

True Halotherapy



History, technology development

The role in medicine and the medical application of

Dry Salt Aerosol Inhalation

Dr. Tamas Bakonyi, MD, DPD, MICGP Climatherapy Clinic Maynooth, Ireland

Dr. Joachim Riethmüller, pediatrician, pediatric intensivist, pediatric pulmonologist, UKT, Germany

Bart Zonnenberg, Microsalt International BV, The Netherlands

Introduction

In the past 10 years, an ancient therapy that has been applied for decades in Eastern European countries, has evolved into a modern alternative medication-free treatment for the airways. The inhalation of dry salt aerosol has been providing beneficial effects to large numbers of people suffering from respiratory discomforts already for decades.

As a result of this, in combination with commercial opportunities that have arisen, a wide variety of inhalation applications based on salt aerosol has been offered for both prophylactic and curative purposes. As an alternative medication-free treatment method, the therapy is offered to various markets. Respiratory clinics, rehabilitation centers and clinics but also wellness centers are adopting the therapy as a means to provide health support to their customers.

Slowly but surely, this medication-free therapy is gaining more acceptance among physicians who see and hear about the benefits this side-effect-free therapy can provide and research that is being performed to learn and understand the mechanisms of actions better. By professionalizing the therapy, customers and patients will not only gain maximum benefits from it. The therapy will be made available to more and more people as well, because therapeutic dry salt aerosol inhalation centers are opening its doors in more and more cities. Currently, a variety of Microsalt customers are providing Dry Salt Aerosol therapy to their customers. Among them are luxury hotels and spas who provide the availability of Dry Salt Aerosol climates as a preventative means to clean airways, as well as physicians and clinics who offer the therapy for curative purposes.

This booklet aims to introduce the reader into what dry salt aerosol inhalation is and what it can bring to people suffering from (temporarily) respiratory discomforts. It also provides a clear view on how it should be applied and provides an overview of some of the researches that have been performed up till now. Additional researches are being planned and executed today to further extend our knowledge and increase the availability of this therapy in the future.

Bart Zonnenberg



Microsalt international BV

History:

About 20 Million years ago Eastern Europe was partially covered by a shallow sea. With the disappearance of the sea, large amounts of layered salt were left behind. Nowadays they are bedded between 10 and 300 meters below the surface.

In the 14th century people started to mine salt for their own use and trade. Among other locations, large salt mines were developed in the South of Poland near Krakow leaving huge chambers deep in the mountains. Salt miners had very hard work day by day in these mines.

Recognizing the effect on health

In 1843 one of the local doctors, named Felix Boczkowski has made his scientific observation that people who worked in salt mines rarely ever suffered from respiratory problems particularly asthma, COPD, hay fever and cough.

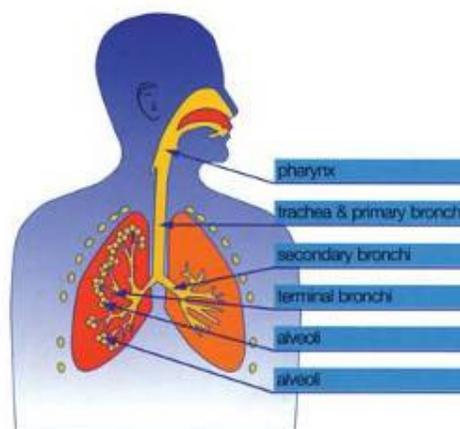


Due to high demand for salt cave therapy in the last decade of the previous century, entrepreneurs started to create artificial salt caves. As a result of that, there are several different types of salt caves at this moment. The wide variety of different technologies shows that the **exact mechanism** of the therapeutic action **has partially still not been fully understood** by many businesses. There are salt cave suppliers who believe and/or tell that the enormous amount of Himalayan salt is able to

produce the therapeutic environment in an artificial salt cave. Others think that the negative ions from the salt crystals have a therapeutic effect:

Scientific studies have proven that there is one factor responsible for the beneficial effect of salt aerosol inhalation therapy. This is the **microscopic fine dry salt particle afloat in the air**, which can be found in natural salt caves due to huge surfaces of salt and natural ventilation.

