurrent diseases and contribute to recovery acceleration [14].

Halotheapy as a method of primary and secondary prevention of respiratory diseases

It is extremely expedient to apply HT for primary and secondary prevention of RD. Application of this method in rehabilitation complex in sanatoria-preventoria in COPD patients and persons exposed to risks (working under unfavorable conditions) enables to reduce the morbidity rate in RD group and dependent labor losses in 1.5-2 times, prevent basic exacerbation. Application of HT is effective in 82% patients with hay fever.

Application of preventive procedures for smokers and individuals exposed to exogenous risks enables restoring of mucociliary transport, eliminating initial obstruction, restoring pulmonary host defense.

It offers the challenge to apply HT especially with haloinhalator Haloneb (more simple and easy method) as primary preventive measure for people working under unfavorable production conditions.

Upon applying haloinhalations within a three-month period twice a week on preventive basis the morbidity rate of common colds both in patients with chronic nonspecific pulmonary diseases (CNPD) and in conditionally healthy but exposed to COPD development persons was reduced. In the group taken HIT, it was recorded that common cold cases were almost 4 times less and "symptom" days were 5.6 times less as compared with the control group. These data confirmed that both HT and HIT are effective as primary and secondary preventive measures of RD.

Results of halotheapy application at diseases associated with chronic nonspecific pulmonary diseases

When considering the close interrelation between upper and lower airways and significant influence of ENT-pathology in development and advance of CNPD we focused on research of HT application particularities with available concomitant pathology. Antiedematous, antibacterial and immunostimulative action of haloaerosol has a beneficial influence on upper respiratory mucosa with a number of pathologic conditions (allergic and vasomotor rhinitis, chronic rhinosinusopathy, adenoiditis, chronic pharyngitis and others). When applying HT as a method for nasal pathology medical treatment it allows to achieve positive results in 72% - 87% cases. Positive dynamics at chronic allergic and vasomotor rhinitis and rhinosinusopathy under the dry fine sodium chloride aerosol demonstrated rhinodema and perirhinal edema reduction, nasal resistance reduction measured with the whole-body plethysmography method in 2.1 times. Dry sodium chloride aerosol takes beneficial effect on pituitary membrane and paranasal sinuses in more than 60% patients with chronic sinusitis. In 90% patients with acute sinusitis 2-3 procedures of HT prescribed upon primary puncturing have sanitation action. At chronic pharyngitis the treatment positive effect manifested in improvement of mucosa state, disappearance of

discomfort events in throat can be achieved approximately in a half of cases. In patients with chronic tonsillitis HT is effective in combination with sanation procedures [16].

Application of HT is successful for rehabilitation of patients with skin diseases (neurodermatitis disseminata, allergic dermatitis, eczema, psoriasis, streptoderma and others), especially in cases if associated with bronchopulmonary pathology. Positive results of HT were obtained in patients with atopic dermatitis. Treatment effect was more apparent in patients with exudative form of the disease within the remitting phase of acute inflammatory exudative implications or state stabilization. Good results of HT were achieved at pyococcus neurodermatitis complications as well as in cases of pyoderma manifestations as spontaneous pathology. Procedures in hal chambers take a health-improvement cosmetic effect on skin integument especially at liability to inflammatory pathology.

Application of halotherapy in elderly age and in patients with concomitant cardiac pathology

The long-term application of HT demonstrated safety of this method with regard to development of side effects on cardiovascular system allowed applying such method in patients with COPD and concomitant cardiac pathology including the elderly age groups. Application of HT in patients with BA and COB elderly 60 years with concomitant cardiac pathology (coronary heart diseases- CHD), discirculatory encephalopathy allowed to achieve the positive clinical effect without any negative reactions [11, 12, 19]. It is expedient to apply the rehabilitation complexes including in addition to HT, exercise therapy, massage, balneotherapy, local procedures of magnetotherapy, ultrasound therapy, aeroionotherapy in such cohort of patients.

During the last years HT has been increasingly applied in sanatorium-and-spa treatment. Patients of different groups and generally with concomitant pathology are directed in such sanatoria. Scientific observations and clinical experience with regard to application of a controlled microclimate enabling to select the adequate mode of curative concentration of dry salt aerosol totally demonstrated the beneficial effect of HT on cardiovascular system state.

HT has been commenced to apply within a rehabilitation program of patients with cardiac pathology including the patients undergone the coronary artery bypass graft surgeries [2]. These observations revealed that addition of HT to the rehabilitation complex resulted in moderate reduction and stabilization of arterial blood pressure both directly upon procedure (on average by 15-20 mmhg) and upon treatment course. Clinical dynamics was especially apparent in patients with concomitant cardiorespiratory pathology at that it was observed in haemodynamic indices and respiratory system state (dyspnea reduction, fall and decrease of expiratory dyspnea episodes intensity, expectoration improvement) as well. In these patients the reduction of bronchodilatory therapy range considerably influenced the rhythm disturbance episode rate.

Thus, these researches revealed safety and efficiency of HT application in patients with cardiac pathology

Application of halotherapy in rehabilitation treatment complex

HT can be successfully combined with other physiotherapeutic and drug-free methods. Efficiency of HT considerably increases if combined with drainage exercises, breast vacuum massage, exercise therapy [9, 10]. HT gives a good account in combination with magnetotherapy, laser therapy, ultrasound therapy, low-frequency electromagnetic field therapy [3, 5, 19]. It is very efficient to combine HT with normobaric hypoxitherapy [4, 8].

Multiway action of different drug-free and physiotherapeutic methods forms prerequisites for the holistic approach to prevention and rehabilitation treatment in patients with respiratory diseases. In the context of predominant action of physical factors and clinical particularities of bronchopulmonary diseases the complex rehabilitation programs including HT combined with other physical methods such as apparatus aromaphytotherapy, dosaged aeroionotherapy, different types of massage, exercise therapy, resistive breathing exercises, respiratory vibrotherapy and etc. have been developed

Treatment course is rated for 2-3 weeks with daily procedures of 1 to 2 hours, which are sequentially conducted (Fig. 2). Methods aimed to obstruction component reduction, optimization of respiration pattern, respiratory muscles exercises (different types of resistive exercises: PEP-mask, RID,

transcutaneous diaphragmatic electrostimulation and others) precede the inhalation methods in view of their potentiating action. In accordance with indications it is expedient to combine physical inhalation factors with medical nebulizer therapy.

Thus, a large scope of research and accumulated experience of practical application are evidence of efficiency and top range for curative-rehabilitation and preventive application of HT in routine of various medical and preventive treatment facilities.

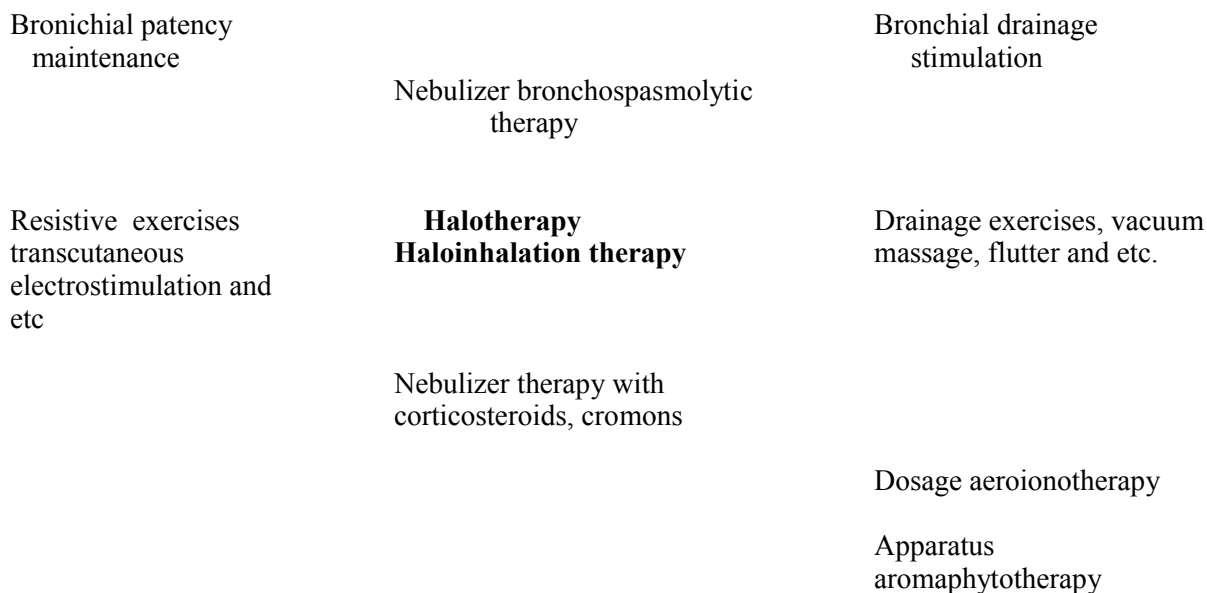


Fig. 2. Sequence of procedures of aerosol therapy complex.

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HALOTHERAPY OF RESPIRATORY DISEASE

A. V. Chervinskaya

ABSTRACT

In the scientific review the method of halotherapy simulating the parameters of salt spelaean clinic microclimate is described. The data with regard to the development of method, principles and advantages of halotherapy with a controlled microclimate of halochambers and haloinhalation therapy with portable haloinhalator are presented. Operative factors, pathophysiological foundations of curative action of this method, particularities of symptom dynamics within the treatment course and factors of clinical pattern change with different pathologies are analyzed. Data of clinical efficiency and substantiation of method application for rehabilitation treatment in patients with bronchopulmonary pathology as a method of primary and secondary prevention of respiratory diseases for ENT and skin diseases as well as in persons with concomitant cardiac pathology were presented.

Halotherapy in Controlled Salt Chamber Microclimate for Recovering Medicine

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Summary

The review presents the method of halotherapy which models the microclimate parameters of salt speleoclinics. It gives historical data on the method development, principles and advantages of halotherapy by means of controlled microclimate. The influence of the main curing factor – the dry fine-grained sodium chloride aerosol, and pathophysiological basis of curing effect of the halotherapy method are under review in the article. The article describes the method of controlled halotherapy and its technology, that is the halocomplex equipped with a controlled halogenerator.

Data on clinical efficacy and the grounds for the method usage in the recovering treatment for bronchopulmonary and otorhinolaryngologic pathologies, skin diseases and combined cardiovascular pathology, as well as preventive measures against respiratory diseases are cited. Efficacy of halotherapy in treatment and recovery of children is under review. Foundations for perspective usage of halotherapy in all kinds of medical and recovering establishments are given.

Key words: halotherapy, speleotherapy, drug free method, salt room, salt cave, salt chamber, halochamber, halocomplex, halogenerator, dry sodium chloride aerosol, respiratory diseases.

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Beginnings of halotherapy

In the last decade the usage of therapeutic air with the modeling of natural factors has become notable among physical methods used in recovering and resort medicine.

Speleotherapy (ST) is one of the methods which have given rise to further development of the whole trend in modern recovering medicine. ST («speleon»- Greek - «cave») – means usage of the underground caves microclimate for treatment. The most perspective and popular trend of ST is the treatment in the microclimate of salt caves (as a rule they are former salt mines). The overwhelming mass of all rock-salt deposit was formed in the Permian geological epoch. Ancient underground salt deposit is used for salt extraction (halite, sylvinite).

In 1843 a Polish doctor F. Bochkowski was the first

to assume, that air sated with particles of salt has a therapeutic action. In 1958 in the salt mines of Velichka, Krakow province, the first salt medical resort for patients with lung diseases was founded. Today speleotherapy has become a conventional effective non-drug method of treatment. In many countries they created speleotherapeutic clinics on the basis of natural caves — Austria (Salzebad-Salzeman), Poland (Velichka), Romania (Siget), Azerbaijan (Nakhichevan), Kirgistan (Chon-Tuz), Russia - Perm area (Berezniki), Carpatho-Ukraine (Solotvino), Ukraine (Artemovsk, Donetsk area), Byelorussia (Soligorsk). Speleotherapeutic clinics are mainly located at a depth of 200 - 300 meters. Some of them (Duz-Dag, Chon-Tuz) are situated at a height of midmontane above sea level.

The microclimate of different speleotherapeutic clinics (temperature, humidity, air composition,

presence of aeroions and others) has specific features. It is characterized by temperature and pressure constancy, gas composition of the air, low relative humidity, increased content of negative ions, absence of bacterial flora and allergens, slightly increased content of carbonic acid. The main component that determines special efficacy of treatment especially in salt caves is the presence of the finest salt particles in the air - dry salt aerosol of certain density (concentration) and particle size. The salt speleoclinics treat patients with chronic lung diseases (CLD) with the medical action of air sated with particles of rock salt.

Aerosol composition in speleoclinics depends on the structure of speleo forming rocks. The main component of aerosol in salt caves is sodium chloride. It is the main component of halite speleoclinics (Solotvino, Velichka, Chon-Tuz and others) and constitutes the major part (60-80%) of aerosol in sylvinite speleoclinics (Perm Region). Density (concentration) of salt aerosol in different speleoclinics varies within 1 to 20 mg/m³, (often from 2 to 5 mg/m³). The fact that the natural salt aerosol contains considerable amount of respirable particles (1-5 μm) which are the most effective in respiratory tract is of high significance. Moreover, it is the salt aerosol which cleans the air of underground clinics by creating nonbacterial and almost sterile atmosphere.

ST in the microclimate of salt mines has a nonspecific hyposensitizing effect, leads to reduction of infectious and inflammatory process in respiratory apparatus, and stimulates different units of local and general protective mechanisms. In the process of treatment the organism adapts to specific properties of microclimate which causes reorganization of functioning of all body systems. Research held in different speleoclinics made possible to determine the ST prescriptions and to develop differentiated complexes of its usage (1, 27, 37).

ST in salt caves has won the recognition of patients and physicians as an efficient drug-free method. However, undoubted exclusiveness of the method and related to it small number of beds, high price of treatment and necessity to move to other climatic zones have naturally restricted its spreading. ST prescription is also restricted with contra-indications which considerably constrict the circle of patients.

Tendency to use medicinal quality of salt caves microclimate for treatment of the wider circle of patients has motivated for the search for ways of reconstruction of artificial microclimate in medical establishments. ST has underlain the methods which use microclimatic factors of

salt speleoclinics in ground-based premises. The method of usage the salt caves microclimate in ground-based premises in mid 80s was given the name of «halotherapy» in St. Petersburg, Russia («hals»-Greek – «salt»). Later while using premises for treatment they started to apply other names, such as «speleoclimatotherapy», «speleotherapy» and others. In the scientific publications method halotherapy (HT) is called «haloaerosol therapy» as well.

Aggregate usage of active factors of salt caves, and namely dry sodium chloride aerosol as the main factor, certain stable comfortable room temperature and optimum air moisture have recently got the definition of «speleo impact».

Technique of the method

While modeling the salt cave microclimate various techniques have been used. Long since the first attempts to create the microclimate it has been determined that indoors it is impossible to create the atmosphere of fine sodium chloride aerosol with the only use of such passive methods as salt coating of walls (halite or sylvinite) (23). This method turned out to be ineffective. Salt bricks which cover the walls can be used only in decorative purposes. In the premises where along with salt blocks so called filters – saturators, labyrinth partitions and ventilation systems served as presumable sources of sodium chloride aerosol, the concentration of aerosol particles has been insignificant or they were absent; that is the necessary concentration and dispersion of particles has not reproduced.

Modern theoretical ideas and accumulated practical experience on the formation means and mode of behavior of aerosols have revealed that for indoor reproduction of therapeutically significant parameters of aerosol (concentration, necessary contents of respirable particles) special aerosol equipment is needed, that is halogenerators - the generators of sodium chloride aerosol. Walls with salt coating may fulfill only auxiliary functions like mental and emotional impact on patients, some maintenance of temperature and moisture conditions and air purity (due to interaction with sodium chloride aerosol produced by the halogenerator), contribute to noise absorbing.

Air saturation with moist aerosol as a result of saline solution dispersion by means of inhalers is sometimes used to create the microclimate. The essence of such method is a group inhalation of saline solutions. Besides, because of instability of moist aerosol in the indoor air it is almost impossible to measure it. Inhalations of saline solutions are more well-handled through nebuliser.

Another important function of the dry sodium chloride aerosol is to maintain hypobacterial and allergen-free air. Indoors, where there is no necessary level of dry sodium chloride aerosol, no air purification occurs, and during the treatment patients run the risk of infectious contamination concerned with accumulation of products from expired air and secretion of respiratory tract. The problem also occurs when spraying moist sodium chloride aerosol which does not possess bactericidal activity.

Analysis of the impact of sodium chloride microclimate has revealed that for optimization of the one treatment and the whole course duration, its high efficacy and safety it is necessary to measure out the level of the dry sodium chloride aerosol concentration taking into account the characteristic features of respiratory diseases as well as those of other pathologies. With regard to modern requirements for representation the microclimate of salt speleoclinics the method of controlled HT is now used (12, 29). The controlled HT provides for creation and maintenance of all the parameters of the method, differentiated dosing and controlling the level of sodium chloride aerosol in the process of treatment.

Together with studies of the method acting the equipment for its implementation has been developed and improved. The method of controlled HT is carried out with the halocomplex equipment based on the halogenerator which creates and maintains the level of natural concentration and parameters of sodium chloride aerosol with several modes of treatment by monitoring in the medical facilities like halochamber, haloroom, haloward. Some institutions with the aim of attraction of clients call the facility equipped with the halocomplex «salt room», «salt grotto», «salt cave» etc. Such names are often used for rooms with salt coating of walls but not equipped with halogenerators. The main difference is in the fact that without special aerosol equipment it is impossible to create natural environment of sodium chloride aerosol.

The halocomplex with controllable microclimate consists of two equipped rooms as a rule. The main treatment room is meant for patients sitting in comfortable armchairs. In the adjacent room, the operator's room is for the staff, the operator, who operates the halogenerator and registers patients (fig.1). The halogenerator provides for feeding of the dry fine-grained aerosol composed of prevailing respirable particles fraction (over 80%).

At present halogenerators GDA 01.17, HALOSPA-01 (UAB Halomed, Lithuania) and ASA-01.3 (JSC Aeromed, Russia) is used to equip halocomplexes. For the purpose of maintenance of prescribed

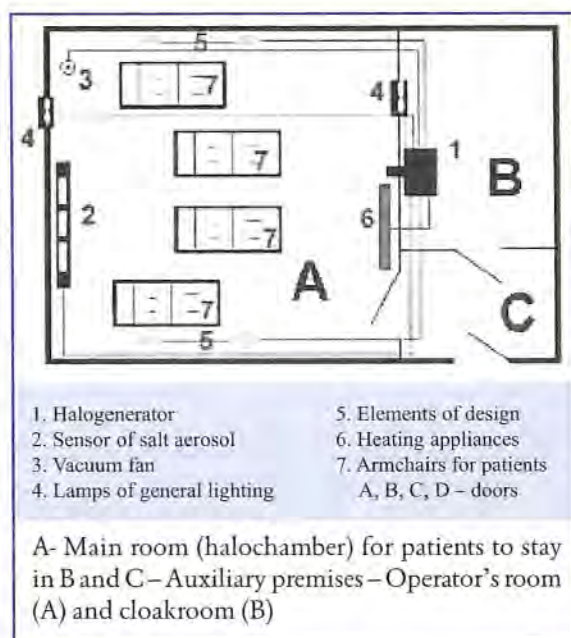


Fig. 1. Sample plan of controlled halocomplex.

treatment modes in the treatment room a sensor of continuous control of aerosol mass concentration is installed. The halogenerator's microprocessor processes sensor's signals by feed back coupling and maintains the prescribed salt aerosol parameters by means of automatic tuning to different space of the room. Microprocessor block can also provide for lightning and ventilation systems between the treatments. In the treatment room the sensors maintain the microclimate with the temperature of 20-24°C and humidity of 40-60%. As it was mentioned earlier salt coated walls are of auxiliary significance.

Halorooms where the halogenerator is located directly in the treatment room have been used for HT recently. Halorooms can also function in their full value without salt coating. Such a variant which is the most cost-effective has been widely used in pediatric practice, preschool institutions and schools where playing environment and special interior design are created.

Main treatment factors of halotherapy in controlled microclimate

Dry fine-grained sodium chloride aerosol of certain ranges with controllable medicinal concentrations (modes).

The main mass of particles in aerodispersed environment (over 80%) consists of respirable fraction (1-5 μm), and it is because of that the aerosol effectively influence all sections of respiratory tract.

Due to dispersant method of dry aerosol formation by means of heavy mechanical effect on salt crystals, particles obtain high surface energy and negative electric charge. Physicochemical properties of dry aerosol determines the specific character of the HT method which characteristic feature is in multi component curing effect of extremely small doses of the substance. The concentration of fine-grained sodium chloride aerosol in treatment room is from 1 to 10 mg/m³ and is maintained within certain limits (modes): the 1st mode - 1,0 mg/m³; 2nd mode - 1,0-3,0 mg/m³; 3rd mode - 3,0-5,0 mg/m³; 4th mode - 7,0-10,0 mg/m³ (12).

Dosing and management of salt aerosol parameters are necessary for efficient and safe usage of the method taking into account variety of nosological forms. It makes optimization of treatment and course duration possible which becomes more and more topical for medical and sanitary institutions.

Hypobacterial and allergen-free air.

Particles of dry salt aerosol which interconnect due to electrostatic interacting forces with particles of aerial contamination quicken their settling thus purifying the air in the room.

Aeroionization. At decomposition of salt particles as a result of heavy mechanical effect in the halogenerator obtain high surface energy and negative electric charge. When aerosol particles interact with air molecules it causes aeroionization of air (6-10 nK/m³). Light negative ions are accessory factors of therapeutic impact on the organism and purification of indoor air.

Stability of optimal microclimatic parameters.

Curing air has stable humidity of 40-60% and constant temperature of 20-24°C which are the most favorable and comfortable for respiratory organs and stability of aerodispersion environment.

Design of natural salt cave, aesthetic attraction.

Have positive influence on mental and emotional sphere, create comfortable conditions for carrying out treatment.

Action mechanisms

According to experimental and clinical studies, among salt aerosols the dry sodium chloride aerosol (haloaerosol) is the most effective for the respiratory tract. Action mechanisms of dry sodium chloride aerosol present in underground clinics and used in the HT method are well founded in the series of studies (3, 7, 8, 17, 18). Physical characteristics of haloaerosol are of great importance. Prevalence of respirable particles in its composition guarantees the efficiency of action and penetration of all

sections of respiratory tract right up to the deepest. Surface energy of dry salt aerosol produced in the halogenerator is higher if compared with aerosol produced by dispersion of liquid. Particles of negative charged aerosol possess one more important property, and namely they stimulate the work of respiratory epithelium cilia. Studies of absorption of liquid-droplet (moist) and dry aerosol of sodium chloride in respiratory organs ascertained that the extent of delay of particles with equal dispersity is higher in dry aerosol. Moist sodium chloride aerosol which is fed indoors by means of different types of nebulisers (jet, ultrasound etc.) is less effective as compared with the dry one (31, 38). Moreover, high humidity indoors can cause respiratory discomfort and other side effects.

Experimental and clinical data have allowed formulating the idea of mechanisms of HT action. The main acting factor is the dry fine-grained sodium chloride aerosol which:

- acts as a physiological osmolar stimulus, improves rheological properties of bronchial mucus and assists in ciliated epithelium function;
- causes fluid outflow from vessels to bronchus gap thus assisting in decrease of edema in bronchus walls and stagnation in their vessels;
- stimulates elimination of opportunistic microflora (*S. neumoniae*, *H. influenzae* and etc.);
- has a bacteriostatic effect;
- increases the number of phagocytes of respiratory tract and intensify phagocytic activity (increase in macrophages activity);
- positively influences local immune and metabolic processes (increase in SIgA and lactoferrin in pharyngeal and bronchial wash-outs, normalization of serotonin secretion; decrease in initially heightened level of catecholamines, serotonin, and histamine in bronchoalveolar lavage;
- enhances electrophysiological cell activity of mucosa epithelium;
- increases colonization resistance of epithelium cells regarding to opportunistic microflora;
- assists in restoring of biocenosis in respiratory tract;
- improves condition of systemic immunity.

Thus, the dry fine-grained sodium chloride aerosol has mucolytic, bronchodrainage, antiinflammatory and immune-response modulating effect on respiratory tract. It has airway «cleansing» (enhance host defense) effect and indirectly improves general host defense (fig. 2). Haloaerosol has an antiphlogistic and sanitating influence on airway surface liquid at its affection caused by infection and inflammation as well as by irritation due to pollutants. Improvement of drainage function and decrease in inflammation of respiratory tract contribute to abatement of

hyperreactivity and decrease of bronchospastic obstruction component (9).

Light negative aeroions that are present in halochamber activate metabolism and local defense of biological tissues, stabilize processes of vegetative regulation, have favourable effect on cardio-vascular system, endocrine system, gastrointestinal tract, mucosa of respiratory apparatus and have adaptogenic effect on central and peripheral stress-limiting systems of the organism. Staying in the halochamber breaks the contact with external unfavourable effects as allergens and pollutants, stabilizes vegetative nervous system and has a positive psycho-emotional effect. Taking into consideration all curing factors it was ascertained that the microclimate created by halocomplex influences the respiratory tract, immune and cardio-vascular system, cutaneous covering, vegetative nervous system and psycho-emotional sphere.

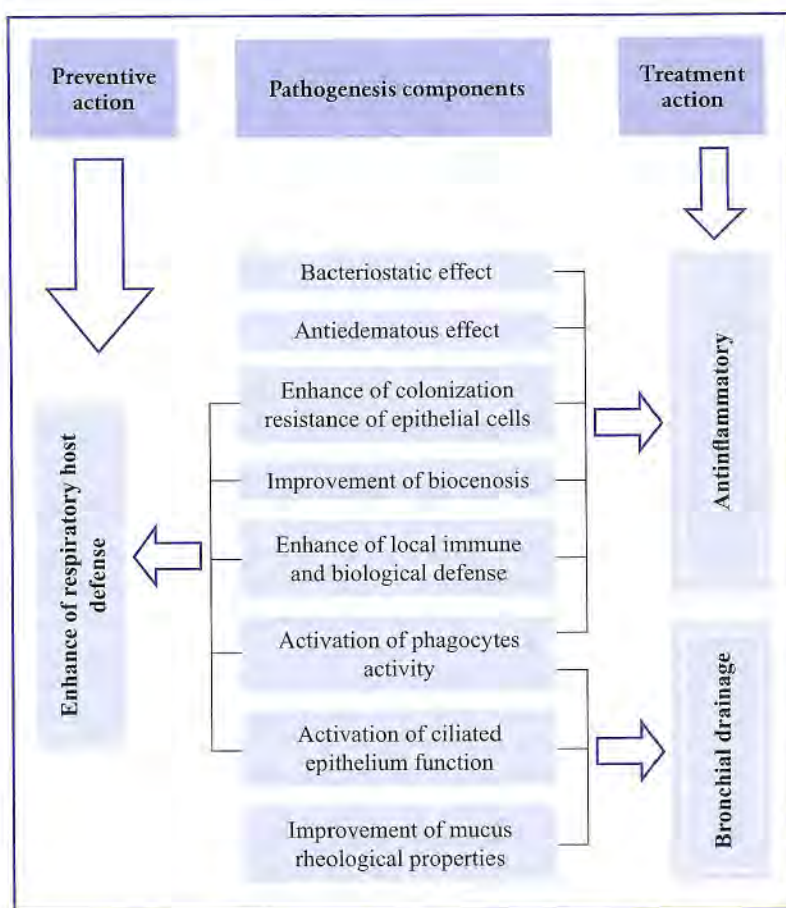


Fig. 2. Action of dry fine-grained sodium chloride aerosol on respiratory tract (Chervinskaya A.V., 1998).

Description of the method

During HT procedure patients (as a rule 4-6 persons) sit in comfortable armchairs in the treatment room (halochamber, haloroom). HT treatment usually is accompanied by tranquil music and/or psycho-suggestological programs; for children tales and calm musical entertainment programs are broadcasted. During the day several HT sessions (4-5 on average) are held. Between the sessions rooms have an airing for half an hour.

HT course consists of 10-20 daily treatment sessions of 30 minutes for children and 40-60 minutes for adults. HT courses with rehabilitation and preventive purposes are advisable to get 1-2 times a year. HT courses are expedient in work collectives during unfavorable weather seasons with the aim of prevention of acute respiratory viral infections and exacerbations of respiratory diseases. Preventive HT is also advisable for pollen allergy. It is appropriate to start treatment shortly before or with the appearance of its first symptoms. In that case HT contributes to interruption of

contact and elimination of pollen allergens out of respiratory tract.

Controlled HT provides for differentiated application of certain concentration (modes) of dry fine-grained sodium chloride aerosol according to clinical features of the disease and characteristics of the external respiration function (12, 16).

Areas of application

Possibility of choosing parameters of aerosol speleoimpact which is brought about when using controlled HT ensures the method adaptation to conditions of various fields of medicine and hygiene.

HT is described for all the most widespread respiratory diseases. As a rehabilitation method HT is prescribed to patients with acute bronchitis, prolonged pneumonia, chronic obstructive pulmonary diseases (COPD), asthma of different stages and different clinical and pathogenetic variants of their course including hormone dependent

forms, bronchiectasia, cystic fibrosis. Dosing of treatment taking into account concentration of salt aerosol allows applying the method at heavy forms of diseases with considerable obstructive dysfunction. Controlled randomized placebo studies showed (3, 7, 9, 10, 25) that method inclusion in the complex of recovering treatment and rehabilitation of patients with chronic bronchopulmonary pathology (asthma, COPD) allows achieving maximum clinical effect at 82 - 96% of patients at the most optimal doses of medication therapy and contributes to raising efficiency of treatment and prolongation of remission.

In pediatric practice HT is most frequently used in treatment and rehabilitation of children with asthma in post-attack period and in between attacks (efficiency of 75-85%). High efficacy was achieved in treatment of children with recurrent bronchitis especially in obstructive forms. Scope of HT therapeutic effect allows considerably decrease prescription of antibacterial medicine which prevents dysbacteriosis and allergic reactions in children (22, 26, 30). Preventive courses for frequently sick children diminish the risk of recurring diseases and contribute to speeding up of recovery (24). Long-term clinical application of HT method in various fields of medicine (pulmonology, allergology, paediatrics, otolaryngology, dermatology and others) as well as studies of its mechanisms has brought to understanding that the method has pronounced recovering effect. In Russia halocomplexes are used in hundreds of health centers. Recently halocomplexes have been used in SPA-industry. Method usage in the recovering complex in health and preventive centers in patients with lung diseases and with risk factors (those working in adverse conditions) makes possible to achieve respiratory sickness rate of 1,5-2 times less and prevents exacerbation of main disease (13). HT is used in a complex treatment of patients with occupational lung diseases (25). Application of HT is effective in 82% of patients with pollen allergy (2). Preventive HT treatment for smokers and patients with exogenous risk factors allows recovering of mucociliary clearance, liquidates first manifestations of obstruction and restores respiratory tract defense (5, 6). With the help of preventive usage of 2 times weekly HT treatment during three months decrease in sickness rate of acute respiratory viral infections was attained in patients with chronic pulmonary diseases as well as conditionally healthy but threatened with COPD development (15).

Application of special modes of salt aerosol concentration makes it possible to use HT not only for respiratory diseases but also in the fields

of otolaryngology and dermatocosmetology. Dry aerosol of sodium chloride has an antiphlogistic and antiedematous effect on nasal and pharyngeal mucosa as well as that of accessory sinuses of nose in chronic pharyngitis, rhinitis and sinusitis. Immune-modeling effect of haloaerosol has been proved in otolaryngological pathologies (35). HT usage as a method of conservative treatment of nasal pathology allows attaining positive results in 72%-87% of cases with the largest effectiveness in vasomotor and allergic rhinitis (4). Dry aerosol of sodium chloride has a favorable effect on mucosa of nose and accessory sinuses in chronic sinusitis (21). In 90% of patients with acute sinusitis 2-3 inhalations of aerosol of dry sodium chloride aerosol prescribed after initial puncture have sanifying effect (28, 31).

Controlled HT is successful for treatment of skin diseases (diffusive neurodermatitis, allergic dermatitis, eczema, psoriasis and others) (32, 36). Staying in halo-chamber has a positive cleansing effect and restores biocenosis of skin covering, and improves microcirculation, all of which is used in cosmetological programs (19).

Long-term usage of HT has shown the safety of the method as for side effects on cardio-vascular system which allows using it in patients with COPD having associated cardio-vascular pathology, old age group included. HT usage in patients with asthma and COPD with associated cardio-vascular pathology (ischemia, hypertension and discirculatory encephalopathy) at the old age allowed attaining positive clinical effect in the absence of any negative reactions (11, 34). Positive results of HT usage have been achieved in patients in postoperative period after coronary artery bypass grafting (14). In such patients rehabilitation complexes including therapeutic physical training, thorax massage, balneotherapy and local treatment of magnet therapy, ultrasound and aeroion therapy along with HT are advisable.

Research and clinical experience of controlled microclimate application with the ability to choose appropriate mode of curing concentration of dry sodium chloride aerosol on the whole have demonstrated positive effect of HT on the state of cardio-vascular system. At present controlled HT is included cardio-vascular pathology in the cardio-vascular pathology programs of rehabilitation of patients with cardio-vascular pathology (20, 33).

