The effects of using of Dry Salt Inhaler (DSI) on adults with asthma and COPD

Product manufacturer: Salt Pharma Srl Brasov, Romania

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Introduction

Speleotherapy and halotherapy are relatively old therapeutic methods sometimes recommended for chronic obstructive disorders.
Treatment in natural salt cave (speleotherapy) has been known for a long time.
The purpose of our study is to prove the efficacy of the Dry Salt Inhaler on adults diagnosed with asthma (both mild and severe) and COPD regarding the quality of life and the improvements of spirometry values.

Primary objective

Our aim was to evaluate the effects of inhaled dry salt in stage 2 and 3 COPD patients and also patients with asthma, in terms of ventilatory parameters – based on spirometry and the quality of life – based on our own design questionnaire.

Secondary Objective

We also aimed to achieve long-term improvements of life quality and decreased incidence of respiratory infections – mainly on patients that have persistent symptoms of asthma and COPD.

Material and methods

The study was conducted on a patient pool of 38 individuals selected as following:
Inclusion criteria:
A subject was considered eligible for inclusion if all of the following applied: diagnosed with stage 2 or 3 COPD, more than 1 year in treatment, diagnosed with asthma (mild, both persistent or intermittent, moderate or severe), more than 1 year in treatment, was able to understand and endorsed the written informed consent and presented no other serious respiratory pathology (such as tuberculosis, lung cancer, pulmonary fibrosis, etc).
Exclusion criteria: had a current cardio-vascular diagnosis such as (arterial hypertension, heart failure, arrhythmias), had a life threatening diagnosis or one that could interfere with study procedures, being pregnant or having the intention to remain pregnant, being under 18-years old (as there is no data to sustain safety in child administration), being sodium chloride intolerance, having a psychiatric / severe neurologic condition or abandoned the study.

The Study Design

Sample size: 21 patients concluded until abstract submission, 38 until present time.
We designed this study to be a double-blind, randomized trial, single crossed.
The initial pool of patients was divided in 2 arms of population:
The *PII* group was the group that initially took placebo for the first time and then continued to DSI inhaler for the next 2 periods
The *IPI* group was the group that took DSI inhaler device for the first time and at the second visit (V_1) they were crossed with the ones in *PII* group.

The treatment period was 6 weeks of standard asthma / COPD therapy according to GOLD 2005 guidelines, and one 15-20 minutes inhaling session, preferably during the evening, using the DSI device. For evaluation of patients we used 2 methods: **a quantitative evaluation** based on spirometry and pulmonary function report printed after the spirometry **and a qualitative evaluation** based on a life quality-improvement questionnaire that we design for this – questionnaire meant to evaluate how patient felt while on treatment with DSI device in terms of ease of breath, relief of chronical symptoms, improvement of overall patient's functionality.

Results

Our results have shown an overall improvement of the quality of life, expressed both orally by the patients and observed after the gathering of data from the forms. Both asthma and COPD patients have spoken of a "feeling of breath relief" after only one day of use, and also they mentioned the improvement of their functionality. All the patients mentioned the increase production of expectorated sputum after 2 – 3 days of use and, differentiating from placebo groups, the ones using active-substance DSI did felt better overall at the end of the in-between-visits period.
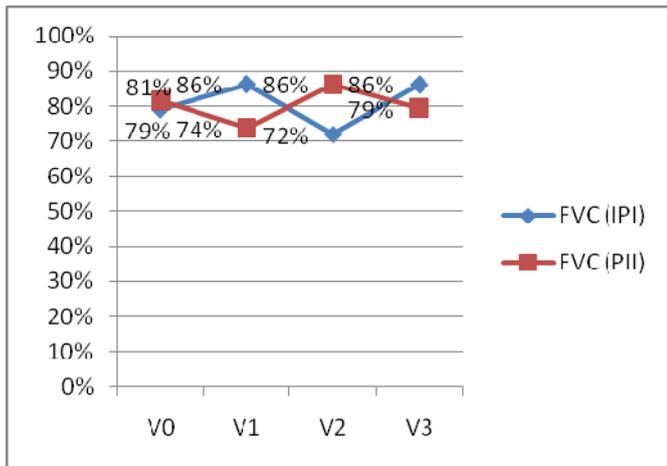
Figure 1 - The Evolution of FVC parameter. IPI = population Inhaler - Placebo Inhaler. PII = Population Placebo - Inhaler - Inhaler