Halotherapy is a treatment based on the inhalation of small salt particles with the purpose to clean the airways. Halotherapy was developed as an above-ground alternative for speleotherapy.



How it is offered by various suppliers: The halotherapy concepts that are offered by various providers, mimics the atmospheric ambiance that is found in underground salt caves and salt mines. This reflects in the building up of walls made from salt rocks or sea salt plaster as well as a thick layer of salt granulate that covers the floor. Most of the rooms have little air supply where the ventilation of the rooms is done once per hour during 10 to 15 minutes.



A large number of commercial suppliers build salt caves or salt grottos and sell these rooms mostly to wellness centers where the rooms are used as relaxation rooms.

The marketing around these salt rooms tell the customer that residing in the room is good to treat or cure an extensive list of discomforts. This would be caused

by the fact that salt particles are freed from the walls and floor and so can be inhaled by the customer. When measuring salt concentrations inside the salt rooms that do not use technology to actively bring salt particles into the air, it must be understood that there is hardly any or no salt aerosol floating in the air.



There are salt caves that have been equipped with devices that grind rock salt or sea salt in smaller particles that are blown inside the room. The devices are so-called salt generators. This increases salt concentrations significantly. Most of the devices are started every hour and run for about 45 minutes. After 45 minutes, people leave the room and the remaining salt inside the room is removed by means of the ventilation system. Every full hour the device is started again. Effectively the customer inhales a certain quality of salt aerosol for about 30 minutes as the customer requires a certain salt concentration before it brings results that are promised.

At present, an increasing number of companies have developed technology to create a certain quality of dry salt aerosol. The basic technology used is the same in most of the devices: Produce a micro-cyclone where you create fine salt granules. The salt granules rub each other and the friction will make the salt granules smaller and smaller. There is a big difference in the quality of salt aerosols that are produced by the various devices.

A big technical challenge when creating a high-quality salt aerosol is to deal with managing humidity during the process while salt is very sensitive to humidity. When it absorbs humidity, it becomes less suitable or unsuitable for the procedure. Humid salt will lose its physical properties which are responsible for its positive therapeutic action. Apart from Microsalt, none of the other suppliers actively dry the air in both the device as well as the room in order to create a high-quality dry salt aerosol climate.

Except from one provider (Microsalt), all devices require salt refilling every hour. Unfortunately, only very few suppliers can truly claim they can regulate the salt concentrations inside the room. Two suppliers measure actual salt concentrations inside the therapy room. Other devices are just switched on.

- The ideal device produces a salt aerosol by using minimum amounts of salt and create very little residue that cannot be used.
- The ideal device should be able to separate particles under 5 microns from bigger particles and bring these smaller particles into the therapy room only.
- The optimal salt aerosol particle size ranges from 0,1 to 5 micron where 90% is smaller than 2 micron.
- The ideal device is able to maintain a stable concentration during the whole day by either accurately measuring concentration levels inside the therapy room or by defining interval settings for releasing predefined amounts of salt aerosol per a number of seconds related to the room volume.
- The ideal device does not require hourly maintenance by means of employees.
- The ideal device has to be very user friendly.
- The ideal device is connected online for remote control and service.



Salt stories

A strong asset that is marketed is the type of salt that is used. People like to believe that the inhalation of mineral-rich salts is healthy and therefore suppliers talk about the great characteristics of Himalaya salt and Dead Sea salt preferably. Because of the commercial drive behind the companies who build salt rooms that are covered with salt and sell their devices to grind salt, little



attention is paid to create a fully controlled dry salt aerosol microclimate saturated with a clean, high-quality salt. The type and quality of salt largely determines the effectiveness of the treatment. In addition, some salts can cause side-effects like irritation on the eyes and throat. In addition, there is little attention paid to the most important air characteristic

requirement, humidity. Apart from one supplier (Microsalt), salt cave suppliers provide ventilation systems but no air treatment systems including active drying possibilities.

