

FORCED IONIZATION OF IN-DOOR AIR AS AN ADJUVANT ALTERNATIVE IN THE THERAPY OF ASTHMA AND CHRONIC BRONCHITIS

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SUMMARY

Goal: The estimation of the impact of forced ionization (NaCl) of in-door air, as an adjuvant therapy of chronic bronchitis and asthma, using a device manufactured in Romania.

Protocol: a controlled placebo study for a period of 12 month. Location: patients registered in the outpatient clinic of pulmonary diseases and from a GP consulting room.

Participants: 30 patients (9F and 21 M) suffering from simple chronic bronchitis (11) and bronchial asthma (19) associated with allergic rhinitis. The patients were distributed in 2 lots, Lot I (the study), including 17 patients, and Lot II (the placebo), including the other 13 patients, with a comparable distribution per age, pathological profile and standard treatment.

Measured variables: the basic spirometric parameters (FEV₁, FVC), the number of recurrences, the necessity of a symptomatic medication, the indices of living quality.

Results: in the control lot there were noticed a minimum improvement of FEV₁ (increase of 11%) the improvement of the clinical scores (diminution of cough, sputum volume, nasal congestion, ocular pruritus and so on). The effects of these modifications were an improvement of the living quality, more rare hospitalizations and a diminution of the symptomatic medication.

Conclusions: as an ancillary treatment, the forced ionization of in-door air, though it does not improve significantly the pulmonary function, improves, however, the quality of the patients' life and diminishes the rate of annual hospitalizations. It is worth being mentioned the method advantages: there is no risk, is cheap and adapted to the living space.

INTRODUCTION

The increase of morbidity of the persons suffering from an inflammatory disease of the lung, as asthma or bronchitis, is associated with the increase of air pollution with particles. As a hypothesis it is supposed that the inhaled airborne particles can amplify the inflammation of the breathing way present in these diseases, worsening the symptomatology. But the penetrability of an inhaled agent depends on its type (aerosol, dry powder), characteristics (concentration/tonicity, aerodynamic diameter), aerosol using conditions (ultrasonic nebulizer, or with IPP and so on), as well as on the bronchial obstruction degree when the aerosol is inhaled (Barry P., Fouroux B-2000). Given these considerations, in the attempt to heal the airways, various devices (MDI, diskhalers, turbohalers) and substances (broncho-dilator and anti-inflammatory, culminating with corticoids) (Boe J, Dennis J -2000) were efficiently used. But the high price of these drugs and the handling of the inhaling devices, raised for discussion the adjuvant alternatives by which physiologic (normotonic solution of NaCl) or pharmacologic (magnesium sulphate, manitol, furosemide) agents, cheap and simply to be administered (speleotherapy, inhaling from nebulizers, with or without a mask, simple spray, and so on) were used for the same goals: the diminishing of inflammation and bronchial hyperreactivity, the restoring of muco-ciliary clearance and so on) (Kugelman A, Durand M – 1997). Starting from the indisputable benefits of speleotherapy (using of the salt mines in the treatment of the obstructive bronchial syndromes), it has been looked for the creation of some microclimates simulating the conditions in a mine. Our study can be included in this last category, where the salt from a mine is placed in a device which spreads it in the environment.

MATERIAL AND METHOD

The study goal was the estimation of the impact of the forced ionization of in-door air, by using of a device developed in Romania: SALIN produced by Tehno Bionic S.R.L. Buzau.

The device working principle consists in the forced air passing through some plates with sediment layers of micro crystallized salt, which modifies the air composition and quality due to the salt sublimation.

Participants: 30 patients (9F and 21 M) suffering from simple chronic bronchitis (11) and bronchial asthma (19) associated with allergic rhinitis. The patients were distributed in 2 lots, Lot I (the study), including 17 patients, and Lot II (the control placebo), including 13 patients, divided per age and comparable pathological profile (table I). For Lot I, the air ionization was associated with the standard treatment and was carried out in the living room or in the bedroom, and for the Lot II, the device worked without the salt plates in it, the patients being treated only conventionally (the controlled placebo study).

Only patients suffering from asthma, the 2nd – 3rd stage, were included. We proceeded to such a selection to limit the errors which can be induced by the intensely fluctuating feature of the intermittent or mild stage (the Ist one), and by underestimations caused by the phenomenon of clinical tolerance occurring more frequently in the 4th – 5th stages. These were the reasons why only the patients suffering from bronchitis, the IInd stage (according to the international classification from Stocholm – 1999) were included, namely with simple chronic bronchitis, with a moderate pulmonary dysfunction (FEV₁>50%) without any other diseases, malnutrition, or chronic use of steroids, without bronchial colonization with intensely pathogenic germs (Enterobacteriaceae, Ps aeruginosa) and frequent exacerbations (table I).