As shown in Figure 1, the FVC is improving with about 9% from the placebo use to active-substance use, proving the efficacy of the DSI device therapy and, correlating these results with the increased sputum
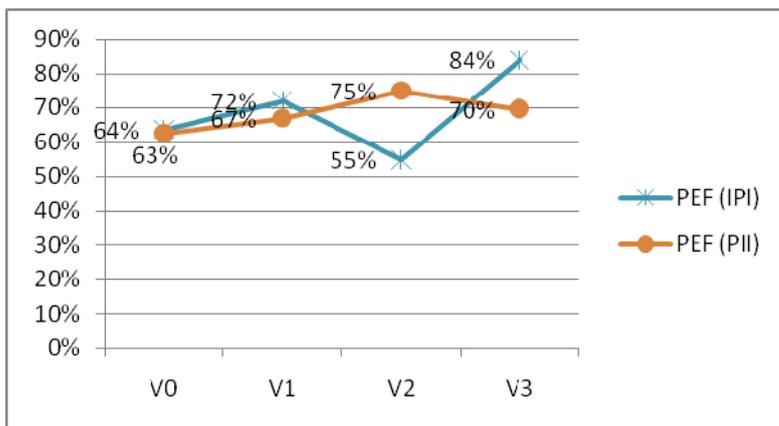

Figure 2 - The Evolution of PEF parameter. IPI = population Inhaler - Placebo Inhaler. PII = Population Placebo - Inhaler - Inhaler

expectoration, we can conclude that, in terms of air quantity, the DSI device increases the flow of air after use.
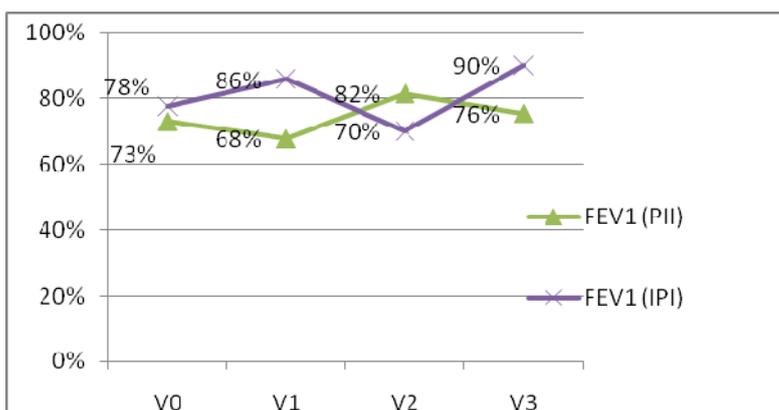

Figure 3 - The Evolution of FEV1 parameter. IPI = population Inhaler - Placebo Inhaler. PII = Population Placebo - Inhaler - Inhaler

During the investigation of FEV1 parameter we have found that both populations (PII and IPI) improved their breathing parameter, as shown in Figure 3 - The Evolution of FEV1 parameter. IPI = population Inhaler - Placebo Inhaler. PII = Population Placebo - Inhaler - Inhaler, the best improvements being shown versus placebo periods both in IPI and PII populations.

PEF parameter also showed improvements (Figure 2 - The Evolution of PEF parameter. IPI = population Inhaler - Placebo Inhaler. PII = Population Placebo - Inhaler - Inhaler) mostly on the population that started with the active-substance DSI device, fact that lead us further to the conclusion that, being used constantly and continually – without interruptions, for a long period of time, the DSI device may consistently contribute to improvements in overall functionality of patients. Since PEF is a high indicator of functionality from the larger airways, once again we can conclude that using the DSI device, additionally to sputum expectoration, the bronchial lumen is more relieved.