How it should be offered:

As the market for wellness and alternative health treatments is maturing rapidly, a large number of suppliers see revenue potential in the salt treatment business and start to sell “halotherapy rooms”

in any format. This development is normal in any young market but requires close attention and the definition of a “standard” on how true halotherapy should be provided.

Microsalt collaborates with general practitioners who operate salt rooms for their patients and medical scientists who perform research on how halotherapy treatments can bring the biggest benefits to people suffering from respiratory discomforts. This has resulted in extensive knowledge about how halotherapy should be offered.

Treatment requirements: The following specifications should be paid attention to and applied during a dry salt aerosol inhalation session and throughout the whole treatment period:

1. Length of session
2. Duration of treatment period
3. Air characteristics
4. Salt quality, particle size and type of salt
5. Body position

1. Length of session.

The amount of salt aerosol inhalation is dependent on 2 factors. 1 factor is the concentration salt aerosol that is in the air. The other factor is the duration of salt aerosol inhalation. Apart from 2 respiratory disorders (Cystic Fibrosis and PCD), the quality of the treatment of all other respiratory disorders is dependent on the length of time that salt aerosol is inhaled. The minimum time required for an optimal session should be at least 45 minutes. What is important though is that during all these 45 minutes, the right salt concentration needs to be in the inhalation room. Traditional salt caves that do use salt generators run 45 minutes but start each time without salt aerosol inside the room. The effective time therefore can be a lot less. Depending on room size, most sessions in these types of rooms effectively take 30 minutes where the customer stays inside the room for 45 minutes.

2. Number of sessions and treatment courses

With a wide variety of functional disorders of the respiratory system, caused by various reasons, you can imagine that there is no standard duration time that dry salt aerosol inhalation therapy should take. The duration of a treatment period should be associated with the respiratory disorder or discomfort. Below you find a table with recommended treatment frequencies and duration of the therapy related to the respiratory disorder.

Respiratory Discomfort	weeks	Frequency per week	total sessions	Number of courses per year
Bronchial Asthma	5	4	20	1-2
COPD*	5	4	20	2 to 4
Cystic Fibrosis*		7		
Seasonal allergy	4	3 to 5	12 to 20	1 preferably before the hay fever season
Cold	2	3	6	After the acute symptoms subside
Sinusitis	2	3	6	After the acute symptoms subside
Laryngitis	2	3	6	After the acute symptoms subside

COPD* & Cystic Fibrosis* COPD and Cystic Fibrosis patients should treat themselves permanently if possible as these are chronic and permanent diseases.

3. Air characteristics

Saturating air with a dosage of salt aerosol in an undefined quality is easy and can be done by using devices that crush salt into smaller parts. But in order to let these salt particles effectively work, the air in which they float needs to be of a specific quality. Too often we hear stories from people who have visited a salt cave, who have a slight headache during and after the session. This has nothing to do with salt but with the quality of the air in which the customer has resided.

Temperature:

The temperature is not very critical when it comes to creating a high-quality salt aerosol microclimate, however temperature largely determines whether the customer finds it pleasant to stay inside a room for about 1 hour.

In many salt caves, blankets are distributed to stay warm as the average temperature is around 20°C. As long as the customer is sure that he gets an unused and clean blanket, this temperature is OK.

There are also salt rooms that have temperatures up to 60°C. They call them salt saunas and this is an attempt to combine an existing concept with a new one. **Inhaling salt particles with a temperature higher than 50 degrees Celsius is dangerous and can damage the airways!** Residing in a room temperature higher than 30°C for more than 20 minutes is not pleasant. In addition, the customer will most probably start to perspire.

The optimal temperature range for Dry Salt Aerosol Inhalation rooms reaches from 22°C up to 28°C, depending on how the people are dressed inside the room.

Humidity:

Controlling and managing humidity is the most important criterion when setting up a professional halotherapy room. In order to create the right halotherapy room conditions, a halotherapy room needs to have a relative humidity below 40%. There are 4 main reasons for controlling a strict relative humidity regime inside a halotherapy room.

