

Active Air Inhalation and COPD

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Introduction.

COPD (chronic obstructive pulmonary disease) is a chronic disease with significant progressive course of the disease resulting in reduction of pulmonary functions and leading to emphysema and cardiovascular complications.

Prevalence of COPD is 8-10% with relative high mortality (around 25% for male patients, around 14% for female patients). The therapy of the disease is very complex, should be continuous, though worsening the patients' quality of life.

The aim of the study was to proof the possibility of activated air inhalation as a supplemental therapeutic method to existing treatment with inhalation of Beta2-mimetics with ipratropiumbromide.

Methodology and material.

Placebo controlled study started March 2008 and ended March 2010.

For study, there were two groups of patients, each of 12 patients, only males.

Group 1:12 patients, age from 49 to 67 years, average $58,08 \pm 5,08$. The disease lasting from 4 to 10 years, average $7,42 \pm 1,58$. Spirometry (by GOLD) from degree 2 to 4, average $2,58 \pm 0,58$. 4 of them were smokers, 8 non smokers.

This group was with regular Active Air® inhalation of 20 minutes duration (modus AE 5/5),twice daily. The inhaler was given to the patients home.

Group 2 (placebo): 12 patients, age from 49 to 66 years, average $57,45 \pm 5,77$. The disease lasting from 5 to 11 years,

average $7,18 \pm 1,32$. Spirometry by GOLD from degree 2 to 3, average $2,5 \pm 0,5$. 4 of them were smokers, 8 of them non smokers.

For this group, the Active Air was artificially modified: it was made a shunt, so, the inhalation was running as with activated air but the patient did not know that he is inhaling normal air without passing through inhalation tube (not activated air). The way of use was the same, it means twice daily inhalation, the Active Air inhaler was set up to modus AE 5/5, 20 minutes.

Both groups were inhaling home twice daily, the period of therapy was 24 weeks (6 months). For estimation of inhalation results were used spirometry parameters FEV1/FVC % and FEV1 %, measured every begin and end of inhalation therapy.

For spirometry was used spirometer SPIROLAB II, produced by MIR Medical International Research S.r.l., via del Maggiolino, 125,00155 Roma, ITALY .

Statistical significance was provided by criteria of Chi-test and Student t-test.

Results and discussion.

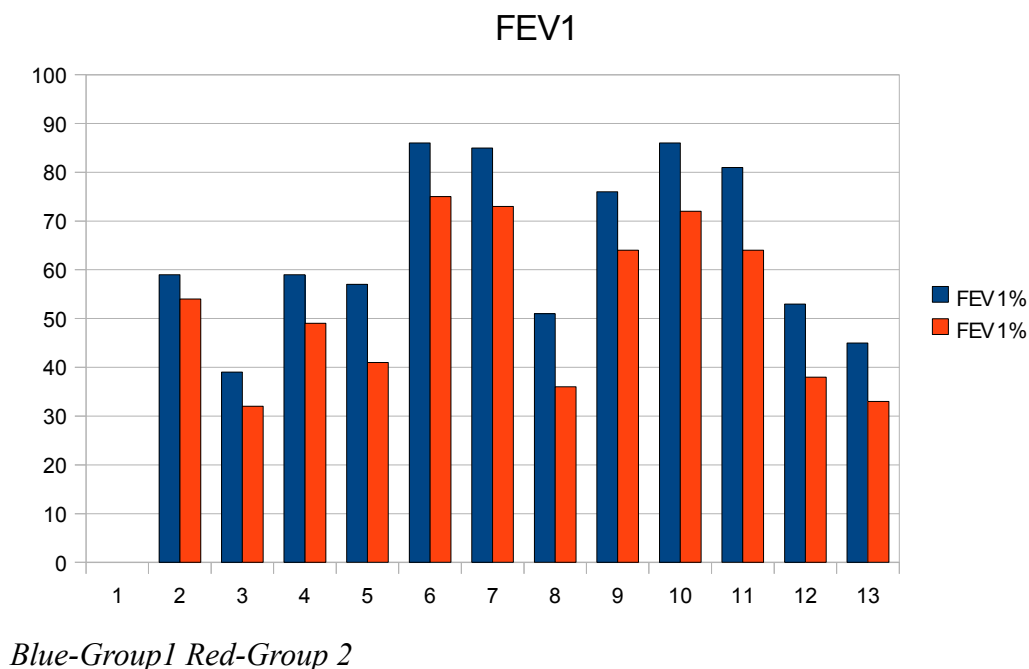
Inhalation of activated air significantly improved spirometry parameters. The inhalation was realized home twice daily in duration of 20 minutes with modus AE 5/5 with use of Active Air® inhaler by both groups of patients. The inhalation lasts 6 months (24 weeks, respectively 23 weeks).

The improvement was statistically significant in both monitored parameters: FEV1/FVC% and FEV1%. This

improvement was followed with subjective improvement of dyspnea and expectoration and with reduce of inhalations frequency.