Practical application of halotherapy

HT can be successfully combined with other physiotherapeutic and drug-free methods. HT efficacy increases in conjunction with drainage gymnastics, ►

vacuum thorax massage and kinesiotherapy. HT usage together with aeroionotherapy, aromatherapy, phytotherapy, magnetotherapy, laser therapy, ultrasound, low-frequency electromagnetic field, and normobarometric hypoxithery has made a god showing.

In Russian Federation HT has been officially authorized for medical usage by the Ministry of Public Health. At present controlled halocomplexes have been installed in more than 1000 medical and sanitary institutions.

The analysis of HT application during the last 7 years (2000 - 2006) has shown that the method is being used by various medical, preventive and sanitary institutions. In the most demand HT is in sanatoria and health resorts (43%). During the last years the method has been introduced in sanitary programs in SPA facilities. Halocomplexes (halochambers and halorooms) are widely used in out-patient department, physiotherapeutic, therapeutic, pulmonological, rehabilitation and ENT- department in hospitals, medical units of industrial enterprises (34%). In out-patient department and hospitals the most reasonable organizational form for HT application is a daily clinic. Practical experience has shown that HT usage is advisable for children and adolescent practice in children pre-school facilities and schools (23%). Because of wide possibilities of preventive effect this segment continues growing.

Conclusion

Thus the ST method has been further developed into a new medical technique – the controlled HT. The achievement of the method is in the principle of controlling the parameters which ensures dosing and control of employed natural factor – dry sodium chloride aerosol. Scientific grounds for action mechanism, proven clinical efficiency verified by research on standards of evidence-based medicine and practical application in various fields of public health determine broad prospect of the method in rehabilitation, sanatoria and health resorts and preventive medicine. Numerous research and wide experience of practical application confirm the efficacy and broad opportunities of HT usage as rehabilitation and preventive medicine in all kinds of medical and recovering establishments.

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HALOTHERAPY: HISTORY AND EXPERIENCE OF CLINICAL APPLICATION

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This is the first article of the series concerning the role of dry sodium chloride aerosol in managing upper and lower respiratory tract pathologies, mechanisms of its action, clinical results, and technical approaches to aerosol delivery to patients.

Speleotherapy forms the background for the development of halotherapy.

Last years demonstrate the increase of doctors and researches who understand the reasonability of use of therapeutic methods based on application of natural or physical factors for stimulating mechanisms of sanogenes, and restoration of organism compensatory abilities.

Modern pharmaceuticals provide sufficiently effective and quick eradication of acute pathology, resolution of exacerbation of chronic diseases. Frequently repeated, prolonged or, what is worse, continuous drug therapy, however, is associated with possible development of allergic or toxic reactions, development of antibiotic tolerant species of microorganisms, wide spreading of dysbacteriosis and other side effects.

The off-stated reason inspires physicians to revise centenary experience of our forefathers and to work out new drug free and physiotherapeutic methods of treatment. Speleotherapy (from Greek "speleon"- cave), in particular, is used for managing respiratory tract pathologies.

Speleotherapy is a therapeutic method based on prolonged staying under the specific microclimate of caves, salt mines, grottoes, mines etc. Specific microclimate features depend upon character of underground cavities. The microclimate is characterized by constant temperature, pressure, gaseous and ion air composition, low relative humidity, increased ionization, prevalence of negatively charged ions, presence of various salt aerosols, increased radioactivity (in caves), the absence of bacterial flora and allergens, slightly increased contents of carbon dioxide.

The management of respiratory tract diseases by staying in caves was scientifically explained in the 40's of our century. German researches compiled data on positive influence of prolonged staying of many people in the cave of Klutert that was used during the Second World War as a bomb shelter by citizens of Ennepetal. Those time many patients with bronchial asthma and chronic bronchitis demonstrated complete resolution of the diseases or considerable improvement of their condition. Further, due to clinical and experimental studies carried out by K. Spannagel, M.D., Ph.D. [38] a new scientifically explained trend — speleoclimatotherapy — aimed at the management of respiratory tract pathologies was developed.

At present several countries have speleotherapeutic clinics developed on the basis of natural caves — Hungary, Slovenia, Bulgaria, Austria, Germany, Georgia.

Artificial caves are, as well, applicable for the therapy as natural ones. Among these may be exhausted salt mines or specially cut niches in the salt stratum where such clinics are created.

Polish doctor F. Bochowski for the first time offered supposition that air saturated with salt particles provides the main therapeutic influence in 1843. Salt mines of Velichka in Krakow province was the place where he created salt spa, and where more than hundred years ago in 1958, research and clinical resort for pulmonic patients were organized.

The examples of use of salt mines for therapeutic purposes may be found as well in other countries - Salzbad-Salzeman in Austria, Velichka in Poland, Siget in Romania, Nakhichevan in Azerbaijan, Chon-Tuz in Kirgizstan, Berezniki (Perm region) in Russia, Solotvino (Zakarpatian region) and Artemovsk (Donetz region) in Ukraine, Soligorsk in

Belorussia. All these clinics for patients with chronic non-specific lung diseases (CNLD) are based on the therapeutic action produced by cave air saturated with particles of rock salt.

Thus, salt therapy or halotherapy (HT) (from Greek "halos"- salt) is a part of speleotherapy.

Big experience in managing patients with various forms of CNLD proved high efficacy of speleotherapy undertaken in the microclimate of salt cave in Solotvino. Achieved therapeutic effect in patients with bronchial asthma (BA) of different age groups and variants of the disease was confirmed by results of biochemical, immunologic, microbiological tests. Speleotherapy in the microclimate of salt mines provides non-specific hyposensitizing effect, decrease of infections and inflammatory process activity in the respiratory tract, stimulation of various stages of local and general protective mechanisms. During the treatment organism adapts to the specificity of microclimate, which causes the reorganization of all functional systems of an organism [24]. Multiple science studies allow working out indications for speleotherapy and differential complexes of its application.

Speleotherapy is widely recognized as highly effective drug-free therapy. However, the necessity of acclimatization of a patient arriving from other climatic zones, difficulties associated with crossing, shortage of beds in comparison with amount of persons seeking for a help and a lot of contraindications hamper the wide distribution of this method of treatment.

The development of artificial microclimate of salt caves

The next step in the development of therapy with the help of inhalant substances containing dry sodium chloride aerosol was the creation of ground clinics with artificial microclimate similar to underground clinic environment. Among the first who started to work in this direction was the Uzhgorod branch of Odessa Science Research Institute (SRI) of Spa Therapy. In 1980 MD Torokhtin and V.V. Zheltvay reported about their invention on the approach to managing BA in the ground clinic where inner microclimate is modeled to obtain one similar to underground salt mine [25].

In 1982 in Perm Medical Institute there was made a climatic cell for managing respiratory allergic diseases which environment, according to the report of inventors, modeled the microclimate of speleoclinic [5]. In 1984 another kind of ground facility for managing respiratory pathologies was introduced, it was called "Halocamera" [19]. The following years were marked by appearing of comparable objects united under such names as "Halocamera", "Climatic camera"[8, 9, 18, 20].

Generally, all these structures have common characteristics, which may be united in accordance with their functional purposes. These are walls covered with various salt-derived materials or made of rock-salt bricks, devices for preparation and conditioning of the air, and machines for saturating cell air with salt aerosol. Another feature of all these structures is the deficiency of technical means for microclimate parameter control and their maintaining at the required levels. The study of halocameras produced by different manufactures revealed that microclimate characteristics within these structures differed greatly from those in natural objects. In particular, heat and humidity regime may be reproduced, however, such an important parameter, as aerosol concentration can not be guaranteed by available control equipment. The values of dispersion of sodium chloride particles and their quantity in the air vary within broad limits.

Halocameras equipped with salt powder spraying devices based on the principle of boiling layer demonstrate the following dynamic of air dispersed media during a session: the first minutes of a session are characterized by peak-like increase (3 times an even more) of salt aerosol concentration over the necessary level, by the 25-30th minute the concentration reaches trace level [14]. That is why more than half of patients demonstrate worsening of their condition as a reaction to management in these cells that in some cases necessitates additional administrations [10]. Moreover, physical and chemical characteristics of salt particles determine the specificity of their behavior, which differs greatly from that described

in literature [16]. Due to the rapid coagulation and sedimentation of the particles the qualitative composition of the dispersion changed with the following increase of geometrical dimensions of particles and decrease of respirable fraction share in the cell atmosphere [14]. That is why it is important to refresh particles during a session.

In cells where salt aerosol source is represented by, so called, saturating filters, labyrinth partitions [8,9], particles concentration does not increase higher than 1 mg/m^3 , that subsequently requires the prolongation of a session and the whole course of treatment and restricts the possibilities of HT.

However, the study on therapeutic action of dry sodium chloride aerosol revealed that the achievement of therapeutic effect and avoidance of side effects and complications from HT required strict maintaining of parameters of air dispersed media during HT (aerosol concentration, dispersion of the particles), and may be provided only by permanent monitoring of the parameters. Moreover, the experience of HT application demonstrated that management of patients with respiratory tract diseases (RTD) necessitates differential approach to the choice of therapeutic concentrations.

Taking into consideration medical demands for the method, a new generation equipment based on principles of controlled and manageable air dispersed media has been developed [11]. Modern halocomplex (manufactured by SC "Aeromed") comprises halogenerator with a microprocessor control, probes for constant measuring of temperature, relative humidity, and mass concentration of aerosol throughout a session. Halocomplex generates and maintains concentration of highly dispersed haloaerosol at the preset necessary level. Respirable fraction of this aerosol according to optic-based measuring exceeds 97%. Concentration of dry sodium chloride aerosol in the therapeutic cell may vary from 0.5 to 9 mg/m^3 , accordingly to preset limits (regime);

I regime — 0.5 mg/m^3 , II regime — $1.0\text{-}3.0 \text{ mg/m}^3$, III regime — $3.0\text{-}5.0 \text{ mg/m}^3$, IV regime — $7.0\text{-}9.0 \text{ mg/m}^3$. Moreover, this equipment does not need any special preparations of salt used for a session.

The assessment of microbial contamination in the therapeutic cell of halocomplex demonstrated that during a session 1 m^3 contained from 30 to 132 saprophytic microorganisms (according to WHO standards on air sterility 1 m^3 should contain less than 300 microbial bodies). Sanitary important microorganisms (viridans, haemolytic, staphylococci, streptococci) are not revealed. These findings correspond to the sanitary and hygienic parameters of underground speleotherapeutic clinic air.

Additional psychosuggestive effect during HT sessions may be achieved through the application of special audiovisual programs.

Mechanisms of halotherapy action

In contrary to speleotherapy based upon the therapeutic action produced by a complex of natural factors, HT is a method of aerosol therapy. Therapeutic action is provided by air dispersed media saturated with dry sodium chloride aerosol at mass concentration varying from 5.5 to 9 mg/m^3 and particle size of $1\text{-}5 \text{ mkm}$., these parameters were borrowed from different speleotherapeutic clinics. Haloaerosol has a considerable level of volumetrical negative charge of the particles ($6\text{-}10 \text{ nK7m}^3$). The air has comfortable temperature ($18\text{-}24^\circ\text{C}$) and relative humidity ($40\text{-}60\%$).

Some studies demonstrated that sodium chloride aerosol improves rheologic properties of bronchial contents facilitating normalizing of mucocellular clearance [33,36,40]. The presence of sodium chloride is necessary for normal functioning of bronchial ciliated epithelium [69], whereas sodium chloride contents in bronchial secretion of patients with chronic pulmonary pathology is decreased [30]. Sodium chloride aerosol provides bactericidal and bacteriostatic impact on respiratory tract microflora [17,37], stimulates alveolar macrophage reactivity, facilitating the increase of phagocytic elements and their phagocytic activity [12], produces anti-inflammatory action [35]. Haloaerosol has a considerable level of

volumetrical negative charge of the particles (6-10 nK7m³). High negative charge also has therapeutic significance and improves stability of the aerosol [4, 14].

Together with biological properties of sodium chloride aerosol, its physical characteristics are, as well, very important for the HT method. The prevalence of respirable fraction (1-5 mkm) share in haloaerosol (97%) provides its penetration into all sections of respiratory tract up to its deepest parts.

The basic nature of the method is application of dry sodium chloride aerosol. The study of droplet and dry sodium chloride aerosol absorption in the respiratory tract revealed that the highest degree of particles delay in case of equal dispersion was higher for dry aerosol [13], therefore the application of dry highly dispersed aerosol allowed the administration of lower doses and prevention of unfavorable side effects.

The use of dry aerosol permits to produce optimal temperature and humidity parameters in the camera. That allows avoiding the development of respiratory tract mucus edema and bronchial spasm, reactions common in patients when moist aerosols are used.

Additional effect produced by HT is explained by patient staying under conditions of hypoallergenic, hypo bacterial air surrounding, noiseless, comfortable psychological atmosphere.

Results of clinical application of controlled therapeutic microclimate of halocamera for managing patients with bronchopulmonary and upper respiratory tract pathologies

HT was used in practical health care since mid 80-s. In 1989 the method was officially recognized by Ministry of Health Care of the USSR and was largely used in various clinical establishments. The experience of HT demonstrated that the achievement of therapeutic effect and avoidance of side effects and complications necessitates strict maintaining of preset parameters of air dispersed media in halocamera. In 1995 based on experience of clinical application of the controlled therapeutic microclimate — HT — new practical recommendations which stipulates obligatory control and management of microclimate parameters in HC in the regime of real time, and differential approach to the selection of sodium chloride aerosol concentration [29] were adopted by Ministry of Health Care and Medical Industry of the Russian Federation.

Evaluation of therapeutic results of more than 4000 of the patients management in various clinical establishments according to improved method confirms its high efficacy. Thus, doctors of practical medicine reported that positive results of this method application were achieved in 82-97% of patients with different pathologic variants of BA, pollinosis, chronic non-obstructive and obstructive bronchitis (CNB and COB), acute bronchitis (AB) with recurred and persisting duration, bronchiectatic disease (BED), upper respiratory tract pathologies, and some forms of skin diseases [2, 6, 15, 23, 26]. The carried out therapy allowed to decrease the morbidity of these respiratory tract pathologies and associated with it economical loss by 1.5-2 times [27].

The overwhelming majority of patients demonstrate positive dynamics of their symptoms that proved the amelioration of respiratory passages drainage; easier expectoration of sputum, which becomes less viscous; decrease in cough intensity; changes in lung auscultation. These were associated with the number and severity of dyspnea attacks and discomfort on exhalation. The application of HT facilitated the efficacy of drug therapy and decrease of drug doses. Half of patients who were administrated inhalant corticosteroids as anti-inflammatory management could stop this therapy. One third of patients could lessen the dose of corticosteroids. 60% of patients who were treated with inhalant (3-agonists, sympathomimetics managed to stop their intake or lessen daily dose [23, 31, 32, 34]. Long term follow up revealed that 80% of patients demonstrated 3 to 12 months duration of uneventful period with the mean value of 8.5 months.

Functional testing of bronchopulmonary system may prove clinical efficacy of the method. Thus, the analysis of volume-flow loops of forced exhale revealed significant improvement of its parameters after HT course. However, there were no significant differences in parameters of external breathing function prior and immediately after the HT session [22]. While the further analysis of volume-flow loops demonstrated significant increase of bronchial passability by the seventh day of treatment [32]. The comparison of clinical and functional results suggests that HT does not provide direct impact on bronchospastic component of obstruction, but improves bronchial passability due to the gradual influence on its discrynic and inflammatory components [6, 7, 28].

Good results were also achieved in HT application for patients with vasomotor rhinitis of neurovegetative and allergic forms. The improvement of nasal breathing occurred in 98% of cases. The achieved positive result was proved by 21% mean decrease of nasal resistance measured by body plethysmography in this group of patients. Simultaneously patients with X-ray signs of edema in paranasal sinuses demonstrated considerable decrease of its intensity and sometimes its complete resolution [3].

HT management of patients with chronic tonsillitis resulted in reduced subjective and objective signs of concomitant pharyngitis, easier discharge of tonsil caseous contents and tonsil cleaning in 50% of cases. No exacerbation of the disease was revealed during the follow up period of 6 to 12 months. HT used as a part of rehabilitation therapy for patients following endonasal and endolaryngeal surgery resulted in accelerated postoperative wound healing due to the apparent anti-inflammatory influence of the aerosol. Moreover, patients with acute and indolent sinusitis subjected to HT demonstrated complete absence of purulent discharge in sinuses during repeated punctions, proving thus bactericidal effect of the therapy [1, 2].

HT provides positive effect on humoral and cellular immune system in patients with CNLD, stimulates metabolic activity of lung tissue, and causes non-specific desensitizing effect on an organism [6, 21]. The study of HT efficacy suggests that local sanogenic and anti-inflammatory action of dry highly dispersed sodium chloride aerosol provides indirect positive impact on the general organism reactivity.

Thus, the experience of HT clinical application, the study of its efficacy for different pathologies allowed optimizing the parameters of HT method, and working out the differential approach to its administration and enlarging the indications. The study of the specific action of the method was associated with the development and perfection of the equipment meant for this method. Clinical backgrounds together with new technical solutions permitted to work out new medical technology — manageable therapeutic halocamera microclimate.

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PROSPECTS OF HALOTHERAPY IN SANATORIUM-AND-SPA DERMATOLOGY AND COSMETOLOGY

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In sanatorium-and-spa sector the drug-free methods for treatment of dermatoses and recovery of skin integument become more and more popular. These methods are the part of the programs in rehabilitation dermatology, cosmetology, rejuvenation, clearance and others.

Among the modern therapeutic methods based on the application of natural factors the mostly accepted is halotherapy (HT) - method of treatment under conditions of salt mines microclimate, developed on the basis of speleotherapy.

HT simulates the principal parameters of salt mines in room conditions. The main curative factor of HT is associated first of all with the dry superfine sodium chloride aerosol. Unique effect on organism is related with its' specific physical properties.

The researches have proved natural aerosol environment in rooms can be created by special medical equipment - halogenerators. Due to the specific way of generation (by the using of disperse method), dry sodium chloride aerosol acquires a negative charge and high surface energy. Due to its' physical properties haloeaerosol provides electro-ionic effect on the walls respiratory tract and skin integument. The particles of sodium chloride aerosol penetrate deeply into respiratory tract where they enhance immune defense and provide bronchodrainage, bacteriostatic and anti-inflammatory effect. As a result, recovery and clearance of respiratory tract internal environment occur. Efficiency of this method for prevention and rehabilitation treatment of different respiratory diseases has been proved thus far. Possibility of choosing aerosol effect level in a controlled halocomplex has ensured application of this method in various branches of rehabilitation medicine and adjustment of treatment for particular patient. This method is widely used in rehabilitation and recovery pulmonology, otorhinolaryngology, allergology and pediatrics. **At present time the using of halogenerator and monitoring devices enables the application of special dermatocosmetological modes of dry sodium chloride aerosol concentrations.**

Sodium chloride particles have a beneficial influence not only on respiratory system, but integumentary system and hairs as well, providing healing and cosmetic effect. Depositing on open skin areas, haloeaerosol increases activity of skin cell ion channels and activates electrophysiological activity that determines skin protective properties. Research of skin microbiocenosis showed normalization of superficial autoflora composition after administering HT. Also bacteriostatic, antiedematous and anti-inflammatory effect of dry superfine sodium chloride aerosol was confirmed.

Salt aerosol microcrystals effect results in Ph normalization and induction of reparative- regenerative processes in derma, increases skin turgor, stimulates growth and improves hairs health. Dry salt aerosol takes beneficial effect on skin microcirculation. Increasing of permeability and electrophysiological activity of the cellular membrane dry salt aerosol helps in penetration of various remedies, used in dermatology and cosmetology and potentate their effectiveness.

Multipurpose physiological effect of dry sodium chloride aerosol ensures perspective application of HT for various skin problems.

By the end of HT course the positive dynamics has been observed in 65-75% patients with atopic dermatitis. It resulted in decreasing of itching, solution or reduction of lichenification, drying of small fissures, scratches, reducing of sympathicotonia symptoms. Positive effect is more apparent in patients with exudative form of the disease within the remitting phase of acute inflammatory exudative events. Good and sufficiently immediate effect can be achieved in patients with secondary streptoderma implications. Soon after 2-3 procedures elements of skin eruption were disappearing and by the end of the course almost complete solution of streptoderma

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implications has been noted. In patients with pyoderma there was observed improvement, expressed in of exanthema elements solution between the 2 and 3 procedures. Positive effect of HT was observed in patients with psoriasis (resulted in infiltration reduction, and central resolutiondf plates).

Considerable anti edematous and anti-inflammatory effect of dry sodium chloride aerosol is used in post surgical rehabilitation. which is especially important for aesthetic surgery. Improvement of local microcirculation, edema reduction and clearance under the influence of haloaerosol may be efficiently applied in curative cellulite programs. During the dissociation, sodium chloride microcrystals within skin area increase passive transport, which exponentiates application of various curative and cosmetological agents. This effect is perspective to combine HT with local use of creams, ointments and etc.

Respiratory and intergumentary systems are physiologically closely interrelated. Combination of pulmonary and cutaneous pathology (e.g. bronchial asthma and neurodermatitis) is very common. By its treating effect on respiratory tract sodium chloride aerosol provides concurrent detoxification and lymphodrainage influence and as a result the general health improves (including sensitization reduction). These effects contribute to skin clearance, recovery of protective properties, improvement of skin tone and turgor. (This phenomenon can be strictly shown in women who have given up smoking).

There is no doubt that that in order to gain a permanent positive effect when treating cutaneous pathology it is necessary to restore systemic biological protection. In this meaning HT is proved to be the method, which along with the local effect ensures systematic immunobiological action as well. As a result of HT application the positive shifts in systemic humoral and cell- mediated immunity with the background of decreasing of inflammatory process activity and antigens elimination are observed. Positive dynamics of parameters featuring imbalance in lipid peroxidation - antioxidants (LPO-AD) system is extremely important as it comes as an evidence of the systemic antioxidant effect of HT. Systemic immunobiological effect of HT is also highly significant for its application in cosmetological and rejuvenating programs.

Psycho-emotional factor in ethology and pathogenesis of cutaneous pathology is very important as well. During the staying in halochamber any contact with external disturbances (allergic agents, pollutants, noise and others) is cut off and gives positive psycho-emotional and antidepressant effect. Light negative air ions inside of chamber stabilize the vegetative regulation processes; beneficially influence on cardiovascular and endocrine systems and gastrointestinal tract.

Common indications for HT application in skin and cosmetologic programs:

- atopic dermatitis, diffuse and exudative form in maintenance phase;
- recurrent urticaria;
- psoriasis in maintenance phase;
- eczema;
- sebaceous hypersecretion (seborrhea adiposa);
- pyodermatites;
- pinta and onychomycosis;
- thermal cutaneous lesions;
- postoperative states (aesthetic surgery);
- comedogenous disease (acne); - cellulite;
- fading skin; - trichopathy.

Efficient application of the controlled halotherapy combined with the comfort and positive impression of procedures specifies its perspective in sanatorium-resort and spa industry.

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Halotherapy for Treatment of Respiratory Diseases

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ABSTRACT

This work elucidates the questions upon the development of a new drug-free method of a respiratory diseases treatment. Halotherapy (HT) - is mode of treatment in a controlled air medium which simulates a natural salt cave microclimate. The main curative factor is dry sodium chloride aerosol with particles of 2 to 5 mkm in size. Particles density (0.5-9 mg/m³) varies with the type of the disease. Other factors are comfortable temperature- humidity regime, the hypobacterial and allergen- free air environment saturated with aeroions.

The effect of HT was evaluated in 124 patients (pts) with various types of respiratory diseases. The control group of 15 pts received placebo. HT course consisted of 10-20 daily procedures of 1 hour. HT resulted in improvements of clinical state in the most of patients. The positive dynamics of flow-volume loop parameters and decrease of bronchial resistance measured by bodyplethysmography were observed. The changes in control group parameters after HT were not statistically significant. The specificity of this method is the low concentration and gradual administration of dry sodium chloride aerosol. Data on healing mechanisms of a specific airdispersive environment of sodium chloride while treatment the respiratory diseases are discussed.

INTRODUCTION

The considerable increase of allergic diseases and reactions and of other serious complications due to drug therapy explains the interest of clinicians to the development of drug-free methods of treatment. Halotherapy ("halos" in Greek means a salt) is one of such methods. Halotherapy (HT) is mode of treatment in a controlled air medium which simulates a natural salt cave microclimate.

Treatment in natural salt cave (speleotherapy) has been known since long. The efficacy of speleotherapy is associated with unique cave microclimate. The natural dry sodium chloride aerosol is the major curative factor of the cave microclimate. It is formed by the convective diffusion from salt walls. Other factors such as comfortable temperature and humidity regime, the hypobacterial and allergen-free air environment saturated with aeroions enhance the therapeutic effect.

A suggestion that it is the air saturated with saline dust that causes the main curative effect in the speleotherapy of patients with respiratory diseases was first formulated by a

Key words: halotherapy, speleotherapy, dry sodium chloride aerosol, respiratory diseases.

Polish physician F.Bochkowsky in 1843. Salt mines are known to be used for therapeutic purposes in other countries as well such as Austria (Solzbud-Salzeman), Rumania (Sieged), Poland (Wieliczka), Azerbaijan (Nakhichevan), Kirgizia (Chon-Tous), Russia (Berezniki, Perm region), the Ukraine (Solotvino, Carpathians); Artiomovsk, Donietsk region).

Speleotherapy has been recognized as highly effective drug-free treatment method. Great experience in the treatment of patients with various forms of chronic nonspecific pulmonary diseases has proved speleotherapy to be very effective under the conditions of the salt mine microclimate of Solotvino. The therapeutic effect has been proved by the data of biochemical, immunological, and microbiological research (Simyonka, 1989, Slivko, 1980, Yefimova et al, 1990, Zadorozhnaya et al, 1986). It is assumed that during treatment, the organism adapts to specific features of the microclimate and alters all its functional systems.

However adaptation of patients who came from different climate areas, travel and transport problems, limited number of beds keep back its wide spreading. So HT has been worked out.

DESCRIPTION OF HALOTHERAPY

HT is performed in a special room with salt coated walls - Halochamber. Dry sodium chloride aerosol (DSCA) containing the dominating amount of 2 to 5 mkm particles (Table 1) is produced by special nebulizer.

TABLE 1

Fractions of dry sodium chloride aerosol fractions in halochamber (according to data of optical devices).

Size of particles, mkm	Fractions, %
1 - 2	35.4 ± 2.1
2 - 5	61.8 ± 3.3
5 - 10	2.8 ± 0.4
> 10	0.003

TABLE 2

Composition criteria requirements for salt to be used in halotherapy.

Chemical composition of salt	%(mass)	Chemical composition of salt	%(mass)
Na, not less than	97.70	Fe ₂ O ₃ , not more than	0.01
Ca-ion, not more than	0.50	Na ₂ SO ₄	0.50
Mg-ion, not more than	0.10	Water insoluble sediment, not more than	0.45
SO ₄ -ion, not more than	1.20	Moisture in rock-salt, not more than	0.25
K-ion, not more than	0.10	pH of NaCl solution	6.5 - 8.0

The constant level of desirable aerosol mass concentration in the range of 0.5-9 mg/m³ is maintained automatically. Composition of the salt used for HT is shown in Table 2 (The Russian State Standard is 13830-84). The temperature of 18-22°C and 45-55% humidity of the medium are maintained by air conditioning system and heating devices. The HT process and microclimate parameters are controlled with computer.

The treatment in Halochamber is conducted daily, the duration of the procedure is 1.0 hour, and that of the course - 12-25 days. The duration of each course and parameters of aerosol medium depend on nosology, clinical features, phase of the disease, etc. and are prescribed by the physician (Table 3). The duration of the course and the DSCA concentration may be changed during the period of treatment in accordance with the requirement of the changing state of the patient.

The patients breathed quietly while reclining in a special chairs. Therapy is accompanied by musical psychosuggestive program and demonstration of slides. HT is carried out either alone or in association with base medication and other methods of treatment.

TABLE 3
Concentrations of dry sodium chloride aerosol and duration of halotherapy.

Disorders	Specificity	FEV ₁ (% Pr.)	Concentration (mg/m ³)	HT duration (days)
Bronchial asthma	Allergic		0.5 - 1	12 - 14
	Infection- dependent	< 60	0.5 - 1	18 - 21
> 60		1 - 2		
Chronic obstructive bronchitis		< 60	0.5 - 1	18 - 21
Chronic nonobstructive bronchitis			3 - 5	18 - 21
Bronchiectasis		< 60	1 - 2	21 - 25
		> 60	7 - 9	
Cystic fibrosis			3 - 5	21 - 25

MATERIAL AND METHODS

HT was administrated in a group of 124 patients (54 males and 70 females) aged from 16 to 62 years (mean age 34.3 + 2.5 years) with various types of chronic nonspecific pulmonary diseases (Table 4). In all of the patients (pts), the disease was in the stage of a prolonged exacerbation. Before treatment 95% of pts of the main group had cough, half them (47% had severe attacks of coughing with scanty viscous sputum. Most of pts (81%) suffered from attacks asthma so that one third of them used combined medication to control it. Auscultation revealed harsh and weakened breathing, and dry rales in 58% of patients.

60% of pts received a base therapy (beta-agonists, theophyllines, chromoglycate natrii, corticosteroids, etc.), the effect of which was insufficient and did not allow to achieve a complete remission. The pts had not taken any antibacterial medicine.

The control group was presented by 15 pts (7 females and 8 males) aged from 18 to 56 years (mean age 38.4+1.5 years). Placebo course consisted only of 10 procedures of musical psychosuggestive program with slides demonstration in an ordinary room.

The pts condition was assessed by daily medical supervision, with functional and laboratory tests made before and after HT, as well as every 7th day during treatment. A series of examinations in the control group consisted of tests similar to those for the main group of pts.

TABLE 4
Studied patients.

Disease	Number of patients
Bronchial asthma:	87
mild	32
moderate	34
severe	21
Chronic bronchitis:	26
nonobstructive	12
obstructive	14
Bronchiectasis	6
Cystic fibrosis	5
Total	124

Standard method of flow-volume loop was registered by "Pneumoscreen" ("Jager", Germany). The following parameters were assessed: vital capacity (VC), forced VC (FVC), forced expiratory volume in the 1st sec (FEV₁), peak expiratory flow (PEF), forced expiratory flow at 50% FVC (FEF₅₀). The character and the extent of bronchial patency impairment were estimated according to predicted values and limits of norm and its deviation (Klement et al, 1986). Dynamics of the indices was assessed from differences in their absolute meaning before and after therapy and was expressed in % of the initial value. Individual assessment of the results was achieved by comparing changes in the parameters and their variability. Inhalation bronchospasmodic test with 0.4 mg of Berotec was carried out in 56 patients before and after therapy (Melnikowa & Zilber, 1990). When the test was positive obstruction was considered to be reversible i.e., bronchospastic component was significant in the genesis of obstruction. Airway resistance (Raw) and intrathoracic gas volume (ITGV) were measured by "Bodyscreen" ("Jager", Germany). Total lung capacity (TLC), residual volume (RV) and their ratio (RV/TLC) were calculated on the base of spirometry and bodyplethysmography data. Raw analysis was carried out in absolute values, whereas other parameters were given in Predicted values (Kristufec et al, 1979). Diffusion capacity of the lungs by steady state method (DL_{ss}) was measured by "Transferscreen" in absolute values and as % of predicted values (Pivotean & Dechour, 1968).

Standard methods of variation statistics were used for group analysis of the material, t-Students test being used for significant differences in independent and correlated samples.

RESULTS

Clinical studies

After 3-5 sessions of HT 70-80% of pts (according to nosology) presented some improvements: expectoration of good amount of sputum- it being less tenacious and easier to discharge, better auscultatory pattern of the lungs, less frequent occurrence of cough attacks or respiratory discomfort. Some pts with severe and moderate bronchial asthma (BA) (35 patients - 27% of the total number) experienced difficulty in brining up phlegm and worsening of cough during 3-4 days after 3-4 sessions. These manifestation seem to be due to temporal bad bronchial drainage resulting from hypersecretion of mucus and discharge of old clots of secretion from bronchi of smaller diameter. Expiratory dyspnea appeared or became more pronounced in 18 patients (15% of cases) at different periods of HT. Those were mainly

the patients with exercise-induced asthma and aspirin-induced asthma. None of the pts complained of bad condition during HT procedures.

By the end of the course of HT all pts felt better: they slept well, had no fatigue and weakness, and their nervous system stabilized. Clinical symptoms analysis demonstrated that the number of asthma attacks and respiratory discomfort cases decreased significantly as compared to the initial ones (81% and 52%, respectively, $p < 0.001$). The number of asthma attacks controlled by combined medication also decreased (32% and 2%, respectively, $p < 0.001$).

The cases with cough occurred more rarely (95% and 70%, respectively, $p < 0.001$), cough became easier and more productive, the amount of sputum reduced, it became mucousal. The number of patients with signs of vasomotor rhinitis decreased (61% and 24%, respectively, $p < 0.001$).

Corticosteroids were discontinued in 50% (11 pts) of pts with corticosteroid therapy (22 pts). Those were the cases when inhaled corticosteroids were prescribed as antiinflammatory agents. In 7 pts it was possible to reduce the dose. 41 pts (60% of pts who inhaled beta-agonists) were able to discontinue beta-agonists or reduce their dose. Reduction (or cancellation) in bronchodilator and inhaled corticosteroid consumption was an indicator of clinical benefit.

The clinical state of 85% pts with mild and moderate BA, 75%-with severe BA, 98%-with chronic bronchitis, bronchiectasis and cystic fibrosis improved after HT. The pts were examined 6 and 12 months after the first HT course. No aggravation of the disease were seen from the 3d to the 12th month. The average duration of remission was 7.6 - 0.9 m. Most of the pts (60%) used no medication and sought no medical advice.