1. Dry Salt Aerosol should stay as dry as possible as long as it has not been inhaled. Salt does not lose its powerful characteristics as long as it is kept very dry. This is the main reason why dry salt can hardly be smelled or tasted. Salt can be noticed at the moment it has become wet. The dryer salt is, the higher the hygroscopic effect is inside the airways which is one of the important mechanisms.
2. A big advantage of dry salt is that particles don't stick easily to each other when they bounce into each other. In fact it is very unlikely that dry particles bounce against each other due to their slight negative charge. This ensures that the particle size that has been created is maintained which ensures deep penetration inside the airways.
3. When particles are relatively wet, they do not only stick to each other because they lose their negative charge, but they also fall a lot faster on the floor as a result of their weight.



4. An important last reason is that salt only starts to get aggressive as of 40% RH and above. Below this relative humidity, salt is just dust and does not affect building materials with corrosive effects.

Air exchange:

Sufficient air exchange during a session is paid little attention to in most halotherapy rooms. Usually the air is exchanged after each session and so before each following session. It is important to supply fresh, clean and dried air inside the room constantly during a session though. This is done by means of adsorption drying devices in combination with air conditioning equipment. Room volume air exchange should be between 2,5 to 5 times every session in order to keep the air quality of sufficient levels. Of course exchanging more air volume is possible but this will result in significant salt aerosol exhaust. In that case it will be hard to maintain sufficient salt aerosol concentrations.

4. Salt quality, particle size and type of salt

The effectiveness of salt aerosol inhalation is largely determined by the quality of the salt aerosol inhaled. The quality of the salt aerosol is based upon the following 3 factors:

- A. Type of salt
- B. Particle size
- C. Quality of salt

A. Type of salt.



There are 3 basic types of salt, being rock salt, sea salt and vacuum salt. Rock salt is carved out of salt mines. This salt is usually very old and very hard. It is also mineral rich and therefore relatively good to use in food as long as it is clean. It also is good for skin treatments. Himalaya salt is a good example of mineral-rich rock salt.

Sea salt is very mineral-rich as well and also relatively hard. Sea salt is promoted heavily by many

providers of salt products within the wellness industry.

Vacuum salt is salt that has been derived from underground earth layers by pressing boiled water inside the layers in order to create a brine. This brine can be sucked up through pipes, dried and cleaned. Vacuum salt usually is a relatively young salt and mostly very clean as it has not been in direct contact with the surface before it is sucked up as a brine. It is relatively poor in minerals compared to the 2 other salt types. The advantage of young salt is that it creates rounded salt particles when micronized. Hard salt that is micronized is very sharp and has all kinds of shapes. This can be noticed on eyes and throat when residing in a salt room where rock salt or sea salt is used. As it is known that mineral-rich salts are good to digest, there is no proof that the inhalation of minerals is healthy. For this reason, Medical institutes refuse to use mineral-rich salts for inhalation purposes.

B. Particle size.

Salt particles viewed under a microscope



Particle size largely determines the depth of penetration inside the airways. Various salt generators available to market create a salt aerosol that is relatively large.

Salt Inhalation penetration research using NGI



In order to guarantee that salt inhaled during a Dry Salt Aerosol Inhalation session reaches not only the main tract and bronchi but also the bronchiole and alveoli, salt aerosol particle size should have a size between 0,1 and 5 micron. A significant part of this particle range should be smaller than 2 micron.

C. Quality of salt.

High quality halotherapy requires the highest quality salt available and this means that the cleanest salt available should be used. This salt should contain a NaCl percentage of at least 99,9%.

Medical application of the dry salt aerosol

Inhalation therapy in the treatment of respiratory diseases

There has been a continuous interest by scientist in the treatment of the respiratory diseases with the inhalation of healing agents. Theoretically both the upper airways (nasal cavity, paranasal sinuses, and pharynx) and lower airways (larynx, trachea, bronchial tube system, and alveoli) can be reached by inhalation techniques. In practice there are well known challenges with this therapeutic approach.



- Drug delivery with conventional methods is inefficient. Problems arise from excessive particle aggregation in the inhaler, deposition in the mouth and throat, dose dependent side effects of the delivered drug.
- With medical delivery devices, inhalations deliver a low percentage of the dose into the lower airways. With an excellent technique and the

newest devices only 20-25 % of the drug can travel to the lower airways. 75-80% of the medication is deposited in the throat and the mouth.