Table I. The structure of the studied lots

Lots of patients	Lot I (the study): 17		Lot II (the placebo): 13	
Number of patients	AB: 10	Bronchitis: 7	AB: 9	Bronchitis: 4
Age(year)	34 ± 7,7	46 ± 9,2	36 ± 11,8	43 ± 8,3
Sex M	7	6	6	3
F	4	1	3	1
Disease duration	5-25	6 -14	3-22	8 -11
Stage/severity	7 st II, 3 st. III (GINA classification)	Chronic simple bronchitis *	7 st. II, 2 st. III (GINA classification)	Chronic simple bronchitis *

* Stage II in the International Classification of the Bronchitis (Stockholm, 1999).

Localization: patients registered in the outpatient clinic of pulmonary diseases and from a CP consulting room.

The study protocol: a physician specialized in pulmonary diseases diagnosed and monitored. The usual control was made every 2 months (with the exception of spirometry which was performed at the beginning and after 6 and 12 months) and any time the patients or the general practitioner required. The study was carried out for 12 months.

The device was placed next to the patient's bed, not farther than 1m, with the exhalation window directed towards the patient level. The device operated for minimum 8-10 hours /day at the last level (12) and at the last but one level (9) of intensity, at least during the night; the door and the windows of the room were closed with the view to increase as much as possible the concentration of Na aerosols. Every 3-4 months the set of plates inside the device was changed!!!(inclusively to the placebo lot).

The observation period of 12 months enabled us to appreciate more accurate the recurrences, as both diseases, but especially asthma are known as having a significant fluctuating evolution ,

modulated by various factors: exposure to antigens, season, atmospheric pollution, vaccinal status, and so on.

Measured variables: the basal spirometric parameters (FEV₁, FVC), PEF, the number of recurrences, the demand for symptomatic medication, the indices of living quality.

A questionnaire for the clinic score estimation was used – the bronchial obstruction, the signs of rhinitis, - adapted from Elisabeth Juniper (Juniper E, O'Byrne P et al., 1999 și 2000). (table II).

Table II

(a) Frequency of nocturnal awakening (T)	(b) Symptoms intensity in the morning (M)
0 – never 1 – maximum 1- 2 /month 2 – maximum once a week 3 – several times/week 4 – continually	0 – absent 1 – very little 2 – little 3 – moderate 4 – severe enough 5 – severe 6 – very severe
(c) Limitation of the physical effort(E)	(d) Intensity and duration of dyspnoea (D)
0 – absent 1 – very little 2 – little 3 – moderate 4 – very limited 5 – extremely limited 6 – totally limited	0 – absent 1 – very small 2 – small 3 – moderate 4 – high enough 5 – high 6 – very high
(e) Wheezing duration (W)	(f) Demand from β_2 agonist(no. of puffs/day) (B2)
0 – absent 1 – almost absent 2 – a short period of time 3 – a moderate period of time 4 – a long period of time 5 – majoritatea timpului 6 – all the time	0 – absent 1 - puffs/day = 1-2 2 - puffs /day = 3-4 3 - puffs /day= 5-8 4 - puffs /day = 9-12 5 - puffs /zi = 13-16 6 - puffs /day > 16
(g) Sputum output (S)	(h) Allergic rhinitis or with an allergic component (R)
0 absent 1. intermittently present 2. permanently present: < 30 ml/zi 3. permanently present: 30 – 50 ml/zi 4. permanently present: > 50 ml/zi 5. frank suppurative feature	0 absent 1 Intermittently nose 2 Permanently 3 aqueous rinoree ± sneeze ± tears intermittently 4 aqueous rinoree ± sneeze ± tears, quasipermanently 5 smell absence + at least 2 elements from 1 to 4
(i) Pef score	(j) FEV ₁ score
0 > 95% of the one predicted 1 - 95-90% 2 - 89-90% 3 - 79-70% 4 - 69-60% 5 - 59-50% 6 < 50% of the one predicted.	0 > 95 % of the one predicted 1 - 95-90% 2 - 89-90% 3 - 79 –70% 4 - 69-60% 5 - 59-50% 6 - < 50% of the one predicted

To establish the scores and for classification in different stages during the first month , the clinical parameters were exclusively studied ,and during the last week of the first month, the specific anti-asthma/ bronchitis treatment was interrupted the clinical examination being doubled by the functional one, by associating the PEF- metry, PEF value was related .

These variables were analyzed in the beginning and the clinical-functional study was performed every 2 months, and was focused on the estimation of clinic scores, the demand for β_2 – agonists, the pulmonary function (PEF+ FEV₁), the annual recurrences.

The patients received the standard treatment according to the disease gravity,in case of asthma,and the conventional one in case of chronic bronchitis; including the vaccinations (anti-flu and anti-pneumococive),too.

Results

The procedure is well tolerated, only 3 patients mentioning the noise of the device; though slightly unpleasant, nobody renounced to the treatment. The device can be handled easily and is extremely cheap; the plates were replaced twice/year and the electric power consumption was insignificant.

