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QUALITY OF LIFE, FORCED EXPIRATORY VOLUME IN ONE SECOND AND BODY MASS INDEX IN PATIENTS WITH COPD, DURING THERAPY FOR CONTROLLING THE DISEASE

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Abstract: Patients with chronic obstructive pulmonary disease (COPD) are characterized by an impaired lung function and limited exercise tolerance. Medication and rehabilitation programmes are generally directed towards relief of symptoms and improvement of lung function and exercise tolerance.

130 patients were included in the examination with diagnosed chronic obstructtive pulmonary disease, stable form, 114 male and 16 female, of whom 121 were smokers and 9 were non-smokers. Inclusive criteria were FEV1 < 50% from predicted (with moderate and severe level of the disease), the relation FEV1/FVC < 70%, the test of reversibility with β2-agonist < 15%. The patients were followed up for 18 months. They were evaluated at the start, and then at the end of the study. During the examination 9 patients were excluded because they did not obey recommendations of the examination, and three patients died during the examination. At the end of our study 77 patients in group I, 66 male and 11 female, were evaluated, and 41 patients, 35 male and 6 female, in group II. The patients were divided on the basis of BMI (body mass index), group I with BMI from 21 to 28 kg/m^2 and group II with BMI < 21 kg/m^2. The mean age of the patients was 63 ± 7.2 years in group I, and 68 ± 8.3 in group II. The values of FEV1 at the start were 1.33 ± 0.35L (43 ± 8.1%) in group I, and 0.89 ± 0.27 L (28 ± 7.9%) in group II. Both were significantly lower in group II ($p < 0.001$). At the end of the study the values of FEV1 were lower in both groups than at the start (Fig. 1).

At the start of the study SGRQ scores in group I were significantly lower ($p < 0.001$) than in group II. This indicated a better quality of life in patients with BMI from 21 to 28 kg/m^2. The SGRQ scores at the end of the study were also significantly lower in group I ($p < 0.001$). And they were lower than at the start in both groups, indicating a better quality of life in patients with COPD after18 months' regular use of therapy (Fig. 2).

The values of Pearson's coefficient r = -0.49 ($p < 0.05$) in group I and r = -0.35 (0.05) in group II, shows that between these two variables there is an indirect, or negative correlation; lower values of FEV1 are associated with higher SGRQ total scores.

It can be concluded that regular use of therapy for controlling the disease leads to improved quality of life in COPD patients, which is not associated with improvement in lung function. Patients with malnutrition (BMI < 21kg/m^2) have lower values of FEV1, and they have higher SGRQ scores of quality of life. High levels of SGRQ scores are associated with lower values of FEV1.

Key words: COPD, therapy, quality of life, forced expiratory volume in one second, body mass index.

Introduction

The medications available for COPD have been shown to reduce or abolish symptoms, increase exercise capacity, reduce exacerbations and improve health status. At present, apart from smoking cessation, no treatment has been shown to modify the rate of decline in lung function. As a general rule, the inhaled route is the preferred one and a combination of different drugs should be used in more advanced disease. Improvement of quality of life is one of the aims of treatment of COPD. Health care used by COPD patients appears to be related even more to an impaired quality of life than to the severity of the lung disease itself. [1]

Quality of life may be defined as the gap between that which is desired in life and that which is achieved. This definition is conceptually useful, but not very practical in medicine, since it is too broad. The concept of Health Related Quality of Life is more valuable, since its terms of reference are restricted to disturbances of daily life and well-being specifically due to disease. Many factors influence quality of life impairment in COPD patients. Reliable measurement of the impact of the disease requires standardized questionnaires, which can apply to every patient. In many situations, it is necessary to measure the effect of disease so that patients' end treatment can be compared. [2, 3]

The role of respiratory function tests in COPD encompasses diagnosis, assessment of severity, prognosis and monitoring the course of the disease. The dominant functional abnormality is airway narrowing, and this is most commonly assessed using tests based on forced expiration. The functional measurements are essential since symptoms and signs cannot predict the degree of airway narrowing. In COPD, impaired lung function is most usually summarized in terms of the forced expiratory volume in one second (FEV1). Simple spirometric indices have the advantage of ease of performance, good reproducibility and a well-established relationship with prognosis. Sequential

measurements of FEV1 are essential for monitoring the prognosis of the disease. The development of severely impaired lung function in COPD is believed to result from many years moderately accelerated decline of lung function. Yearly decrements have been reported as ranging 48–91 ml/yr. In natural history, it is well known that the level of lung function determines the course of lung function decline to a large extent, so lower lung function is associated with more rapid decline as well as lower survival. [4, 5]

