

Results of application of the TDI-01 individual respiration device by patients sustaining bronchial asthma of medium seriousness course (stage 3 in the unstable remission phase (remitting exacerbation)).

The work has been performed at the Moscow Medical Institute for Stomatology at the Department for internal diseases NO.3 (Head of the Department – academician of the Russian Academy of Medical Sciences, Professor, PhD in medical sciences Y.I. Sokolov).

Performers: PhD in medical sciences, Prof. M.V. Baluda; Candidate of medical sciences, an assistant J.I. Demidov; Candidate of Medical Sciences, an assistant V.V. Serov; Head of biochemistry laboratory for scientific problems, Candidate of medical sciences A.S. Razin

Moscow, 1998

The purpose of the study at hand was to explore the impact of the TDI-01 individual respiration device on respiratory system in the course of complex therapy of bronchial asthmatic patients.

To achieve the said target the following tasks were defined:

1. To compare the efficiency of the conventional therapy and a complex approach, consisting of the TDI-01 respiration device application in combination with medicamentous treatment of bronchial asthmatic patients.
2. To estimate the influence of hypercapnic conditioning by application of the TDI-01 device on the clinical manifestations of bronchial asthma, pulmonary ventilation condition, gas exchange and lipid peroxide oxidation processes.
3. To test the recommended mode of application of the Frolov's individual respiration device in a complex therapy of bronchial asthma of medium seriousness course (stage 3) in the unstable remission phase (remitting exacerbation).

In coping with the defined tasks 20 bronchial asthmatic patients were examined. 12 patients (6 males and 6 females) formed the main group of the examined, their average age being 43,9, 11 patients had exogenous bronchial asthma of medium seriousness course - 3 and 1 of the observed suffered from the endogenous form of asthma (the aspirin variant) with elements of atopia towards epidermal, pollen antigens (stage 3).

8 of the patients formed the control group, who by the basic selection parameters (diagnosis of the disease, form, stage, age and sex) did not differ from those of the main group. The difference was that the main group patients worked under the health improvement correction technique using hypercapnic respiration exercises through the TDI-01 apparatus.

The patients were examined at the hospital (SPGMIM) on the 10th – 12th day of their admittance to the pulmonology department, after the acute manifestations of bronchial asthma had been eliminated and after a short course of systemic glyocorticoids application and parenteral sympathomimetics and xantine derivatives introduction had been completed. Thus, the patients at the time of our initial examination and the beginning of the respiration device TDI-01 application in the main group were in the unsteady remission stage, which called forth continuation of the inhalation glyocorticoids intake by all the patients (prevalently in hacort of 1 500 mcg daily dose), together with bronchi dilators of short-term effect (berotec, ventolin 600 - 800 mcg of daily dose) and prolonged theophyllines (teopec 0,3 twice a day).

To study the respiratory system condition special instrumental methods of examination under application of the apparatuses "Transferscreen-2" and "Bodyscreen-2" of "Erich Jaeger"'s manufacture (Germany). These included: spirometry, pneumotachicometry, bodyplethysmography and carbonic oxide transfer factor determination (lung diffusion capacity) in the regimen of stable condition. We ascribed to the special laboratory methods the analysis of condition of the system "lipoid peroxide oxidation – antioxidant shield", with calculation of content of secondary products of lipoid free radical oxidation (malonic dialdehyde) in erythrocytes (MDA er) and in plasma (MDA pl) (method by M.S. Gonchyarenko, 1985), and calculation of the ratio AOA – the sum of MDA er and MDA pl to estimate the functional anti-oxidation supply of the body (FAS). Statistic processing of the results was done in accord with non-parametric criteria by Wilcoxon and variation statistics with the Student's t-criterion use.

Allowing for a considerable importance of psychological conditioning of bronchial asthmatic patients, as well as for the need of their active involvement into the curative process with therapeutic purposes, we had preliminary conducted elucidating conversations with every patient.