Since the ventilatory parameters of a patient with asthma or COPD cannot be spectacularly boost even with standard bronchodilators in such a short time, the differences between the average values obtained in FVC, FEV1 and PEF between V0 and V4 are clear signs of improvement and the differences between the two populations show that continuously usage of the DSI is better and indicated.

In terms of quality of life, our results showed definite improvements and the consented values come to strengthen the patients' stories about the sensation of relief and better breathing. The overall unanimous perception was that since they started to use the DSI device, the quality of breathing and their functionality improved as well as the relief of the resident symptoms. Analyzing this data we were surprised to notice that the two populations, both IPI and PII, had different initial scores – after the first use, since some of them used the Placebo-device and the others were using the active-substance DSI device.

Figure 4 - Scores of the 2 population during the First visit (V1). R1 - R5 are the answers to the 5 questions from the questionnaire at the first visit. For example, R1(IPI) means the answer to the first question given by the population that took Inhaler-Placebo – Inhaler, so it is their first answer (being at visit 1) and

after the use of the active-substance inhaler (IPI). shows the answers of the two populations at the first visit.

The final average scores and the differences between them are shown in the following figures (lower values are better)
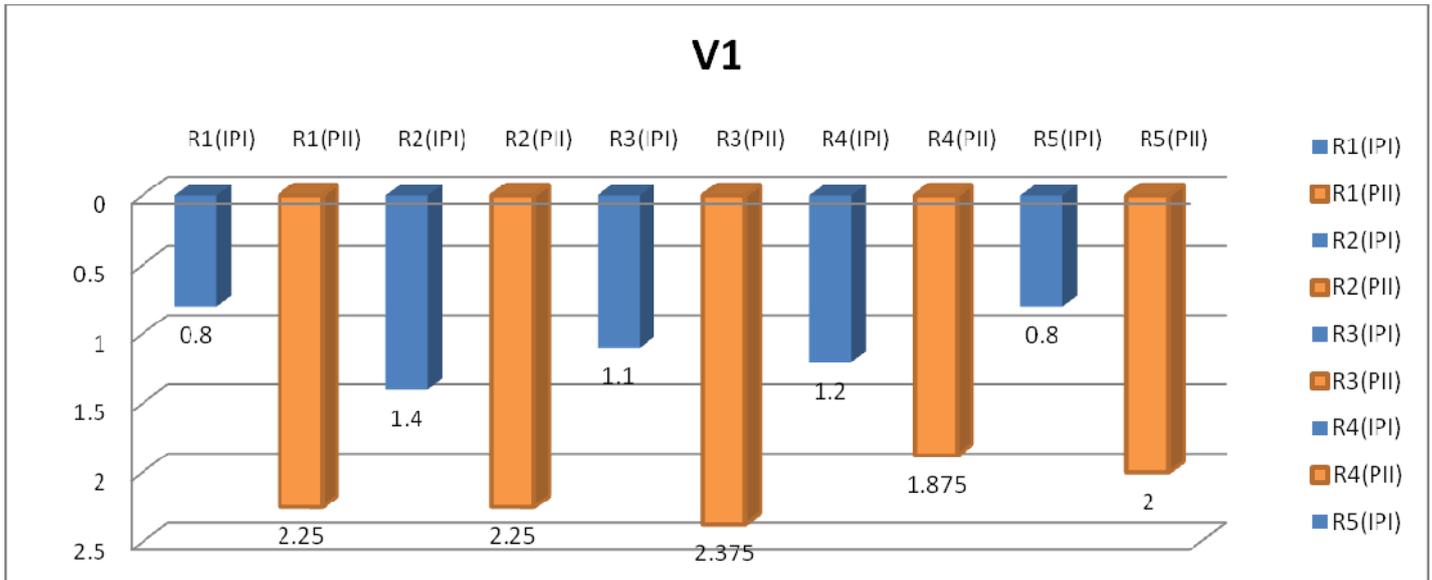
V1