A number of patients with COPD lose body weight and suffer from malnutrition, so the association between being underweight and increased mortality risk has been established in numerous retrospective studies. Although it is not fully understood why these patients become underweight, weight loss and specifically loss of fat mass is generally the result of negative energy balance and appears to be more prevalent in patients with emphysema. [6]

Four factors predicting the risk of death in patients with COPD have been evaluated: the body mass index, the degree of airflow obstruction, the degree of dispnea and exercise capacity, measured by a six-minute walking test. It has been found that the body mass index is the best predictor of all. [7, 8]

Aim of the study

1) to examine the influence of therapy on quality of life and on the FEV1 in a group of patients with a stable form of COPD with normal body weight and with malnutrition, with a moderate to severe level of airway obstruction (FEV1 < 50%), and 2) to determine the correlation between the levels of FEV1 and quality of life scores in both groups of patients during therapy for controlling the disease.

Material and methods

Study design and population: 130 patients were included in the examination with diagnosed chronic obstructive pulmonary disease, stable form, 114 male and 16 female, of whom 121 were smokers and 9 were non-smokers. Inclusive criteria were FEV1< 50% from predicted (with moderate and severe level of the disease), the relation FEV1/FVC < 70%, the test of reversibility with β2-agonist < 15%. BMI (body mass index) in patients was < 28kg/m^2. The last criterion was taken to exclude obese patients from the examination. Exclusive criteria were diagnosed as bronchial asthma, bronchiectasiae, lung carcinoma, congestive heart disease, hepatic and renal failure. The patients were followed up for 18 months, (from November 2007 to April 2008). They were evaluated at the start, and then at the end of the study. During the examination 9

patients were excluded because they did not obey the recommendations of the examination and three patients died during the examination. At the end of the study 118 patients, 102 male and 16 female, 109 smokers and 9 nonsmokers, were analyzed.

On the basis of values of BMI, the patients were divided into two groups, with **normal body weight** (BMI of 21–28 kg/m^2) and **underweight** (BMI < 21kg/m^2). During examination patients received therapy for controlling the disease: Tabl. Aminophyllin R a 350 mg. 2 × 1 daily, Spray Ventolin (as a rescue medicine), Spray Seretide (Fluticasone propionate + Salmeterol) 250 micrograms 2 × 1 inhalations daily, anticholinergic.

Measures

The quality of life measurements in our study were done by using the St.George's Respiratory Questionnaire (SGRQ), a standardized questionnaire which is specifically for COPD and bronchial asthma. It has been shown to be valid, repeatable and sensitive. The questionnaire has three components: 1) **symptoms:** distress due to respiratory symptoms; 2) **activity:** disturbances to mobility and physical activity; and 3) **impacts:** overall impact on quality of life and wellbeing. A **total** score is calculated from all three components. The scoring range for the components and total score is 0–100 with a score of 100 indicating maximum disability. [9, 10, 11]

The BMI (body mass index)was determined as the ratio of weight/height (kg/m^2).

FVC and FEV1 were measured three times, and the best one taken as a valid value. They were measured with a spirometer (MINATO, AUTOSPIRO AS–505).

Statistical analysis: Data for continuous variables are presented as means ± SD. After checking for a normal distribution, the changes in each variable of baseline outcome measures between the two groups and the measures after 18 months were analysed with Student's t-test for dependent samples. The relationship between the data from the SGRQ questionnaire and from spirometry was examined using Pearson's coefficient of linear correlation (r). Significance level was set at $p < 0,05$.

Results

At the end of our study 77 patients were evaluated in group I, 66 male and 11 female, 72 smokers, 5 non-smokers, and 41 patients, 35 male and 6

female in group II, 37 smokers and 4 non-smokers. This data showed that the majority of patients with COPD were smokers and male. The patients were divided on the basis of BMI (body mass index), group I with BMI from 21 to 28 kg/m^2 and group II with BMI < 21 kg/m^2.

The mean age of the patients was 63 ± 7.2 years, and ranging from 49 to 83 years in group I, and 68 ± 8.3 years in group II, ranging from 50 to 86 years, which indicated that patients in group II (lower BMI) were older (Table 1).