Lung function studies

Before HT bronchial obstruction was found in 83 pts (67% of all cases), 1/3 of them (25 pts) had marked impairment. By the end of the therapy bronchial obstruction was found in 50% of the pts but the number of cases with marked impairment were diminished (16 pts) (Fig.1).

Direct effect of a HT procedure on bronchial patency was studied in 12 pts. The difference between the average flow-volume loop parameters in the group after 1 procedure was insignificant ($p > 0.05$) when compared to the initial values.

Individual analysis showed that 5 pts had a significant increase of the parameters, a decrease was seen in 4 pts and in 3 cases there were no changes. On the basis of these data it is impossible to estimate the real action of DSCA on bronchial patency.

The patients showed significant increase of FVC, FEV₁, PEF, FEF₅₀ by the 7th day; of FVC and FEF₅₀ by the 14th day and of FVC, VC and PEF by the end of HT (Table 5). There was no difference in the extent of the parameter changes after the 7th day and by the end of the treatment.

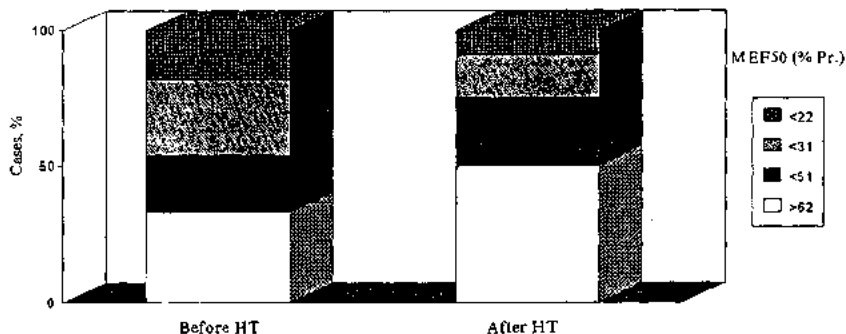


FIGURE 1. Bronchial obstruction before and after halotherapy (number of patients - 124)

TABLE 5

Change of flow-volume loop parameters at various terms of halotherapy (Mean±SE)

Parameter, % baseline	Treatment		
	7 days	14 days	End of course
Number of cas	115	98	124
VC	0 ± 0.9	2 ± 1.3	2 ± 0.9*
FVC	2 ± 0.9*	3 ± 1.3*	2 ± 1.0*
FEV ₁	3 ± 1.2*	3 ± 1.6	2 ± 1.3
PEF	4 ± 1.4*	3 ± 1.9	3 ± 1.2*
FEF ₅₀	7 ± 1.5*	7 ± 2.9*	2 ± 2.0

* significant (p < 0.05, here and further) changes vs initial values (paired t-test)

Findings of bodyplethysmography and diffusion capacity of the lungs are given in Table 6. After the HT there was a significant decrease in Raw and RV/TLC, other parameters changes were insignificant.

To know whether the initial extent of obstruction had any effect on the dynamics of bronchial patency during HT all pts were divided into four groups according to the extent of obstruction (Table 7). Group I included patients with normal indices of forced expiration (FEF₅₀ >62%Pr.); group II - with mild impairment of bronchial patency (FEF₅₀ <51%Pr.); group III - with moderate (FEF₅₀ <31%Pr.), and group IV - with severe obstruction (FEF₅₀

TABLE 6

Bodyplethysmography and diffusion capacity of lung before and after halotherapy (M ± SE), number of patients-85.

Parameter (% Predicted)	Treatment	
	before	after
VC	99 ± 3	102 ± 3
ITGV	141 ± 4	133 ± 5
RV	156 ± 6	139 ± 7
TLC	111 ± 2	109 ± 3
RV/TLC	142 ± 5	126 ± 6*
Raw ^x	0.37 ± 0.04	0.28 ± 0.02*
DL _{ss}	83 ± 7	79 ± 4

^x in kPa/l/s

* significant differences as compared to "before"

TABLE 7

Dynamics of bronchial obstruction indices at the end of halotherapy as compared to initial extent of obstruction (M ±SE).

Parameter, (% baseline)	G r o u p s			
	I FEF ₅₀ > 62%	II FEF ₅₀ < 51%	III FEF ₅₀ < 31%	IV FEF ₅₀ < 22
Number of cases	41	31	27	25
VC	- 1 ± 1.1	1 ± 1.3	8 ± 2.5*	14 ± 4.9* ^{OX}
FVC	- 1 ± 1.2	0 ± 1.4	5 ± 2.9	14 ± 4.9* ^O
FEV ₁	- 3 ± 1.3	0 ± 1.9	7 ± 4.2 ^O	25 ± 8.1* ^O
PEF	1 ± 1.6	- 1 ± 1.9	4 ± 4.2	37 ± 10.2* ^O
FEF ₅₀	- 3 ± 2.9	- 1 ± 3.7	22 ± 9.0* ^O	33 ± 11.9* ^{OX}

* significant changes as compared to initial values

^O significant difference from groups I and II

^X significant difference from groups III.

<22%Pr.). At the end of HT the indices in groups I and II did not differ from the initial ones. In group III values of FEF₅₀ became significantly higher and in group IV all indices significantly increased. The extent of changes of group IV indices was significantly greater than of groups I and II. Similar findings were obtained on the 7th and 14th day HT. Irrespectively of the therapy duration the greatest dynamics in bronchial patency was found in group IV (severe obstruction), not so marked one was in group III (moderate obstruction), and no dynamics was seen in groups I and II (slight or no obstruction).

Relationship between the character of obstruction disorders and the changes in indices during the course of therapy was studied. According to the findings of broncholytic tests the pts were divided into two groups: those with reversible, and irreversible obstruction. No significant differences in the parameter changes by the end of HT as compared to initial parameters were found (p>0.05). Both in the presence of bronchospasm and its absence the efficacy of HT on bronchial patency was the same.

Control group.

One-two day after beginning of therapy many placebo pts (80%) felt better and slept normally which seemed to be associated with psychotherapeutic effects. However, no objective improvement in their lung auscultation picture was noted. There were no significant changes of flow-volume loop parameters as compared to initial values after the course of placebo (VC- -3±5.0; FVC- -3±4.3; FEV₁- -3 ±3.4; PEF- -6±2.6; FEF₅₀- -2±3.8).

At the same time, 20% of pts with prevailing allergic mechanism of the disease had positive dynamics of function values which was probably associated with no exposure to allergens.

DISCUSSION

The course of HT resulted in improvements of clinical state in the most pts. In the overwhelming majority of cases, the number and intensity of asthma attack and respiratory discomfort decreased or disappeared, which allowed, in a number of cases, to cancel or

reduce the dosage of beta-agonists. The most pts showed positive dynamics of symptoms indicative of a better drain function of their airways: sputum secretion alleviates, it becomes less viscous, coughing relieves, and the auscultative picture of the lungs alters. The difficulty in bringing up phlegm and worsening of cough during 3-4 days seemed to be due to temporal bad bronchial drainage resulting from hypersecretion of mucus and discharge of old clots of secretion from bronchi of smaller diameter.

The similar clinical results were obtained in other investigations. Efficacy of this method has been noted in pts with various pathogenic variants of BA, chronic bronchitis, acute bronchitis, bronchiectasis, upper airways diseases, etc. (Alexandrov & Chervinskaya, 1994, Chervinskaya et al, 1993, 1994, Norvaishas et al, 1992, Pokhaznikova et al, 1992, Telyatnikova et al, 1992, Tikhomirova et al, 1993).

In our investigation the improvement in the clinical state of pts was accompanied by positive dynamics of the functional measurements. HT gave significant improvement in bronchial patency which started on the 7th day and persisted to the end of the course. There was no direct bronchospasmolytic effect. The dynamics of bronchial patency depended upon the initial extent of obstruction: the more marked was bronchial obstruction, the better were the results of HT. The effect depended not upon the character of obstruction (reversible or irreversible).

Thus, clinical functional results suggest, that HT have gradual positive influence on bronchial obstruction. With this mode of therapy which is based on cumulative action, there should be series of procedures. It seems to be associated with improvement of mucociliary clearance and decrease of bronchial inflammation. Conception of antiinflammatory influence is confirmed by the data of cytobacteriologic examinations (Chervinskaya et al, 1994). The evaluation of brush samples from nosopharynx mucosa in HT showed that the average amount of neutrophils, macrophages and lymphocytes diminished. The index of epitheliocyte infection with pneumococci and that of adhesion the average number of pneumococci per one affected epitheliocyte decreased. These indices are indicative of elimination in pathogenic microorganisms and of decrease in inflammatory reaction of the mucosa. Other investigation demonstrated decrease the amount of neutrophils and pathogenic microorganisms and increase the amount of alveolar macrophages in bronchial secretion of pts with BA, chronic obstructive bronchitis and cystic fibrosis after HT (Voronina et al, 1994). Research testified of positive effects of HT on the state of humoral and cellular immunity in patients with BA (Spesivkyh et al, 1990, Torokhtin et al, 1987); decrease of IgE level was observed (Dityatkovskaya et al, 1993). Certainly, the arguments of mucociliary clearance change of pts in HT are necessary.

HT is type of aerosol therapy, taking from speleotherapy main acting factor. Curative effect of HT is caused by aerodispersed environment saturated with dry sodium chloride aerosol with predominance amount of particles of 2 to 5 mkm in size. Such particles can penetrate deep into the smallest airways.

In our view, the positive effect of HT can be accounted for the following. One of the pathogenetic mechanisms of obstructive pulmonary diseases is mucociliary clearance impairment. Normal function of mucociliary clearance depends on the amount and viscoelastic properties of the airway surface liquid, together with the number and function of the cilia. Aerosol of sodium chloride initiates the fluid release into the bronchial lumen, and influences the viscoelastic properties of the bronchial secretion by changing the conformation of protein molecules and releasing water into the outer layers of the clots which promotes evacuation of bronchial sputum (Clarke et al, 1979, Pavia et al, 1978, Wurtemberger et al, 1987). In addition, sodium chloride is the main component of the airway surface liquid, the mucus layer and the periciliary fluid, it is needed for normal functioning of bronchial ciliary epithelium (Welch M.J., 1987). According to the evidence by certain authors, the amount of sodium chloride in bronchial secretions in patients with chronic pulmonary pathology is lower (Brogan et al, 1971). It is possible, inhalation of this chemical compound compensates for its deficit in the lungs and improves the ciliary epithelium drainage function.

Sodium chloride aerosol causes bactericidal and bacteriostatic effects on the respiratory airways microflora and prevents the development of inflammatory processes (Simyonka, 1989, Rein & Mandell, 1973). The intensity of this action depends on the concentration of the aerosol that causes dehydration of microbial cells and the impairment of the albuminous

structure of the cells killing the microorganisms. Another mechanism is possible which causes adhesion of small particles of salt to microbial bodies. As their mass grows, they precipitate rapidly.

The experiments show that low doses of DSCA have a beneficial effect on phagocytic activity of alveolar macrophages (Kononov et al, 1992) and hence on bronchial clearance and elimination of foreign agents.

Thus, sodium chloride aerosol improves rheological properties of the bronchial contents, decreases edema of bronchial mucosa and contributes to functioning of cilia epithelium, it has an bactericidal action, enhances functioning of alveolar macrophages.

The study of halochamber aerodisperse environments allowed to establish that the negative volumetric charge of dry aerosol particles was considerable (6-10 nK/m³) (Kononov et al, 1990). Higher negative charge of particles is of therapeutic significance as well (Afanasyev, 1990).

However, it is known, that sodium chloride aerosol is an osmolar stimulus, it can result in the airways hyperreactivity (Schoeffel et al, 1981). The HT specificity is the low concentration and gradual administration of DSCA. Salt consumption during a procedure depends upon the regimen chosen and is about 1-9 mg. In compare: sodium chloride aerosol inhalation challenge is used for diagnosing hyperreactivity of the airways. Hypotonic (less than 0.9%) or hypertonic (2-5%) solutions of sodium chloride are usually employed. When the inhalator production is 1 ml per minute, 20 mg of sodium chloride (measured as a dry substance) gets into the airways during 1 min of the challenge test with 2% solution and the amount reaches 50 mg in case of 5% solution. Compare: during a minute session of HT 0.05-0.10 mg of dry sodium chloride penetrates into the patient's airways when the concentration in the Halochamber is 5 mg/m³. Sodium chloride aerosol in low concentration does not affect the airway mucosa thus preventing any side effects. Besides, using of dry aerosol permits to achieve the suitable humidity of environment and to avoid the adverse reactions of airways, associated with humidification (Linker, 1982).

In summary, theoretical prerequisites and the data of clinical functional studies obtained allow to suggest that efficacy of HT results from the combination of the curative properties of sodium chloride aerosol and the way of its administration. At the same time HT mechanisms of influence are not yet studied well enough, which fact requires continuation of research.

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EFFECT OF DRY SODIUM CHLORIDE AEROSOL ON THE RESPIRATORY TRACT OF TOBACCO SMOKERS

Alina V. Chervinskaya, St.Petersburg, Russia

BRIEF SUMMARY

To estimate the changes in the airway of tobacco smokers after inhalations of dry sodium chloride aerosol the group included 47 males was examined. They were employees of an instrument manufacturing plant of St. Petersburg. Men aged from 35 to 60, who have been smoking about 15-20 cigarettes a day not less than 15 years, having no chronic pulmonary diseases and are not exposed to occupational hazards were eligible for participation in the study. Test group (TG) (24 males) were given 20 procedures (10 min daily) of inhalations of dry sodium chloride aerosol, and placebo group (PG) was included 23 males.

88% of smokers of TG by the end of inhalation course reported easier and/or decreased cough, changes in the character of sputum, which became lighter and clearer. Improvement in the character of sputum was noted only 22% volunteers of PG ($p < 0,001$).

Cytobacteriologic study of brush biopates taken from pharyngeal mucosa was determined that the infection index (II - % of epitheliocytes with adhered cells of *S. pneumoniae*) and adhesion index (AI - the mean number of microbial cells per one epitheliocyte) decreased significantly in the TG ($p < 0,01$). The amount of SIgA in epithelial cells of the oropharyngeal mucosa (estimated by indirect method of fluorescent antibodies) increased significantly in the TG ($p < 0,05$). There were no significant changes at these indexes in the PG.

Conclusion. DSCA relieves the main clinical signs (character of cough and sputum), improves local defense mechanisms and strengthens resistance of mucous membranes of tobacco smokers owing to decreased colonization activity of pathogenic microorganisms and increased SIgA.

INTRODUCTION

It is generally accepted that persons (prs) with exogenous risk factors of COPD (tobacco smokers, prs are exposed to industrial pollutants) are required sanitation of respiratory tract to prevent development of lung diseases.

Considerable efforts have been directed at examining the action of dry sodium chloride aerosol (DSCA) on respiratory tract of the patients with COPD, asthma and the persons with risk factors of COPD. DSCA is characterized with physical properties, differing from those of the saline aerosols. DSCA demonstrated anti-inflammatory activity in the respiratory tract, mucoregulating action. It enhances drainage of the bronchi, activates alveolar macrophages, and improves biocenosis and local humoral immunity.

AIM OF RESEARCH

The aim was to study influence of DSCA on the respiratory tract of tobacco smokers.

STUDY DESIGN AND PROCEDURES

47 male were examined. They were selected after medical and lung function examination. They had the productive cough associated with smoking. Chronic respiratory pathologies had been diagnosed in none of them. The groups did not differ significantly by sex, age, smoking duration and intensity (table 1).

TG were given 20 procedures (10 min daily) using inhaler Haloneb (fig.1), producing DSCA with particles size of 1-5 μm and 0.5 mg/min density (total dose is approximately 5 mg per procedure). PG received inhalation with plain air using inhaler Haloneb, specially designed for the study. It was a single blind study with placebo.

Cytobacteriologic study of brush biopates taken from pharyngeal mucosa was carried out before and

after procedures in the both groups. Brush bioplates were obtained from the antero-medial tonsillar surface, using an endoscope brush fixed on a holder. The degree of the adhesiveness of the strain by microorganisms was estimated by the adhesion index (AI). The AI was found as the mean number of microbial cells per one epitheliocyte; 50 epithelial cells participating in the adhesion process of epithelial cells were counted. The colonizational activity was estimated by the infection index (II), i.e. the percentage of epitheliocytes with adhered cells of pneumococcus per 50 counted cells.

Table 1 Characteristics of the Test (TG) and Placebo (PG) groups

Parameter, M±m	TG	PG	Significant difference
Number of the persons	24	23	
Age, years	49.9±1.2	49.5±1.5	p>0.05
Smoking time, years	(37-60)	(35-60)	p>0.05
	27.9±1.7	26.5±1.7	
Smoking intensity (packs/years)	(14-42) 27,0±2,0	(15-42) 27,9±2.3	p>0.05

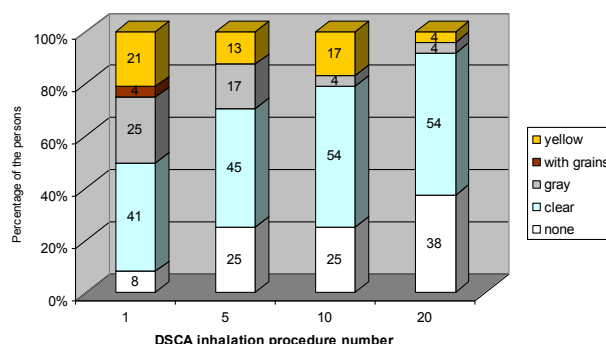
The amount of SIgA in epithelial cells of the oropharyngeal micosa was estimated by indirect method of fluorescent antibodies (RIF).

RESULTS

88% of smokers of TG by the end of inhalation course reported easier and/or decreased cough, changes in the character of sputum, which became lighter and clearer. Improvement in the character of sputum was noted only 22% volunteers of PG (p<0,001).

The character of sputum changed gradually in TG smokers during the course of DSCA inhalations. By the 5th procedure, the number of pts expectorating yellow sputum decreased, and by the 10th - there was decrease in the number of persons expectorating gray sputum (p<0.05). By the end of the course DSCA procedures expectorating of gray or yellow sputum was only in separate cases. The number of pts who stopped producing sputum increased significantly, while sputum turned light in the rest (p<0.01) (fig.2). There were no specific changes in the character of sputum in CG.

Fig. 2. Changes in the character of sputum during the course of the dry sodium chloride (DSCA) inhalations (n-24)



Cytobacteriologic study showed that the II and AI of epithelial cells for etiologically important microorganism *S. pneumoniae* decreased significantly in TG who were given DSCA (fig. 3). The II and AI also decreased significantly as regards another opportunistic microflora (*H. influenzae*, *S. aureus* etc.). These findings suggest decreased colonization activity of opportunistic microflora of the mucus. At the same time, the normal microflora (IA norm.) (*Neisseriae* spp., *S. viridans*, *S. salivarius* etc.) increased significantly, which indicates intensified natural colonization of the mucosa. This combination of the processes suggests increased resistance of the mucosa under influence of DSCA in TG. There were no significant changes in the character of sputum in CG (table 2).

Table 2.

Colonization activity of microflora of brush- samples from pharynx of the Test (TG) and Placebo (PG) groups of smokers before and after inhalations of dry sodium chloride aerosol (DSCA)

Index (M±SD)	Units of measure	TG		PG	
		Before DSCA	After DSCA	Before DSCA	After DSCA
II (<i>S. pneumoniae</i>)	%	28.1±24,9	7.8±9,7***	18.4±22,6	11.8±16,8
II (<i>H. influenzae</i> , <i>S. aureus</i> etc.)	“-“	20.8±31,9	2.4±5,6**	6.9±14,9	5.2±10,5
IA (<i>S. pneumoniae</i>)	Number of the microbes cells	45.4±33,0	13.9±16,3***	25.4±22,9	17.6±18,0
IA (<i>H. influenzae</i> , <i>S. aureus</i> etc.)	“-“	21.6±25,0	4.2±9,3**	9.8±19,5	7.8±17,6
IA norm.	“-“	6.9±7,9	23.0±17,8***	7.5±14,5	9.8±15,2

*Note: significant ($p < 0.05$) changes vs. initial values; ** significant ($p < 0.01$), *** $p < 0.001$ changes vs. initial values

The amount of SIgA increased significantly in the TG (before - $1,5 \pm 0,9$ and after - $2,1 \pm 0,5$, $p < 0,05$). There were no significant changes at these indexes in the PG (before - $1,6 \pm 0,9$ and after - $1,7 \pm 0,9$, $p > 0,05$).

CONCLUSION

Dry sodium chloride aerosol inhalations produce positive effect on the airways of tobacco smokers (versus placebo). DSCA relieves the main clinical signs of tobacco smokers (character of cough and sputum), improves local defense mechanisms and strengthens resistance of mucous membranes of tobacco smokers owing to decreased colonization activity of pathogenic microorganisms and increased SIgA.

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Vopr Kurortol Fizioter Lech Fiz Kult. 2000 Jan-Feb;(1):21-4.

The scientific validation and outlook for the practical use of halo-aerosol therapy.

Chervinskaia AV.

Abstract

The paper describes a new medical technique--halo-aerosol therapy, the main acting factor of which is dry highly dispersed aerosol of sodium chloride in natural concentration. Halo-aerosol therapy represents a new trend in aerosol medicine. It includes two methods: halotherapy and halo-inhalation. Biophysical and pathophysiological foundations of the new method, how it can be realized are outlined. Clinical reasons are provided for application of halo-aerosol therapy for prevention, treatment and rehabilitation of patients with respiratory diseases. Characteristics and differences of the two halo-aerosol therapy variants are analyzed.

PMID: 11094875

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/11094875>



Vopr Kurortol Fizioter Lech Fiz Kult. 2012 Mar-Apr;(2):31-5.

The use of halotherapy for the health improvement in children at institutions of general education.

Khan MA, Chervinskaia AV, Mikitchenko NA.

Abstract

The objective of the present study was to estimate the influence of halotherapy performed in a specialized salt room on the health status of the children frequently ill with acute respiratory diseases. The application of halotherapy was shown to produce well-apparent anti-inflammatory, draining, and sanogenic effects. Observations during 1, 3, 5, and 12-month follow-up periods confirmed the persistence of prophylactic and therapeutic effects of salt therapy. The results of the study were used to develop differential schemes of halotherapy taking into consideration the initial conditions of the children.

PMID: 22908472

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/22908472>



Vopr Kurortol Fizioter Lech Fiz Kult. 1995 Jan-Feb;(1):11-5.

The use of halotherapy for the rehabilitation of patients with acute bronchitis and a protracted and recurrent course.

Borisenko LV, Chervinskaia AV, Stepanova NG, Luk'ian VS, Goncharova VA, Pokhodzeĭ IV, Krivitskaia VZ, Vishniakova LA, Pokhaznikova MA, Faustova ME, et al.

Abstract

Halotherapy was used for rehabilitation in 25 patients with acute bronchitis of long-standing and recurrent types. The main therapeutic action was ensured by aero dispersed medium saturated with dry highly dispersed sodium chloride aerosol, the required mass concentration being maintained in the range of 1 to 5 mg/m³. Therapy efficacy was controlled through assessment of clinical, functional, immunological and microbiological findings. Metabolic activity values were taken into consideration as well. Positive dynamics of the function indices in the clinical picture resulted from elimination of pathogenic agents, control of slowly running inflammatory lesions and stimulation of some immune system factors. Favourable changes in metabolic activity were present: normalization of serotonin excretion, marked decrease of unbalance in lipid peroxidation-antioxidant system.

PMID: 7785211

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/7785211>



SALT•Ed

salt therapy education

What All Type of Spas, Wellness Facilities, and Salt Therapy Providers Need to Know About Misconceptions Regarding Himalayan Salt

The Scientific Research

The **Salt Therapy Association** was formed to provide Education, Research, and Innovation for the salt therapy/halotherapy industry and, as such, we are providing continuing information that is relevant and important for our Facility Members and for those in the industry. We have started a new educational series entitled "SALT-Ed" (salt therapy education) that we will be disseminated through white papers, documents, videos, and webinars.

This first SALT-Ed paper is a reference to the research about Himalayan salt and the 'myth information' regarding health and wellness benefits from claims such as emanating negative ions, purifying the air, and providing any respiratory relief, made about heating (or not heating) Himalayan salt in general, which applies to salt lamps, walls, saunas, spa equipment, and décor.

Not only is there no evidence that heated Himalayan salt produces its advertised health benefits, the notion that it could emit ions in sufficient quantities to have any impact on the surrounding environment or aid in the treatment of respiratory conditions runs against established science and basic chemistry.

Salt Lamps Can't Get Hot Enough to Emit Negative Ions

Science Journalist Signe Dean:

"The usual narrative about these lamps seems to be that heating up a chunk of salt releases ions. However, that simply isn't possible. To break apart the ionic bond between the two chemicals comprising salt, you'd need a far greater energy input than a tiny light bulb can provide. Besides, if that did happen, the salt would emit chlorine gas, and you'd definitely notice that."¹

John Malin, retired chemist formerly with the American Chemical Society

"Unless Himalayan sea salt contains high concentrations of other trace minerals compared with ordinary table salt, the predominant ions that could form from a salt lamp are sodium and chloride ions. But salt is really stable, so you heat it up a little bit and nothing really happens."²



Jack Beauchamp, Professor of Chemistry at the California Institute of Technology:

“We have a lot of experience with observing ions. What we did with the lamp, since it’s supposed to make negative ions, was to place it adjacent to the inlet and, just by itself, we observed no ions at all. We turned it on and looked for negative ions. We looked for positive ions. We waited for the lamp to heat up. The bulb inside eventually does heat the rock salt, but we didn’t see anything.

I can’t think of any physical process that would result in the formation of ions from heating rock salt, with and without the presence of water vapor in any amount. Rock salt has a face-centered cubic structure which would not be expected to give rise to electric fields that would generate ions around individual crystals.”³

Dr. May Nyman, Ph.D., of the American Chemical Society and Professor of Chemistry at Oregon State:

“The only way to get those ions or salts into the atmosphere is using very high energy radiation like using something like x-ray and focused x-rays and we don’t have them in our house or do we want it. The same x-ray you want to examine a broken bone or radiate a tumor. That is the kind of energy it would take to get those salts into the air. We do not want to be exposed to these amounts of x-ray without those amounts of health benefits. And those types of radiation do not exist in our house.”⁴

Dr. John Newsam, Ph.D., of the American Chemical Society and CEO of Tioga Research in San Diego, California:

“That is not happening in a Himalayan salt lamp where you have a flame, incandescent bulb or led bulb. You are not heating up the salt high enough to liberate any of the ions from it. The strength of [sic] between positive and negative ions of salt is very strong and therefore, they want to stay together – they don’t want to scoot off into the atmosphere. A block of salt is not going to liberate any sodium or chloride ions.”⁵

Columbia University Medical Center:

“It would take a Himalayan salt lamp a hundred years to even come close to what an ion machine could generate in an hour.”⁶



Salt Lamps Aren't Capable of Producing Enough Negative Ions to Affect the Surrounding Environment

Negative Ions Information Center:

"Having personally tested a popular brand of rock salt crystal lamp in our lab, we can attest that it was all but worthless as a generator of high-density negative ions.

After measuring the negative ion output level from the salt lamp, we took our sensitive negative ion detector outdoors and measured a far higher level of naturally occurring negative ions than the salt lamp emitted.

If the salt lamp's negative ion output would have been any lower, we could not have measured it. The salt lamp put out such a small level of negative ions that just taking a reading depleted the few negative ions that it did put out, and then the ion detector stopped indicating. We then had to remove the ion detector from near the salt lamp for a few minutes before we could again measure negative ions near the lamp. We couldn't tell the exact level of ions."⁷

A Breath of Reason website:

"It is possible to separate sodium from chloride with high amounts of energy, but we're talking much more than what is put out from a mere 15-watt lamp. But let's just say that somehow this glowing chunk of halite on your nightstand actually does release negative ions to combat the pollutants in the air. What would happen is your salt lamp would basically slowly shrink down to nothing but a pile of pure sodium (not good), and at the same time be emitting chlorine gas (really not good). And then there's the logical paradox that if these negative ions are floating away, leaving the positively charged ions in the lamp, the strong attraction between positive and negative would pull these negative ions right back onto the lamp, negating entirely the purpose of your salt lamp.

[I]f the negative ions did bind to dust particles and allergens, and other pollutants that could trigger asthma symptoms, there's no chance of them being heavy enough to weigh the dust down, trap it against a grounded surface, and make it easy to just wipe away. In a brilliant post on the effectiveness of salt lamps, author D.B. Thomas asserts the weight of the chlorine molecule to be very small. "Chlorine has a relative atomic mass of 35.5. Basically, a 'mole' of chlorine atoms 6.022×10^{23} atoms[sic] would weigh 35.5 grams. Let's break that down to numbers that most people can really understand. $35.5\text{g}/6.022 \times 10^{23} = 5.887 \times 10^{-23}$ grams. Or, 0.00000000000000000000005887 grams." As if that would be enough to bring down a comparatively enormous dust particle."⁸



Salt Lamps Do Not Neutralize Electromagnetic Radiation

Wavelength and frequency determine another important characteristic of electromagnetic fields. Electromagnetic waves are carried by particles called quanta. Quanta of higher frequency (short wavelength) waves carry more energy than lower frequency (longer wavelength) fields. Some electromagnetic waves carry so much energy per quantum that they have the ability to break bonds between molecules. In the electromagnetic spectrum, gamma rays given off by radioactive materials, cosmic rays and X-rays carry this property and are called 'ionizing radiation'. Fields whose quanta are insufficient to break molecular bonds are called 'non-ionizing radiation'. Man-made sources of electromagnetic fields that form a major part of industrialized life – electricity, microwaves, and radiofrequency fields - are found at the relatively long wavelength and low frequency end of the electromagnetic spectrum and their quanta are unable to break chemical bonds.”⁹

Salt Lamps Do Not Benefit Respiratory Health

“Despite numerous experimental and analytical differences across studies, the literature does not clearly support a beneficial role in exposure to negative air ions and respiratory function or asthmatic symptom alleviation. Further, collectively, the human experimental studies do not indicate a significant detrimental effect of exposure to positive air ions on respiratory measures. Exposure to negative or positive air ions does not appear to play an appreciable role in respiratory function.”¹⁰

Heated Salt Lamps Do Not Trap Positive Ions and Release Negative Ions Cleaning and Deodorizing the Ambient Through Hygroscopy

“Some small amount of water vapor in the air might adhere to the salt’s surface, and some of the water vapor might dissociate salt into sodium and chloride ions. But as soon as the water vapor dried, the two ion types would immediately recombine to form salt, so that process is unlikely to produce negative ions either...

As for the idea that water vapor in the room attracts pollutants, then sticks to the surface of the lamp, that, too, makes little sense, he said. Some pollutants in the air might, by chance, stick to water vapor on the surface of the lukewarm piece of rock salt, but there’s no evidence that the meager heat produced by a light bulb could produce significant amounts of pollutant filtering...

In terms of mass removal of pollutants from the air, I just don’t think it can happen, Malin said. Instead, a chunk of charcoal with a fan blowing over it would likely have much better filtering properties...”¹¹



Summation

The research has been conducted and the Salt Therapy Association agrees with the science. The reports that Himalayan salt has magical properties, how it provides wellness, and can aid in the treatment of respiratory issues is a myth. Himalayan salt is for décor. The truth is that wellness and respiratory health comes from halotherapy, where pure grade sodium chloride is crushed, ground, and dispersed by a halogenerator.

While there is some evidence that large amounts of a natural compound concentration in an enclosed space (such as quartz, amethyst, jade or Himalayan salt) can alter the vibrational frequency of the physical environment, since all elements resonate at different frequencies, and, thus, alter the feeling in the room, Himalayan salt décor can create a nice, ambient environment to sit and relax.

There is some scientific evidence about chromotherapy, also known as color therapy, where the warm orange and pink hues of the lighted Himalayan salt bricks or panels create a soothing environment to aid emotional and mental health. The placebo effect is also strong, and Himalayan salt is also very popular as an ingredient in food and skin products.



Citations

- ¹ <http://nevertocurious.com/2015/06/11/salt-lamps-are-pseudoscience/>
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- ³ <http://www.krem.com/news/salt-lamps-dont-actually-make-you-healthy-but-they-do-look-nice/501577955>
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- ⁶ Columbia University Medical Center
- ⁷ <http://www.negativeionsinformation.org/saltcrystallamps.html>
- ⁸ <https://abreathereofreason.com/2014/06/18/salt-lamps>
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- ¹⁰ Dominik D. Alexander, William H. Bailey, Vanessa Perez, Meghan E. Mitchell, and Steave Su, *Air ions and respiratory function outcomes: a comprehensive review*, J Negat Results Biomed. 2013; 12:14 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3848581/>)
- ¹¹ John Malin, retired chemist with the American Chemical Society
<http://www.livescience.com/59328-himalayan-salt-lamp-faq.html>



Voen Med Zh. 1999 Jun;320(6):34-7, 96.

Halotherapy in the combined treatment of chronic bronchitis patients.

Maev EZ, Vinogradov NV.

Abstract

Halotherapy proved to be a highly effective method in a complex sanatorium treatment of patients with chronic bronchitis. Its use promotes more rapid liquidation of clinical manifestations of disease, improves indices of vent function of lungs, especially those values that characterize bronchial conduction (volume of forced exhalations per second, index Tiffno), increases tolerance to physical load, normalizes indices of reduced immunity and leads to increasing the effectiveness of patient treatment in sanatorium.