According to the directions the main group patients in 10-12 days' time under our supervision gained at approx. 20 seconds of the respiratory act duration (RAD) and the fluid (physiological solution) volume used to obtain an additional resistance to inspiration and expiration came to 20 ml. The average duration of the training sessions amounted to 20 minutes twice a day.

Estimation as to the initial condition of respiratory system in the main and the control group we conducted at the remitting exacerbation phase of the primary disease (on the 10-12th day of the patients' admittance to the hospital), since that time the main group's patients were subjected, along with pathogenetic and symptomatic therapy, to the sanative and health improvement program with the TDI-01 device application during the following 10 - 12 days of their stay at the hospital. The control group patients were undergoing a conventional treatment, which included introduction through inhalation of sympathomimetics, glucocorticoids and prolonged theophyllines' intake. On the 24-25 day of the patients' staying at the hospital they were transferred to be treated at an ambulatory clinic, the main group's patients continuing to use the TDI-01 simulator. One month after the patients had been let out of the hospital we conducted a repeated estimation as to the condition of the respiratory system by patients of the 2 analyzed groups.

At the initial functional examination of respiratory system patients of the main and the control groups revealed a moderate disturbance of ventilation of the obstructive type with structural shifts of total lung capacity (TLC), which was accompanied by residual volume (RV) increase (excessive inflation), which accounted for meaningful ventilation and perfusion lack of correspondence, manifested by a true lowering of CO transfer factor in a stable condition (Tf CO st(able)). At the initial examination the main and the control group patients revealed no statistically valuable differences between speed, volumetrical indicants and gas exchange values (see Table No.1).

After 1 months' time we could state a reliable positive dynamics of speed indicants on the computer analysis of the "flow-volume" coil, elimination of pulmonary hyperinflation (RV-residual volume) reached the normal and conditionally normal values $117,2 \pm 7,1\%$ (Table No.1). The mentioned favorable changes in pulmonary ventilation accounted for statistically meaningful positive dynamics of gas exchange in the lungs, which was manifested in Tf CO st rise, the latter being an evidence of ventilation and blood flow ratio improvement in various portions of the lungs.

Adversely, in the control group ventilation and gas exchange indicants did not reveal significant positive changes in the background of conventional therapy, continuing to stay at the level of moderate/considerable deviations from the norm.

In the main group positive changes in the external respiration function combined with positive clinical data, characterized by the following: lowering of dyspnea frequency within 24 hours,

sleep bettering (less frequent asthmatic fits), tolerance to physical load heightening, increase in subjective dyspnea perception threshold (2 of the patients did repeated and successful attempts to cut off labored breathing through the TDI-01 device). The aforesaid clinical changes and positive dynamics of functional indicants enabled us, upon a repeated address of the patients, to reduce the inhalation glyocorticoids dosages from 1 500 mcg to 1 000 mcg, individually reducing the number of sympathomimetics intake times.

In the control group clinical data and external respiration function values had not revealed positive changes whatever, in which regard the patients were recommended for the following 2 months to retain a basic pathogenetic and symptomatic therapy, its extent remaining the same. In studying the system "peroxide lipid oxidation of – anti-oxidation shield", we had initially stated the oxidation stress condition in the main and in the control group, which was manifested by a substantial rise of secondary lipo-peroxidation products level, especially MDAer, which was a sign of considerable destructive alterations' depth in biological cellular membranes in blood plasma, staying within normal values in both groups, nevertheless, under the conditions of such a considerable growth of the free radical oxidation the functional anti-oxidation supply of the body went down abruptly (см. таблицу N2) (see Table No.2).

Against the background of the treatment performed by the main group patients a statistically meaningful reduction of secondary lipid peroxide oxidation products was noted, which resulted in increase of the indicant of the functional anti-oxidation supply of the body (FAS). In the control group we noted positive changes in the system peroxide lipid oxidation – anti-oxidation shield, but the latter were not of statistical significance. It is worthy of note upon 1 month's time after being let out of the hospital both in the main and the control group there remained, nevertheless, a considerable tension in the analyzed homeostatic system, since both the indicant MDAer and the FAS value did not get at normal values, anti-oxidation supply of the body in the main group being reliably higher than in the control one, though.