Figure 4 - Scores of the 2 population during the First visit (V1). R1 - R5 are the answers to the 5 questions from the questionnaire at the first visit. For example, R1(IPI) means the answer to the first question given by the population that took Inhaler-Placebo – Inhaler, so it is their first answer (being at visit 1) and after the use of the active-substance inhaler (IPI).
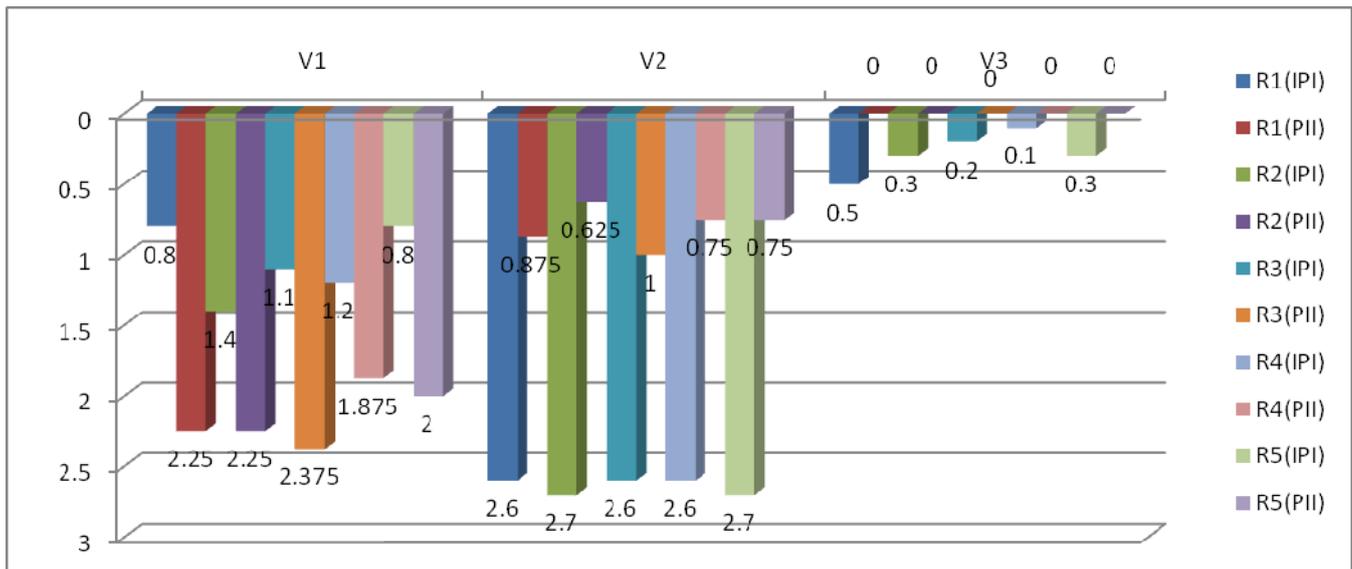

This figure shows the clear differences in average scores from the two populations, registered from the entire questions (R1 – R5).

Figure 5 - The scores given by both populations during the all 3 visits. V1, V2, V3 are the 3 visits, R1-R5 are the answers to the questions from 1 to 5 in questionnaires and each answer has a designated color – the same throughout the 3 visits. IPI means the population that initially took active substance inhaler and then placebo (V1-Inhaler – V2-Placebo – V3-Inhaler) and PII means the population that started with Placebo and then continued with the Inhaler (V1-Placebo – V2-Inhaler –V3- Inhaler)

Furthermore, at V_3, after all the patients took both placebo and active substance, the answers have scores close to "0" meaning definite improvement in both functionality and quality of life.

Looking separately at the two populations, we found that the IPI pool improved their scores with an average of 70% from V_1 to V_3 showing a decrease of their life quality by rating with higher grades (worse) the answers during the V_2 – which, for them, it was the visit after placebo.