PMID: 10439712

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/10439712>



Vopr Kurortol Fizioter Lech Fiz Kult. 1997 Jul-Aug;(4):19-21.

The use of an artificial microclimate chamber in the treatment of patients with chronic obstructive lung diseases.

Chernenkov RA, Chernenkova EA, Zhukov GV.

Abstract

Halotherapy was used for sanatorium rehabilitation in 29 patients with chronic obstructive pulmonary diseases (chronic bronchitis and asthma). Significant positive effects of this method resulted in the improvement of the flow-volume parameters curve of lung function and in hypotensive effects on blood pressure. Halotherapy is recommended for use in patients suffering from chronic obstructive pulmonary diseases with hypertension or coronary heart disease.

PMID: 9424823

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/9424823>



Vopr Kurortol Fizioter Lech Fiz Kult. 2000 Nov-Dec;(6):21-4.

Effectiveness of halotherapy of chronic bronchitis patients.

Abdrakhmanova LM, Farkhutdinov UR, Farkhutdinov RR.

Abstract

The chemoluminescence test in 49 patients with lingering inflammatory chronic bronchitis has revealed inhibition of generation of active oxygen forms in the whole blood, intensification of lipid peroxidation in the serum, depression of local immunity. Administration of halotherapy to the above patients results in correction of disturbances of free-radical oxidation, improves local immunity and clinical course of the disease.

PMID: 11197648

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/11197648>



Klin Med (Mosk). 2000;78(12):37-40.

Effects of halotherapy on free radical oxidation in patients with chronic bronchitis.

Farkhutdinov UR, Abdrakhmanova LM, Farkhutdinov RR.

Abstract

Registration of luminol-dependent chemoluminescence of blood cells and iron-induced chemoluminescence of the serum was used to study generation of active oxygen forms and lipid peroxidation in patients with chronic bronchitis (CB). 49 patients with lingering CB showed inhibition of blood cell function and enhancement of lipid peroxidation. The addition of halotherapy to combined treatment of these patients promoted correction of the disorders and improvement of CB course.

PMID: 11210350

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/11210350>



Vopr Kurortol Fizioter Lech Fiz Kult. 2001 Jan-Feb;(1):26-7.

Efficacy of therapeutic use of ultrasound and sinusoidal modulated currents combed with halotherapy in patient with occupational toxic-dust bronchitis.

Roslaia NA, Likhacheva EI, Shchekoldin PI.

Abstract

Immunological and cardiorespiratory characteristics were studied in 88 alloy industry workers with occupational toxic-dust bronchitis who received the following therapy: sinusoidal modulated currents (SMC), ultrasound (US) on the chest, halotherapy (HT) (52 patients, group 1); SMC + HT (10 patients, group 2); US + HT (15 patients, group 3); HT (11 patients, group 4). The patients did also therapeutic exercise and were massaged (chest). It was found that device physiotherapy (SMC, US) in combination with HT raise the treatment efficacy to 86.5%. This combined treatment is recommended both for treatment and prevention of obstructive syndrome in toxic-dust bronchitis.

PMID: 11530404

[PubMed - indexed for MEDLINE]

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/11530404>



Ann Agric Environ Med. 2014;21(1):124-7.

Salt caves as simulation of natural environment and significance of halotherapy.

Zajac J1, Bojar I2, Helbin J1, Kolarzyk E1, Owoc A3.

Abstract

INTRODUCTION:

Human activity usually leads to a deterioration in air quality; therefore, searching for places that simulate an environment without pollution is important. Artificial salt caves play crucial role, as a kind of therapy, known as halotherapy, based on treatment in a controlled air medium that simulates a natural salt cave microclimate.

OBJECTIVE:

Evaluation of awareness about the existence of salt caves, basic knowledge about the purpose for their presence among people who bought salt caves sessions and checking their subjective estimation of salt caves influence on their well-being.

MATERIAL & METHODS:

303 inhabitants (18-51-years-old) of 3 randomly chosen cities of southern Poland were surveyed using a validated author's questionnaire. Both genders were represented in comparable numbers.

RESULTS:

It was observed that knowledge about the existence of salt-caves is common - 94% of respondents. 96 persons bought at least 3 salt caves sessions. The majority of women did this for therapeutic reasons (57%), and men for both therapeutic and relaxation reasons (both 39%). Both among women and men, the dysfunctions intended to be cured by sessions included problems with throat, larynx or sinus. Depression as a reason for buying sessions was mentioned only by women. In general, those who attended felt better after sessions in salt caves.

CONCLUSION:

Besides the health benefits, people do not have free time for rest and activities in clean air; moreover, stress is inseparable from everyday life, and for that reasons salt caves become places that help to support a proper lifestyle.

PMID: 24738510

For more information, click here: <http://www.ncbi.nlm.nih.gov/pubmed/24738510>



Halotherapy as asthma treatment in children: A randomized, controlled, prospective pilot study.

Bar-Yoseph R, et al. *Pediatr Pulmonol*. 2016.

Abstract

BACKGROUND AND OBJECTIVES:

Asthma is a chronic inflammatory disorder requiring intermittent or continuous anti-inflammatory therapy. Patients often turn to alternative treatments as complements or replacements to conventional treatments. We aimed to evaluate the effect of salt room chambers (halotherapy) on bronchial hyper-responsiveness (BHR), fractional exhaled nitric oxide (FeNO), and quality of life in children with asthma.

PATIENTS AND METHODS:

Children aged 5-13 years with a clinical diagnosis of mild asthma not receiving anti-inflammatory therapy. Patients were randomized in this double-blind, controlled study to salt room with halogenerator (treatment group), or without halogenerator (control group). We evaluated the effect of salt room therapy on BHR, FeNO, spirometry, and pediatric asthma quality of life questionnaire (PAQLQ). The treatment period lasted 7 weeks, 14 sessions.

RESULTS:

Twenty-nine patients were randomized to the salt room with halogenerator (treatment group), and 26 patients to the salt room without salt halogenerator (control group). A statistically significant improvement in BHR was demonstrated in the treatment group, which remained unchanged in the control group. There was no improvement in spirometry or FeNO levels following treatment. The treatment group showed a statistical improvement in most parameters of quality of life questionnaires.

CONCLUSIONS:

Our pilot study suggests that salt room with halogenerator, may have some beneficial effects in mild asthmatic children. Randomized and larger controlled trials with long-term follow-up are necessary.

Pediatr Pulmonol. 2016; 9999:XX-XX. © 2016 Wiley Periodicals, Inc.

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For more information, click here: <https://www.ncbi.nlm.nih.gov/pubmed/27723955>



Voen Med Zh. 1999 Jun;320(6):34-7, 96.

Halotherapy in the combined treatment of chronic bronchitis patients.

Maev EZ, Vinogradov NV.

Abstract

Halotherapy proved to be a highly effective method in a complex sanatorium treatment of patients with chronic bronchitis. Its use promotes more rapid liquidation of clinical manifestations of disease, improves indices of vent function of lungs, especially those values that characterize bronchial conduction (volume of forced exhalations per second, index Tiffno), increases tolerance to physical load, normalizes indices of reduced immunity and leads to increasing the effectiveness of patient treatment in sanatorium.

For more information, click here: <https://www.ncbi.nlm.nih.gov/pubmed/10439712>



The role of non-medicamental technologies in the rehabilitation of the children presenting with acute rhinosinusitis.

Khan MA 1 , Khoruzhenko OV 2 , Vakhova EL 1 , Lyan NA 1 , Radetskaya LI 1

Abstract

Despite the recent achievements in diagnostics and pharmacotherapy of acute rhinosinusitis in the children, the problem of management of this pathology, thus far remains a serious challenge for practical medicine. The objective of the present study was to develop a scientifically sound rationale for the application of halotherapy (HT) and magnetic therapy (MT) or their combination for the treatment of acute rhinosinusitis in the children. The clinical observations and special investigations were carried out in the comparative aspect and encompassed 120 children at the age varying from 5 to 15 years suffering from acute rhinosinusitis. The therapeutic effectiveness of the rehabilitative treatment was evaluated based on the results of the endoscopic study of the nasal cavity, analysis of the X-ray images of paranasal sinuses, rhinomanometry, investigations into the ciliary activity, and assessment of the mucosal immunity. The results of the present study gave evidence of the feasibility of incorporating HT and MT in the combined treatment of the children presenting with acute rhinosinusitis. The integrated use of the two methods proved to have the advantage over the separate application of either of them. The specific effects of HT and MT on the clinical course of acute sinusitis and the functional state of intranasal mucosa are described. The optimal methods of the treatment are proposed.

For more information, click here: <http://europepmc.org/abstract/MED/26595967>



Orv Hetil. 2015 Oct 11;156(41):1643-52. doi: 10.1556/650.2015.30267.

Theoretical basis and clinical benefits of dry salt inhalation therapy.

Endre L1.

Abstract

Dry salt inhalation (halotherapy) reproduces the microclimate of salt caves, with beneficial effect on health. Sodium chloride crystals are disrupted into very small particles (with a diameter less than 3 μm), and this powder is artificially exhaled into the air of a comfortable room (its temperature is between 20-22 °C, and the relative humidity is low). The end-concentration of the salt in the air of the room will be between 10-30 mg/m³. The sick (or healthy) persons spend 30-60 minutes in this room, usually 10-20 times. Due to the greater osmotic pressure the inhaled salt diminishes the oedema of the bronchial mucosa, decreases its inflammation, dissolves the mucus, and makes expectoration easier and faster (expectoration of air pollution and allergens will be faster, too). It inhibits the growth of bacteria and, in some case, kills them. Phagocyte activity is also increased. It has beneficial effect on the well-being of the patients, and a relaxation effect on the central nervous system. It can prevent, or at least decrease the frequency of the respiratory tract inflammations. It produces better lung function parameters, diminishes bronchial hyperreactivity, which is the sign of decreasing inflammation. Its beneficial effect is true not only in inflammation of the lower respiratory tract, but also in acute or chronic upper airways inflammations. According to the international literature it has beneficial effect for some chronic dermatological disease, too, such as psoriasis, pyoderma and atopic dermatitis. This treatment (called as Indisó) is available under medical control in Hungary, too.

For more information, click here: <https://www.ncbi.nlm.nih.gov/pubmed/26551167>



Ter Arkh. 1996;68(8):24-8.

Bronchial hyperreactivity to the inhalation of hypo- and hyperosmolar aerosols and its correction by halotherapy.

Gorbenko PP, Adamova IV, Sinitsyna TM.

Abstract

18 bronchial asthma (BA) patients (12 with mild and 6 with moderate disease) were examined before and after halotherapy (HT) for airways reactivity using provocative tests with ultrasonic inhalations of purified water (UIPW) and hypertonic salt solution (HSS). Bronchial hyperreactivity (BHR) to UIPW and HSS before treatment occurred in 13 and 11 patients (72 and 69%, respectively). HT reduced BHR in 2/3 and 1/2 of the patients, respectively. In the rest patients BHR was unchanged or increased, being so to UIPW only in patients with atopic asthma in attenuating exacerbation. Clinical efficacy of HT and initial BHR to UIPW correlated ($r = 0.56$; $p < 0.05$). No correlation was found between HT efficacy and initial BHR to HSS.

For more information, click here: <https://www.ncbi.nlm.nih.gov/pubmed/9019826>

Original article

The effect of salt chamber treatment on bronchial hyperresponsiveness in asthmatics

Background: Randomized controlled trials are needed to evaluate the effects of complementary treatments in asthma. This study assessed the effect of salt chamber treatment as an add-on therapy to low to moderate inhaled steroid therapy in asthma patients with bronchial hyperresponsiveness (BHR).

Methods: After a 2-week baseline period, 32 asthma patients who exhibited BHR in the histamine inhalation challenge were randomized: 17 to 2-week active treatment, during which salt was fed to the room by a salt generator, and 15 to placebo. The salt chamber treatment lasted 40 min and was administered five times a week.

Results: Median provocative dose causing a decrease of 15% in F_{ev1} ($PD_{15}FEV_4$) increased significantly in the active group ($P = 0.047$) but not in the placebo group. The difference in changes between the active and placebo groups was significant ($P = 0.02$). Nine patients (56%) in the active group and two patients (17%) in the placebo group exhibited at least one doubling dose decrease in BHR ($P = 0.040$). Six patients (38%) in the active group and none in the placebo group became non-hyperresponsive ($P = 0.017$). Neither the peak expiratory flow (PEF) values measured just before and after the treatment, nor FEV_1 values measured before the histamine challenges, changed. The reduction in BHR was not caused by changes in the baseline lung function.

Conclusions: Salt chamber treatment reduced bronchial hyperresponsiveness as an add-on therapy in asthmatics with a low to moderate dose of inhaled steroids. The possibility that salt chamber treatment could serve as a complementary therapy to conventional medication cannot be excluded.

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Key words: asthma; bronchial hyperresponsiveness; complementary treatments; salt chamber; speleotherapy.

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Complementary and alternative medicine is widely used in the treatment of asthma. However, data on the efficacy of these treatments are usually lacking. Randomized controlled trials are needed for exploring their possible effects (1, 2). They can also lead to undertreatment, and it is important to verify if they have any value in the treatment of asthma.

Bronchial hyperresponsiveness (BHR) gives valuable information on the patient's symptoms and airway inflammation (3). It has been used to assess the effect of some complementary treatments; e.g. Sahaja yoga has been shown to be beneficial (4) but short-term acupuncture therapy not so (5).

Subterranean environment therapy is called speleotherapy. Halotherapy is a form of speleotherapy, which makes use of the microclimatic conditions in a salt cave. Natural karst caves have been used for treating asthmatic patients in Germany, Switzerland, Hungary, Bulgaria, the former Yugoslavia and the former Soviet Union. The main therapeutic factors of speleotherapy in caves and mines are thought to be air quality, underground climate

and radiation. Different combinations of temperature, relative humidity, pressure, radiation and aerosols are also vital elements.

The effects of salt mine treatment on health in the village of Solotvino, in the Carpathian Mountains have been investigated by Russian scientists. Natural dry sodium chloride dust which formed as a result of convection diffusion from salty walls was proposed to be the main microclimatic treatment factor. A 'halo-chamber' was constructed to simulate the microclimate of salt mines (6).

The Cochrane Database of Systematic Reviews evaluated the efficacy of speleotherapy in the treatment of asthma (7). It included controlled clinical trials that compared the clinical effects of speleotherapy with either another type of intervention or no intervention at all. Three trials on a total of 124 asthmatic children met the inclusion criteria, but only one trial had reasonable methodological quality (8). In the study by Novotny et al. (8), slight improvement of the lung function was observed at the end of the 3-week treatment period in the

speleotherapy group compared with the control group. In two other trials, it has been reported that speleotherapy had a beneficial short-term effect on lung function as well. It was not possible to assess any other outcome. The conclusion was that the available evidence is insufficient to show speleotherapeutic interventions as an effective treatment measure for chronic asthma. Randomized controlled trials with long-term follow up are necessary (7).

We assessed the effect of the salt chamber treatment as an add-on therapy in patients with persistent asthma who exhibited BHR in the histamine challenge in spite of a low to moderate inhaled steroid dose.

Material and methods

Patients

We selected adult patients who remained hyperresponsive in the histamine inhalation challenge in spite of regular treatment with inhaled steroids. Female and male asthmatics aged ≥18 years were eligible for inclusion if: (1) they used inhaled glucocorticosteroids at a constant daily dose of ≥200 µg for ≥30 days before entry; and (2) they were histamine challenge-positive (PD₁₅FEV₁ ≤ 1.6 mg). Before the histamine challenge, they had to have a baseline forced expiratory volume in 1 s (FEV₁) of ≥70% predicted.

Exclusion criteria included respiratory infection or worsening of asthma within 30 days before entry into the study, current smoking or a history of smoking ≥10 pack-years, other respiratory disease, or severe dysfunction in other organs. Pregnant and lactating women, as well as women of childbearing potential unable to use acceptable contraceptives were excluded.

Subjects were recruited through a local newspaper advertisement (231 responses). After a telephonic interview with a research nurse and doctor, 153 patients were excluded (124 because of inclusion or exclusion criteria, while 29 subjects cancelled their participation before the histamine challenge). Seventy-eight asthmatics underwent a histamine inhalation challenge test for evaluation of airway responsiveness (Fig. 1). Forty-six of the patients were challenge-negative and were hence excluded. Thirty-two patients (41%) were challenge-positive and were randomized in the study – 17 to the active salt chamber treatment and 15 to the placebo treatment. Baseline characteristics of study subjects are given in Table 1. Nine

Table 1. Baseline characteristics of the study subjects

	Active (n = 17)	Placebo (n = 15)
Age, years	53.2 (12.2)	52.1 (14.9)
Female, n	15	14
Atopy, n*	10	9
Duration of asthma treatment, years	8.8 (5.9)	9.6 (7.2)
Inhaled steroid dose, mg†	0.894 (0.506)	0.733 (0.232)
Long-acting beta-2 agonist	9	6
FEV ₁ , l	2.61 (0.77)	2.54 (0.48)
FEV ₁ , % predicted‡	89.5 (17.1)	91.9 (8.5)
FVC, l	3.25 (0.97)	3.21 (0.54)
FVC, % predicted‡	90.4 (15.2)	95.6 (7.1)
Morning PEF, l/min	441 (78.2)	438 (68.7)
Evening PEF, l/min	455 (94.1)	448 (63.6)
PD ₁₅ FEV ₁ , mg	0.488 (0.407)	0.588 (0.407)
Short acting bronchodilator use, n/2 weeks	2.8 (2.8)	1.4 (2.2)
Nocturnal awakenings, n/2 weeks	2.9 (5.4)	0.4 (0.8)
Symptom score, 2 weeks	3.8 (5.2)	3.6 (5.0)

Data are presented as group mean (SD) values and patient numbers.

*Allergic rhinitis or atopic eczema reported by the subject.

†Expressed as beclomethasone equivalent dose (1.0 mg budesonide or 0.5 mg fluticasone equivalent to 1.0 mg beclomethasone).

‡Viljanen et al. (9).

patients in the active group and six patients in the placebo group used long-acting beta-2 agonists but none of the subjects used aminophylline or leucotriene receptor antagonists. There were no significant differences between the groups.

The study was conducted in accordance with the guidelines of the Declaration of Helsinki. The Ethics Committee of South Karelia Central Hospital approved the study protocol and all patients gave their written consent prior to the commencement of the study.

Study design

A parallel-group, double-blind, randomized placebo-controlled trial was conducted. After a 2-week baseline period, patients were randomized to either a 2-week active salt chamber treatment or the placebo. The randomization of patients was carried out in groups of four and the treatment was blinded to the patients, study nurse and investigator. Patients underwent 40 min of treatment every day, five times a week, in the salt chamber of Lappeenranta Spa.

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

Conditions

The salt chamber was 12.5 m² in area with a volume of 27.5 m³. The roof, walls and partly also the floor were covered with 20–50-mm-thick coating of salt (rock salt, NaCl 98.5%). Both the active and the placebo treatments were administered in the same salt chamber. During the active treatment, 3 g of salt was fed into the salt generator (Polar and Iris salt generator; Polar Health Oy, Nummela, Finland; IndiumTop LLC, Tallinn, Estonia) at intervals of 4 min, first being pulverized and then being blown into the chamber through the feed channel. Indoor dust emission, determined by isokinetic samples according to standard EN 13284-1 in the front of the feed channel, ranged from 1.6 to 3.3 mg/s (three measurements).

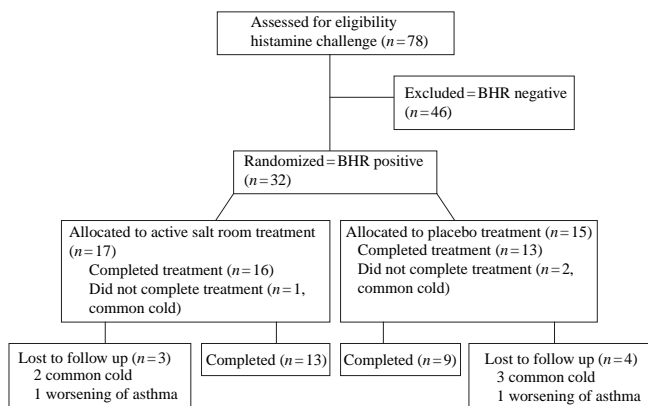


Figure 1. Flow of subjects through study.

Table 2. Salt concentrations (mg/m³) in the salt chamber

Measurements mean	Feeding speed of salt	Blasting volume of the salt generator	Concentration (mean range)
1	3 g/3 min	1/1	14.7
2	3 g/4 min	1/2	7.1 (5.9–8.4)
3	3 g/4 min	3/4	7.6 (6.7–8.1)
4	3 g/4 min	1/4	7.4 (7.3–7.5)

During the placebo treatment, salt was not fed into the salt generator. The generator was, however, running and patients could hear its sound.

The air blast volume of the salt generator and the feeding speed of the salt affected the salt concentration (Table 2). A feeding rate of 3 g every 4 min and a blasting volume of one-fourth of the salt generator resulted in conditions similar to those reported and used in treatment units of eastern and central parts of Europe (8).

The treatments were administered, on average, at a temperature of 23.0°C (range 18.0–27.3°C, $n = 304$) and at 41% relative humidity (range 25–51%, $n = 304$). Indoor air temperature (U-type thermistor probe; Grant Instruments Ltd, Shepreth, UK) and relative humidity values (Vaisala HMP 35 AG, Vaisala Oyj, Finland) were recorded with a datalogger (Squirrel 1000 series; Grant Instruments Ltd).

During the active treatment, the mean salt concentrations of the indoor air of the salt chamber fluctuated from 7.1 to 7.6 mg/m³ (range 0–31.5 mg/m³; $n = 7$). During the placebo treatment, the mean salt concentration was 0.3 mg/m³ ($n = 3$). Salt concentrations were restored to zero level (0–1 mg/m³, $n = 7$) during the 20 min of enhanced ventilation after each treatment period.

Stationary inhalable dust samples were collected with IOM (SKC Inc., Eighty Four, PA, USA) samplers. The sampling head is designed to meet the ACGIH and EN 481 criteria for inhalable dust at a sampling flow rate of 2.0 l/min. Time-dependent variation of dust concentrations was measured with a Respicon TM-SE (Helmuth Hund GmbH, Wetzlar, Germany). The sampler is designed to meet the ACGIH and EN 481 criteria for size-selective sampling of occupational dusts. Particle size distribution was determined by a six-stage cascade impactor. The cut-off points were 10, 5, 2.5, 1.3, 0.65 and 0.3 µm at a sampling rate of 20 l/min. Salt dust concentration, time-dependent variation of salt dust concentration and particle size distribution were measured 1 m above the ground between the seats. While the measurements were being taken, one to four persons stayed in the chamber, simulating the treatment protocol. A particle size <5 µm (aerodynamic diameter) constituted 35–45% of the total particle mass, and a particle size <20 µm correspondingly 88–97% ($n = 4$). Depending on the measurement time, the median of the particle size distribution ranged from 6 to 8 µm ($n = 4$). According to the measurements, both the salt dust concentration and particle size distribution were evenly distributed inside the chamber. Measurement of the conditions was carried out by the Lappeenranta Regional Institute of Occupational Health.

Outcome measurements

The main outcome parameter was BHR. Patients underwent a histamine inhalation challenge three times: at the baseline, at the end of the 2-week treatment, and 2 months after the treatment. The study was conducted outside the pollen season.

The histamine challenge method has been described in detail elsewhere (10). In short, an automatic inhalation-synchronized dosimetric jet nebulizer with the known lung deposition of the aerosol was used to administer histamine and to control breathing

(Spira Elektro 2; Respiratory Care Center, Hämeenlinna, Finland). The non-cumulative doses of histamine were 0.025, 0.1, 0.4 and 1.6 mg, administered within 0.4 s following the tidal inspiration of 100 ml of air. FEV₁, measured with flow/volume spirometry (Medikro, Kuopio, Finland), was used to determine the response. The PD₁₅FEV₁ was calculated from logarithmically transformed histamine doses using linear interpolation.

Peak expiratory flow (PEF) measurements, use of a rescue bronchodilator (puffs per 24 h) and asthma symptoms (wheezing, dyspnoea), were recorded each morning and evening by the patients on diary cards during the study. The number of nocturnal awakenings were also recorded. Wheezing and dyspnoea were each graded on a scale of 0–3 (0 = none; 1 = mild; 2 = moderate; 3 = severe). Total asthma symptom score (on a scale of 0–6) was the sum of wheezing and dyspnoea scores. Baseline diary data for 2 weeks were collected before randomization. The PEF was measured using a mini-Wright peak flow meter (Clement Clark, Harlow, UK), and the highest of three values was recorded. The PEF was also measured just before and after salt chamber treatment.

Statistical analyses

Non-parametric statistics were mainly used. A comparison of the active and placebo groups was made using either the Mann-Whitney *U*-test or the Fischer's exact test, as appropriate. The Wilcoxon signed-rank test was used to analyse the effect of treatments in the two groups. A per-protocol analysis (excluding all participants who failed to complete the protocol) was also carried out using paired (within-treatment effect) and unpaired (between-treatment effect) *t*-tests. If a patient was a non-responder (PD₁₅FEV₁ > 1.6 mg) in the 2-week or in the 2-month histamine challenge, an arbitrary PD₁₅FEV₁ value of 3.2 mg was used. A *P*-value of <0.05 was considered statistically significant. All tests were performed using GBSTAT software Version 6.5 (Dynamic Microsystems, Silver Spring, MD, USA).

Results

Sixteen asthmatics in the active group and 13 in the placebo group completed the 2-week salt chamber treatment. One patient in the active group and two in the placebo group failed to complete the treatment (all because of respiratory infections).

Bronchial hyperresponsiveness

After the 2-week treatment, the median PD₁₅FEV₁ value increased significantly in the active group but decreased in the placebo group compared with the baseline. In the active group, median (range) the PD₁₅FEV₁ value before and after treatment was 0.460 mg (0.020–1.57) and 0.595 mg (0.022 to >1.6) ($P = 0.047$); and in the placebo group 0.720 mg (0.016–1.42) and 0.630 mg (0.085–1.25) ($P > 0.05$). The difference between the changes occurring during the treatment with the salt chamber and the placebo was significant ($P = 0.02$) (Table 3).

The BHR decreased by at least one doubling dose in nine patients (56%) in the active group and in two patients (17%) in the placebo group (Fischer's exact,

Table 3. Per-protocol analysis of changes in spirometric indices, PEF values, bronchodilator use, nocturnal awakenings and symptom scores over 2 weeks active and placebo salt chamber treatment

	Active (n = 16)	Placebo (n = 13)	Active vs placebo difference
FEV ₁ , l	0.04 (-0.18 to 0.10)	0.01 (-0.08 to 0.06)	0.03 (-0.12 to 0.18)
FVC, l	-0.04 (-0.07 to 0.15)	-0.04 (-0.05 to 0.13)	0.001 (-0.13 to 0.13)
Morning PEF, l/min	7.0 (-0.09 to 14.1)	4.4 (-6.0 to 14.7)	2.7 (-9.3 to 14.7)
Evening PEF, l/min	9.3 (2.7 to 15.8)**	4.0 (-5.4 to 13.4)	5.5 (-5.6 to 16.4)
Treatment PEF, l/min	0.8 (-2.5 to 4.1)	4.0 (-0.8 to 8.8)	-3.1 (-8.6 to 2.4)
Short-acting bronchodilator use, n/2 weeks	1.5 (-0.2 to 3.2)	1.1 (-0.2 to 2.3)	0.4 (-1.6 to 2.4)
Nocturnal awakenings, n/2 weeks	2.2 (0.4 to 4.0)*	0.2 (-0.2 to 0.7)	2.0 (0.1 to 3.8)
Symptom score, 2 weeks	1.7 (-1.6 to 4.9)	2.5 (-0.8 to 5.9)	-0.9 (-5.3 to 3.6)

*P < 0.05, **P < 0.01 (within-group difference from baseline).

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). The changes in the individual BHR in the active and placebo groups are given in Fig. 2.

A follow-up histamine challenge was performed 2 months after the salt chamber treatment. There were three dropouts in the active group (two due to common cold and one to worsening of asthma) and four dropouts in the placebo group (three due to common cold and one to worsening of asthma). In the active group, the median (range) PD₁₅FEV₁ value was 0.580 mg (0.067 to > 1.6) and in the placebo group 0.620 mg (0.110 to > 1.6). There were no more significant changes compared with the baseline in the within-group or in the between-group analyses. Four of 13 patients in the active group and one of nine patients in the placebo group were non-responsive to histamine (PD₁₅FEV₁ > 1.6 mg) (P > 0.05).

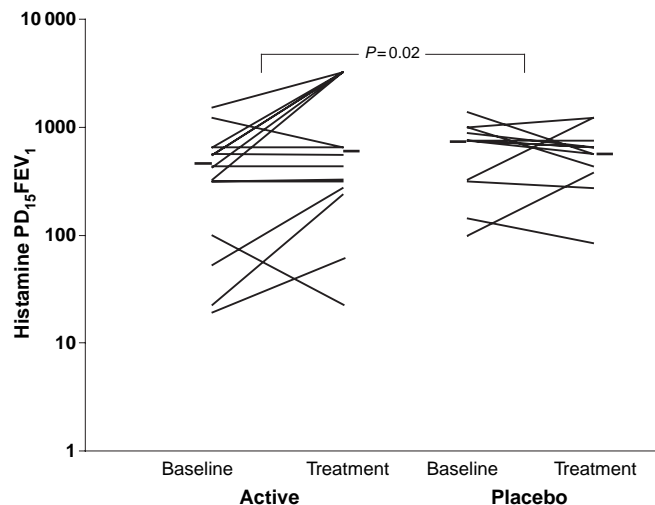


Figure 2. Changes in airway responsiveness to histamine in the active and placebo salt chamber treatment groups. PD₁₅FEV₁ (µg histamine) at baseline and after the 2-week treatment. An arbitrary value of 3200 µg was used in subjects who were challenge-negative. Thick lines represent median values.

Other outcome measures

Changes in spirometric indices, PEF values, bronchodilator use, nocturnal awakenings and symptom scores over 2 weeks of active and placebo salt chamber treatment are given in Table 3. No significant changes in between-group analysis were observed. Statistical significant differences in evening PEF values (P = 0.0085) and in nocturnal awakenings (P = 0.020) were detected in within-group analysis of active group.

Discussion

This study is the first controlled trial investigating the effect of salt chamber treatment on BHR. A 2-week salt chamber treatment reduced BHR as an add-on therapy on a low to moderate dose of inhaled steroids.

The number of patients was small, which increases the risk of error due to chance, and hence our results should be taken as preliminary only. BHR did not differ statistically between active and placebo groups in the baseline. There is, however, a more reactive group in the active treatment group and therefore any change could tend to favour the active group. Being in a trial environment may also have helped compliance and this would have again favoured the active treatment group. The 2-week baseline period may have been the factor leading to an apparent improvement, too. The duration of the effects on BHR and asthma control cannot be reliably estimated as the sample size became too small during the 2-month follow-up. As respiratory viral infections may increase BHR (11), these patients were excluded from the follow-up.

The mechanisms of the effect of salt chamber treatment are unclear and can only be speculated. BHR is a surrogate marker of bronchial inflammation. Sont et al. have stressed the value of a methacholine challenge in guiding treatment; reducing BHR leads to better control of asthma (12). Airway responsiveness to direct bronchoconstrictor stimulus as histamine or methacholine is, however, only loosely related to inflammation (13, 14). Further studies are needed to assess the effect of salt

chamber treatment on more direct inflammatory parameters (e.g. exhaled NO or inflammatory markers in induced sputum).

Airway calibre depends on the balance between the force generated by airway smooth muscle (ASM) and a number of opposing factors, mainly autonomic nervous mechanisms tending to limit ASM tone and mechanical forces opposing ASM shortening (15). Salt chamber treatment did not cause any bronchodilation. Neither the PEF values measured just before and after the treatment, nor the FEV₁ values measured before the histamine challenges changed. Therefore, the reduction in BHR was not caused by changes in baseline lung function as could have been one possible explanation (16, 17).

Bronchial hyperresponsiveness can be reduced by directly affecting airway smooth muscle contractility (18). Some cytokines may act directly or indirectly on ASM cells and alter myocyte function by modulating contractile agonist-induced calcium signalling in human ASM cells (18). There is also a strong positive correlation between bronchial reactivity and the level of intracellular magnesium: magnesium intervenes in the calcium transport mechanism and intracellular phosphorylation reactions (19). Whether these mechanisms are involved in the salt chamber treatment is unknown.

Inhalation of hypertonic saline can cause bronchoconstriction (20). Dry powder sodium chloride has even been used to assess BHR in asthmatics (21). As the resting ventilation is 6–10 l/min, the NaCl dose inhaled by the patients during a 40-min treatment period was about 18–30 mg. This is less than the provocative dose of NaCl causing the FEV₁ to fall 20% from the baseline in an inhalation challenge test using dry NaCl (mean 103 mg) in the study by Andersson et al. (22). It is also far less than the daily sodium intake of female (2.36 g) and male (3.15 g) asthmatics in the study by Sausenthaler et al. (22). In that study, the sodium intake did not alter BHR assessed as PD₂₀ to methacholine but might have increased mild BHR assessed as PD₁₀ (22). In our study, no bronchoconstriction because of the salt chamber

treatment was observed. It is, however, possible that increasing salt concentrations eventually cause bronchoconstriction in sensitive individuals. Salt inhalation may have a U-shaped effect, small and moderate doses being beneficial but higher doses causing adverse effects.