The results thus obtained enable to draw a preliminary conclusion as to positive impact of breathing through the TDI-01 on respiratory system of patients sustaining bronchial asthma of medium seriousness course at the remitting exacerbation phase, sanative and health improvement, as well as rehabilitation effect of which being as follows:

1. Bronchial permeability improvement and reduction of an increased inflation of lungs, which is presumably accounted for by positive pressure at exhalation, provided by the TDI-01 device, preventing the expiratory collapse of minor respiratory tracts and reducing the pronouncedness of trachea-bronchial discinesia;
2. Restoration of disturbed ventilation and perfusion relations and gas exchange optimization;
3. Anti-inflammatory functioning, realized through the free radical lipid oxidation reduction as a result of the TDI-01 device's hypercapnic effect, thus calling forth the increase in respiratory tracts' hyper-activity and speeding up the clinical remission achievement.

Discovering of other mechanisms of the TDI-01 device's impact on the respiratory system of bronchial asthmatic patients, as well as confirming of data presented here, requires further profound research, with the inclusion of dynamic peak-flow-metering, determining the respiratory tracts' reactivity in view of the Frolov's respiration device application and of the analysis of the organism's homeostatic systems' complex (including the proteases-inhibitory balance). We consider the TDI-01 device application in treating bronchial asthma to be quite prospective, particularly if the latter is combined with hyperventilation syndrome, as well as by patients suffering from chronic obstructive bronchitis and pulmonary emphysema.

Table No.1

The external respiration function indicants' dynamics by bronchial asthmatic patients (stage No.3) in relation to a treatment program.

Indicants	The main group (12 patients)			The control group (8 patients)		
	Initially	After the course of treatment		Initially	After the course of treatment	
VC	87,3±3,3%	100,0±4,6%*	s	85,7±5,2%	79,2±4,4%	Ns
RV	151,4±6,8%	117,2±7,1%*	s	147,6±3,8%	151,6±4,8%	Ns
TLC	107,7±8,1%	105,2±7,6%*	ns	99,9±9,6%	96,7±8,6%	Ns
FEV 1	66,8±4,2%	87,8±3,3%*	s	66,0±5,9%	62,8±4,2%	Ns
MVS 75	50,6±4,6%	74,6±2,6%*	s	51,7±2,8%	46,7±5,2%	Ns
MVS 50	41,1±3,9%	65,3±2,9%*	s	38,0±2,7%	32,2±4,6%	Ns
MVS 25	39,2±4,3%	63,6±3,3%*	s	40,8±3,6%	35,0±6,3%	Ns
Tf st	64,1±3,6%	77,1±3,1%*	s	66,6±5,1%	63,3±4,2%	Ns

FEV – forced expiration volume

MVS – maximum volumetrical speed

VC – vital capacity

RV – residual volume

Tf st – transfer factor stable

TLC – total lung capacity

Table N2

Dynamics of indicants of the system "peroxide lipid oxidation – anti-oxidation shield" by bronchial asthmatic patients as related to a treatment program.

Indicants	The main group (12 persons)			The control group (8 persons)		
	Initially	After the treatment course		Initially	After the treatment course	
MDA er	0,129±0,006	0,116±0,004	s	0,124±0,005	0,112±0,007	ns
MDA pl	0,067±0,008	0,044±0,005	s	0,062±0,007	0,048±0,009	ns
AOA	43,0±2,9	49,4±4,5	ns	46,6±4,5	45,1±3,9	ns
FAS	242,6±13,6	306,1±11,9*	s	254,2±11,4	280,9±12,8	ns

s – Dynamics in view of the therapy is statistically meaningful

ns – Dynamics in view of the therapy is statistically insignificant

* - differences with the control group of statistical importance