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Spectacular is the comeback of the scores towards below 1 during the V_3 interview, showing that the placebo interruption worsened the good evolution they had in terms of life quality.
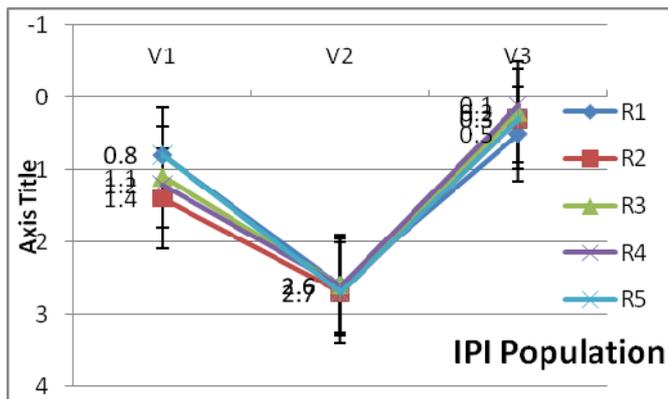

Figure 6 - the evolution of scores within IPI population (Inhaler - Placebo - Inhaler). V1,V2,V3 – are the 3 visits and R1-R5 are the answers to the 5 questions from the questionnaire

The PII population, as shown, had a better evolution, indicating that the usage in a constant manner of the DSI device, without interruptions, may produce definite life-improvement on a long-term period.

The PII group showed improvements from V_1 to V_2 on an average of 63% and total improvement from V_1 to V_3 – as no patient responded that their symptoms bothered them after using the DSI device for a 30 day period. This result translates in the mandatory conclusion that the DSI device is an enhancer in terms of improving the quality of life along with the standard medicines one patient has to take.
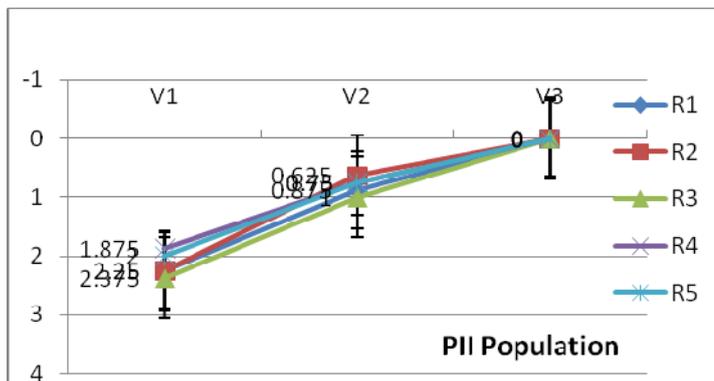

Figure 7 - The Evolution of Scores within PII population (Placebo – Inhaler – Inhaler). V1,V2,V3 – are the 3 visits and R1-R5 are the answers to the 5 questions from the questionnaire

Conclusions

As we studied both the quantitative and the qualitative parameters on a significant pool of patients, we were able to draw conclusions regarding the use of the DSI device on patients with asthma/COPD. Although we found improvements of FVC, FEV1 and PEF parameters on spirometry, the average improvement of these parameters doesn't impress but it cannot be ignored. It is well known the fact that an asthmatic or COPD patient's spirometry values are in dependency with the atmospheric conditions, his life environment, exposure to pollution, etc – these factors being able to change the results of the evaluation. But correlating with the qualitative results, we found that the DSI inhaler has proved its efficacy versus placebo – improving the life quality and the breathing quality of all patients.

Due to the fact that patients have been breathing better and they all were on regular asthma/COPD medicines, the added DSI device increased the sputum expectoration and additionally helped to the relief of respiratory airways. This fact has a major importance in both prevention and speeding up the healing of respiratory infectious diseases that, in some cases, may be life-threatening to a COPD patient. Nevertheless, the DSI device usage on a regular basis and for a long period of time improves the patients' global functioning along with the quality of his life – making them able to do a better job in daily activities and at home, as shown in reading the results from the Life-Quality Improvement Questionnaire.