It is possible that the symptomatic relief the patients reported from salt chamber treatment is associated with the reduction in BHR. All patients used inhaled steroids but still showed a reduction in BHR to an extent which is not easy to attain by any drug treatment. The idea that salt chamber treatment could serve as a complementary therapy to conventional medication cannot be ruled out. No side-effects were observed.

Salt chamber treatment is, however, neither simple nor cost-free. The conditions in the individual salt chambers should be measured and standardized as we did in our study. The possible dose–response effect of salt concentrations should be studied in further trials. The optimum duration or regularity of treatments needed are not known. In practice, the length of individual salt treatments vary widely from 20 min to hours and last five to 25 sessions. The length and regime of our study mirrors the common practice in Estonia and in the salt chamber of Lappeenranta Spa. Health economic aspects should be evaluated. There might be benefits linked to the better control of asthma and reduced use of asthma medication. Expenses linked to the salt chamber treatment, as well as travel costs to the treatment centres, should be evaluated. In future studies, the cost benefit should be compared with other treatment modalities, including the improvement of existing drug treatment.

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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 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.

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Impact assessment of saline aerosols on exercise capacity of athletes

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Abstract

The treatment in natural salt mines (speleotherapy) was known since a very long time ago; the miners and other persons involved in these activities might have known about the great effects of the microclimate within salt mines upon human health, long before they were described in a book published by a Polish doctor in 1843. The effectiveness of speleotherapy is associated with the unique cave microclimate; the sodium chloride aerosols represent the main curative factor. The saline aerosols are formed off the salt walls by convective diffusion.[1] Halotherapy is the natural therapy method which borrows the main curative factor for speleotherapy, meaning the saline aerosol particles dispersed in the salt mine microclimate.[2]The salt room microclimate should have a constant humidity (a relative air humidity of 40-60%) and a temperature of 18-24° Celsius, as these parameters create favourable conditions for patients and they are a stable environment for aerosols.[3-4] The precinct should also ensure a stable environment, bacteria- and allergen-free; studies have shown that the microbial contamination during a halotherapy session is of 130-200 saprophyte microorganisms to 1m³ of air (the WHO standards regarding air sterility are of > 300 microorganisms/1m³ air). Thus, a 10-20 minutes break after each session is necessary to purify the air within the chamber.[1]

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Keywords: saline aerosols, halotherapy, athletes, performances;

1. Introduction

1.1. The Benefices of Halotherapy

As concerns the breathing system of the person in the precinct of the salt room, there is a permanent high concentration of dry saline aerosols. This concentration is considered therapeutic if it exceeds 1mg/m³. By inhaling these aerosols, the airways are “cleaned” of focuses of infection (staphylococci and streptococci) – present at adults and especially children –which trigger and maintain many respiratory conditions (in most cases with relapses, becoming chronic) and gradually lead to a decrease in the body immunity. Salt is bactericide by nature, not allowing the microbial cultures to develop, behaving like a disinfectant in most cases. Through the deposition or absorption of salt ions, both for the superior and the inferior airways, mostly in case of small aerosols, conjugated with the hygroscopic property, an effect of dilution of impurity or foreign matter depositions takes place (including microorganisms). These microorganisms lead to breathing disorders or dysfunctions, starting from simple hoarseness, and up to bronchitis and asthma. [1,6-8]

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The observations over time regarding the persons with breathing disorders showed that the respiratory tract mucus thickens when losing humidity and salt; the body cannot compensate the lack of necessary fluid and salt (especially Na⁺ ions). [8]

Through its electro-chemical properties, salt, and mostly saline ions, once deposited on the respiratory tract, not only eliminate bacteria and microorganisms, but also determine the emollition, liquefaction and fluidization of the mucus off the airways, thus extracting the foreign matters among the cilia within the micro-cavities of the respiratory tract, determining the progressive and long-term relief of breathing, the natural and easy expectoration, the elimination of allergen or bacterial matters through the reflex phenomena of coughing, nose secretions, expectorations, etc., characteristic symptoms for the airways' relief. [4-7]

1.2. Main Objective

The study concerns the adapting level of athletes' bodies and developing the effort capacity to natural saline underground factors, insufficiently valorised, or not properly used in sports, and elaborating effective halotherapy technologies

1.3. Hypothesis

We will try to extend the research referring to the effect of exposing athletes to saline aerosols, of adapting the cardiovascular system to effort and of improving the sports performances, as well as to the influence of halotherapy upon certain indices of the breathing system. Concretely, our hypothesis is that saline aerosols are effective in treating respiratory conditions, and we will try to prove that by exposing athletes' bodies to saline aerosols the respiratory and cardiovascular indices will improve, as well as athletes' performances.

Material and Methods

The study was carried on with a sample of 12 middle-distance runners, aged between 14 and 16. The assessment of their cardiovascular and respiratory functions will take place at the Laboratory of functional explorations, testing the effort capacity and evaluating the physical development within the Sports Clinic of Iași.

Within the research we will be monitoring the following factors:

- Respiratory indices: vital capacity (VC), maximum expiratory volume per second (MEVS), maximum ventilation (V max), peak expiratory flow (PEF);[5]
- cardiovascular indices: Blood pressure at rest (BP), heart rate at rest (HR);[4]
- cardiovascular indices during effort: the Martinet test (lab test) allows the momentary evaluation, and the evolution in time regarding the functional capacity of the cardiovascular system, being a useful means, often used in carrying on sports training [6-7]. The test proposed by Martinet assesses the cardiovascular response to low-intensity, standard, non-specific, cabinet, short-term effort.

The investigations concerning the respiratory and cardiovascular system took place after 21 days of salt therapy. The halotherapy was carried on in an air-proof chamber, providing a precinct with saline aerosols through domestic SALINE aerosol devices, produced by Biotehnic SA Buzău. The functioning principle of the device is forcing the air to pass through the NaCl recrystallized granules, leading to alterations in the air composition and quality due to salt nanodispersion, as air ions with negative charge. The chamber was clean, well ventilated, with comfortable temperature and humidity.[2]

There was a daily exposition after practices, as recovery period after the training effort. There was a gradual exposition to the saline aerosols – 20 minutes the first day, 25 minutes the second day, up to 60 minutes a day. The last four days the exposition was reduced by 5 minutes, thus avoiding the sudden interruption of the treatment. During the halotherapy session the subjects breathed normally, being relaxed, and the post-effort recovery had a total of 21 sessions per participant.

3. Results and Discussion

- **Respiratory parameters**

Table 2. Proportion of subjects with alterations of respiratory parameters

Respiratory parameters	Initial test				Final test			
	Increase		Decrease		Increase		Decrease	
	c.a.	%	c.a.	%	c.a.	%	c.a.	%
VC (litres)	6	50	6	50	11	91	1	9
MEVS (l/s)	9	75	3	25	12	100	–	–
V max. (l/min)	9	75	3	25	12	100	–	–
PEF (l/s)	8	67	4	33	11	87.5	1	9

Before halotherapy, half of the subjects had higher values of vital capacity, compared to the normal one, and the other half – lower values. After halotherapy the percentage of those with higher vital capacity increased (Table 2).

The same positive aspect applies to MEVS and V max.: after the treatment all the subjects presented increased values.

Of all the subjects, only one had a decrease in the VC and PEF after the treatment (possibly caused by a momentary indisposition).

Analysing the average values of the four breathing volumes, registered before and after the treatment, we see they increased after the halotherapy session attended by the subjects.

Table 3. Average values of respiratory indices

Respiratory indicators	Subjects	Initial test		Final test		P
		m	σ	m	σ	
VC (litres)	12	481.1	102.09	542.7	99.9	0,1494
MEVS (l/s)	12	425.3	68.4	484.8	74.4	0,0530
PEF (l/s)	12	8.1	1.25	10.3	1.20	0,0002
Vmax (l/min.)	12	1276.1	205.3	1454.6	223.3	0,0002

All subjects had higher values of the four respiratory volumes after halotherapy, with significant differences four three of them (Table 3). For the VC, with no significant differences, we should mention as favourable aspect the increase tendency.

- **Respiratory index**

The respiratory index is calculated with the following formula:

$$R = VC \text{ (cm)} / G \text{ (kg)} \times 1/10$$

It is very useful to calculate the R, because we can easily orient towards the functional lung potential of the subject, thus being a compulsory functional parameter when determining the general biologic potential. In our case, the subjects scored over 6, meaning that they have a “very good” and “excellent” respiratory index. We should also stress the fact that, after the halotherapy treatment, there was an increase in the percentage of subjects who scored over 8 – the maximum score (Table 4).

Table 4. The subjects' scores within the respiratory index scale

Score	Initial test		Final test	
	c.a.	%	c.a.	%
Low (0-4)	–	–	–	–
Average (4-5)	–	–	–	–
Good (5-6)	–	–	–	–
Very good (6-8)	8	67	3	25
Excellent (over 8)	4	33	9	75
Total	12	100	12	100

- **Cardiovascular indices**

Table 5. Assessment of the cardiovascular system – initial and final test

	Heart rate at rest	Systolic BP at rest	Diastolic BP at rest
Initial test	71.30	118	67.9
Final test	69.12	116.5	66.6
Reference values	60-90 b/min	100-140 mmHg	60-90 mmHg

The assessment of the cardiovascular system at rest is very important during the medical examination because we can detect problems that would become acute during sports effort. We followed the heart rate at rest, which was within the normal rates approved by WHO. The rest bradycardia was registered at athletes with increased sports value, the average value, towards the inferior limit of heart rate, being the expression of the bio-positive adaptation to effort, which means an economical work of the heart at rest. Bradycardia in case of athletes is secondary to the increase in the systolic volume, allowing a constant, basic heart debit.[8]

WHO admits the following values of blood pressure at rest: BP max. 100-140 mmHg; BP min. 60-90 mmHg; differential BP 40-50 mmHg. and average BP of 90-100 mmHg., for both athletes and non-athletes . Blood pressure at rest, in case of human subjects within our research, registered values within the range approved by WHO.

- **Cardiovascular indices during effort**

Table 6. The Martinet test– initial and final test – average values of heart rate

	Clinostatim	Orthostatim	Effort	Post effort 1 min	Post effort 3 min	Post effort 5 min	Dorgo index
Initial test	64.7	73.4	107.3	89.6	64.6	64.6	-1.66
Final test	60.3	70.5	103.8	84.71	60.3	60.3	-3.43
Reference values	60-90 b/min	+ 10-12 b/min					B (-5-0)

The initial Martinet test indicated normal values of heart rate at rest, between 60 and 90 beats/minute. There were values of 60- 80 beats/minute in clinostatim, and in orthostatim the average values of heart rate indicated an increase by 10-12 beats/minute.[5-9]

The values of post-effort heart rate registered a 40-50%, increase, without exceeding 120 beats/minute. The HR values came back to normal three minutes post-effort in case of all the athletes, which shows a good functional state.

The Dorgo index of recovery was calculated at the end of the test, using the average HR values. The index had values between -2.05 and -0.01, with a -1.66 average; the GOOD qualifier [4-6].

The final Martinet test showed an improvement of heart rate at rest by 5-10 beats/minute, with values between 60 and 75 beats/minute. The average values of post-effort heart rate have also improved – 98-108 beats/minute, without exceeding 120 beats/minute.

The Dorgo index of recovery, calculated for average HR vales during the intermediary tests, was also positively altered, with values between -3.95 and 1.46, with GOOD qualifier.

The cardiovascular regulation tests are indicators of body adaptation to effort, and only indirectly of the effort capacity, allowing to assess the effectiveness of training methods used for a certain amount of time [6]. The

quality of cardiovascular regulation is the better, the lower the heart rate and blood pressure values on the same effort scale, the sooner values at rest come back to normal, and if the Dorgo values are negative [7].

4. Conclusions

- After the halotherapy treatment, there was an increase in the respiratory volumes (VC, MEVS, V max., PEF) for all subjects investigated. There was also an increase in the percentage of subjects with “excellent” respiratory index
- As concerns the breathing system, there was an improvement in the breathing mechanics, as well as an increase in the oxygen saturation of arterial blood and in the resistance to apnea and hypoxia.
- Due to the recovery, which took place in mediums with saline aerosols, the breathing was more effective, both regarding the gaseous exchanges, and using tissue-level oxygen.
- The assessment of standard cardiovascular system during effort, the Martinet test, indicated better values during the final tests, and the cardiovascular assessment tests are indicators of body adaptation to effort and only indirectly of the effort capacity, allowing to assess the effectiveness of training methods used for a certain amount of time.
- We have also noticed a decrease in the heart rate and breathing rate during the training session effort, which was possible due to the cardiovascular adaptation and regulation of athletes’ organism.

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Surveys on therapeutic effects of “halotherapy chamber with artificial salt-mine environment” on patients with certain chronic allergenic respiratory pathologies and infectious-inflammatory pathologies

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Abstract

Halotherapy (HT), derived from speleotherapy in salt mines, is also a drug-free therapeutic method. HT effects vary depending on the therapeutic method and the structure of halotherapy environment.

The purpose of this article is to show the HT effects of “halotherapy chamber with artificial salt-mine environment” of the National Institute of Rehabilitation, Physical Medicine and Balneoclimatology (INRMFB), on patients with bronchial asthma and other chronic, infectious-inflammatory and allergic respiratory diseases, describing the clinical effects on certain nonspecific resistance factors, on markers of inflammatory processes and on certain immunological changes.

Patients were clinically assessed, with the application of hematologic investigations, analysis of nonspecific resistance to infection and of inflammatory process markers, immunologic assessments, analysis of sodium and potassium concentrations, of mineralocorticoid function and other biochemical tests.

For the experimental HT therapy performed in the “halotherapy chamber with artificial salt-mine environment” of INRMFB, 15 patients suffering from bronchial asthma, allergic rhinitis, chronic bronchitis, chronic obstructive bronchopneumopathy were selected, based on specific medical indications and contraindications and applying ethical principles, as well as 4 patients with similar pathologies for the control group, who underwent in-home drug treatment.

After the specific halotherapy treatment on patients with bronchial asthma, chronic bronchitis and chronic obstructive bronchopneumopathy, which also showed other chronic, infectious-inflammatory and allergic respiratory pathologies, triggering of anti-inflammatory (and also anti allergic) mechanisms and healing effects on inflammatory process were noted. Data acquired also proved the halo therapeutic effect causing the reduction of sensitiveness of body in patients with bronchial asthma.

Keywords: Halotherapy, bronchial asthma, inflammatory process, therapeutic effects

Abbreviations: HT=Halotherapy, INRMFB=National Institute of Rehabilitation, Physical Medicine and Balneoclimatology

Introduction

Halotherapy, derived from speleotherapy in salt mines, is also a drug-free therapeutic method, applied especially on patients with bronchial asthma and chronic bronchitis. Following the “survey for the innovative use of potentially therapeutic salt-mine environment factors, in health and balneoclimateric tourism; modeling solutions”, the conceptual model was elaborated, subsequently converted into an experimental functional model entitled “halotherapy chamber with artificial salt-mine environment”, destined for surface halotherapy and built within the National Institute of Rehabilitation, Physical Medicine and Balneoclimatology.

This model was followed by surveys in the underground salt-mine environment, destined to assess the presence and quality of factors with speleotherapeutic / halotherapeutic potential, medical-biological multi-discipline surveys, including organismic and cellular-level analysis, before and after the experimental halotherapy treatment, on lab animals – Wistar rats with pathology experimentally induced by sensitization with ovalbumin.

Based on the experimental results acquired [1,2], the “Inception medical indications for the selection of patients with certain chronic respiratory pathologies for experimental halotherapy treatment” were elaborated.

Notably, in the infectious-inflammatory or allergic systems and mechanisms of the body and organismic or cellular components were involved.

The phagocytosis process is one of the promptest defensive mechanisms against infection. The phagocytic cells are generated from precursor cells of bone marrow and they divide into macrophagous and microphagous cells. In blood, macrophagous cells are represented by monocytes, and microphagous cells – by polymorphonuclear neutrophils (PMN), which account for app. 60% of leukocytes and which are also the most significant phagocytic cells [4].

Materials and methods

The selection of patients intended for the application of experimental HT treatment in the “halotherapy chamber with artificial salt-mine environment” of INRMFB was made based on medical indications and contraindications obtained, including:

I. Indications

1. Patient age: 7-60 years old; infants under 10 years must be accompanied by parents.
2. Gender: female or male.
3. Non-allergic / intrinsic / non-atopic asthma, allergic / extrinsic / atopic asthma, asthmatic bronchitis:
 - (1) With negative allergological tests or atopic skin tests (for non-allergic / intrinsic / non-atopic asthma) or positive tests (allergic / extrinsic / atopic asthma);
 - (2) eosinophils (Eo) – high or normal count in blood and / or in expectorated sputum;
 - (3) relatively non-severe clinical evolution;
 - (4) asymptomatic period with or without bronchial obstruction, without asthmatic seizures;
 - (5) symptomatic period with proven bronchial obstruction, without asthmatic seizures or severe asthmatic conditions;
4. intermittent bronchial asthma, without medication or with symptomatic medication (patient's medication):
 - (1) with no asthmatic seizures or severe asthmatic conditions;
 - (2) with no negative evolution (frequent seizures or severe asthmatic conditions) caused by physical stress (Exercise-Induced Asthma);
 - (3) with no negative evolution (frequent seizures or severe asthmatic conditions) caused by humidity, changes in air temperature, gases of other microclimatic parameters (Airways Asthma);
 - (4) with or without non-allergic rhinitis;
 - (5) with or without nasal polyposis;
 - (6) with or without sensitiveness to aspirin or other drugs;
5. chronic bronchitis, asymptomatic or symptomatic period without a negative evolution, without medication or with symptomatic medication (patient's medication);
6. chronic obstructive bronchopneumopathy (BPOC), asymptomatic or symptomatic period without a negative evolution (no aggravation / acute exacerbation, no wheezing respiration, persistent cough with the production of sputum and shortness of breath), without medication or with symptomatic medication (patient's medication);
7. allergic and chronic, infectious-inflammatory rhinitis and sinusitis, intermittent or slightly persistent, asymptomatic or symptomatic period without a negative evolution, without medication or with symptomatic medication (patient's medication);

II. Contraindications:

1. Complications of asthmatic seizures (status asthmaticus, atelectasis - relatively frequent, mediastinal and subcutaneous emphysema, cor pulmonale, pneumothorax, respiratory acidosis).
2. Severe persistent form of bronchial asthma, with no drug control.
3. Asthma with continuous dyspnea and severe asthmatic conditions with violent, subintractant seizures, with a duration of 12-48 hours, treatment-resistant, no cough and expectoration, with: polypnea, asphyxia, cyanosis, vascular collapse, drowsiness.
4. Bronchial asthma with negative evolution (frequent seizures or severe asthmatic conditions) caused by physical stress (Exercise-Induced Asthma).
5. Bronchial asthma negative evolution (frequent seizures or severe asthmatic conditions) caused by humidity, changes in air temperature, gases of other microclimatic parameters (Airways Asthma).
6. Severe medication-related complications (severe bronchospasm, asphyxia, severe allergic reaction, anaphylactic reaction and swelling Kwinke, anaphylactic shock, status asthmaticus).
7. Acute bronchitis.
8. Heart failure II – III.
9. Tuberculosis.
10. Sub-compensated and decompensated cardiopathies.
11. Cardiosclerosis.
12. Hypertonia II-III.
13. Acute renal diseases, lithiasis, enuresis.
14. Acute hyperacid gastritis.
15. Hepatitis or acute cholecystitis.
16. Diabetes, severe form.
17. Colagenosis, acute rheumatic diseases.
18. Cerebral trauma, neuroinfections, cerebral dysfunctions / central or peripheral neurologic diseases, epilepsy.
19. Otitis, acute internal ear diseases.
20. Claustrophobia, depressions, neurosis.
21. Emphysema and BPOC complications (acute respiratory failure with acute infections, chronic cor pulmonale / right side ventricular hypertrophy due to pulmonary hypertension, pneumothorax).

22. Post-surgery period up to 2 months.
23. General contraindications for referral to balneary treatment and physiotherapy.



Fig. 1 Halotherapy chamber with artificial salt-mine environment” of INRMFB, Bucharest, 11A, Ion Mihalache Blvd.

When patients for the experimental HT treatment were selected, 18 patients were investigated (16 adults and 2 infants with ages between 6–13 years) with bronchial asthma and chronic bronchitis, chronic obstructive bronchopneumopathy, of whom 14 had bronchial asthma with therapeutic control and partial control (atopic - 2, mixed-12; moderate - 2), also suffering from other pathologies like allergic rhinitis (including moderate persistence), rhinosinusitis, respiratory virosis, viral post-pneumonia condition, chronic gastritis, duodenal ulcer, ischemic coronary disease, light mitral failure, atopic dermatitis, chronic bronchitis, hypertensive cardiomyopathy, HTAE 1-2 degree, lumbar discopathy, cervical spondylosis, osteoporosis, hypothyreosis, hemorrhoid disease, dyslipidemia, obesity III degree, urinary infection; 4 patients with chronic bronchitis or chronic obstructive bronchopneumopathy (II and III) with acute exacerbation of GOLD (1 case), showing arrhythmia, tachycardia, dyslipidemia.

Subsequently, all the patients underwent medical-biological investigations.

After medical and medical-biological investigations, 15 patients (suffering from bronchial asthma, but also from allergic rhinitis, chronic bronchitis, chronic obstructive bronchopneumopathy) were chosen for the experimental halotherapy (HT) treatment in the “halotherapy chamber with artificial salt-mine environment” of INRMFB (**Fig. 1**).

A control group was also investigated, which included 4 patients with bronchial asthma, chronic bronchitis, chronic obstructive bronchopneumopathy, which was subject to in-home drug therapy, with no speleotherapy in salt mines or halotherapy [3].

Results

Thus, during the first 3-7 days of HT procedure, occurrence and onset of irritative cough was noticed in 7 patients (5 patients with bronchial asthma, 1 – with chronic bronchitis and 1 – with chronic obstructive bronchopneumopathy) out of the 15 patients from the group subjected to HT treatment. The clinical adaptation of patients to the underground environment condition was found after 5–10 days of HT procedures, depending on the pathology and clinical progress of illness. After 10 days of HT procedures, a scarceness of cases and significant reduction in severity – until full regress – of irritative dry cough was seen in investigated patients, and after 12–15 of specific HT treatment – absence of dry cough and wheezing, and also for 2/3 of investigated patients (suffering from bronchial asthma, chronic bronchitis, chronic obstructive bronchopneumopathy) – rare cases of cough with viscous expectoration (1–3 expectorations in the last HT treatment procedures), and also cough with liquid expectoration and increase of expectorated sputum volume was noticed (in 3 patients with bronchial asthma and 1 patient with obstructive bronchopneumopathy).

During the treatment period, no severe asthmatic conditions or additional infections occurred. ¼ of the investigated patients were characterized after 15 days of HT procedures, or 5–10 days after the HT treatment was ceased, or after gradually reducing the dose of specific medications (antihistaminic, bronchiolitis drugs, corticosteroids inhalers) to 20-30%.

The patient with bronchial asthma and duodenal ulcer ceased the halotherapeutic treatment during the 3rd HT procedure, upon recommendation of the INRMFB physician, due to duodenal pains, and another patient with chronic bronchitis – during the 7th HT procedure, due to digestive issues occurred at home before the HT procedure, and resumed treatment after three days. The halotherapeutic treatment was also interrupted in one patient with bronchial asthma, during the 10th HT procedure, on the family doctor's recommendation, due to acute exacerbation of cervical spondylosis pains.

The data gathered proved the need for additional specific surveys on patients with chronic infectious-inflammatory and allergic respiratory diseases accompanied by other pathologies.

The average blood count of phagocytes – neutrophils PMN in patients with bronchial asthma and other respiratory allergies, as well as in patients with chronic bronchitis or chronic obstructive bronchopneumopathy was found to be lower compared to the lower limit of “normal (reference) values”, cases with lower test values being noted in 9 of 13 patients with bronchial asthma and other allergies (namely, for app. 2/3 of the respective patients group, $P < 0,05$) and in patients with infectious-inflammatory bronchopulmonary diseases (chronic bronchitis, chronic obstructive bronchopneumopathy). The relative count of formasan-positive PMN neutrophil cells (in nitroblue tetrazolium test) was found to be high in blood for most investigated patients (12/13 – cases of bronchial asthma and other allergies $P < 0,01$) and for patients with chronic bronchitis or chronic obstructive bronchopneumopathy. Thus, most of the investigated patients showed a deficit in the phagocytosis activity prior to the halotherapeutic treatment and also a decrease in the oxidative metabolism of phagocytes – granulocytes PMN in blood being noted.

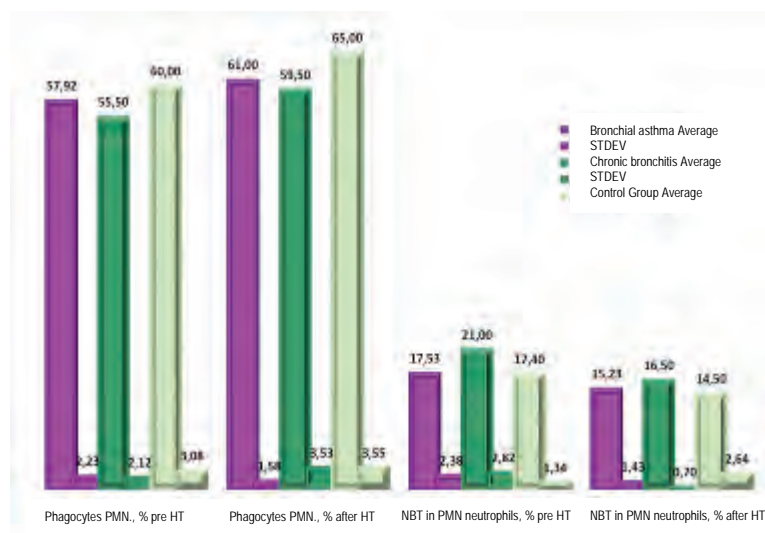


Fig. 2 The results of the phagocytosis process for neutrophils PMN (in blood) in patients with bronchial asthma and other chronic infectious-inflammatory or allergic respiratory pathologies prior and after the experimental halotherapy treatment in “halotherapy chamber with artificial salt-mine environment” (11A Ion Mihalache Blvd., INRMFB) and in control group patients

Based on data acquired after the experimental halotherapy (HT) treatment, the triggering of non-specific resistance parameters of the body was noted (phagocytosis of neutrophils PMN, intra-cellular redox of neutrophils in NBT test) in patients (including infants) subjected to specific halotherapy treatment, compared to “normal values” and to values found in control patients, respectively with chronic respiratory pathology and drug treatment ($P > 0,05 < 0,1$ and $P > 0,1$).

The results obtained showed the positive effect of experimental halotherapeutic treatment related to the stimulation of phagocytosis process and the increase in non-specific anti-infection resistance of the body, a fact noted based on the ascendant trend of phagocytes PMN in blood and the activation of oxygen-dependent bactericide action of granulocytes PMN (nitroblue-tetrazolium test) in patients with bronchial asthma and allergic rhinitis and in those with chronic bronchitis, chronic obstructive bronchopneumopathy ($P > 0,1$). Still, the fact that the low number of patients with chronic bronchitis and chronic obstructive bronchopneumopathy did not allow the mentioning of significant positive changes should be mentioned, and, therefore, in this case, the extension of the respective surveys is needed.

Conclusions

The assessment of results achieved in the investigated patients with bronchial asthma, chronic bronchitis and chronic obstructive bronchopneumopathy, after a specific halotherapy treatment, indicates the triggering of an anti-inflammatory (including anti-allergic mechanisms) mechanism and a decreasing trend of the inflammatory process.

Data acquired indicate a decrease in the body's sensitiveness and in infectious-inflammatory process in patients with bronchial asthma after HT treatment, and it also proves the need to extend the period or to repeat the halotherapeutic treatment.

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SALTMED - THE THERAPY WITH SODIUM CHLORIDE DRY AEROSOLS

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Abstract. To assess the effects of halotherapy, we conducted a retrospective study on patients with obstructive bronchial disorders (asthma and chronic obstructive pulmonary disease), treated in the UPU-SMURD department of the Bucharest Emergency Hospital. The respiratory frequency, the ventricular aspect and the oxygen saturation were measured in all patients (initially and every 20 minutes, for an hour), as well as the blood gases (initially and after an hour). Saline inhalation determines a quicker improvement of parameters defining the respiratory failure in the worsening of obstructive pulmonary diseases.

Keywords: obstructive bronchial disorders, SaltMed, halotherapy

Introduction

Background

Halotherapy (gr. halos = salt) uses aerosol microparticles of salt (sodium chloride) to treat respiratory diseases. It appeared as an alternative to speleo-therapy (gr. speleos = cave), a therapeutic method used in Eastern Europe in salinas from the beginning of 19th century [1].

In the 80's in the Soviet Union "halochambers" are conceived and used, which render the salina microclimates. The method is subsequently extended in Europe and North America to treat especially asthma [2].

The specialists focused then on the creation of "portable" devices that can be used in ambulances, in hospitals as well as at home. In Hungary a "ceramic pipe" was conceived that contained saline

microparticles and through which the air was inhaled, while exhalation was nasal.

In Romania, the company TehnoBionic conceived a filter cartridge with saline microparticles that are nebulized by force under pressure of air or dehumidified oxygen, being connected to a face oxygen mask [3].

Principle of the method

The micronized sodium chloride (1-5 μm) is easily breathed in the upper and lower respiratory tract. At this level, it dissolves in the sol phase of the mucus layer that covers the respiratory epithelium. Here, through local osmotic effect, the water in the interstitial tissue is attracted to the respiratory tract lumen. The inflammatory edema thus decreases and the mucus quantity increases [4].

The mucus becomes more fluid and is easily mobilized to the cilia of respiratory epithelial cells, to be eliminated at pharynx level and then expectorated through coughing.

Through this easy mechanism the sodium chloride (NaCl) has a beneficial effect at respiratory tract level, improving a number of symptoms that appear in the acute disorders of the respiratory

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tract [5,6,7].

Thus, the nebulization of saline microparticles in the respiratory tract is a therapeutic method to be used in respiratory disorders such as: asthma, chronic obstructive pulmonary disease, pneumonia etc.

It seems that the method acts in pulmonary infectious disorders by decreasing the microbe contamination of upper respiratory tract (especially with staphylococci) in children with respiratory allergy. The capacity to kill bacteria could be explained through the complex immunomodulatory effects that the procedure determines: it increases the number and activation of T lymphocytes, it normalizes the number of B lymphocytes, it increases the level of IgA [3].

Though there are studies regarding the effects of halotherapy in other pulmonary pathologies as well: cystic fibrosis, acute respiratory distress syndrome, acute pulmonary injury etc., the effect is not fully demonstrated, though it seems to be favorable [4,8].

To assess the effects of halotherapy, we conducted a retrospective study on patients with obstructive bronchial disorders (asthma and chronic obstructive pulmonary disease), treated in the UPU-SMURD department of the Bucharest Emergency Hospital.

Material and methods

We conducted a retrospective group study on 393 patients who came to the UPU-SMURD department of the Floreasca Emergency Hospital, Bucharest, or who were transported by cars belonging to SMURD Bucharest due to worsening of asthma or of chronic obstructive pulmonary disease. All patients received standard treatment with inhalatory betamimetics, corticotherapy and

oxygen and 204 of them were additionally treated with saline inhalations.

The respiratory frequency, the ventricular aspect and the oxygen saturation were measured in all patients (initially and every 20 minutes, for an hour), as well as the blood gases (initially and after an hour).

For statistic purposes, the Mann-Whitney U test was used in the univariate analysis (the variable distribution was not normal) for parameter comparison between the SaltMed group and the standard therapy group, as well as for the assessment of differences between the average improvement of PaO₂ and PaCO₂ during the first hour, between the group treated with SaltMed and the untreated group. In order to evaluate the differences between the two groups as far as the other repeatedly measured parameters are concerned (respiratory frequency and SaO₂, measured 4 times each, every 20 minutes), the General Linear Model for repeated measures was used, in which the initial PaO₂, age and sex were introduced as covariable. The statistic analysis was conducted with SPSS 16.0 for Windows, SPSS Inc.

Results

Out of 393 patients, 204 received standard treatment and SaltMed treatment, while 189 only received standard treatment. The basal characteristics of the two groups are presented in table I.

This table shows that the patients in the group treated with SaltMed were in general in a more serious condition as they were older and the CO₂ partial pressure was higher, while the oxygen saturation and partial pressure were lower.

Despite this situation, at the end of the first hour

Characteristic	SaltMed treatment (n=204)	Standard treatment (n=189)	P
Age*	64 (35. 88)	59 (3. 88)	0.001
Males **	115 (61%)	131 (64%)	0.532
Basal respiratory frequency *	23 (18. 37)	23 (18. 36)	0.764
Basal SaO ₂ *	90 (78. 97)	94 (75. 99)	<0.001
Basal PaO ₂ *	61.5 (47. 96)	80 (42. 97)	<0.001
Basal PaCO ₂ *	58 (35. 80)	44 (35. 95)	<0.001

Table I. Basal characteristics of the two groups of patients

* Average (min, max) (distribution was not normal); data were compared based on Mann-Whitney U test

**Number (percentage); data were compared based on X² test

of therapy all parameters were significantly better in the SaltMed group (table II).