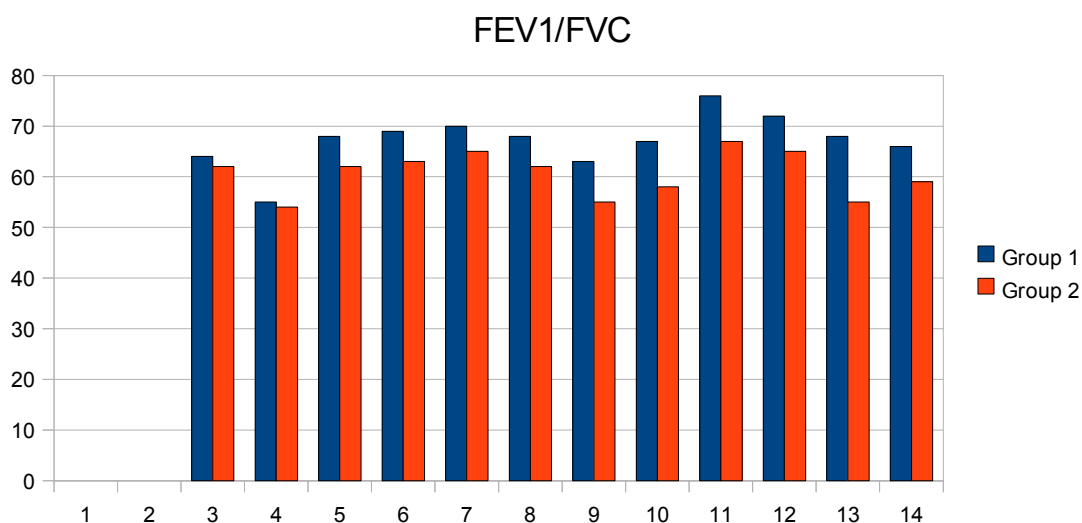
The results are shown in following tables.

Table 1:



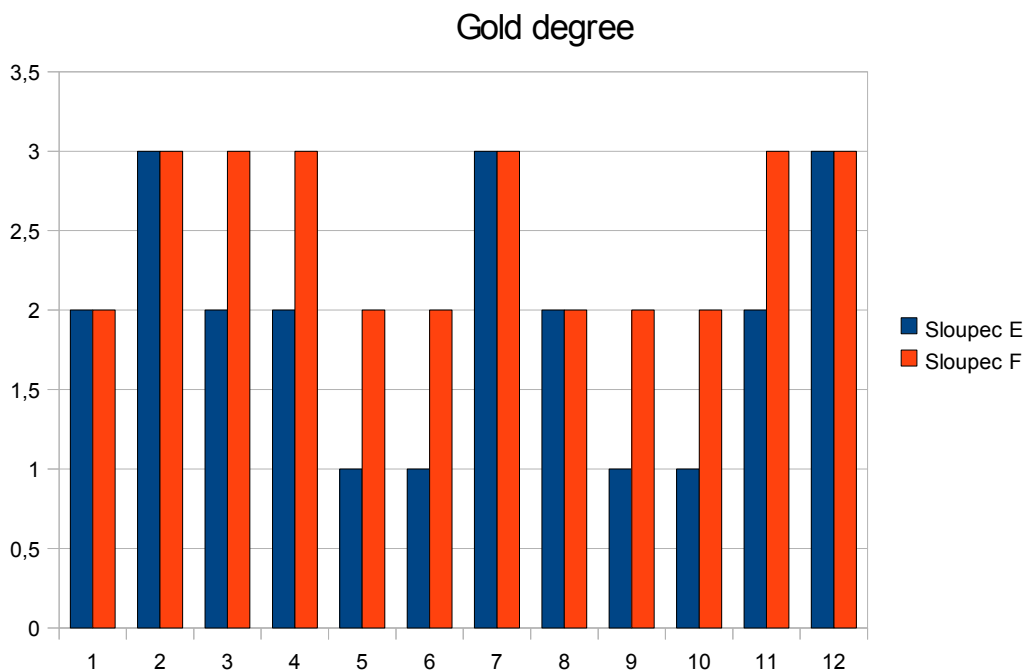
FEV1% results after 6 months inhalation. Significantly improved this spirometry parameter in Group 1 (blue columns) in comparison with Group 2 (placebo-red columns). Statistical significance $p < 0,09$.

Table 2:



FEV1/FVC% results after 6 months inhalation. Significantly improved this spirometry parameter in Group 1 (blue columns) in comparison with Group 2 (placebo-red columns). Statistical significance $p < 0,001$.

Table 3:



Gold degree of classification of disease severity (1=light degree, 2=moderate degree, 3=severe degree, 4=very severe degree). Significant improvement in Group 1 (blue columns) in comparison with Group 2 (placebo-red columns).

Statistical significance $p < 0,04$.

The study results approved the possibility of treatment of patients suffering from COPD with help of activated air inhalations. It is necessary to submit, that the number of studied patients is too small for better validity of this study. However, the inhalation of activated air could become one of possibilities to extend therapeutic spectrum of COPD treatment.

The study with statistically higher number of patients is required.

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