Sputotherapy and halotherapy are relatively old therapeutic methods recommended for chronic obstructive disorders but there is not enough available scientific data to prove and quantify their efficacy. In Romania there are over 20 natural salt caves, some of them having own therapeutic unit.

Accounting the mechanisms of halotherapy (mucolytic, anti-bacterial, anti-inflammatory, immune-modulating, hyporesensibilizing), the salt-aerosols help in improving the respiratory act and, overall, the quality of life. The salt aerosols enhance phagosome acidification by stimulating the Na+H+ pump (Grinstein and Furuya, 2001), decrease the consistency of sputum, by the hypertonic effect (Chiruta and Moscalici, 2009) and act as local steriliser.

The aim of the study was to prove the efficacy of adding a dry salt inhaler to regular broncho-dilatatory medication to patients with obstructive respiratory diseases.

**Rationale**

The least improved parameter in IPI population study group was the forced vital capacity (FVC) – showing the chronic characteristic of the obstruction. As the results show, these patients’ respiratory potential gain on V1, after halotherapy cure, was not maintained through V1 to V2 – the period of placebo treatment. Although during the period V2 – V3 they received again active-substance DSITM device, the initial improvement was not again achieved.

**Methods and Materials**

- The study was prospective, double-blind, randomized trial, single crossed
- We enrolled 128 patients previously diagnosed with COPD (st. II – III) and asthma, from 2 medical centers in Iasi and Vaslui, Romania (72 females and 56 males, 76 diagnosed with asthma and 52 with COPD).
- There were 4 visits (V0, V1, V2, V3) during the 12 months of study
- The initial pool was randomized and divided in 2 arms of population that were crossed after first evaluation visit.
- The groups were initially named “Blue Group” and “Yellow Group”. After the completion of study they were renamed to show the order of salt aerosols administration versus placebo: “IPI Group: Inhaler – Placebo – Inhaler” and “PII Group: Placebo – Inhaler – Inhaler” (fig 1)
- The treatment period was 20 minutes/day - aerosol inhalation session. We analyzed the evolution of spirometry parameters FVC, FEV1 and PEF and also a Quality of Life Questionnaire with 5 items concerning: the quality of sleep, the symptoms after the night sleep, the perception of respiratory noises (chest-smores, wheezing), the restrictions of daily activities and the presence and intensity of shortness of breath (dyspnea).

**Results**

Our study results were divided in 2 categories: the quantitative results – evolution of spirometry parameters and the qualitative results – evaluations of the scores from the QoL questionnaire.

We analysed three spirometry parameters: FVC, FEV1 and PEF. Their initial and final mean values showed an overall improvement in all three, particularly in PEF parameter – showing the benefits of this natural technique for asthma patients. (Table 1).

We found out that in IPI Population, the most improved parameter was PEF (from 65% to 106%) showing the asthma patients crisis exit and no further relapse, also improved expiratory flow by increased sputum expectoration in patients with COPD (figure 2).

For the qualitative appreciation of the effects of halotherapy using the DSITM device, we used a 5 questions QoL* questionnaire. The scores were listed as a scale of symptoms intensity with “0” meaning - no symptoms and “6” meaning severe symptoms. We noted the answers R1 – R5 from each visit. The evolution of scores from each answer/visit showed improvements in both groups. The PII group constantly delivered decreased scores, improving their quality of life outcome by 80% (2.30 to 0.42). The IPI group, due to placebo-brake during V1 – V2, had a worsening of symptoms and thus a decrease in quality of life comparing to previous period and so their overall improvement was by 24% (2.07 to 1.58). (Figure 4)

Although the figure above shows the average scores, the improvements at the question level were different between the two group. We found out that the items with the greatest impact on quality of life were restriction of daily activities (greatly improved in both groups) and the shortness of breath (dyspnea) improved mostly on PII group.

Patients also mentioned, at the discussions after evaluation visit V3, that the use of a device such as the one we had for this study (DSI salt pipe) seems to be more efficient than the visits to the halocabs or the salt mines.

**Conclusion**

- Overall, throughout the study, the clinical status of all patients improved significantly.
- The initial gain in respiratory potential was maintained only if the halotherapy was continued. The IPI group evolution showed that after the placebo cure, when they received active substance again, their improvement was lower than the initial one.
- The halotherapy, although was added to chronic treatment previously prescribed for each patient by their doctor, significantly improved the quality of breathing and the quality of life for these patients.
- For the maximum efficiency, the halotherapy must be used as added therapy for at least 2 months for it’s effects to be quantifiable and significant improvement recorded.

**References**

6. The effects of using a plastic Dry Salt InhalerTM (DSI) on adults with asthma and COPD. Cristea R., Mitrea Rou, A. Medicina in Evoluție, Timișoara, ISSN 2065-378X, XVI – 1, 325-331.

The Effects of Using A Dry Salt Inhaler Aerosols on Adults with Obstructive Respiratory Pathology

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**Figure 2 – The Evolution of Spirometry Parameter in IPI Population**

The evolution of parameters in PII population showed a constant improvement after the initial placebo cure that did not modify the spirometry. The most improved parameter was also PEF (67% to 74%) followed by FEV1 (+8%). The evolution of FVC, although improved, did not showed clinical significance (+3%). (Figure 3)

**Figure 4 – The Evolution of Scores from the Quality of Life Questionnaire**

Although the figure above shows the average scores, the improvements at the question level were different between the two group. We found out that the items with the greatest impact on quality of life were restriction of daily activities (greatly improved in both groups) and the shortness of breath (dyspnea) improved mostly on PII group.

Patients also mentioned, at the discussions after evaluation visit V3, that the use of a device such as the one we had for this study (DSI salt pipe) seems to be more efficient than the visits to the halocabs or the salt mines.

**Figure 1 – The study Design**

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**Table 1. The Evolution of Mean values for spirometry parameters analyzed on the entire patients’ population**

<table>
<thead>
<tr>
<th>Parameter/Visit</th>
<th>V0</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Av. FVC</td>
<td>82%</td>
<td>87%</td>
<td>84%</td>
<td>86%</td>
<td>4%</td>
</tr>
<tr>
<td>Av. FEV1</td>
<td>80%</td>
<td>89%</td>
<td>86%</td>
<td>94%</td>
<td>14%</td>
</tr>
<tr>
<td>Av. PEF</td>
<td>66%</td>
<td>68%</td>
<td>67%</td>
<td>91%</td>
<td>25%</td>
</tr>
</tbody>
</table>

**Figure 3**

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**Table 2**

<table>
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<tr>
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