- After forced inspiration the patients are asked to hold their breath as long as they can in order to allow the medication to distribute and adhere to the mucus membrane of the airways. Shortly after the patient has to blow out the air and therefore removes the non-deposited fraction of the drug. Patients use their forced vital capacity (The maximum volume of air that can be voluntarily moved in and out of the respiratory system) when inhaling this way. The emphasis is on speed in order to reach the maximum depth and penetration of the medication.
- With repeated actuations patients would be able to deliver more medication into their lungs but the dose dependent side effects of the medication do not allow this action.

Inhalation of dry salt aerosol during a certain period of time:

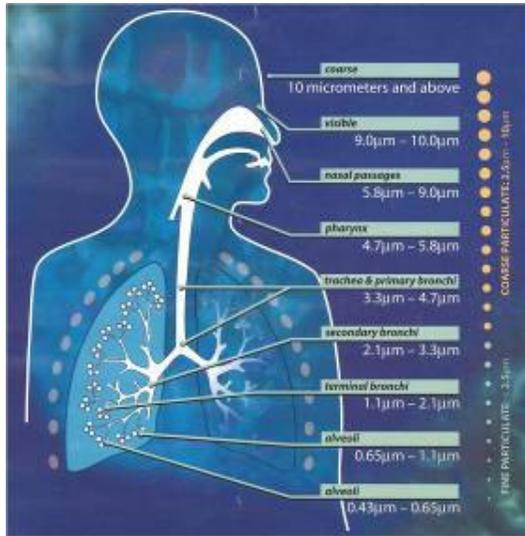
It is a so-called climatherapy. Climatherapy (also called climatotherapy) is a discipline of medicine, defined as-"staying in a standardized, controlled climatic area for a certain period of time".

During this time patients inhale the especially composed air with their normal breathing activity.

Unlike the drug delivery devices, during climatherapy **the patients are breathing with their normal** breathing (tidal volume: 0,5 liter tidal flow rate 500ml/s) at the rate around 12-20 per minute. During one session (60 minutes) one patient breathes in and out around 1000 times. He is inhaling the air containing invisible, dry floating salt aerosol around 1000 times. The salt concentration in the treatment room depends on the preset concentration and the quality of the device. Due to this repeated exposure the dry salt aerosol can reach and be deposited into the lower airways.

Calculating the maximum of salt aerosol which can be absorbed by the airways when using a dry salt aerosol concentration of 15mg/m³ in the treatment room:

The volume of a person normally breathing in and out is about 0,5 liter. Breathing 1000 times in and out the volume of the air we can take in to the airways is 0,5 liter x 1000 = 0,5 cubic meter. If one cubic meter contains 15 mg salt an average intake of salt is around 7.5 mg if we suppose that the whole amount of inhaled salt is deposited and absorbed.



(just to compare: 25 gram of salty crisp contains 300 mg salt).

Pharmacological effect of the microscopic, dry salt crystal aerosol:

Dry salt particles deposited in the conduction and respiratory airways have five major mechanism of action:

1. Dry salt Aerosol is very hygroscopic. It attracts humidity quickly and as much as possible. When salt particles are inhaled and deposited in the bronchial tree on mucus, the mucus is fluidized. This increases an easier expectoration of mucus. Patients experience looser sputum which is much easier to remove by coughing.
2. An advantage of this is that therefore, obstruction inside the airways, caused by mucus, is decreased.
3. Dry salt Aerosol may lessen the destructive inflammatory process in the airways. Clinical studies have found that the inhalation of dry salt aerosol results in decreased colonization activity of pathogenic bacteria flora.
4. Dry Salt Aerosol acts as a mucokinetic . Salt increases the mucociliary activity-clearance and can therefore act as an expectorant. By the slight activity increase, dirt and mucus is removed more and faster.
5. Inhalation of dry salt aerosol may improve both the humoral and cellular immunity of the epithel and is therefore able to improve the local immune defense mechanisms.