Among the symptoms, noticed both at asthmatic patients and at those suffering from bronchitis, the cough was the more frequent: 74%, 84% respectively. The cough, predominant in the morning, was irritating at the asthmatic patients or often productive at the bronchitis patients. Nocturnal awakenings were more frequently met at the asthmatic patients (48%). Dyspnea was present at 61% and the wheezing and the effort limitation at 48% of the patients. The calculation of the average clinical score is more relevant than the symptoms frequency, corresponding better to the severity degree in accordance with the GINA classification.

By examining the dynamic of symptomatology in the lot with asthmatic patients, a significant improvement of the scores regarding the symptoms in the morning (figure 1), the nocturnal awakenings (figure 2) and of the symptomatology relating to the allergic rhinitis (figure 3) can be noticed: with reference to the lot of the patients with bronchitis, only the dypnoea showed a significant improvement (figure 4).

For the other scores the changes were not significant. As the score estimation at the moment T12 was only a snapshot, it seemed more appropriate to us to compare the scores in the beginning of the study with the medians of the intermediary scores, so that T12 in the respective figures represents the median line of the values T4-T12.

Bronchial asthma-Symptoms in the morning
Comparisons between the moments T0 and T12

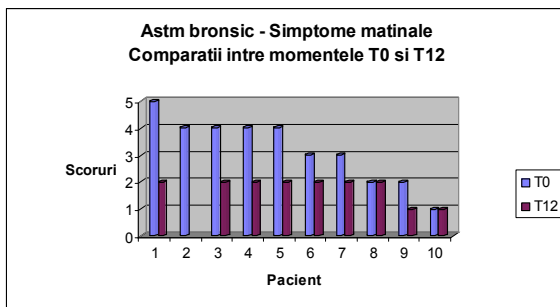


Figure 1

Bronchial asthma - Nocturnal awakenings
Comparisons between the moments T0 and T12

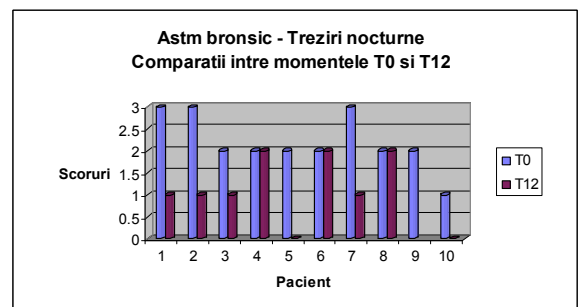


Figure 2

Bronchial asthma- Rhinitis(symptomatology)
Comparisons between the moments T0 and T12

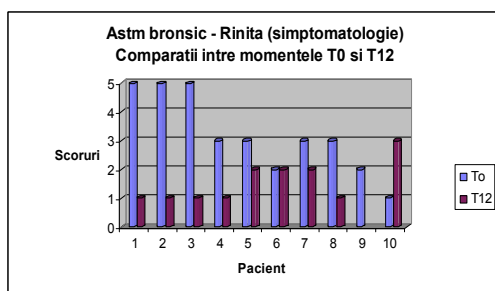


Figure 3

Bronchitis – dyspnea (intensity)
Comparisons between the moments T0 and T12

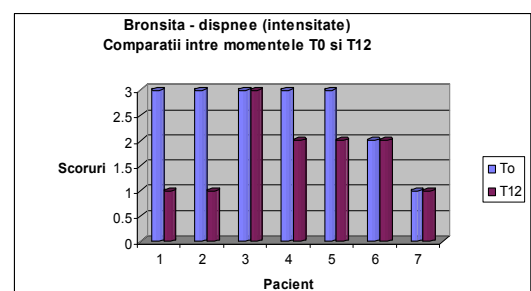


Figure 4

Thus, we applied the non-parametric test Wilcoxon (the rank sign) to each lot (both with asthma and bronchitis) and we obtained the following results (table 3 and 4):

Asthma	p-level	Significance
T*	0.0499	S
M*	0.0076	FS
E*	0.0277	S
W*	0.0431	S
D*	0.9	NS
B2*	0.2249	NS
R*	0.0499	S
global	< 0.001	ES

*T,M,E,... represent abbreviation of the symptoms in table I

Table 3

Bronchitis	p-level	Significance
M*	0.138	NS
E*	0.0678	NS
D*	0.0179	S
W*	0.9	NS
B2*	0.3613	NS
S*	0.1088	NS
global	< 0.001	ES

*T,M,E,... represent abbreviation...

Table 4

When we compared the scores of the study lots to the scores of the control lots with the one of the control one, we applied the non-parametric test Mann-Whitney, the following results being obtained (table 5 and 6).