Moreover, the SaO₂ and the respiratory frequency were significantly improved in the SaltMed

Parameter	SaltMed treatment (n=204)	Standard treatment (n=189)	P
Respiratory frequency *	17 (15. 32)	19 (16. 32)	0.764
Basal SaO ₂ *	98 (82. 100)	97 (83. 99)	<0.001
Basal PaO ₂ *	92 (56. 98)	85 (54. 97)	<0.001
Basal PaCO ₂ *	38 (32. 77)	41 (34. 99)	<0.001

Table II. Respiratory parameters of the two groups of patients after the first 60 minutes of treatment

* Average (min, max) (distribution was not normal); data were compared based on Mann-Whitney U test

The PaO₂ improvement was significantly better in the SaltMed group as compared to the group without SaltMed (p<0.001, fig. 1); the same was valid with respect to PaCO₂ decrease (p<0.001, fig. 2).

group as compared to the witness group after adjustment for age and initial PaO₂, which were significantly different between groups (in favor of the witness group) (p<0.01, fig. 4).

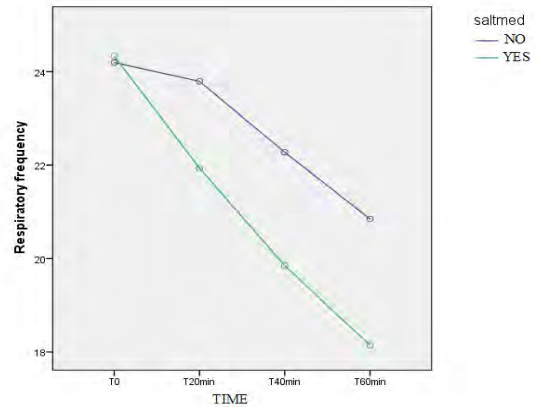
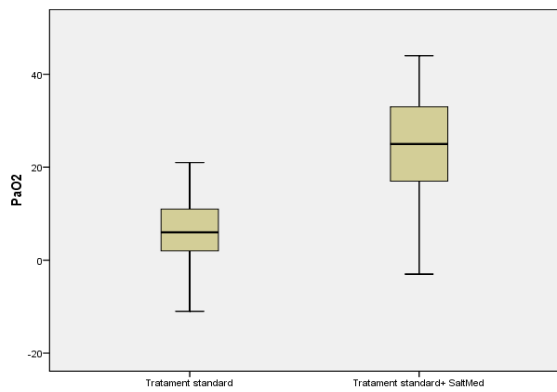


Figure 1. Improvement of PaO₂ in the two groups of patients (SaltMed group and witness group)

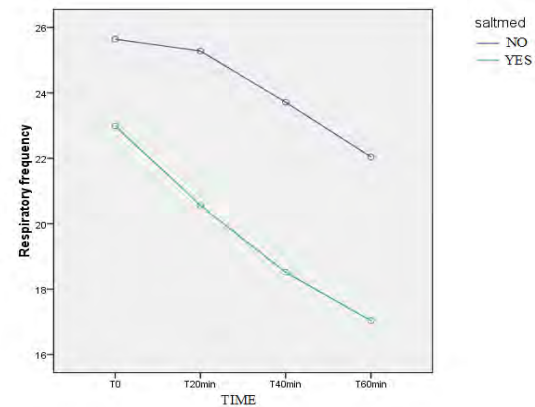
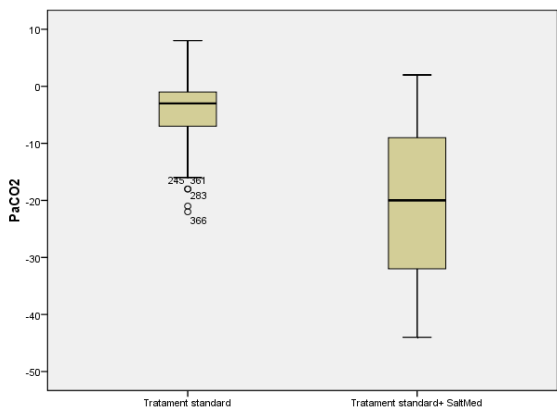


Figure 3. SaltMed effect on respiratory frequency, gross (a) and adjusted for initial PaO₂ and age (b)

Figure 2. Improvement of PaCO₂ in the two groups of patients (SaltMed group and witness group)

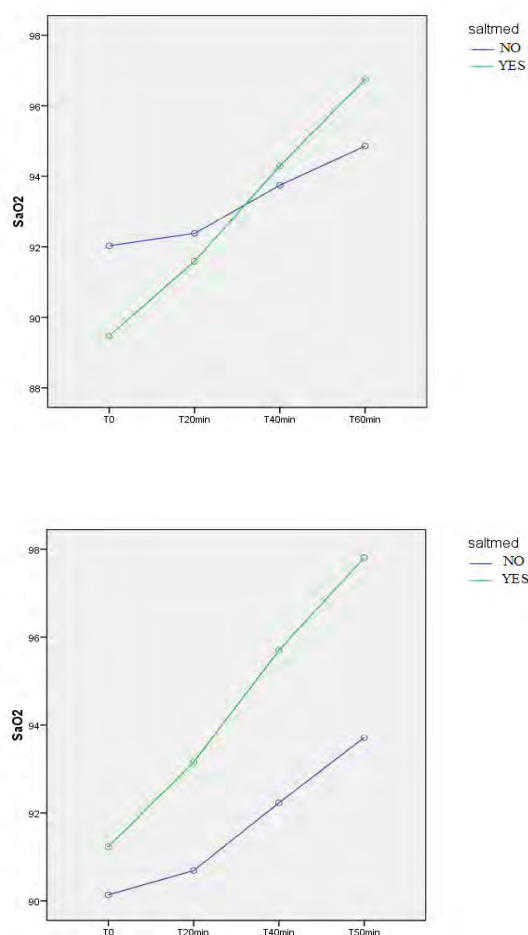


Figure 4. SaltMed effect on oxygen saturation, gross (a) and adjusted for initial PaO₂ and age (b)

Discussions

This study proves that halotherapy added to the initial treatment of patients with chronic obstructive pulmonary disease and asthma with acute respiratory failure leads to significant improvement during the first hour of all clinical and paraclinical parameters: respiratory frequency, O₂ saturation and partial pressure of blood gases.

No orotracheal intubation was necessary in the group that benefited from halotherapy in order to facilitate mechanical ventilation during the first hour of therapeutic assistance, so it can be an option in the non-invasive management of such patients.

Though it was not quantified, it needs to be stated that patients that benefited from halotherapy with SaltMed tolerated very well the administration of saline microparticles and presented no emetic side effects, as it usually happens when humid nebulization is used, where the use of bronchodilating and/or mucolytic substances has a strong emetic effect, which makes the action hard to tolerate by

the patient.

The fast improvement of the respiratory failure in the emergency room makes it possible for the patient to be quickly hospitalized in a unit where no intensive care measures are needed, avoiding thus the agglomeration or even the blocking of the emergency room.

One of the study limits is that it is only an observational study and the results can be affected by systematic selection errors. Based on data analysis, it seems that SaltMed treatment was applied especially to patients in a more serious condition (table I) and in this case the treatment results are more spectacular. It is necessary to conduct a randomized clinical trial that confirms these results as other confusion factors may be involved, which were not recognized or measured in this study.

Another limit is that patients were only monitored during the first hour since the SMURD team was requested or since they came to the emergency room, so we do not know if the good results in the first hour were maintained over the following hours or if the results extended to the necessity of hospitalization, hospitalization duration, life quality, necessity of intubation or even mortality, for which further studies are requested.

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A review of halotherapy for chronic obstructive pulmonary disease

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Background: Chronic obstructive pulmonary disease (COPD) is a chronic, progressive disease and is treated with inhaled medication to optimize the patient's lung health through decreasing their symptoms, especially breathlessness. Halotherapy is the inhalation of micronized dry salt within a chamber that mimics a salt cave environment. Recent media reports suggest that this therapy may help with the symptoms of COPD.

Objective: To critically evaluate and summarize the evidence for the use of halotherapy as a treatment for COPD.

Design: A review using systematic approach and narrative synthesis.

Data sources: Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, MEDLINE, EMBASE, CINAHL, and Google Scholar were searched. Two reviewers independently reviewed abstracts and selected eligible studies based on predetermined selection criteria.

Results: Of the 151 articles retrieved from databases and relevant reference lists, only one randomized controlled trial met the inclusion criteria. A meta-analysis was unable to be conducted due to the limited number of published studies. Inclusion criteria were subsequently expanded to allow three case-control studies to be included, ensuring that a narrative synthesis could be completed. From the pooled data of the four studies, there were 1,041 participants (661 in the intervention group and 380 in the control group). The assessment of methodological quality raised issues associated with randomization and patient selection. Three themes were identified from the narrative synthesis: respiratory function, quality of life, and medication use.

Conclusion: Themes generated from the narrative synthesis data reflect outcome measures regularly used for interventional research associated with COPD. From this review, recommendations for inclusion of halotherapy as a therapy for COPD cannot be made at this point and there is a need for high quality studies to determine the effectiveness of this therapy.

Keywords: salt therapy, speleotherapy, lung disease, aerosol, chronic disease, salt cave

Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic, progressive disease with symptoms of dyspnea, increased respiration rate, sputum production, and a reduced exercise intolerance.¹ In 2008, the World Health Organization estimated that COPD was the tenth most prevalent cause for moderate to severe disability,² and was the fourth leading cause of death, worldwide.³ With this significant burden, the impact of this disease on individuals, families' quality of life, and the associated health care expense, COPD is recognized as an international health priority.^{1,3,4}

COPD is managed with inhaled medication with the view to optimize the patient's pulmonary function and reduce symptoms. Pulmonary rehabilitation is recommended for those patients with Medical Research Council dyspnea score of 3 or more¹ as

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there is substantial evidence of its benefit to these patients.^{5,6} However, other therapies such as speleotherapy and halotherapy are being recommended in the wider community⁷ and are often described as well-researched treatments for people with COPD.⁸ In Eastern Europe, natural salt caves have been used to help relieve symptoms of chest conditions.⁹ This therapy is known as speleotherapy, where a natural salt cave climate is used as a therapy for ill health.¹⁰ The unique characteristics of the microclimate within the caves are stable air temperature, moderate to high humidity, the presence of fine aerosol elements (sodium, potassium, magnesium and calcium), as well as a lack of airborne pollutants and pollens.¹¹ Halotherapy builds on this premise and is used as an above-ground alternative for speleotherapy.¹² Halotherapy is a treatment consisting of inhalation of small salt particles in a controlled environment of a halochamber.^{11,12} This room is designed to replicate the natural microclimate of a salt cave. Halotherapy treatment has been associated with relief of respiratory conditions such as asthma, cystic fibrosis, and COPD, as well as relieving integumentary conditions such as eczema and dermatitis.^{9,11} A recent study of bronchiectasis patients found halotherapy to be of little benefit.¹³ Despite these findings, there appears to be an increasing number of

commercial halotherapy treatment centers in Australia, the United States of America, Europe, and Canada that are aimed at treating respiratory and other medical conditions.

Halotherapy has received prominent television media coverage in Australia from Channel 9's *A Current Affair*^{8,14,15} and Channel 7's *Today Tonight*^{7,16} and abroad from Cable Network News' *Vital Signs*,¹⁷ as well as from other television program providers such as the British Broadcasting Corporation¹⁸ and the National Broadcasting Corporation.¹⁹ National and international media current affair and news reports^{14-16,19} suggest that halotherapy may help with a variety of respiratory illnesses including relieving the symptoms of COPD. The assertion behind these reports is that inhaled dry salt therapy may assist people with COPD by increasing the liquefaction of airway secretions, which, in turn, enhances the expectoration of airway mucous secretions. With the increase in the commercial availability of halotherapy as an alternative complementary treatment, it is timely to undertake a review of this therapy for COPD to appraise the evidence for the complementary therapy. An extensive search of a number of databases did not identify any published systematic reviews that assessed halotherapy as an intervention for people with COPD. Therefore, this review sought to investigate

Table I Summary of included review articles

Article	Aim	Sample	Method
Nurov (2010) ²⁴	To assess the immunological features of COPD patients after speleotherapy	One hundred twenty-four participants randomized into two groups. Treatment group 103 participants (60 male, 43 female) and control group 25 participants (14 male, 11 female).	Randomized control trial. Immunological studies at time one (before treatment), at time two (after treatment), and time three (6 months after treatment).
Chervinskaya and Ziber (1995) ¹¹	To assess the effect of halotherapy on various types of respiratory diseases	Treatment group – 124 participants, 54 males, 70 females, mean age 34.3±2.5 years. Control group – 15 participants not described.	Prospective case-control study. Lung function studies before and after trial.
Oprita et al (2010) ²³	To assess the effects of halotherapy on patients with asthma and chronic obstructive pulmonary disease	Two hundred four participants (61% males, mean age 64 years) received standard treatment and SALTMED treatment. One hundred eighty-nine received only standard treatment (64% males, mean age 59 years).	Retrospective case-control study. Respiratory characteristics reported before treatment and 1 hour after treatment.
Horvath (1986) ¹⁰	To examine whether a stay in a cave microclimate could further improve respiratory symptoms of patients with COPD or bronchial asthma	One hundred fifty-one participants – (89 males, 62 females, mean age 46 years, 101 participants with chronic bronchitis, 50 with bronchial asthma) treatment with climatotherapy. Two hundred thirty participants – (137 males, 93 females, mean age 49 years, 141 participants had chronic bronchitis, 89 had bronchial asthma) treatment was CRR consisting of speleotherapy in combination with rest, breathing exercises and relaxation training.	Retrospective case-control study. Clinical state reported as improved, unchanged, or deteriorated. Medication request dosage changes before and after 3 weeks of treatment. Mean FEV ₁ before and after treatment.

Abbreviations: COPD, chronic obstructive pulmonary disease; CRR, complex respiratory rehabilitation; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; PaCO₂, partial pressure of carbon dioxide in arterial blood; PaO₂, partial pressure of oxygen in arterial blood; PEF, peak expiratory flow; SALTMED, saline inhalation; SaO₂, oxygen saturation.

halotherapy as a therapeutic intervention for people with COPD to determine the effectiveness of this therapy.

Methods

Search strategy and selection criteria

A search of electronic databases was conducted from January 2013 to February 2013. The electronic databases searched were the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, MEDLINE, EMBASE, CINAHL, and Google Scholar. The literature review search strategy (Supplementary material) used a combination of MeSH terms found in the title and/or abstract for halotherapy and chronic obstructive pulmonary disease and the following search terms were used: COPD; chronic bronchitis; emphysema; halotherapy; halochamber; speleotherapy; spelaeotherapy; cave; salt mine; potash mine; vital air room; climate chamber; saltpipe; and sopipa. Reference lists in retrieved papers were hand-searched for other possible studies. All prospective randomized controlled trials were included where trials compared halotherapy or speleotherapy with a control group. Abstract and full text articles that were not in English were excluded. After abstracts were retrieved, two reviewers applied the inclusion and exclusion criteria. Full text articles were subsequently obtained and reviewed by two independent

reviewers (RR and SMSS) (Table 1). A third reviewer (NJR) was the arbiter should any disagreement regarding the inclusion of articles occur.

Quality assessment

The methodological quality of the selected articles was assessed by two reviewers (RR and SMSS) using the Scottish Intercollegiate Guidelines Network (SIGN) methodology quality checklists for controlled trials and case-control studies (Table 2).²⁰ These checklists were used to assess issues pertinent to well-conducted randomized controlled trials and case-control studies. The risk of bias was assessed using the Cochrane classification with four criteria: sequence generation; allocation concealment; blinding; and incomplete outcome measurement.²¹ Any disagreements regarding risk of bias were resolved through discussions between the reviewers and the arbiter (RR, SMSS, NJR).

Data abstraction

The search revealed 151 published abstracts after excluding the duplicates. The abstracts were screened using the selection criteria and 150 articles were excluded. The flow diagram of the selection process is illustrated in Figure 1. Only one randomized study met the inclusion criteria; therefore, it

NHMRC level of evidence	Major findings	Strengths and limitations
II	Increase in concentration subpopulations in all studied lymphocytes, normalization and correlation of subpopulations of CD4+ and CD8+ lymphocytes, and increase in neutrophil phagocytosis activity. Overall immune status improvement in 97.8% of treatment group and 67.5% of control group.	One treatment facility. Moderate sample size. Randomization unblinded. Unequal chance of allocation. Recruitment strategy not identified. Nil ethical considerations. Patients' clinical status not reported.
III-2	After treatment – decreased bronchial obstruction, decreased medication use, and increase in FVC, FEV ₁ , PEF. Participants slept better, decreased fatigue. Cough became less frequent, easier, and more productive.	One treatment facility. Moderate sample size. Recruitment strategy not identified. Many respiratory diseases grouped together. Nil ethical considerations reported. Control group not adequately described before or after treatment.
III-2	Respiratory rate, SaO ₂ , PaO ₂ , and PaCO ₂ were all significantly improved in the group receiving the standard treatment in combination with the SALTMED treatment as compared to the group receiving only the standard treatment.	One treatment facility. Large sample size. Only short term results, no longer term follow up. Asthma and COPD results reported together.
III-2	Clinical state improved in group receiving CRR compared to 72.8% receiving climatotherapy. For patients receiving CRR, FEV ₁ improved from 1,468±631 mL to 1,676±706 mL compared to the patients receiving climatotherapy FEV ₁ who improved from 1,638±613 mL to 1,666±684 mL.	One treatment facility. Large sample size. Asthma and COPD results reported together. Initial clinical state of group receiving CRR was more severe than group receiving climatotherapy.

was not possible to undertake the meta-analysis. The inclusion criteria were expanded and a further three case-control trials were included. A number of commentary papers were excluded. The two reviewers (RR and SMSS) were in agreement for the studies to be included and the arbiter (NJR) was not required to resolve any conflicting opinion. On completion of the methodological quality assessment, each manuscript was summarized and, due to the heterogeneity of reported outcomes, a thematic analysis was conducted. Thematic analysis is a process that seeks to describe the data in rich detail in order to identify, analyze, and report patterns known as themes from within the data.²² The combined data of the four studies were analyzed thematically.

Findings

Thematic analysis

Summary data including characteristics of the study regarding the four studies are summarized in Table 1. The three themes identified from the data were respiratory function, quality of life, and medication use.

Respiratory function

All of the case-control studies (n=3) reported improved respiratory function to varying degrees and detailed improvements in many lung function tests including forced vital capacity, forced expiratory volume in 1 second (FEV₁), oxygen saturation, partial pressure of oxygen in arterial blood, and partial pressure of carbon dioxide in arterial blood. Although the lung function tests utilized by the researchers are a reliable method to assess respiratory function, each study reported using different tests which made any comparison of the results difficult.

Oprita et al²³ report that, after 60 minutes of treatment, there was an improvement in oxygen saturation from 90%

to 98% in the treatment group (n=204) as compared to the control group (n=189) improving from 94% to 97%. Similarly, the improvement in partial pressure of oxygen in arterial blood for the treatment group was from 61.5 mmHg to 92 mmHg compared to 80 mmHg to 85 mmHg for the control group. The partial pressure of carbon dioxide in arterial blood considerably decreased in the treatment group from 58 mmHg to 38 mmHg and in the control group from 44 mmHg to 41 mmHg.

Horvath¹⁰ documented an improved respiratory function by measuring the FEV₁ before and after treatment. The mean FEV₁ for the treatment group (n=230) improved from 1.47±0.63 L to 1.68±0.71 L after patients were enrolled in a complex respiratory rehabilitation that included speleotherapy for a specific time period. The control group (n=151), who received climatotherapy, had an improvement from 1.64±0.61 L to 1.67±0.68 L. Nurov's²⁴ study reported improved immune function after speleotherapy but did not report specifically on lung function of COPD patients. Nurov concluded that patients with COPD receiving speleotherapy improved their immunological status and, as a consequence, reduced the inflammatory process particularly during exacerbations.

Quality of life

Horvath¹⁰ and Chervinskaya and Ziber¹¹ reported speleotherapy and halotherapy (respectively) as improving the quality of life for patients suffering from COPD. Horvath reported that 90.4% of patients receiving the speleotherapy improved their clinical state in comparison to 72.8% of patients in the control group. The participants' clinical state was scored each day by the participant and physician jointly on the basis of symptoms and complaints. The authors suggested that the improved clinical state for COPD patients improves their life

Table 2 Methodological assessment of included articles

	Q1	Q2	Q3	Q4	Q5	Q6
Randomized controlled trial	Aims	Randomization	Concealment	Double blinding	Similar TG and CG	Treatment is the only difference between TG and CG
Nurov (2010) ²⁴	✓	✓	Unable to report	×	✓	✓
Case-control studies	Aims	Comparable populations	Consistent exclusion criteria	Percentage of cases and controls	Comparison of cases and controls	Clearly defined cases
Chervinskaya and Ziber (1995) ¹¹	✓	Unable to report	Unable to report	Unable to report	×	×
Oprita et al (2010) ²³	✓	✓	✓	Unable to report	✓	✓
Horvath (1986) ¹⁰	✓	✓	Unable to report	Unable to report	✓	✓

Note: Overall acceptability is indicated by (-) unacceptable, (+) acceptable, and (++) excellent.

Abbreviations: Q, question number; CG, control group; TG, treatment group.

quality by decreasing exacerbations, reducing hospitalization, improving physical tolerance, and reducing fatigue. Nurov²⁴ reported that positive shifts in immunological status resulted in improved clinical symptoms, but elaboration or description of clinical symptoms were not provided.

Medication use

The use of medication was an outcome measured in two halotherapy studies. Chervinskaya and Ziber¹¹ and Horvath¹⁰ indicated that patients were able to decrease their medications. Chervinskaya and Ziber reported that up to 50% of patients in their study were able to discontinue their inhaled corticosteroids therapy and nearly a third of participants continued their inhaled steroid therapy at reduced dosages. In Horvath's study, medication use was recorded as a bi-level outcome with the first outcome being reduction or omission and the second outcome being an unchanged dosage. However, with 95% of participants having either reduced or omitted medication, the type of medication or dosage is not detailed.

Discussion

From this review of literature, it has become apparent that there have been very few rigorous studies published on this topic and, hence, this reduces the potential for evidence to support this therapy. It should be noted that only one randomized trial was found after an extensive search of the literature. As a result, the inclusion criteria for this review were widened to include relevant case-control studies that met all other inclusion criteria. The randomized trial by Nurov²⁴ studied the immunological features of patients with COPD before and after speleotherapy, demonstrating increased levels of lymphocytes and increased neutrophil phagocytosis activity. When assessing the methodological quality of studies included in this review, a number of concerns were identified.

Specifically, in Nurov's study, the method of randomization appeared unclear and there was a lack of detail regarding demographic and disease related information including medications being used by participants.

Other concerns related to the studies included in this review pertain to the lack of detail in regard to the participants' primary medical condition of either asthma or COPD and discrimination in the results between these two medical conditions. Medication information including type and dosage was also lacking in all studies. There were significant differences at baseline between treatment and control arms in the study by Oprita et al²³ and the treatment group appeared to have more severe COPD. In Horvath's⁵ study, the patients in the treatment group had a significantly lower FEV₁ prior to the intervention than the control group. Whilst the Oprita study appears to be a well-constructed retrospective case-control study with positive results for the use of sodium chloride dry aerosols, as the investigators only assessed patients 1 hour after treatment, longer term conclusions such as quality of life would be difficult to assess.

In light of the lack of scientific evidence for the use of halotherapy in COPD, future studies need to be designed to provide the best available evidence and randomized controlled trials need to be considered. This approach would address the methodological concerns identified through this review such as participant selection bias, blinding of participants to the intervention, and the concealment of allocation to intervention or control group.

Study limitations

The limitations associated with this review were restricted by the availability of published research associated with halotherapy as a therapeutic intervention for COPD. The studies included in this review were found to have a

Q7	Q8	Q9	Q10	Q11	
Outcome measured in standard, valid, reliable way	Drop out percentage	Intention to treat analysis	Results comparable for all sites	–	Overall acceptability (++, +, –)
✓	Not reported	✓	N/A		+
Clearly defined controls	Concealment	Outcome measured in standard, valid, reliable way	Address possibility of confounding factors	Confidence intervals provided	Overall acceptability (++, +, –)
✗	Unable to report	✗	✗	✗	–
✓	Retrospective case-control study	✓	✓	✓	++
✓	Retrospective case-control study	✓	✓	✗	+

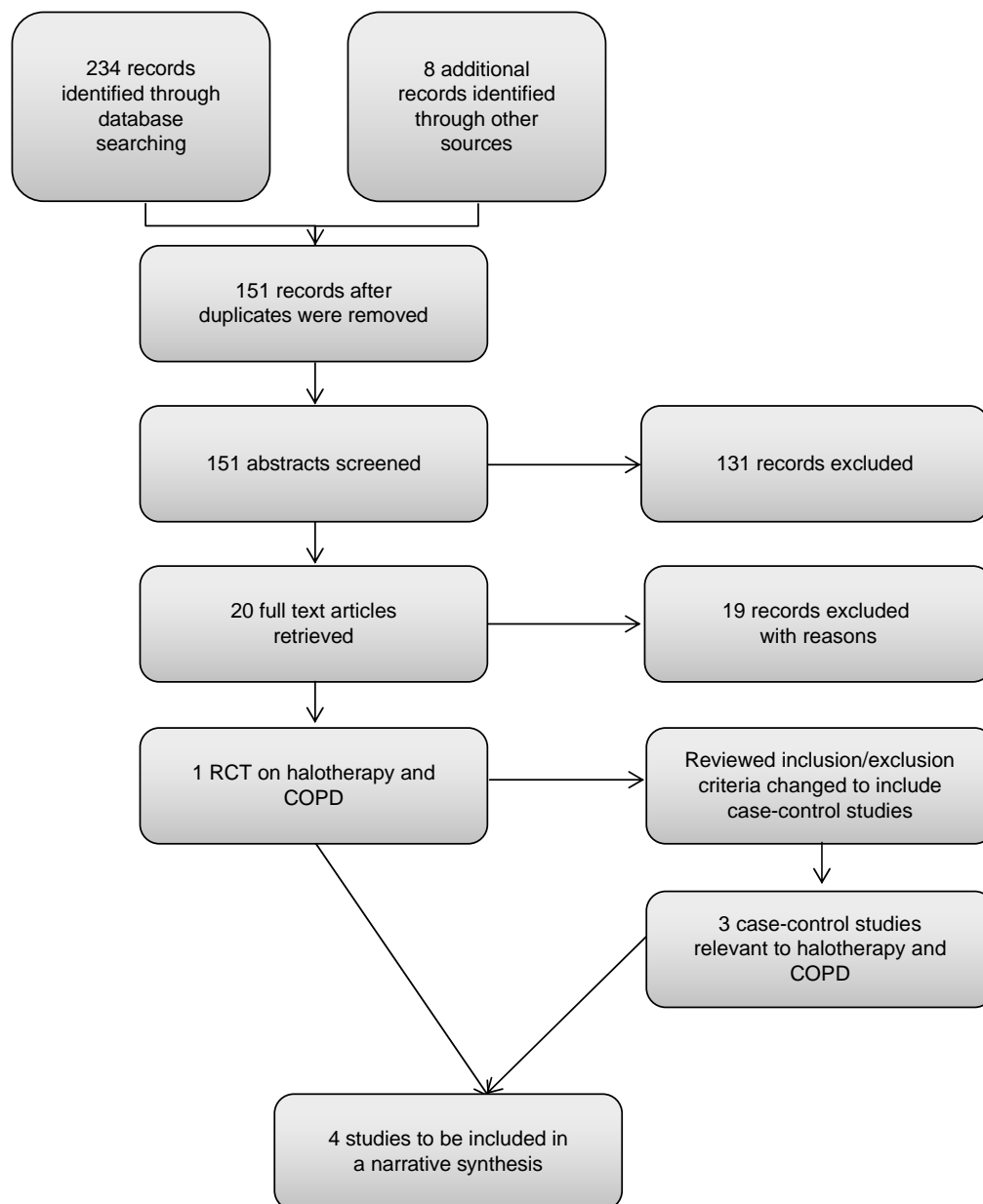


Figure 1 Flow chart of systematic search.

Abbreviations: COPD, chronic obstructive pulmonary disease; RCT, randomized controlled trial.

number of methodological concerns and limited reporting of baseline data. All studies in this review lacked detail on ethical considerations such as ethical approval, processes for informed patient consent, and funding disclosure. The outcome measurements using lung function tests varied between studies and, as such, a comparison of their results was not possible.

Conclusion

For halotherapy to be considered as an evidence based therapy for people with COPD, there needs to be high quality research

undertaken to fully examine the effects of this therapy and its impact on the quality of life of people with COPD.

Disclosure

The authors report no conflicts of interest in this work.

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Supplementary material

Search strategy

A systematic search of the bibliographic databases was conducted using the following search terms: COPD or “Chronic bronchitis” or Emphysema and Halotherapy* or

halochamber* or spelaeo* or speleo* or cave* or salin* or “salt min*” or “potash min*” or subterraneootherap* or “vital air room” or “climat* chamber” or karst* or SaltPipe or Sopipa.

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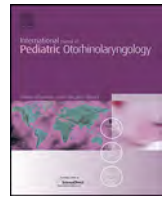
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Double-blind placebo-controlled randomized clinical trial on the efficacy of Aerosal[®] in the treatment of sub-obstructive adenotonsillar hypertrophy and related diseases ☆☆☆



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ABSTRACT

Background: Adenotonsillar hypertrophy (ATH) is a frequent cause of upper airways obstructive syndromes associated to middle ear and paranasal sinuses disorders, swallowing and voice disorders, sleep quality disorders, and occasionally facial dysmorphisms. ATH treatment is essentially based on a number of medical–surgical aids including nasal irrigation with topical antibiotics and corticosteroids and/or treatment with systemic corticosteroids, immunoregulators, thermal treatments, adenotonsillectomy, etc.

Objectives: The aim of the present study is to assess the efficacy of Aerosal[®] halotherapy in the treatment of sub-obstructive adenotonsillar disease and correlated conditions compared to placebo treatment.

Methods: A total of 45 patients with sub-obstructive adenotonsillar hypertrophy were randomized to receive either Aerosal[®] halotherapy or placebo for 10 treatment sessions. The main outcome was a reduction greater than or equal to 25% from the baseline of the degree of adenoid and/or tonsillar hypertrophy.

Results: In the intention-to-treat analysis, a reduction of the degree of adenoid and/or tonsillar hypertrophy $\geq 25\%$ from baseline after 10 therapy sessions was found in 44.4% of the patients in the halotherapy arm and in 22.2% of the patients in the placebo arm ($P = 0.204$). Among the secondary outcomes, the reduction of hearing loss after 10 treatment sessions in the halotherapy arm was higher than the placebo arm ($P = 0.018$) as well as the time-dependent analysis showed significantly improved peak pressure in the Aerosal[®] group ($P = 0.038$). No side effects were reported during the trial. In addition, the therapy was well accepted by the young patients who considered it as a time for play rather than a therapy.

Conclusions: Aerosal[®] halotherapy can be considered a viable adjunct, albeit not a replacement, to conventional medical treatment of sub-obstructive adenotonsillar syndrome and related conditions. Further research is however needed to improve ATH treatment.

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1. Introduction

Symptomatic adenotonsillar hypertrophy (ATH) is a frequent cause of obstructive syndromes ascribable to mechanic obstruction in the oropharynx and resulting upper aerodigestive tract encumbrance [1]. The syndrome, which usually affects children aged 3–10 years, is characterized by middle ear, nasal passages, paranasal sinus symptoms, voice and swallowing disorders, poor sleep quality, and occasionally facial dysmorphisms and dental malocclusion [2–7].

ATH has a typical onset after the third year of life with symptoms progressively worsening with a peak age incidence between 4 and 8 years [8].

☆☆ Trial registration number: NCT01574885 (ClinicalTrials.gov Identifier).

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The management of this condition has changed dramatically over the last few years thanks to technological advances in diagnostic criteria specificity that once used to rely almost exclusively on rather empirical and vague clinical parameters [9,10]. As a result, it has been possible to define a more accurate nosologic picture of ATH which has allowed for a more targeted therapeutic strategy essentially based on the use of several therapeutic aids (topical antibiotics and corticosteroids to clear nasal passages and/or systemic corticosteroids, etc.) [11–19]. In this connection, in the past few years several investigators have studied the beneficial effects of salt (halotherapy from the Greek word for salt, *halos*) on a number of respiratory system conditions (rhinosinusitis, allergic rhinitis, otitis, bronchitis, and asthma) [20–23] as well as on some dermatological pathologies (atopic dermatitis and psoriasis) [24–26]. Halotherapy is based on a non pharmacological approach as it relies on the release of micronized medical sodium chloride into an indoor climate-controlled environment. The release is meant to recreate the conditions occurring in nature in salt mines and caves. Occasionally a small amount of micronized iodine is added to mimic the experience of being on a real naturally occurring seashore. Salt therapy has been practised in old salt mines of Central and Eastern Europe for centuries where it is still common being considered a full-fledged medical treatment.

The aim of the present study was to assess the efficacy of Aerosal[®] in the treatment of sub-obstructive adenotonsillar hypertrophy and correlated disease versus placebo treatment.

2. Materials and methods

2.1. Patients

Patients were recruited from the Department of Otolaryngology (ENT) of Bari University General Hospital after approval had been obtained by the institutional ethics committee. Inclusion criteria were as follows: age range: 4–12 years; genders: both; pathology: sub-obstructive adenoid hypertrophy lasting from at least six months and associated with sleep-disordered breathing (respiratory pauses or sleep apnea) and/or recurrent serous otitis media; suspension for over 3 months from the start of the study of any immunosuppressive treatments (cyclosporin and systemic steroids). Exclusion criteria: patients with acute bronchopulmonary disease, tuberculosis, severe hypertension, hyperthyroidism, cancer (chemotherapy), intoxication, heart failure, bronchial asthma or iodine allergy. Patients were still allowed to use topical therapy with nasal washings and topical steroids.