Table 1 – Табела 1

Clinical and physiological data of patients who completed the study
Клинички и физиолошки податоци на пациентите кои ја завршија студијата

group	**I**	**II**
n	77	41
age	63 ± 7.2	68 ± 8.3
FVC L	1.92 ± 0.41	1.48 ± 0.28
FVC %	62 ± 5.4	46 ± 9.1
FEV1 L	1.33 ± 0.35	0.89 ± 0.27
FEV1 %	43 ± 8.1	28 ± 7. 9
BMI kg/m^2	21 – 28	< 21
FEV1/FVC	0.67 ± 0.13	0.59 ±0.11
male	66	35
female	11	6
smokers	72	37
non-smokers	5	4

The values of FVC at the start were 1.92 ± 0.41 L (62 ± 5.4%) in the patients in group I, and 1.48 ± 0.2 L (46 ± 9.1%) in group II. The ratio FEV1/FVC was 0.67 ± 0.13 in group I and 0.59 ± 0.11 in group II. The values of FEV1 at the start were 1.33 ± 0.35L (43 ± 8.1%) in group I, and 0.89 ± 0.27 L (28 ± 7.9%) in group II. Both were significantly lower in group II ($p < 0.001$) (Table 2).

At the end of the study after a follow-up of 18 months the values of FEV1 were 1.30 ± 0.31 L (41 ± 8.1%) in group I, and 0.79 ± 0.29 L (26 ± 8.0%) in group II. The values of FEV1 were significantly lower in group II ($p < 0.001$) versus the values of FEV1 of group I (Table 3). Also at the end of the study the values of FEV1 were lower in both groups than the values at the start (Fig. 1).

Table 2 – Табела 2

Values of FEV1 (forced expiratory volume in one second) at the start of the study in both groups of patients with different BMI
Вредноста на форсираниот експираторен волумен во првата секунда (FEV1), на почетокот на истражувањето кај двете групи пациенти со различен BMI

BMI kg/m^2	n	FEV1 L	FEV1%
I group (21–28)	77	1.33 ± 0.35	43 ± 8.1
II group (< 21)	41	0.89 ± 0.27	28 ± 7.9
p		< 0.001	< 0.001

Table 3 – Табела 3

Values of FEV1 (forced expiratory volume in one second) at the end of the study, after 18 months' therapy, in both groups of patients with different BMI
Вредноста на форсираниот експираторен волумен во првата секунда (FEV1), на крајот на истражувањето, по 18 месеци терапија, кај двете групи со различен BM

BMI kg/m^2	n	FEV1 L	FEV1%
I group (21–28)	77	1.30 ± 0.31	41 ± 8.1
II group (< 21)	41	0.79 ± 0.29	26.3 ± 8.0
p		< 0.001	< 0.001

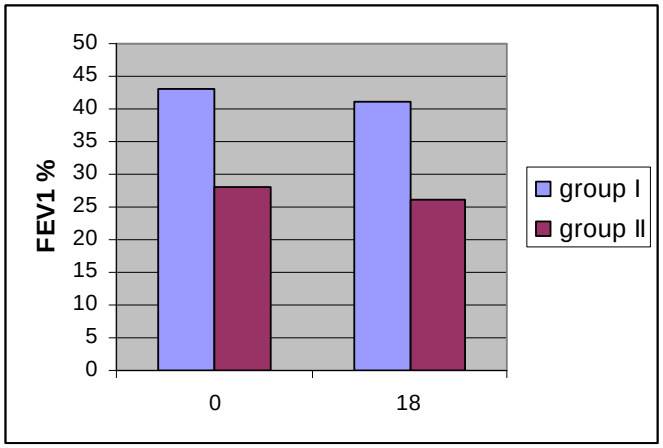


Figure 1 – Values of FEV1 at start of study and after 18 months
Слика 1 – Вредноста на FEV1 на почетокот на студијата и по 18 месеци

At the start of the study SGRQ scores in group I were: total 50.2 ± 5.8, symptoms 60.6 ± 6.7, activity 72.8 ± 4.7, impacts 52.3 ± 8.2, in group II they were: total 62.7 ± 5.1, symptoms 70.1 ± 4.1, activity 81.1 ± 3.6 and impacts 61.8 ± 5.9. They were all significantly lower ($p < 0{,}001$) in group I. This indicated a better quality of life in patients with BMI from 21 to 28 kg/m^2. (Table 4)