Astm	p-level	Semnific.
T*	0.0067	FS
M*	0.3285	NS
E*	0.5098	NS
W*	0.6347	NS
D*	0.6569	NS
B2*	0.4082	NS
R*	0.2376	NS
global	0.0022	FS

*T,M,E,... represent abbreviations of the symptoms in table I

Table 6

Bronșită	p-level	Semnific.
M*	0.138	NS
E*	0.0678	NS
D*	0.0179	S
W*	0.9	NS
B2*	0.3613	NS
S*	0.1088	NS
global	< 0.001	ES

*T,M,E,... represent abbreviations of the symptoms

Table 5

The fact that the global estimation of all symptoms in those two lots (study and control) has a significance much different from the significances obtained per each symptom is due to the insufficient number of cases.

The examination of the pulmonary function both at asthma and bronchitis suffering patients has not indicated a significant improvement: the asthmatic patients showed a FEV₁ of : 74.54± 4.35% at T0 and 77,12±6,13%at T 12 m and the bronchitis suffering patients showed 76,18±12,14% at T0 and 74,45±4,67 at T12m . Considering the digit 2 as an acceptable number of recurrences/year, both for the lot with asthma and the lot with bronchitis, graphically underlined in the figures 5 and 6, we compared using Ztest of significance, the ratio of 4 out of 10 persons (asthma, Lot I of study)with 8 out of 9 persons (asthma, Lot II of control) and we obtained the value p=0.0414(significant differences)analogous, ratio 1 out of 7 patients(bronchitis, lot I of study) and 3 out of 4 patients

(bronchitis, lot II of control) and we obtained the values $p=0,0749$ (significant differences at the limit, having in view the small number of investigated subjects).

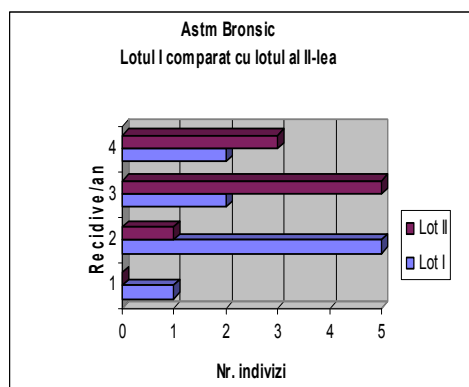


Figura 5

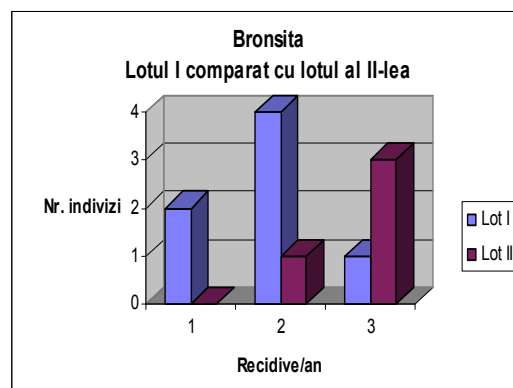


Figura 6

Answering to a simple questionnaire relating to the estimation of the living quality, the most patients (67%) alleged an improvement, 30% did not feel any improvement, and 1 patient (3%) claimed a worsening.

DISCUSSIONS

The salt and water transport across alveolar and distal airway epithelia is under elucidation, its alteration being involved in the generation of some severe diseases: cystic fibrosis, pseudoaldosteronism. The studies performed at molecular and cellular level, as well as on animals demonstrated that the fluid reabsorption from the distal airways of the lung is a phenomenon directed by the active transport of sodium. Several studies in-vivo, in-situ or on an isolated lung identified catecholamine dependent mechanisms, as well as other independent mechanisms which modulate the fluid transport by activating the Na, K-ATPase or by increasing the apical up-take due to the opening of "some channels for water" also called aquaporins, of 30kDa). (Matthay M Folkesson H., - 1996). Therefore, the interventions intended to modify the osmolarity of the pericilliary bronchial fluid can have significant consequences on local homeostasis and pulmonary function.

Anderson SD, Spring J (1997) in a rigorous study, compared the effect of wet aerosol of NaCl 4.5% with the effect of the aerosol inhalation as a dry powder, in variable quantities (5,10,20 or 40 mg). The results were overlapped and reproducible, concluding that the dry powder can replace the wet aerosols of NaCl (solution) in the tests made to provoke or estimate the bronchial hyperreactivity. The penetrability could be first determined by the magnitude of the bronchial constriction at the time of inhalation (Laube B, Swift D - 1986) and, further, by the aerosol tonicity (Phipps P, Gonda - 1994), as the hypotonic solutions penetrate deeper.

Numerous studies attested the idea that the hypertonic aerosols (4.5%) of NaCl cause bronchial hyperreactivity, reason why these are used in clinic for the provoking tests, next to histamine, methacholine, according to some having higher specificity and predicting value than the first ones. But, the isotonic aerosols have not noxious effects.