2.2. Technical specifications of salt room “Aerosal[®]”

2.2.1. Salt room

Both walls and ceiling of the multilayer sea wood salt room (2.30 mt. × 2.90 mt. × 2.20 mt.) are completely covered with ESCO (European Salt Company) type certified-origin iodized rock salt. The floor, which is also made of multilayer sea wood, is covered with about 500 kg of RESIMAX type certified-origin rock salt (Figs. 1 and 2).

The room environment is not contaminated with pathogenic microorganisms (as certified by SAS 90[®] measurements). Patients can settle into comfortable chairs inside the room where the dry salt aerosol is blown through a PVC pipe (described below). A centrifugal extractor fan (air flow rate 90 m³/h), placed on the side opposite to the PVC pipe ensures a number of complete changes of air in full compliance with requirements in terms of CO₂ ppm values, i.e. <750 ppm. Also temperature and humidity are kept at constant values ranging between 20 °C and 24 °C and 44% and 60%, respectively (TESTO 435-4[®] Digital Multimetric measurements).



Fig. 1. “Salt Clinic”. 3D design: reception/welcome area (a); waiting room with children's recreation area (b); “Aerosal[®]” halotherapy room (c). ENT Care Unit (d). Cabinet containing the Dry Salt Aerosol Generator – University General Hospital – Bari (Italy).

2.2.2. Dry salt aerosol generator

The dry salt aerosol generator is encased in a cabinet placed outside of, albeit contiguous to, the salt room (Fig. 1d). A standard amount of NaCl (salt sachet) is fed into the dry salt aerosol generator to be blown into the salt room in the form of aerosol through a PVC (polyvinyl chloride) connector. The size of NaCl, micronized particles ranges from 0.23 to 20 μm (data collected by portable laser aerosol spectrometer Model 1.109 with GRIMM[®] technology). Particle density ranges from 20 to 35 μg/m³ and is kept constant over time thanks to an electronic system.

2.2.3. Salt sachet: salt features

The salt sachet contains 30 g of NaCl, 20 g of micronized RG (Reagent Grade) salt (according to Ph Eur Current Edition), and 10 g of non micronized ESCO iodized feed salt to prevent aggregation and keep an appropriate level of iodine exposure.

2.3. Clinical and instrumental evaluation

After collection of medical history, all the patients underwent clinical and instrumental exams as follows: ENT visit with inspection of the oropharyngeal tract and tonsillar hypertrophy staging (0°–4°) [27], flexible fibroscope nasal endoscopy (ENT 2000



Fig. 2. “Aerosal[®]” Halotherapy Salt Room where children are always highly compliant as they consider treatment sessions as opportunities for play and recreation. ENT Care Unit–University General Hospital – Bari (Italy).

flexible Ø 3.4 mm fibroscope – Vision Sciences[®], USA) to assess the degree of adenoidal hypertrophy [10]. Pure tone audiometry was performed in a sound-proofed cabin using pure tones (250 ms duration, 25 ms rise/fall time, 50% duty cycle) at octave frequencies from 125 Hz to 8000 Hz with a maximum intensity of 120 dB SPL with an Amplaid 309 clinical audiometer (Amplaid, Milan, Italy). Tympanometric measurements were performed using a 220 Hz probe tone with an Amplaid 770 clinical tympanometer (Amplaid, Milan, Italy). Air conduction pure tone average was obtained by the mean of thresholds at 0.5, 1, 2 and 4 kHz. Tympanograms were classified according to Jerger in types A, B and C [28]. Nasal cytology was performed by anterior rhinoscopy, using a nasal speculum and good lighting. Scrapings of the nasal mucosa were collected from the middle portion of the inferior turbinate, using a Rhino-Probe[®] [29]. Samples were placed on a glass slide, fixed by air drying and then stained with the May-Grunwald Giemsa (MGG) method (Carlo Erba[®], Milan, Italy) [30]. Cell counts, bacterial and fungal analysis were carried out by a semi-quantitative grading, as proposed by Meltzer and Jalowayski [31]. The semiquantitative evaluation of the biofilms [32] was performed by counting the number of infectious spots (ISs) in 50 microscopic fields, always at a 1000× magnification (oil immersion). Sleep evaluation was carried out overnight by means of wrist-worn pulse oximeters Wrist Ox₂[™] Model 3150. The parameters studied were: basal SpO₂%; event data index (adjusted index, 1 h⁻¹) and time (%) with SpO₂ value below 95%. It was decided to use pulse oximetry [33] instead of “gold standard” polysomnography [34] to study patients’ sleep patterns as the former makes overnight studies easier for patients at home (the protocol envisaged three such studies in three months, two of them with only a 15-day interval). In addition, important guidelines [35,36] do indicate pulse oximetry as a method with a high positive predictive value of OSASs (97%) [37].

2.4. Study design

After having given their written informed consent all the eligible patients were randomized on a 3:2 basis to receive either Aerosal[®] or placebo. Central stratified blocked randomization using telephone was adopted with patients, investigators and outcomes assessor being all blinded to randomization rules. Aerosal[®] treatment consisted of 10 daily sessions (5 sessions for week) of micronized iodized salt (sodium chloride) – with the addition of iodine – inhalation in a chamber reproducing the microclimate of a natural salt cave. Each daily session lasted 30 min. Treatment with placebo comparator was performed in the same way as halotherapy but with no salt release in the room. All patients underwent a complete clinical evaluation at baseline, at the end of therapy period (10 sessions) and 3 months after the end of treatment (follow-up).

2.5. Outcome measures

The primary outcome measure, evaluated both after 10 sessions of therapy and at the 3-month follow-up, was an adenoid and/or tonsillar hypertrophy reduction $\geq 25\%$ from baseline as assessed by the physician on a standardized four-point rating scale. Secondary outcome measures included instrumental assessments: any reductions in terms of adenoid and/or tonsillar hypertrophy degree; any reductions of hearing loss ≥ 10 dB of the 4-frequency (0.5, 1, 2 and 4 kHz) pure tone average, as well as any other significant gain; any improvements in of tympanometric values, i.e. transition from type B curve to type C/A curve or from type C curve to type A curve for both sides; any change in tympanogram peak pressure (daPa); any changes in pulse-oximetric values (increase in SpO₂% mean levels, reduction of the event data index

(adjusted index, 1 h⁻¹), reduction of sleep time percentage with SpO₂ levels <95%; any reductions of the main inflammatory immune cells (neutrophils, eosinophils, and mast cells) as assessed by nasal cytology. The number of side effects reported either during treatment period or after the end of treatment, if suspected to be related with this latter, was also included in secondary outcome measures.

2.6. Statistical analysis

Data were presented as medians with ranges and/or inter-quartile ranges (IQRs), or numbers with percentages. Baseline variables and changes in outcomes were compared between groups by using the Mann–Whitney *U* test for continuous data and Fisher’s exact test for categorical ones. Overall time-dependent variations in primary and secondary outcomes were evaluated by Friedman’s test for repeated measures with Page’s test for trend in time variations. An intention-to-treat approach was adopted in primary analyses. This approach considered patients withdrawn prematurely from the study as treatment failures in the two study arms. Intention-to-treat analysis was then complemented by per-protocol analyses which considered only those patients who had completed the study period. In the study design phase it had been calculated that a total of 64 patients would be needed for the study to have a 40% success rate in terms of primary outcome in the halotherapy group as against 10% in the placebo group ($\alpha = 0.05$, $\beta = 0.20$). Statistical analysis was carried out by using MATLAB software (MathWorks, Natick, MA, USA). Two-sided *P*-values <0.05 were considered to indicate statistical significance in all tests.

3. Results

Between February 2012 and March 2012, 49 patients were screened, 45 of whom (24 boys and 21 girls, average age 6 years) underwent randomization. The reason for exclusion was age outside the study inclusion criteria age range ($n = 4$). Recruitment halted prematurely due to technical and legal issues related to the certification of the device. The baseline characteristics of randomized patients in the two arms of the study are given in Table 1. One patient, randomized to the placebo group, withdrew after the first week of treatment for an episode of acute tonsillitis requiring antibiotic treatment, and one patient, randomized to the Aerosal[®] arm, withdrew during the follow-up period for exacerbation of upper airways symptoms. Both arms were matched in baseline characteristics (data not shown).

3.1. Effectiveness

Fig. 3 shows the distribution of variations of measurements from baseline in both arms after 10 treatment sessions in terms of (i) reduction of the degree of adenoid and/or tonsillar hypertrophy; (ii) reduction of hearing loss and (iii) tympanometry improvement. All outcome measures and their departure from baseline at the end of treatment sessions and at the 3-month follow up are reported in Table 2. Assuming intention-to-treat analysis as a reference, a reduction of the degree of adenoid and/or tonsillar hypertrophy $\geq 25\%$ from baseline after 10 therapy sessions was found in 44.4% of the patients in the halotherapy arm and in 22.2% of the patients in the placebo arm ($P = 0.204$). These results increased to 59.3% and 38.9%, respectively at the 3-month follow up ($P = 0.231$). Other substantial changes in adenoid or tonsillar hypertrophy were not found to have a statistical significance at any other point in time.

Among secondary outcomes hearing loss reduction was found to be significant ($P = 0.018$) after 10 treatment sessions in the halotherapy arm compared to the placebo arm, even though the

Table 1
Baseline characteristics of randomized patients.

	Aerosal (N=27)			Placebo (N=18)		
	N (%)	Median (IQR)	Range	N (%)	Median (IQR)	Range
Gender (male/female)	14 (51.9)			10 (55.6)		
Age		6 (4)	4–12		4.5 (2)	4–10
Weight (kg)		25 (13.5)	15–56		20 (5.5)	14–41
Height (cm)		120 (24.2)	97–160		110 (10)	95–131
BMI (kg/m ²)		17.4 (2.3)	14.3–25.5		16.9 (3.5)	11.6–23.9
ATH age at onset (years)		3 (2.5)	0–7		2 (1)	1–6
ATH duration (years)		3 (5.2)	1–9		2 (1)	1–5
ATH familiarity	13 (48.2)			6 (33.3)		
Previous topical treatments	19 (70.4)			13 (72.2)		
Previous systemic treatments	21 (77.8)			10 (55.6)		
Previous ENT pathologies	22 (81.5)			14 (77.8)		
Current topical treatments	5 (18.5)			4 (22.2)		
Adenoid hypertrophy degree		3 (0)	3–4		3 (0)	2–4
Tonsillar hypertrophy degree		3 (0.8)	1–4		3 (1)	1–4
Nasal cytology						
Neutrophils (any)	17 (63.0)			11 (61.1)		
Eosinophils (any)	9 (33.3)			2 (11.1)		
Mast cells (any)	3 (11.1)			1 (5.6)		
Audiometry (dB) ^a		17.5 (19.4)	10–40		15 (25)	10–45
Tympanometry (right)						
Type A curve	10 (37.0)			4 (22.2)		
Type B curve	12 (44.4)			7 (38.9)		
Type C curve	5 (18.5)			7 (38.9)		
Tympanometry (left)						
Type A curve	6 (22.2)			5 (27.8)		
Type B curve	18 (66.7)			8 (44.4)		
Type C curve	3 (11.1)			5 (27.8)		
Tympanometric peak, right (daPa)		−168 (126)	0–302		−214 (123.8)	0–296
Tympanometric peak, left (daPa)		−223.5 (124)	0–304		−240 (133.5)	28–300
Pulse-oximetry indexes						
Mean SpO ₂ % levels		96 (1.6)	91.4–97.6		96.1 (2.2)	89.3–97.5
Apnea events (1 h ^{−1})		1.2 (4.1)	0–24.5		1 (1.4)	0–9
Sleep time % with SpO ₂ <95%		11.4 (25.7)	0.1–95.9		8.5 (41.5)	0–87.6

ATH, adenotonsillar hypertrophy; ENT, otolaryngology; IQR, interquartile range; range = Min – Max. There were no significant differences in baseline characteristics between the two arms of the study.

^a Average audiometry (left/right) evaluated at the frequencies of the tone range (0.5, 1, 2, 4 kHz).

difference between the two arms was not statistically significant at follow up ($P = 0.107$). The overall time-dependent analysis of variations showed a significant difference between the two arms for hearing loss reduction with a significant decreasing trend

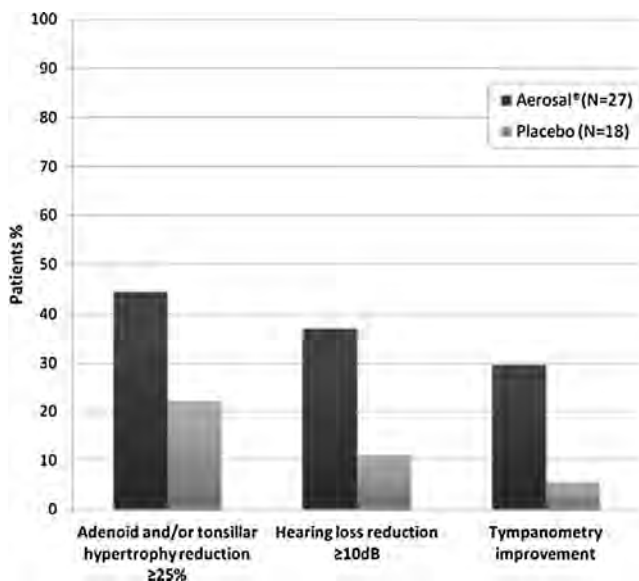


Fig. 3. Distribution of study arms after 10 treatment sessions from baseline according to reduction of adenoid and/or tonsillar hypertrophy degree, hearing loss reduction and tympanometry improvement.

($P = 0.010$) in the treatment arm, while no significant trend was observed in the placebo arm ($P = 0.165$).

The analysis of the tympanograms showed that after 10 treatments tympanogram type improved in 29.6% of the patients in the Aerosal[®] arm compared to 5.6% of patients in the placebo arm ($P = 0.064$). No difference was however observed between the two arms at the 3-month follow up. Also in this case the time-dependent analysis showed significantly improved tympanogram in the Aerosal[®] group compared to the placebo group on both sides ($P = 0.002$). A significant trend was observed for both sides in the treatment arm ($P = 0.005$ for the right side and $P < 0.001$ for the left side), while in the placebo arm a significant improvement was observed only on the left side ($P = 0.015$). The analysis of the peak compliance showed that even if at T_1 and T_2 there were no significant differences between the two groups in terms of peak changes, the time-dependent analysis showed significantly improved peak pressure in the Aerosal[®] group compared to the placebo group on both sides ($P = 0.038$).

The other secondary outcomes did not exhibit major differences between the two arms.

In more detail, as far as nasal cytology is concerned, 37.0% of patients in the Aerosal[®] arm and 22.2% of patients in the placebo group exhibited a reduction $\geq 50\%$ of the principal inflammatory immune cells after 10 treatment sessions ($P = 0.343$). These proportions were found to be 37.0% and 33.3%, respectively at follow up evaluation ($P = 1$).

Regarding pulse oximetry values, baseline SpO₂ did not show any statistically significant variation after 10 sessions ($P = 0.880$), as was the case for the other two parameters under study, i.e.

Table 2
Intention-to-treat analysis of primary and secondary outcomes at T₁ (10 sessions of therapy) and T₂ (3 months from the end of treatment) compared to baseline.

	Aerosol (N=27)		Placebo (N=18)		P-value ^a
	N (%)	Median (IQR)	N (%)	Median (IQR)	
T₁					
Reduction of adenoid hypertrophy degree (%)		0 (25)		0 (0)	0.734
Reduction ≥25%	8 (29.6)		3 (16.7)		0.482
Reduction of tonsillar hypertrophy degree (%)		0 (31.2)		0 (0)	0.197
Reduction ≥25%	9 (33.3)		3 (16.7)		0.308
Reduction of adenoid and/or tonsillar hypertrophy degree ≥25%	12 (44.4)		4 (22.2)		0.204
Hearing loss reduction ^b (dB)		5 (13.8)		0 (10)	0.018
Reduction ≥10 dB	10 (37.0)		2 (11.1)		0.086
Tympanometry improvement ^c	8 (29.6)		1 (5.6)		0.064
Tympanometric peak pressure change (daPa)		−21.5 (79.5)		−1 (74)	0.141
Nasal cytology reduction ^d ≥50%	10 (37.0)		4 (22.2)		0.343
Increase of mean SpO ₂ % levels		−0.1 (1.9)		0.1 (2.8)	0.880
Reduction of apnea events (1 h ^{−1})		−0.5 (4.9)		0 (1.4)	0.372
Reduction of sleep time % with SpO ₂ <95%		3.6 (14.6)		−2.5 (57.4)	0.424
T₂					
Reduction of adenoid hypertrophy degree (%)		0 (18.8)		0 (25)	0.967
Reduction ≥25%	7 (25.9)		6 (33.3)		0.739
Reduction of tonsillar hypertrophy degree (%)		0 (31.2)		0 (0)	0.070
Reduction ≥25%	11 (40.7)		3 (16.7)		0.111
Reduction of adenoid and/or tonsillar hypertrophy degree ≥25%	16 (59.3)		7 (38.9)		0.231
Hearing loss reduction ^b (dB)		2.5 (14.4)		0 (10)	0.107
Reduction ≥10 dB	10 (37.0)		4 (22.2)		0.343
Tympanometry improvement ^c	9 (33.3)		3 (16.7)		0.308
Tympanometric peak pressure change (daPa)		−60.5 (104.4)		−44 (78.5)	0.509
Nasal cytology reduction ^d ≥50%	10 (37.0)		6 (33.3)		1
Increase of mean SpO ₂ % levels		0.2 (2.2)		0.2 (2)	0.772
Reduction of apnea events (1 h ^{−1})		0.2 (2.8)		−0.9 (2.1)	0.102
Reduction of sleep time % with SpO ₂ <95%		0.4 (28.5)		0.3 (22.2)	0.917

IQR, interquartile range.

^a Mann–Whitney *U*-test for continuous variables, Fisher's exact test for categorical variables.^b Reduction of average audiometry (left/right) evaluated at the frequencies of the tone range (0.5, 1, 2, 4 kHz).^c Improvement was defined as defined as the passage from type B curve to type C/A curve or from type C curve to type A curve for both ears sides.^d Any reduction of principal inflammatory immune cells (neutrophils, eosinophils, and mast cells).

reduction of the event data index ($P=0.372$), and reduction of sleep time with SpO₂ <95% ($P=0.424$). Pulse oximetry values remained mostly unchanged at follow up.

The results of the per-protocol analysis did confirm the main findings and were generally overlapping intention-to-treat outcomes (data not shown).

4. Discussion

The growing prevalence of conditions (both allergic and infectious) affecting the upper airways has stimulated a whole series of studies on topical treatments in a view to reducing the side effects of systemic treatments and improving clinical response in terms of improvement of nasal symptoms [38–40].

The latest guidelines issued by EPOS 2012 [41] on obstructive and infectious nasal sinus disease include among therapeutic aids (antibiotics, topical steroids, and topical decongestants) also nasal saline irrigation, thus emphasizing the crucial role of this treatment in reducing nasal congestion and mucopurulent discharge by a washing process that restores mucociliary clearance and prevents both locoregional (otitis, rhinosinusitis) and distant inflammation (rhinobronchial syndrome, bronchitis, pneumonia, asthma, etc.) [42–44].

In addition, in the last few years some literature studies [20–26] have reported a new therapeutic-preventive role for sodium chloride in what has come to be called “halotherapy” and in the applications of this latter in the different branches of medicine, in particular respiratory and dermatological disease. As a matter of fact, for hundreds of years salt has been recognized as an agent to treat respiratory and skin conditions. The history of using salt caves for healing (speleotherapy from Greek *speleos* = cave and therapy)

different ailments by assimilating dust-like salt particles goes back to ancient times. These caves used for therapeutic purposes are still in use in many Central and Eastern European countries including Austria (Solzbad-Salzetnan), Romania (Siedged), Poland (Wieliczka, one of the UNESCO World Heritage Sites), Azerbaijan (Nakhichevan), Kirgizia (Chon-Tous), Russia (Berezniki-Pern), and Ukraine (Solotvino-Carpathians e Artiomovsk-Donietsk).

The possibility of recreating the microclimate (Table 3) of these caves in a room has given a new impulse to studies and research efforts on the potential therapeutic effects of this treatment.

As far as the present study is concerned, the first finding has been the absence of adverse effects. None of the children enrolled in the study exhibited episodes of respiratory distress (dyspnea, bronchial hyperactivity, asthma), skin itch or eyes disorders, both during treatment and in the hours immediately after treatment. In addition, a high compliance to treatment has been observed as children did not consider their HT sessions as a therapy, but rather as a time for play or recreation as they spent their 30-min sessions playing, watching TV (cartoons, wildlife shows, etc.) (Fig. 2). Only two children withdrew from the study; one of them (in the placebo arm) withdrew during the first week of halotherapy for an episode

Table 3
Salt room microclimate features.

Size of iodized NaCl particles released	0.23–20 μm
Particles density	35–50 μg/m ³
Air exchange	90 m ³ /h
CO ₂ ppm	<750
Temperature	20–24 °C
Humidity	44–60%

of acute tonsillitis with high fever, the other dropped out in the follow-up period for increased adenotonsillar hypertrophy associated with sleep respiratory disorders with an indication for adenotonsillectomy. Being specific to the natural course of the conditions in question, these episodes have not been considered as adverse events connected to the halotherapeutic treatment.

However the most interesting aspects emerging from the present study have been those related to the assessment of the real impact of halotherapy on both the lymphatic component (adenotonsillar component) and co-morbidities, namely ear conditions and sleep disorders. Actually, the numerous studies conducted so far on halotherapy have mainly been focused on lower airways conditions (cystic fibrosis, bronchitis, and asthma [21–23]).

Our study has highlighted a $\geq 25\%$ reduction of the adenotonsillar tissue in 44.4% of the patients treated versus 22.2% of the placebo controls. In our view, far from being statistically significant ($P = 0.204$), this finding has a clinical value that deserves further study. This pattern has also been confirmed by the pulse-oximetric data that, far from being statistically significant, have shown a decreased event data index (adjusted index) as well as a reduction of the sleep time percentage with $SpO_2 < 95\%$. Based on our results it is possible to calculate that approximately 140 patients (70 in each arm) would be needed to show a significant reduction of the adenotonsillar tissue as expressed in the primary outcome. It is therefore unlikely that the loss of power due to the reduced number of patients enrolled in the study (45) compared to the planned number (64) had a significant impact on our findings. The reduction of some clinical and endoscopic parameters also in the control group should however be justified by the fact that the very young patients actually spent their time in a “salted” environment where their same manipulation of salt released microparticles of sodium chloride available for inhalation.

Among secondary end-points, end-of-treatment improvement of hearing loss has been found to be statistically significant in the halotherapy group ($P = 0.018$) compared to the control group. The statistical analysis has demonstrated a significant improvement of both tympanogram and hearing loss in the Aerosal[®] group.

The treatment of otitis media with effusion (OME) is still controversial today. While this condition has a high likelihood of a spontaneous recovery [45], so far no medical therapy has been shown to be effective to treat OME, as indicated by recent reviews [46–49]. The presence of a control group in our study does rule out the possibility that the improvements observed are linked only to a spontaneous recovery from the disease. Even though the effectiveness of sodium chloride in OME treatment has never been reported in literature studies, the potential mechanisms of action could be ascribed to decongestion of nasal passages and tubaric orifice respiratory mucosa as well as to a restored mucociliary clearance that would favor middle ear aeration-draining mechanisms. This assumption is substantiated by literature studies that report the efficacy of those treatments targeted to improve middle ear ventilation. Perera et al. reported some evidence that autoinflation devices may be of benefit in the short-term in treating children with otitis media with effusion [50]. Similar results were reported in a group of children affected by OME treated with swallowing and auto-inflation exercises, including Valsalva maneuver [51]. Finally even if the improvement of hearing threshold was on average of only 5 dB, it is important to remember that the pre-treatment threshold was on average between 15 and 17.5 dB, therefore a 5 dB change together with a change in tympanogram is clinically relevant. A longer treatment could however further improve the hearing thresholds.

No statistically significant difference has been found in terms of sleep quality and nasal immunophlogosis parameters. Recent work on bronchial immunophlogosis confirms these findings [52].

5. Conclusions

Halotherapy accounts for a relatively new, completely natural therapeutic remedy which does not call for any pharmacological administration and is based on the healing capacities of natural salt micronized and released into an indoor environment by means of specific techniques. Halotherapy administered by Aerosal[®] system has been shown to have a statistically significant effect on OME. Aerosal[®] halotherapy has also been found to be partially effective in reducing adenotonsillar hypertrophy. The beneficial effects of the treatment in question have been shown for some “time-dependent” parameters, therefore additional studies should be conducted in a view to defining treatment modalities likely to result in a better clinical response. New double-blind, placebo-controlled, randomized clinical studies should also be performed on more complex conditions including asthma, cystic fibrosis, chronic pulmonary disease and dermatological conditions.

In addition to being a safe treatment, the Aerosal[®] Halotherapy system has been well accepted and tolerated by our young patients who experienced their halotherapeutic sessions as a time for play and recreation and not as a real medical treatment. Therefore Aerosal[®] Halotherapy might constitute a valuable adjunct (and not a replacement) to current orthodox medical treatment of adenotonsillar disease and correlated conditions.

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Conflict of interest

None declared.

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Halotherapy and Buteyko Breathing Technique – a possible successful combination in relieving respiratory symptoms

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ABSTRACT

Speleotherapy and halotherapy are relatively old therapeutic methods sometimes recommended for chronic obstructive disorders. As part of rehabilitation programs, the need to introduce a natural approach on patient already receiving classical therapy seems to improve their clinical status as well as their quality of life. Buteyko breathing technique has known benefits in pulmonary rehabilitation and it is used to improve respiration and control chronic respiratory symptoms as part of respiratory exercising. In this short study we assessed the improvement of the control pause – a parameter used in Buteyko breathing exercising on patients receiving halotherapy for a day. The results showed a small improvement in their control pause, meaning that halotherapy, combined with Buteyko breathing technique may be a solution to enhance the respiratory status of chronic respiratory patients.

KEYWORDS : halotherapy, Buteyko, control pause, chronic respiratory patients.

Introduction

Halotherapy is a well-known natural therapy using NaCl aerosols for the relief of respiratory symptoms. Although the method has been known for centuries, the actual scientifically proof of the NaCl aerosols has been first documented by Felicz Bockowski in 19th century by observing the health of miners working in the salt mines (1).

NaCl aerosols resulted from natural sources are poly-dispersed systems with special nano-structural properties that have a different distribution and concentration within the environment - resulting a different environmental activity depending on temperature, humidity and probably the most important factor – the source (2). Many authors have theories about the efficiency of NaCl sources on respiratory symptoms relief, some claiming that natural saline environments – such as salt caves and natural formed halo-chambers are more efficient, others considering that a controlled saline environment – such as aerosoling devices are more efficient. Considering the difficulty of conducting a clinical study in a natural halo-chamber and multiple biases that can occur, it is pertinent to affirm that the conclusions of the scientific data collected from studies, conducted with artificial saline sources, provide enough evidence that a controlled NaCl aerosols emitting device is at least as efficient as any natural halo-chamber, and also safer and more accessible.

All areas are kept moist by airway mucus production - produced by mucous cells in the airway epithelial layer and submucosal glands in partially. This secretion (3) captures and encompasses particles in the air we breathe, preventing reaching and deposited in the airways and alveoli.

Buteyko technique is known to be responsible for reducing by 90% the use of rescue medication in asthma and up to 30% of background medication (4). Dr. Buteyko brought together as "diseases of civilization" diseases such as: allergies, asthma, COPD, fibrosis (asbestoses, silicosis, anthracnose, etc).

The common cause of these diseases is, after Dr. K. Buteyko, alveolar hyperventilation or breath deeply unjustified. In the 80s, he proposed to study a simple, respiratory dimming or "normalization" respiratory rate as physical exercise in patients with pulmonary pathology.

Based on the theory that there is a certain tolerability of CO₂ produced as a resultant of human body metabolism he defines normal respiration as a balanced equilibrium between the

production and the disposal of CO₂. Thus, he states that breathing more results in insufficient elimination of CO₂ and therefore disruption of metabolism.

Materials and Methods

The known mechanism of halotherapy are: boosting local immunity in the respiratory system (by phagosomal acidification), bacteriostatic effect of the Chloride ion, increased mucociliary clearance (by osmotic mechanisms and thinning of the secretions), anti-inflammatory effect and local hypo-sensitization.

The film of mucus is constantly renewed due to the kinetics of ciliary epithelium - performing cilia movement of "sweeping" with a frequency of 10-20 times / second by moving to the throat mucus layer at a rate of about 1cm / minute. This mucus containing particulate matter captured (which can be bacterial inclusions) is subsequently removed by coughing or swallowed. This mechanism is added nasal turbulence due to its efficiency particle diameter no larger than 5 microns can penetrate the lungs (3).

In the light of this theory, the Buteyko technique uses a new parameter – named, "the control pause" – a method of measuring the rough tolerance of CO₂. The control pause basically means the amount of seconds that a subject can hold his breath after a full expiration, Buteyko linking this capability proportional to the CO₂ metabolism and respiratory disorders by stating that a lower control pause is associated to a lower control of the respiratory disorder (5).

Considering these two alternative medicine methods used in relieving respiratory symptoms, we proposed a trial in order to determine if using halotherapy for 20 minutes a day modifies the control pause of clinical healthy subjects, thus raising the probability of improving the CO₂ metabolism.

We selected 33 subjects, 22 males (all smokers) and 11 female (non smokers), about the same age, and we assessed the initial control pauses before halotherapy (Table 1).

For these subjects we assessed the peripheral oxygen saturation (SaO₂) and calculated a mean for each gender group (M – male group, F – female group), the mean cardiac frequency (bpm – beats per minute) and mean control pauses.

After using a clinical tested Dry Salt Inhaler for 20 minutes (nasal breathing through the inhaler), we assessed the control pauses of the subjects again.

Gender	Mean Age	Smoking status	Initial Pulsoxymetry		Initial Control Pause	After HT Pulsoxymetry		After HT Control Pause
			Mean SaO2	Mean Cardiac Frequency	Mean Values	Mean SaO2	Mean Cardiac Frequency	
M	35	yes	97%	92	22,82"	97%	89	27,55"
F	32	no	97%	72	28,44"	99%	71	32,53"

Table 1. The data collected from the subjects before and after using halotherapy (HT). SaO₂ – peripheral saturation in oxygen measured by pulsoxymetry.

Results

The results centralized in Table 1 showed a significant improvement of the control pauses of all three subjects but the most important aspect, it seems that the smokers had a better control pause after using halotherapy than the non-smoker.

The average improvement of the control pause was by 20% - 4,73 seconds in the male group showing significant improvements of the smokers, comparable with the non-smoker – female group 4,09 seconds – 14%.

We observed also a decrease in mean cardiac frequency – male group scored a mean CF of 89 bpm and female group had a mean CF of 71 bpm.

Conclusions

Although the tests were ran on a very small group, the results are promising and open the way to a more complex and extended clinical trial to be conducted on healthy subjects as well as on patients with obstructive respiratory disorders.

Halotherapy seems to improve the control pauses of healthy subjects after a 20 minutes cure, accented in smokers, but implications on CO₂ metabolism and further long-term benefits on respiratory function needs a more extensive clinical study with the assessments of CO₂ arterial levels in dynamics.

Discussions:

In a 1993 publication, Dityatkovskaya et al., Cited in the publication "Respiratory Diseases for Halotherapy" (6), researchers observed a significant decrease in IgE effect and improved humoral and immune status of patients bronchial cells with asthma who were doing and meetings halotherapy inside mines. Notable observation is the same researchers confirmed an increase in mucociliary clearance and an increase ciliary movements in the same patients.

Another important aspect of halotherapy is the ability to reduce the chance of respiratory infections by default bactericidal effect of Cl⁻ ion and by activating phagocytosis. This is an important benefit for patients with COPD exacerbations infectious as life threatening danger. As more and more studies are trying to elucidate and demonstrate the exact action mechanism of saline aerosols on the human respiratory system, the halotherapy gets the attention of more and more doctors and patients (3).

Another important technique used in relieving respiratory symptoms is the method attributed to the Ukrainian researcher and doctor Konstantin Buteyko. The Buteyko method or Buteyko Breathing Technique is a form of physical therapy, first formulated in 1950 by dr. Buteyko, that proposes the use of breathing exercises as a complementary treatment for asthma symptoms as well as other conditions (7). Although downgraded from evidence A to evidence B in GINA 2015, the asthma management guide still lists the breathing exercises as important tools of helping the patients achieve normal functioning.

The technique uses the principle that hyperventilation and subsequent or coexisting hyperinflation during an asthma attack is an endless feedback loop that eventually leads to increased CO₂ metabolism disturbance.