Table 4 – Табела 4

SGRQ scores at start of study in both groups of patients with different BMI
SGRQ скоровиште на почетокот на студијата кај пациентите со различен BMI

BMI kg/m^2	n	SGRQ total	symptoms	activity	Impacts
I group (21–28)	77	50.2 ± 5.8	60.6 ± 6.7	72.8 ± 4.7	52.3 ± 8.2
II group (< 21)	41	62.7 ± 5.1	71.0 ± 4.1	81.1 ± 3.6	61.8 ± 5.9
p		< 0.001	< 0.001	< 0.001	< 0.001

The SGRQ scores at the end of the study in group I were: total 43.9 ± 6.5, symptoms 54.2 ± 7.2, activity 66.1 ± 5.6 and impacts 42.2 ± 8.4, in group II they were: total 59.3 ± 5.7, symptoms 67.0 ± 5.1, activity 77.1 ± 3.8 and impact 57.8 ± 6.2. The scores were significantly lower in group I (Table 5). And they were lower in both groups than at the start, indicating a better quality of life in patients with COPD after 18 months' regular use of therapy (Fig 2).

Table 5 – Табела 5

SGRQ scores at end of study after 18 months of therapy in both groups of patients with different BMI
SGRQ скоровиште, на крајот на истражувањето по 18 месеци терапија, кај двете групи пациенти со различен BMI

BMI kg/m^2	n	SGRQ total	symptoms	activity	Impacts
I group (21–28)	77	43.9 ± 6.5	54.2 ± 7.2	66.1 ± 5.6	42.2 ± 8,4
II group (< 21)	41	59.3 ± 5.7	67.0 ± 5.1	77.1 ± 3,8	57.8 ± 6.2
p		< 0.001	< 0.001	< 0.001	< 0.001

At the end we used Pearson's coefficient of linear correlation to show the correlation between the values of FEV1 and SGRQ total score in patients from both groups. (Figs. 3 and 4) The values of Pearson's coefficient $r = -0.49$ ($p < 0.05$) in group I and $r = -0.35$ ($p < 0.05$) in group II, show that between these two variables there is indirect, or negative correlation, and lower values of FEV1 are associated with higher SGRQ total score.

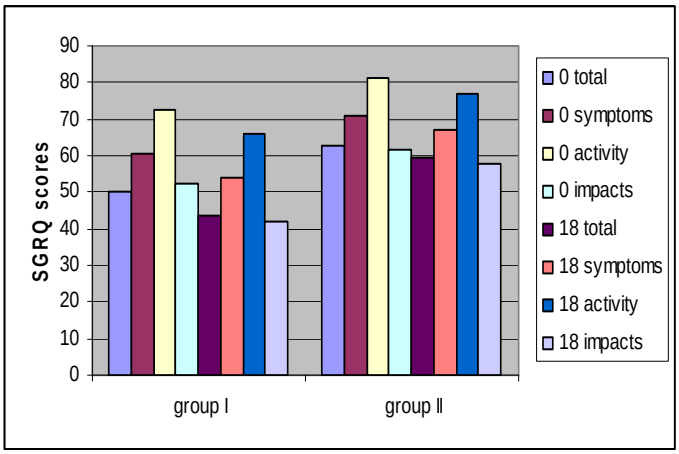
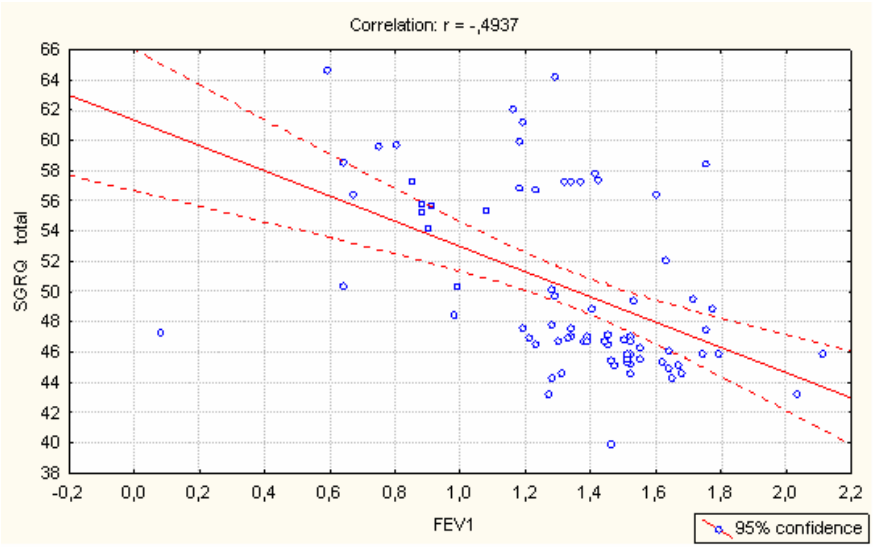
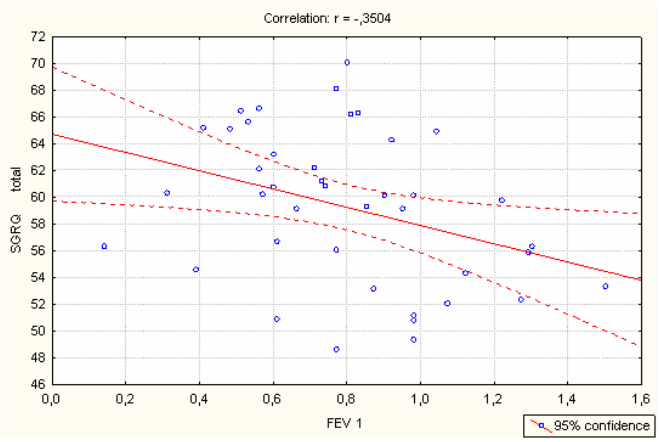