However, the non-isotonic concentrations of non-isotonic aerosols, either hypo- or hyper-, as these modify the osmolarity of bronchial pericilliary fluid, can induce a crisis of bronchial spasms (Basir R - 1995, Smith C 1987); there are evidences that the modification of the osmolarity of the fluid in the airways causes a release of some mediators from the bronchial inflammatory cells.

On the other hand, speleotherapy offers a natural example of a beneficial impact on most of the chronic pulmonary disease. The speleotherapy implies the using of the underground environment (

especially of the salt mines) in the treatment of the chronic obstructive pulmonary diseases. Little known in U.S.A. and U.K., this procedure is largely used in central and Eastern Europe. However, in the Western Europe authors, like Sadaul P (1981) mention it as having beneficial effects to over 90% of asthmatic persons who resorted to this therapeutical alternative, too. Chernova O, Matiushina S (1996) showed the capacity of speleotherapy in salt mines to diminish the microbial contamination of the upper air ways (especially with staphylococcus), for children with respiratory allergy. The bactericide capacity could be explained by the complex immunomodulating effects this procedure induces: the increase of the number and the activation of T lymphocytes, the normalization of the number of B-lymphocytes, the increase of the IgA level (Simionka I, Chonka I – 1989). Abdullaev A and Gadzhiev K (1993) demonstrated the efficiency of speleotherapy in diminishing the obstructive symptom on 216 children with atopic asthma. Further, Gorbenko P și Adamova I (1996) on 18 patients with bronchial asthma, attested the effect of bronchial hyperactivity lowering after the exposure to halotherapy. In the same period, Borisenko L și Chervinskaia (1995), specified a concentration of NaCl ions between 1 – 5mg /m³ spread in the air as dry powder as having a therapeutical value.

Given these considerations the method proposed by us is thought as **an artificial micro-speleotherapy**.

We achieved a continuous air ionization with dry powder of NaCl, which we supposed spread for 8-12 hours in a large environment, as a room could be, that would never get to a hypertonic concentration, on a contrary.

However, there is a limit as we do not know the quantity of ions delivered per minute in the environment and /or the concentration/m³.

In the future, the possibility to quantify these ions would offer the certitude that concentrations of non-istonic aerosols are avoided.

Only one patient, an asthmatic subject, claimed a worsening of the general condition after the air was ionized with Salin ; we do not know if that was just a subjective impression or a rise of an atmospheric concentration of the Na which increases HRB, as he refused the test of bronchial provoking with methacholine.

Though the pulmonary function does not appear modified, the improvement of symptoms like the sensation of humid neck with claims of impurities / stagnant secretions on pharynx-traehea(the increase of nasal permeability), sometimes with the snoring elimination, a reduced coughing , a lowering of sputum volume and a easiness to remove it, the smell improvement (2/5) gave the patients more quiet nights with an attenuated symtomatology in the morning, with more seldom and less discomfortable rhinitis phenomena, all these being reflected in the improvement of the living quality.

CONCLUSIONS

As an adjuvant treatment, the forced ionization of in-door air, though it does not improve significantly the pulmonary function, improves, however the quality of the patients' life and reduces the rate of annual hospitalizations. It is worth being mentioned the method advantages: has no risk, is cheap and adapted to the living space.

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FORCED IONIZATION OF THE INDOOR AIR - AN ADDITIONAL METHOD IN THE TREATMENT OF THE RESPIRATORY DISEASE IN CYSTIC FIBROSIS

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PREMISE OF THE PAPER

- The respiratory disease from CF is the main factor, which influence the prognosis.
- Setting up of an well-organized therapeutic plan appropriate to the patient's age and clinical state, is the only chance for ameliorating the prognosis of these patients.
- The daily home therapy with mucolytic substances in aerosols represents one of the compulsory steps of the treatment. RH-DNAse is the best option for this point of view.
- Unfortunately, in the countries with a low economical standard as Romania, there is a very low possibility to have access to the rh-DNAse treatment because of the very high costs.
- The concentrated NaCl solutions in aerosols as well as the courses of treatment performed in regions rich in Na ions (saline, seaside) have been beneficial for as an adjuvant in the treatment of CF.
- Starting from the favorable effect of the NaCl treatment, "*Tehno Bionic*" - Buzau, Romania planned and built the "Salin" device for the forced ionization of the indoor air.
- Principle of the method: *forced passing of the air through microcrystal salt deposit plates*. This procedure leads to changes of the air composition and quality by salt sublimation.

AIM OF THE PAPER

- *The aim of this paper is to check the therapy's efficiency upon the patients with CF and chronic respiratory disease by forced ionization of the indoor air.*

MATERIAL AND METHODS

- This study has been realized within a 6 months interval on two lots of CF children and teenagers followed up by the Centre of CF from Timisoara (Fig. 1).