Based on the available clinical studies and our professional, personal experience, in our opinion inhalation of dry salt aerosol with controlled parameters in a standard environment can be beneficial for patients suffering from certain respiratory conditions.

The above mentioned therapeutic recommendations reflect our therapeutic method and practice.

Dr Tamas Bakonyi MD, DPD, MICGP
Salt Cave Climatherapy Clinic
Maynooth, Ireland

Dr. Joachim Riethmüller, pediatrician,
Pediatric intensivist, pediatric pulmonologist
University Clinic Tübingen, Germany

Available clinical studies and relevant scientific publications regarding dry salt aerosol inhalation therapy

Mohammed Ali: Pulmonary Drug Delivery in Handbook of Non-Invasive Drug Delivery Systems Non-Invasive and Minimally-Invasive Drug Delivery Systems for Pharmaceutical and Personal Care Products 2010, Pages 209-246

1. Chervinskaya A.V., Biskys V. Aerosol respiratory hygiene as a main part of prevention of chronic obstructive pulmonary diseases (COPD) and health promotion for patients in hospitals // 14th International Conference on Health Promoting Hospitals, Palanga, Lithuania, May , 2006, II-5.3.
2. Chervinskaya A. V. Effect of dry sodium chloride aerosol on the respiratory tract of tobacco smokers // The Europ. Respir. Journ.-Abstracts 16th ERS Annual Congress, Munich, Germany, September 2-6, 2006. – P. 106s-107s.
3. Chervinskaya A. Mechanism of action of the dry sodium chloride aerosol and its clinical efficiency in prophylaxis and rehabilitation // Balneol. Pol. – 2007. – Vol. 49, N 3 (109). - P. 197.
4. Chervinskaya A. Halotherapy in health resort medicine// 36th Congress of the International Society of Medical Hydrology&Climatology. Abstracts book. - Porto, 2008. - P. 29-30.
5. Chervinskaya A. Dry sodium chloride aerosol against acute respiratory viral infections// The Europ. Respir. Journ, – 2009. - 34: Suppl. 53. - 401s.
6. Chervinskaya A. V. Respiratory hygiene with the dry sodium chloride aerosol // 14th Annual Congress of the European Respiratory Society, Glasgow, September 2004: Abstract Book.- 2004. – Ref. 2514.
7. Mokina N. A., Geppe N. A. Alternative methods at bronchial asthma of children // 14th Annual Congress of the European Respiratory Society, Glasgow, September 2004: Abstract Book.- 2004. – Ref. 1069.
8. Chervinskaya A.V., Silber N.A., Alexandra A.N. Halotherapy for treatment of bronchial asthma (abstract) // XIV World congress of asthmology - Interasma 93, Israel. – 1993. - P. 59.
9. Konovalov S.I., Chervinskaya A.V. Saline aerosol effect on pulmonary phagocyte system (abstract) // International symposium of speleotherapy. Sotolvino-Ukraine, 1993.-P. 24.
10. Chervinskaya A., Alexandrov A., Zilber N., Stepanova N. Effect of halotherapy in patients with bronchial asthma and allergic rhinitis (abstract). XV International Congress of allergology and clinical immunology, Sweden, 1994. - P. 175.
11. Chervinskaya A., Alexandrov A., Strashnova O. Effect of dry sodium chloride aerosol in patients with bronchial asthma // Allergy & Immunology (abstr. Interasma 95). - 1995. - V. 27, N. 7.- P. 221.
13. Chervinskaya A. V., Kvetnaya A. S. Therapeutical effects of the dry sodium chloride aerosol on physiological properties of the respiratory mucosa // Pulmonology. Supplement abstract book: 3-rd Congress of European Region International Union against Tuberculosis and Lung Diseases (IUATLD).– 2004. – Res. 322.
14. J. Hedman , T. Hugg , J. Sandell , T. Haahtela The effect of salt chamber treatment on bronchial hyperresponsiveness in asthmatics Allergy Volume 61 Issue 5, Pages 605 – 610 Published Online: 30 Mar 2006