In 2006, Russian Breathing Center stated that the procedure is the most effective non-pharmacological management of asthma and respiratory pathology generally practiced so pulmonologists, pediatricians and free – professionals. It consists of a series of lectures and exercises that revolutionizes the concept of "Respiratory Physical Education"

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ХАЛОТЕРАПИЯТА – АЛТЕРНАТИВА ЗА ПАЦИЕНТИТЕ С БЕЛОДРОБНИ ЗАБОЛЯВАНИЯ

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РЕЗЮМЕ

Халотерапията е алтернативен метод за лечение на множество респираторни заболявания. През последните десетилетия се радва на доверието на все повече хора в целия свят. Натриевият хлорид има доказано **антибактериално, антимикотично и противовъзпалително** действие и е абсолютно необходим за нормалното функциониране на бронхиалния ресничест епител. Статията разкрива благоприятните ефекти на солта върху дихателната система, показанията и противопоказанията за провеждане на това лечение, както и възможностите за комбиниране с други средства на физикалната терапия.

Ключови думи: халотерапия, белодробни заболявания, инхалации с натриев хлорид

Солта е използвана заради оздравителните си качества и терапевтичните си ефекти от хилядолетия в различни географски региони и различни култури. В наши дни употребата на солта, известна като **халотерапия** е проучвана в множество научни изследвания, обхващащи периода от 1800 година до наши дни, от учени в цяла Европа и Далечния Изток. През последните десетилетия са публикувани множество проучвания, които доказват ефективността на халотерапията и приложението ѝ при различни заболявания. Солта като средство за лечение е документирана за първи път през 1843 година, от полския терапевт **Феликс Бочковски**. Той забелязал, че хората, работещи в солните мини в Полша, се радват на отлично здраве, въпреки тежките условия на работа и недоимъчното хранене. Освен това, те почти никога не страдали от простуда и всякакви белодробни заболявания, които били често срещани при останалото население. Това накарало лекаря да направи проучвания, при които се установява, че това се дължи на наситения със сол въздух, който миньорите вдишват ежедневно. Така постепенно солните мини в Полша и Източна Европа стават популярни санаториуми, привличайки посетители от целия свят.

HALOTHERAPY – AN ALTERNATIVE METHOD FOR THE TREATMENT OF RESPIRATORY DISEASES

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ABSTRACT

Halotherapy is an alternative method of treating respiratory diseases. This kind of treatment has become more and more popular in last decades. Sodium chloride has a proven antibacterial, antimycotic and anti-inflammatory effect and is of great importance for the normal function of the bronchial ciliated epithelium. This article reveals the benefits of salt in regard to the respiratory system, indications and contraindications for this kind of treatment and the possibilities for combining it with some other physical therapy methods.

Keywords: halotherapy, respiratory diseases, salt inhalations

Salt has been used for millennia in different parts of the world by different cultures because of its health benefits and therapeutic effect. Nowadays, the use of salt, known as **halotherapy**, has been the subject of numerous scientific studies conducted by scientists from Europe and the Far East, encompassing the period from 1800 up to present times. Many studies have been published in the last few decades. They present the efficiency of halotherapy and its application in various diseases. Salt as a means of treatment was first described in 1843 by the Polish therapist **Feliks Boczkowski**. He noticed that people working in the salt mines in Poland enjoyed excellent health despite the harsh working conditions and the lack of sufficient food. In addition to this, they almost never suffered from colds or any respiratory diseases, which were frequently observed among the rest of the population. This prompted the physician to conduct research by which he established that all this was due to the saturated with salt air that the miners breathed daily. Thus, salt mines in Poland and Eastern Europe gradually became popular sanatoriums, attracting visitors from all over the world.

In the last decades halotherapy has gained the trust of more and more people around the world and has been spreading quickly to Western Europe, Canada, Israel,

През последните десетилетия халотерапията се радва на доверието на все повече хора в целия свят и се разпространява бързо в Западна Европа, Канада, Израел, Северна Америка и много други страни.

Ефективността на лечението със сол се дължи главно на две причини:

- **солта има антибактериално, антимикотично и противовъзпалително действие** (установено е, че средата в солните стаи е 3 пъти по-стерилна дори и от най-чистата хирургическа зала).
- солта има естествената способност да излъчва отрицателни йони, с което се неутрализира положителният заряд.

Доказано е, че това е един високо ефективен метод за благоприятно повлияване на редица белодробни заболявания с бързо обратно развитие на симптоматиката, подобряване на белодробната вентилация и толеранса при физическо натоварване, като също се повишават имунитета и защитните сили на организма (6).

Основен лечебен фактор е натриевият хлорид с размер 2 до 5 милимикрона на частиците в аерозола. Проучване на Червинская, включващо 124 пациента с различни белодробни заболявания, показва значително подобрение в клиничния статус при по-голямата част от тях след пребиваване в солна стая за един час в продължение на 15 – 20 дни (3). Подобни резултати представя и друго проучване, базирано на хемолуминисцентен тест, при 49 пациента с хроничен обструктивен бронхит. Халотерапията води до позитивни промени в оксидацията на свободните радикали, подобрява локалния имунитет и клиничната картина на заболяването (2,4).

Имунологични и кардиореспираторни показатели са изследвани при 88 металурзи с доказан токсичен прахов бронхит. Проведена е терапия с със синусоидално модулирани токове и ултразвук в междуребрена зона, дихателни упражнения, комбинирани с масаж и халотерапия.

Пациентите са разделени в три групи:

1. лечение с халотерапия и ултразвук
2. лечение с халотерапия и синусоидално модулирани токове
3. само халотерапия.

Проучването доказва, че комбинирането на халотерапия с методи на апаратната физиотерапия повишава ефекта от солната терапия с 86.5%. А комбинацията от електропроцедури и халотерапия може да се използва, както за лечение, така и за профилактика на обструктивния синдром при

North America, and many other countries.

The efficiency of salt therapy is mainly due to two reasons:

- **salt has an antibacterial, antimycotic and anti-inflammatory effect** (it has been established that the environment in salt rooms is three times more sterile than the cleanest operating room);
- salt has a natural ability to emit negative ions, neutralizing a positive charge.

It has been proven that this is a highly effective way of positively influencing numerous respiratory diseases with a prompt resolution of symptoms, improvement of pulmonary ventilation and tolerance of physical strain, and an increase in the immunity and protective capacity of the organism (6).

The main therapeutic factor is sodium chloride with an aerosol particle size of 2 to 5 millimicrons. A study by Chervinskaya, including 124 patients with different pulmonary diseases, showed a considerable improvement of the clinical status of the majority of the participants after a one-hour stay in a salt room daily, for a period of 15-20 days (3). Similar results were observed in another study based on a chemiluminescent test in 49 patients with chronic obstructive bronchitis. Halotherapy led to positive changes in the oxidation of free radicals and improved local immunity and the clinical presentation of the disease (2,4).

Immunological and cardiorespiratory indicators were studied in 88 metallurgists diagnosed with toxic dust bronchitis. The conducted therapy consisted of sinusoidal modulated current and ultrasound in the intercostal region, and respiratory exercises combined with massage and halotherapy.

The patients were divided into three groups:

1. halotherapy and ultrasound treatment;
2. halotherapy and sinusoidal modulated current treatment, and
3. halotherapy alone.

The study proves that combining halotherapy with the use of physiotherapy equipment increases the efficiency of salt therapy by 86.5%. The combination of electric current procedures and halotherapy can be used both for treatment and prevention of obstructive syndrome in toxic dust bronchitis (7).

Sodium chloride is vital for the normal functioning of the bronchial ciliated epithelium. The observed effects of the aerosol therapy are as follows: a relief in expectoration, decrease in sputum viscosity, cough improvement, and positive changes in the auscultatory findings. In addition, sodium chloride has a bactericidal and bacteriostatic effect on the respiratory microflora. The cytobacteriological examination of bronchial and nasopharyngeal secretions from patients with asthma,

токсичния прахов бронхит (7).

Натриевият хлорид е абсолютно необходим за нормалното функциониране на бронхиалния ресничест епител. В резултат на аерозолотерапията по време на процедурите се установява облекчение на експекторацията, намаляване на вискозитета на храчките, облекчение на кашлицата и положителни промени в аускултаторната картина. Освен това натриевият хлорид осигурява бактерициден и бактериостатичен ефект върху дихателната микрофлора. Цитобактериологично изследване на бронхиални и назофарингеални секрети на пациенти с астма, хронична обструктивна белодробна болест (ХОББ) и муковисцидоза доказва, че халотерапията води до намаляване на неутрофилните клетки и патогенните микроорганизми и увеличава алвеоларните макрофаги. Халотерапията има муколитично, антибактериално, противовъзпалително, имуномодулиращо и хипосенсибилизиращо действие (3).

Халотерапията може успешно да се комбинира с други методи на физикалната терапия. Ефективността ѝ се увеличава при комбинирането с постурален дренаж, вакуумен масаж в проекцията на белодробните върхове, дихателна гимнастика, както и лазертерапия, ултразвук или магнит, приложени в белодробната област. Синергичното действие на халотерапията и физиотерапията са крачка към холистичния подход в лечението на редица заболявания на дихателната и сърдечно-съдовата система.

Лечението се провежда в специални солни стаи, оборудвани с халогенератор, който диспергира солта в помещението. Помещенията за халотерапия са с ниска влажност на въздуха и температура в зоната на комфорта – 22-24°. При провеждането на самата процедура пациентите се настаняват в солната стая или пещера и в продължение на 45 минути дишат наситения със сол въздух, който се транспортира до най-малките бронхи, както и в синусите и носната кухина. От особена важност е ниската влажност в помещението.

Броят на сесиите зависи от състоянието на пациента и естеството на неговото заболяване. За хронични дихателни заболявания, като астма, бронхит, синусит, алергии е силно препоръчително да се извършат поне 12 до 20 сесии, по 45 минути всяка и то в колкото е възможно най-кратък период от време. Колкото по-често се провеждат, т.е. колкото по-малко е отстоянието между две процедури, толкова по-бързо настъпват резултатите и толкова по-трайни са те. Препоръчително е халотерапията да се повтаря до 3 пъти годишно, за да

chronic obstructive pulmonary disease (COPD), and cystic fibrosis shows that halotherapy leads to a decrease of neutrophils and pathogenic microorganisms, and increases the alveolar macrophages. Halotherapy has mucolytic, antibacterial, anti-inflammatory, immunomodulating and hyposensitive effect (3).

Halotherapy can successfully be combined with other physical therapy methods. Its efficiency is increased when accompanied by postural drainage, vacuum massage on the projection of the lung apices, respiratory gymnastics, as well as laser therapy, ultrasound or a magnet, applied in the pulmonary area. The synergic action of halotherapy and physiotherapy is a step towards the holistic approach in the treatment of various respiratory and cardiovascular diseases.

The treatment is conducted in special salt rooms, equipped with a halogenerator, which disperses the salt in the room. The halotherapy rooms have air with low humidity and a temperature in the comfort zone – 22-24°. When conducting the procedure, the patients are left in the salt room or cave for 45 minutes and breathe the saturated with salt air, which is transported to the smallest of the bronchi as well as to the sinuses and the nasal cavity. The low humidity in the room is of vital importance.

The number of sessions depends on the patient's condition and the nature of the disease. For chronic respiratory diseases, such as asthma, bronchitis, sinusitis, and allergy, it is highly recommended to conduct at least 12 to 20 sessions, 45 minutes each and for the shortest period of time possible. The more frequently conducted they are, i. e. the shorter the time between two procedures, the faster the results are observed and the longer-lasting they are. It is recommended to conduct halotherapy 3 times per year in order to maintain and stabilize the positive results.

Halotherapy is indicated in most **respiratory diseases**, including:

- respiratory tract infections;
- asthma;
- allergic and chronic bronchitis;
- frequent colds;
- pharyngitis;
- sinusitis;
- rhinitis;
- tonsillitis;
- pneumonia, after an acute stage;
- chronic obstructive pulmonary disease (COPD).

The main contraindications include hyperthyroidism, active tuberculosis, high-grade hypertension, cardiovascular and respiratory failure, acute-stage blood disorders, and malignant diseases. Caution should be exercised when prescribing this therapy to patients

се поддържа и затвърди положителния резултат. Халотерапията е показана при повечето **заболявания на дихателната система**, включително:

- инфекции на дихателните пътища;
- астма;
- алергичен и хроничен бронхит;
- чести настинки;
- фарингит;
- възпаления на синусите;
- ринит;
- тонзилит;
- пневмония след остър стадий;
- ХОББ.

Основните противопоказания включват хиперфункция на щитовидната жлеза, активна туберкулоза, високостепенна хипертония, сърдечно-съдова и белодробна недостатъчност, кръвни заболявания в остър стадий, злокачествени заболявания. На пациенти с клаустрофобия е желателно терапията да се изписва предпазливо.

По време на самото лечение могат да се наблюдават странични ефекти като засилена кашлица и усилено отделяне на секрети, което по-скоро се смята за положителен ефект, тъй като осигурява прочистване на дихателните пътища и сигнал за пренагласа и реакция на адаптация на организма към съответния дразнител.

Редки странични ефекти са са кожните раздразнения, които нормално отзвучават след 3-ия до 5-ия сеанс. Появата конюнктивит в резултат на раздразна на мукоидната мембрана на окоето е рядък страничен ефект. Той не е причина за прекъсване на сесиите. Препоръчва се в тези случаи престоят в солната стая да е със затворени очи (1).

ЗАКЛЮЧЕНИЕ

Халотерапията е алтернативен метод за лечение на множество респираторни заболявания. Методът е с незначителни странични ефекти. Провежда се в приятна и уютна обстановка, което въздейства благоприятно върху психоемоционалното състояние на пациентите. Положителния ефект от лечението се задържа повече от година. Възможността да се комбинира с други средства на физикалната терапия, както и с медикаментозно лечение, го прави добър метод на избор при леките и средно тежки форми на бронхиална астма, хроничен обструктивен бронхит, състояния след пневмония и редица други белодробни заболявания.

with claustrophobia.

During the treatment itself, certain side effects might be observed, such as increased coughing and more abundant secretion, which is actually considered a positive effect because it leads to respiratory tract clearing and it is a signal for a change and adaptation of the organism to the specific irritant.

Skin irritations are rare side effects and are normally resolved by the third or fifth session. Conjunctivitis as result of irritation of the mucoid membrane is rarely observed. It is not a reason to interrupt the sessions. In such cases, it is recommended to keep the eyes closed when spending time in the salt room (1).

CONCLUSION

Halotherapy is an alternative treatment method in numerous respiratory diseases. It has insignificant side effects. It is conducted in a pleasant and cosy environment, which has a beneficial effect on the psycho-emotional state of the patients. The positive results from the therapy last for more than a year. The possibility to combine it with other physical therapy methods, as well as with pharmacological therapy, makes it a treatment of choice in mild and moderate forms of bronchial asthma, chronic obstructive bronchitis, post-pneumonia states and various other respiratory diseases.

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HALOTHERAPY – BENEFITS AND RISKS

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ABSTRACT

Salt has been used for millennia in different parts of the world by different cultures because of its health benefits and therapeutic effect. Halotherapy is a dry salt therapy that is provided in environments, with special equipment called a halogenerator. In the last decades halotherapy has gained the trust of more and more people around the world and has been spreading quickly in many countries. The positive results from the therapy last for more than a year. The possibility to combine it with other physical therapy methods, as well as with pharmacological therapy, makes halotherapy a treatment of choice in mild and moderate forms of bronchial asthma, chronic obstructive bronchitis, post-pneumonia states and various other respiratory and skin diseases. The insignificant side effects, together with the conduction of this treatment in a cosy environment, have a beneficial effect on the psycho-emotional state of adult patients and children.

The aim of the article is to reveal the benefits of halotherapy as an alternative method for treating pulmonary and skin diseases and some other conditions. Technology and application method are mentioned as well as main therapeutic factors, the positive effects, contraindications for its application and some side reactions that may occur during treatment.

Keywords: *halotherapy, salt therapy, application, indications, side effects*

INTRODUCTION

Salt has been used for millennia in different parts of the world by different cultures because of its health benefits and therapeutic effect, but this was initially proved in 1843 by the Polish therapist Feliks Boczkowski. He noticed that people working in the

salt mines in Poland enjoyed excellent health despite the harsh working conditions and the lack of sufficient food. In addition to this, they almost never suffered from colds or any respiratory diseases, which were frequently observed among the rest of the population. This prompted the physician to conduct research by which he established that all this was due to the saturated with salt air that the miners breathed daily. Thus, salt mines in Poland and Eastern Europe gradually became popular sanatoriums, attracting visitors from all over the world. A new method of treatment was established – Halotherapy (salt therapy). Lately, in many places, predominantly in Eastern Europe, artificial salt rooms and caves have been established, because of uncomfortable feelings when visiting salt mines, their difficult accessibility and too high expenses for their visitation.

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In the last decades halotherapy has gained the trust of more and more people around the world and has been spreading quickly to Western Europe, Canada, Israel, North America, and many other countries. Lots of studies that prove its effectiveness and application with different diseases are published.

The aim of the article is to reveal the benefits of halotherapy as an alternative method for treating pulmonary and skin diseases and some other conditions.

Halotherapy and salt therapy – what is the difference?

Salt therapy can be dry or wet. Halotherapy is a dry salt therapy that is provided in environments, supplied with special equipment called a halogenerator. The halogenerator disperses a precise dry salt aerosol into the salt chamber. According to the Salt Therapy Association there are two types of salt rooms – active and passive. Active salt room is supplied with a special piece of equipment known as a halogenerator where pure sodium chloride is placed and dispersed into microsized particles into the air of the salt room. This kind of salt therapy is called halotherapy. Wet salt therapy includes gargling, drinking salt water, bathing in salt water or nasal irrigations (1).

On the other hand in many SPAs there are rooms filled with large amounts of varying types of salt such as Dead Sea, Himalayan, rock salt, Mediterranean, Caribbean, etc. There is no halogenerator in these chambers and they are created to look like salt caves but they do not provide the same salt air particles present in natural salt caves. They are known as passive salt rooms. The temperature, humidity and airflow are controlled but the concentration of sodium chloride is smaller than in dry salt rooms and the stay in these rooms is not considered to be halotherapy. Passive salt rooms provide an environment suitable for relaxation, meditation and improve the psycho-emotional condition of a person (1). As a result of many scientific searches it is proven that salt therapy is based on the inhalation of salt particles into the upper and lower parts of the respiratory system and penetration through the skin of microsized particles. This is possible to happen only by using halogenerators. That clarifies the difference between ac-

tive and passive salt therapy, and halotherapy and salt therapy.

Technology of halotherapy:

At the base of this technology is the Halocomplex. The Halocomplex consists of a chamber with a halogenerator, and walls and floor covered with salt. In most of the cases the walls and floors are made of sea salt, and do not provide the real treatment. The special salt covering on the walls and floor acts as a buffer for air. Dry sodium chloride is produced in this room by a special nebulizer – halogenerator, which brings a flow of clean, dry air, saturated with highly dispersed negatively charged particles of sodium chloride into the salt room. The halogenerator is supplied with microprocessor that monitors the temperature, relative humidity and mass concentration of aerosol in the chamber (2).

Application method:

When conducting the procedure, the patients are left in the salt room or cave for 45 minutes and breathe the saturated with salt air, which is transported to the smallest of the bronchi as well as to the sinuses and the nasal cavity. The halotherapy rooms have air with low humidity and a temperature in the comfort zone – 22-24°. The low humidity in the room is of vital importance. There are no requirements for special clothing or other equipment. Benefits are better if patients are bare-legged. The number of sessions depends on the patient's condition and the disease treated. Twelve to twenty sessions for 45 minutes each and for a short period of time are recommended for patients with chronic pulmonary diseases like asthma, bronchitis, sinusitis, COPD, allergic disease (3).

The main therapeutic factor is sodium chloride with an aerosol particle size of 2 to 5 millimicrons. A study by Chervinskaya, including 124 patients with different pulmonary diseases, showed a considerable improvement of the clinical status of the majority of the participants after a one-hour stay in a salt room daily for a period of 15-20 days (4). Similar results were observed in another study based on a chemiluminescent test in 49 patients with chronic obstructive bronchitis. Halotherapy leads to positive changes in the oxidation of free radicals, improves local immunity and the clinical presentation of the disease (5,6).

The mechanisms of action of halotherapy are manifold:

- ◇ mucolytic
- ◇ antibacterial
- ◇ anti-inflammatory
- ◇ immunomodulating
- ◇ hyposensitizing.

Halotherapy is a natural and safe treatment without serious side effects. This method is very beneficial for the overall wellness of a person by improving function and removing toxic substances from respiratory system, improving the function and appearance of the skin, boosting the immune system and reducing stress.

There is evidence from several scientific researches that inhaled dry salt particles have bactericidal, moistening and anti-inflammatory properties, which may reduce inflammation in the entire respiratory tract and widen the airway passages. Salt inhalation leads to a quicker improvement of the parameters of respiratory failure, which can be observed in the worsening of obstructive pulmonary diseases (6). Dry salt particles accelerate the transportation of mucus, the elimination of residual toxic substances and foreign allergens. The application of salt therapy thus results in a clean respiratory system with higher oxygen intake, increases energy and improves the immune system.

Scientific researches have confirmed that halotherapy has an influence over superficial and deeper skin layers providing healing and cosmetic effects. This increases activity of the skin cell ion channels, activates electrophysiological activity and improves skin's protective properties. Halotherapy leads to pH normalization and stimulates reparative and regenerative processes in the epidermis and derma, increasing skin rigidity (7). Dry salt improves skin microcirculation and cellular membrane activity, enhances skin regeneration and elasticity, and reduces wrinkles and edema.

The positive effects of halotherapy:

The efficiency of salt therapy is mainly due to three reasons:

1. salt has an antibacterial, antimycotic and anti-inflammatory effect (it has been established that the environment in salt rooms is three

times more sterile than the cleanest operating room);

2. salt has a natural ability to emit negative ions, neutralizing a positive charge;
3. salt is superabsorbent when it is dry.

Indications for use:

Halotherapy is indicated in most **respiratory diseases**, including:

- ◇ respiratory tract infections
- ◇ asthma (8,9)
- ◇ allergic and chronic bronchitis
- ◇ frequent colds
- ◇ pharyngitis
- ◇ sinusitis
- ◇ rhinitis
- ◇ tonsillitis
- ◇ pneumonia, after an acute stage
- ◇ cystic fibrosis.

It has been proven that this is a highly effective way of positively influencing numerous respiratory diseases with a prompt resolution of symptoms, improvement of pulmonary ventilation and tolerance of physical strain, as well as increase in the immunity and protective capacity of the organism (10).

Immunological and cardiorespiratory indicators were studied in 88 metallurgists diagnosed with a toxic dust bronchitis. The conducted therapy consisted of sinusoidal modulated current and ultrasound in the intercostal region, and respiratory exercises combined with massage and halotherapy. The patients were divided into three groups:

1. halotherapy and ultrasound treatment;
2. halotherapy and sinusoidal modulated current treatment, and
3. halotherapy alone.

The study proves that combining halotherapy with the use of physiotherapy equipment increases the efficiency of salt therapy by 86.5%. The combination of electric current procedures and halotherapy can be used both for treatment and prevention of obstructive syndrome in toxic dust bronchitis (11).

Because of the influence of halotherapy over superficial and deeper skin layers which increases the activity of the skin cell ion channels, activates electrophysiological activity and improves skin's protec-

tive properties this treatment can provide healing and cosmetic effects. Halotherapy leads to pH normalization. It stimulates restorative and regenerative processes in the epidermis and derma, resulting in an increase in skin rigidity (7). Dry salt improves skin microcirculation and cellular membrane activity, enhances skin regeneration and elasticity, and reduces wrinkles and edema. Halotherapy can be applied in some **skin diseases (12)** such as:

- ◇ Psoriasis
- ◇ Eczema
- ◇ Dermatitis
- ◇ Acne
- ◇ Rosacea
- ◇ Onychomycosis
- ◇ Skin aging

Halotherapy is conducted in a pleasant and cosy environment, which has a beneficial effect on the psycho-emotional state of the patients. This treatment can be used with some **psychosomatic conditions** including:

- ◇ stress and fatigue;
- ◇ headache,

and also for increasing immune reactivity.

Salt therapy is recommended as an additional treatment for some pediatric diseases. It is safe, non-invasive, with no side effects and potential health risks. Clinical researches have proven that children react quicker and more intensively. There is evidence about the high effectiveness of halotherapy for prophylaxis in frequently ill children and the possibility of its use for the treatment of acute respiratory diseases with children affected with chronic ears, nose and throat (ENT) disorders, respiratory and skin problems (13). This treatment is easily workable with children. There are special salt rooms supplied with toys and occupational appliances which makes children feel calm and comfortable.

Side effects:

During the treatment itself, certain side effects might be observed, such as increased coughing and more abundant secretion, which is actually considered a positive effect because it leads to respiratory tract clearing and it is a signal for a change and adaptation of the organism to the specific irritant.

Skin irritations are rare side effects and are normally resolved by the third or fifth session. Conjunctivitis as result of irritation of the mucoid membrane is rarely observed. It is not a reason to interrupt the sessions. In such cases, it is recommended to keep the eyes closed when spending time in the salt room (14).

Contraindications include hyperthyroidism, active tuberculosis, high-grade hypertension, cardiovascular and respiratory failure, acute-stage blood disorders, contagious diseases, fever, open wounds and malignant diseases. Caution should be exercised when prescribing this therapy to patients with claustrophobia.

CONCLUSION

Halotherapy is an alternative treatment method in numerous respiratory and skin diseases. It has insignificant side effects. It is conducted in a pleasant and cosy environment, which has a beneficial effect on the psycho-emotional state of the patients. This treatment is easily workable with children. The positive results from the therapy last for more than a year. The possibility to combine it with other physical therapy methods, as well as with pharmacological therapy, makes halotherapy a treatment of choice in mild and moderate forms of bronchial asthma, chronic obstructive bronchitis, post-pneumonia states and various other respiratory and skin diseases.

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Dry sodium chloride aerosol against acute respiratory infections

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This poster was presented at the European Respiratory Society (ERS) Annual Congress on 14.09.2009 in Session 206: "Treatment modalities in chest physiotherapy".

Chairs : D. Inal Ince (Ankara, Turkey), K. Wadell (Umea, Sweden)

Brief description

In order to study the preventing efficacy of inhaled dry sodium chloride aerosol against acute respiratory viral infection randomized placebo investigation was provided. Dry salt inhalations with Haloneb® inhaler were provided as a preventive method at the industrial plant. The working persons were undertaken by the inhalations twice a week during three month. They had number of cases and days of acute respiratory viral infection and exacerbation of respiratory diseases significantly less in compare with control placebo group. Morbidity with temporary disability was decreased considerably in compare with the ones at the same period of the previous year. Preventive action of dry salt aerosol against respiratory viral infection was proved. Inhalations of dry sodium chloride aerosol, consisting of two weekly procedures are effective preventing method against acute respiratory viral infections.

Finding can be in use for the medical practice application of the dry salt inhalations and the halotherapy.

Introduction

Dry sodium chloride aerosol (DSCA) is the main acting factor of the speleotherapy (salt cave therapy) and halotherapy (therapy in a controlled air medium which saturated with dry salt aerosol). The researches have been directed at examining the action of dry sodium chloride aerosol on respiratory tract of the patients with COPD, asthma and at risk factors of COPD.

DSCA is characterized with physical properties, differing from those of the saline aerosols. DSCA demonstrated anti-inflammatory activity in the respiratory tract, mucoregulating action. It enhances drainage of the bronchi, activates alveolar macrophages, improves biocenosis and local humoral immunity.

The aim of the study

The main objective was to estimate the preventing efficacy of inhaled dry sodium chloride aerosol (DSCA) against acute respiratory viral infection (ARVI).

Study design

Type: Randomized single-blind placebo study.

Participants: 160 persons were recruited from personnel of an industrial enterprise.

They were randomized in 2 groups - test group (T) (19 male, 61 female, 47.4±8.0 yrs) and control group (C) (22 male, 58 female, 48.8±11.6 yrs).

The groups were comparable as regards age, sex, smoking addiction, exposure to the adverse industrial factors (table 1) and clinical health condition (table2).

Methods:

- Special questionnaires for the study recruiting
- Physician examination
- Special questionnaires for registration of the symptoms acute respiratory viral infections
- Analysis of official statistical data of the temporary disability participants during the study period from January 25 till April 25, years of 2000 and 2001.

Table 1. Exposure to industrial pollutants

	INDUSTRIAL POLLUTANTS						Total	
	galvanic	solder	weld	t ² change	others	combined	n	%
Group								
T	4	8	1	1	10	5	29	36
C	3	5	1	1	7	1	18	23
Significant differences:							p>0,05	

Table 2. Clinical characteristics of the participants of the study

Status	T-group		C-group	
	n	%	n	%
Healthy	17	21	18	22
Risk COPD	34	43	34	43
Chronic Bronchitis	25	31	26	32
Asthma	4	5	2	3
Total:	80		80	

Intervention

T-group was undertaken with 10 min inhalations using a table-mounted Haloneb[®] Salt Inhaler (Aeromed Ltd., Russia) (pic. 1), producing DSCA with particles size mainly of 1-5 μm (pic. 2) and 0.8-1.2 mg/min density flow. Rock salt from Artyomovsk (Ukraine) salt mine was used. The participants inhaled quietly the dry salt aerosol, using a mouthpiece, in the sitting position.

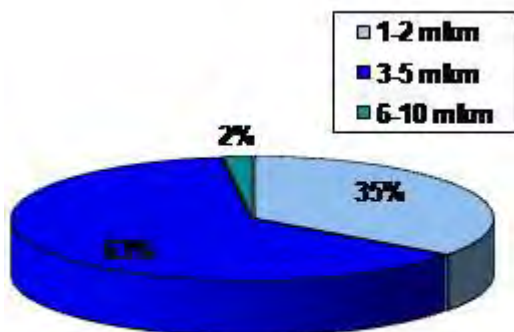
The C-group received 10 min inhalations with plain air.

Each subject was given **2 dry salt inhalations a week during 12 weeks**. A physician regularly examined the subjects of the both groups for possible ARVI.

Haloneb Dry Salt Inhaler



Fractional composition of dry sodium chloride aerosol, producing by Haloneb

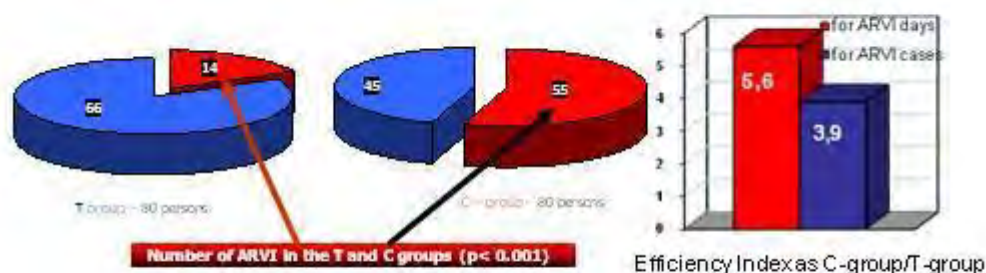


Outcome

For three months observation there were only 14 cases of ARVI and 104 days marked by symptoms of ARVI in the T-group. In the C-group there were 55 cases of ARVI and 585 days of symptoms. T-group participants were affected by ARVI four times less frequently than C-group participants, and the number of days marked by symptoms of ARVI was 5.6 times less (pic. 3).

Analysis of incidences of ARVI showed that they occurred in 60% of participants with risk factors of COPD in C-group subjects against only 18% of subjects with risk factors in the TG ($p < 0.01$). On the whole, 13 subjects (16%) developed ARVI in the T-group against 50 subjects (63%) in the CG ($p < 0.001$).

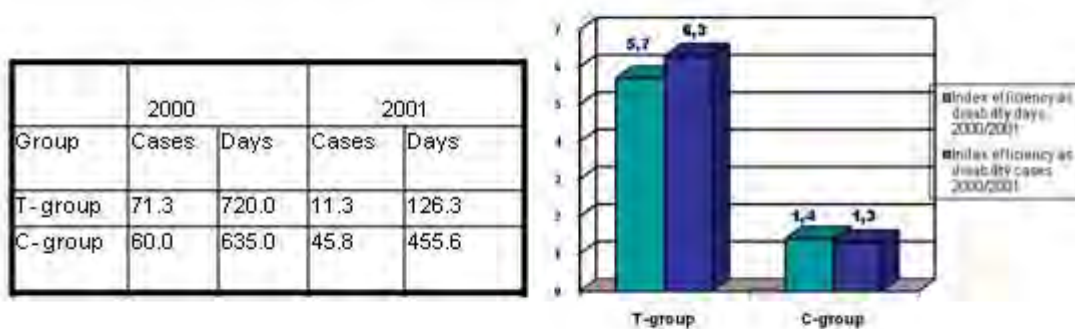
Pic.3. Influence of dry sodium chloride aerosol on the incidence of acute respiratory viral infections during 3 months term



Respiratory morbidity with temporary disability in the T-group during 3 months in 2001 was considerably less in compare with the same period in 2000. The number of disability cases and disability days were significantly less in the T-group in compare with the C-group in the 2001.

The analysis of the efficiency index (ratio of the respiratory disease cases and respiratory disease days in 2000 to those in 2001) showed that this index decreased considerably in the T-group (6.3 and 5.7 times, respectively) compared with the C-group (1.3 and 1.4 times, respectively) (pic. 4).

Pic.4. Respiratory morbidity with temporary disability (per 100 persons) in the groups during 3 months of 2000 and 2001 year



Conclusion

Inhalations of dry sodium chloride aerosol, consisting of two weekly procedures are effective preventing method against acute respiratory viral infections.

Finding can be in use for the medical practice application of the dry salt inhalations and the halotherapy.

This approach may be recommended to healthy persons and patients with chronic respiratory diseases prior to or during cold season.

Key words

Dry sodium chloride aerosol, salt inhalations, halotherapy, respiratory viral infection, prevention