Lot I

- ◆ 10 patients (4 male and 6 female) with their age between 3 and 16 years (1verage 10.3 years) where we applied forced ionization of the indoor air (living room, bedroom).

Lot II (control lot)

- ◆ 8 patients (3 male and 5 female) with their age between 5 and 17 years (average 10.3 years) where the device worked without the salt plates.

- The device worked approximately 8-10 hours/day, at 9V voltage.
- All patients followed the appropriate treatment during this period.
- The studied parameters:
 - The genera clinical state of the patient by subjective self-appreciation at the young people, respectively the parents' appreciation at the younger children;
 - Clinical examination of the respiratory system;
 - FEV 1 value at older children
- The selection criteria for both lots have been (Fig. 2):
 - Patients that have been seriously affected by the disease (3 from lot I, 2 from lot II);
 - Infection with Ps.ae. and/or Staphylococcus aureus
 - Bronchiectasis
 - FEV 1 < 50%

- Patients with a favorable or mild clinical state (7 from lot I, 6 from lot II);
 - Without associated infection
 - FEV 1 > 50-60%

Fig. 1 The age of patients

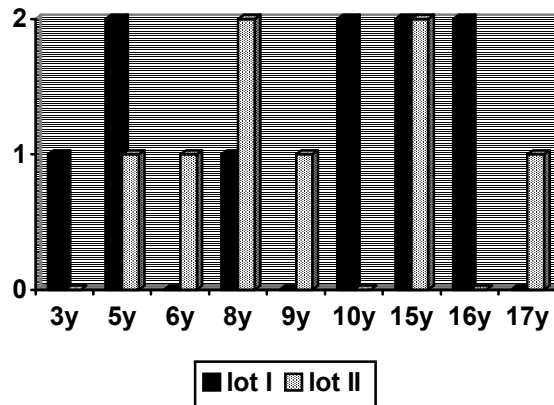
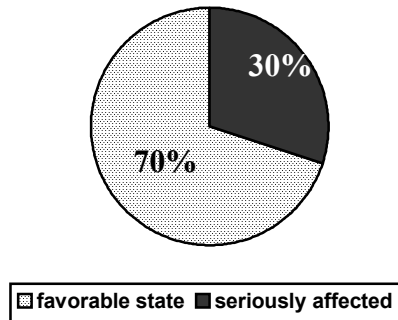


Fig. 2 Clinical status of patients



⊗ In lot I we noticed:

- ⇒ A significant improvement of the clinical state
- The subjective estimation "for better" seen by the patients, respectively by the parents especially in those that have been more seriously affected;
- Improvement of the objective symptoms of the disease:
 - Increase of the sputum elimination within a first stage followed by a significant reducing of its quantity
 - Improvement of the respiratory functional syndrome
 - Reducing of the crackles at auscultation
 - FEV1 Improvement (Fig.3)
- ⇒ From the therapy beginning no patient showed other acute episodes of the respiratory disease that should require another hospitalization.

⊗ In lot II there were no changes similar to those from lot I (Fig. 4)

Fig. 3 Lot I (values of FEV1, before and after treatment)

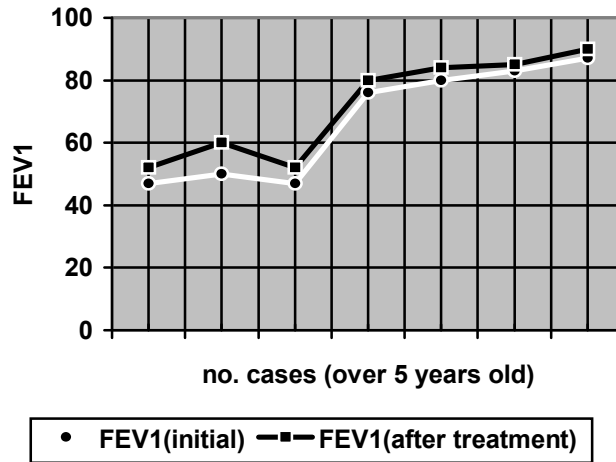
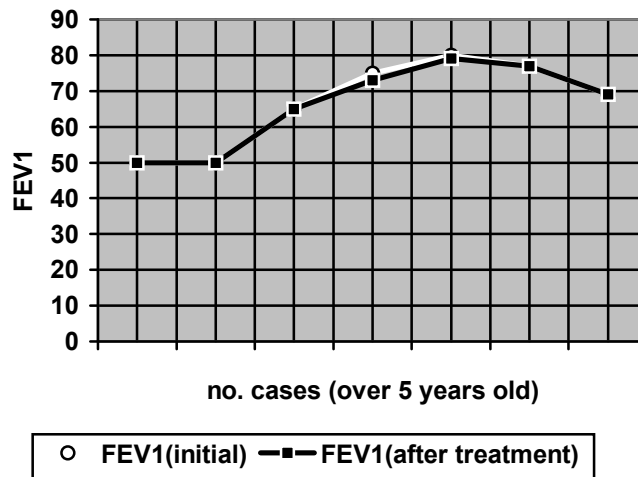


Fig.4 Lot II (Values of FEV1, before and after treatment)



CONCLUSIONS

- ↪ Forced ionization of the indoor air by salt sublimation represents an efficient method of the respiratory disease treatment in CF.
- ↪ The method is an adjuvant, it does not exclude classical therapy.
- ↪ It is a natural method of therapy adapted to the living space and it does not involve any risk
- ↪ It is a quite cheap method of therapy.

SALIN DEVICE – HELPS IN PREVENTING AND TREATING OTITIS MEDIA IN CHILDREN

By: Dr. Zabos Dorinela, ENT specialist
Chem. Constantin Pascu – chemist, Tehno Bionic Buzau

Besides other natural remedies that aim at improving the quality of life, Salin brings back the old concept that every salt mine is a house of health.

The method consists in: forced passing of the air through plates with sediment layers of microcrystallized sodium, calcium and magnesium salts, having an air ionization effect, reducing the carbon dioxide, reducing the bacteria content, smoke and odors indoor and helps increase the fluidity of the airways secretions through quality modifications of the mucus.

The high morbidity rate due to nonsuppurative otic pathology in children, knowing that 80% of infants up to 3-4 years old had at least once an ear inflammation with consequences like impaired hearing due to chronic otitis, made us initiate a study on an alternative and complementary method for preventing and curing nonsuppurative otitis (seromucous acute and chronic otitis media).

Materials and Method:

The clinical and paraclinical introspective and retrospective study (otoscopy, audioimpedantmetry, allergic tests) of a lot of patients with nonsuppurative acute or chronic otic pathology registered in the outpatient's ENT consulting room of the 'Spitalul clinic de Urgenta nr. 3 de copii Louis Turcanu' in Timisoara City, Romania (Louis Turcanu, # 3 Clinic Emergency Hospital for Children)

The lot parameters are as following:

Lot	63 patients
Gender	29 boys
	34 girls
Age	between 1 and 18
Average age	6.9

The study goal is to compare the lot of 63 patients with otic pathology between 01/01/2000 and 31/12/2000, without Salin device (1st LOT) with the same lot using the Salin device between 10/01/2001 and 31/01/2002.

The target of the study is to asses the contribution of Salin device in helping the amelioration and treatment of the respiratory and ear disease and prevention of reoccurrence of nonsuppurative otitis.

The parameters studied are:

- Monthly monitoring of the general clinical state of the patient along with the respiratory and ear symptoms, using a questionnaire filled up by the patient and/or parent
- Otomicroscopy- monthly and during periods when symptoms were more acute
- Audioimpedantmetry - monthly and during periods when symptoms were more acute
- Allergic tests for some patients

Salin device for the 2nd LOT was supplementary introduced along with the appropriate medical or surgical treatment

In the study lot ,the otic pathology was prevalent and the comorbidities were:

- Adenoiditis / chronic adeno-tonsillitis, 21 cases (33%)
- Rhinitis / chronic rhino- sinusitis in 17 cases (27%)
- Bronchial asthma in 5 cases (8%)
- Atopic dermatitis in 2 cases (3%)

Salin device was put to work on an average of 10 hours a day, at a 9 V voltage.
All patients followed the regular medical or surgical therapy suitable for each case.

RESULTS AND COMMENTS

1st LOT – without Salin device

The respiratory symptoms (sneeze, rhinorrhea, nasal obstruction, cough, otalgia, hearing impairment, fever) were present in moderate or severe form in 49 cases (77%) as isolated or associated symptoms.

At otomicroscopy the tympanic modifications were obvious in Valsalva test in 58 cases (92%)

Audioimpedantmetry showed tympanograms type B(73%) and type C (27%)

The allergic tests were positive in 5 cases with asthma and in 3 cases with chronic rinitis.

2nd LOT – with Salin device

- Respiratory and otic symptoms were present in severe or moderate form in 28 patients (44%)
- Otomicroscopy showed tympanic modifications in 41 cases (65%)
- Audioimpedantmetry showed tympanograms type B (24%), type C (53%) and type A (23%). Tympanograms B signals the absence of the air in the middle ear and the possible presence of the fluid in the middle ear; tympanograms C signals the partial absorption of the air from the middle ear and its gradual replacement with transsudate or exsudate. Tympanograms A shows the presence of the air in the middle ear and normal mobility of the tympano-ossicular system. Tympanograms B and C were associated with slight or moderate hearing impairment.
- The allergic tests were positive in 5 cases of asthma.
- The reoccurrence of otitis diminished to 1 outburst a year comparing to 2 outbursts a year for the 1st LOT

CONCLUSIONS:

1. Alleviation of clinic severe and medium symptoms for 33% of the patients along with improvement of respiratory quality and intellectual and physical effort, are clinical arguments that cannot be neglected giving Salin a well-deserved place in medical treatments.
2. Salin helps diminishing macroscopic modifications of the tympanum in 27% of the patients, thus justifying alleviation of otitis clinic symptoms like (otalgia, autophony, decreased hearing)
3. audioimpedantmetry, the best diagnostic method of nonsuppurative middle ear pathology (without perforation), shows the changes from pathology (24% compare to 73% tympanograms type B, 27% compare to 53% timpanograms C) to normal (from 0% to 23 % of Timpanograms A); all these facts show an improvement in tubo-tympanic drainage.
4. Better draining of the tubo-tympanum and airing of the tympanic cavity can happen due to modifications of the quality and / or quantity of the mucus as well as due to the favorable effects of the aeroions on the mobility of the respiratory membrane cilia.
5. Besides symptomatic drugs, antibiotics, vitamins and immune-modulators, antialergic, Salin device has been introduced in the therapy protocols in treating rhino-sinuses pathology and acute and chronic otic pathology. The benefits of Salin are evident, since for 50% of the patients there was a reduction of the antibiotics intake and in asthma cases a reduction of corticoids intake.

6. Salin is a beneficial adjuvant, however without excluding the classic therapy, therefore the patients should be under medical observation.
7. In order to strengthen the therapy in bronchial asthma and in nonsuppurative allergic or nonallergic chronic otic pathology, the patient need to undergo 1 or 2 treatments a year in the salt mines becomes costly considering the travel and other afferent expenses. From this point of view, Salin is becoming a cost effective option.
8. The possibility to use the Salin device in the living space strengthens the therapeutic effect of the treatments in the salt mines.
9. The quantity of otic sero-mucous secretion in the first days after tympanotomy significantly decreased and the tympanum reconstruction duration has reduced from 5-7 days to 4.

Clinical trial on 22 cases of allergic rhinopathy, following the exposure to the microclimate made by the "SALIN" device

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The "SALIN" device offers, beside the known treatments, a new method in the therapy of chronic inflammatory diseases, of the respiratory system.

The Na ion is recognized, both in the reference material and by most of the clinicians, as the main cellular membrane stabilizer of the respiratory epithelium. In the presence of Na ion, it can be noticed an increase in the volume of lung surface liquids. Also the ciliary motility is activated, even in chronic smokers, whose ciliary movement is impaired, inducing a fast clearance of the respiratory secretions.

The Na ion causes the lowering of oropharyngeal airway edema soft palate, posterior portion of the tongue, often met in chronic snoring.

The inflammatory edema that causes sinus ostial obstruction also decreases, leading to the sinus drainage.

These findings are the basis of clinical directions of aerosoltherapy and balneotherapy in different chronic respiratory disease. The "SALIN" device tries to achieve an atmosphere resembling to the atmosphere of the salt mines sanatoriums.

Having at our disposal 22 "SALIN" devices, we recommended a minimum 3 hours a day exposure (on an average of 6 hours) for 3 months to 22 patients with chronic allergic rhinopathy. All these patients were polyallergic but the house dust was met as an incriminated allergen in all of them, without other prevalent diseases.

Their age was between 22 and 53 years old, 15 women and 7 men.

The exposure was made without giving up the antiallergic treatment prescribed by their physicians.

The following signs and symptoms were noticed:

- nasal obstruction
- headache
- rhinorrhea
- sneezing
- cough
- dry throat sensation
- the quality of night sleep
- the quality of sputum

In 13 patients from those previously mentioned, we also examined:

- the edema of uvula
- aelangiectasias of the posterior portion of the tongue
- the aspect of pituitary gland

Results and discussions

We noticed that women are more conscientious in following the treatment.

The quality of sleep was evidently improved in all the studied patients by night exposure to "SALIN".

The nasal obstruction and sneezing were evidently improved in 18 patients representing 81.8 %.

Seromucous rhinorrhea got thicker and more voluminous, in only one case rhinorrhea remained.

Headache as a syndrome was noticed initially in 12 of patients. For half of them the exposure had a favorable result.

Cough was, in general more efficient and wet, the effort for removing the sputum decreased and the sputum got more fluid. The benefit effect was immediately noticed at 7 patients, chronic smokers.

The dry throat sensation was diminished in a better or smaller degree at all the patients.

At the clinic exam of the 13 cases mentioned forward, we noticed the lowering of the edema soft palate after maximum 10 days.

Conclusions

1. The Salin device brings back in present the Na ion as the main cellular stabilizer of the respiratory epithelium.
2. The Salin device represents a convenient alternative of marine aerosolstherapy or halotherapy of the saline sanatoriums.
3. The Salin device represents a useful help in the treatment of chronic affections of the superior respiratory ways as:
 - allergic rhinopaties
 - chronic sinusitis
 - chronic rhinitis.