Figure 2 – SGRQ scores at the start in group I and in group II, and at the end of the study after 18 months of therapy
Слика 2 – SGRQ скоровиште на почетокот, кај група I и група II и на крајот од студијата по 18 месеци со терапија



Pearson's coefficient of correlation r = -0.49 p < 0.05

Figure 3 – *Pearson's coefficient presents the correlation between values of FEV1 (litres) and SGRQ total score of patients in study with BMI from 21 to 28kg/m²*
Слика 3 – *Пеарсоновиот коефициент ја покажува корелацијата помеѓу вредноста на FEV1 (литри) и SGRQ тоталниот скор кај пациентите со BMI од 21 до 28 kg/m²*



Pearson's coefficient of correlation r = -0.35 p < 0.05

Figure 4 – Pearson's coefficient presents the correlation between values of FEV1(litres) and SGRQ total score of patients in study with BMI lower then 21kg/m²

Слика 4 – Пеарсоновиот коефициент ја покажува корелацијата помеѓу вредноста на FEV1 (литри) и SGRQ тоталниот скор кај пациентите со BMI помал од 21 кг/м²

Discussion

Research on the therapeutic efficacy of available treatment regimens for chronic obstructive pulmonary disease (COPD) has changed tremendously over last decade. Before 1985 investigations were merely directed at therapeutic effects on symptoms. After 1985, the first short-term intervention studies appeared in the literature, relating results of treatments not only to symptoms, but also to lung function and hyper-responsiveness. Only at the beginning of the nineties did long-term studies on intervention start to appear. Thus, it became possible for the first time to look at the effect of therapy on lung function decline and exacerbations. The time has now come to look not only at the efficacy of therapy, but also at the cost-effectiveness and at the cost in terms of quality of life. [5, 14, 15] Our data show that long-term therapy improves the quality of life, but has no positive effect on lung function.

Quality of life may be defined as the gap between that which is desired in life and that which is achieved. This definition is conceptually useful, but not very practical in medicine, since is too broad. Jones P. *et al*. demonstrated in several long term studies that regular use of therapy for controlling chronic obstructive pulmonary disease shows improvement of quality of life. [2, 16] This has been first of all a result of reducing the symptoms and improving

exercise tolerance, although in some studies the increase of exercise tolerance was not associated with any significant improvement of quality of life, indicating that a subjective parameter, such as quality of life, is not influenced by exercise tolerance. [11, 12, 13]

In our study after the regular treatment of the disease, at the end of the study, the SGRQ scores were lower in both groups, which indicated a better quality of life.

Therapy, bronchodilatators, as well as inhaled corticosteroids do not change the rate of decline of FEV1 in patients with COPD. COPD, like bronchial asthma, has an inflammatory component, so inhaled corticosteroids are commonly administrated as part of the treatment. Although these drugs may be effective in reducing symptoms, especially reducing the number of exacerbations, a recent meta-analysis suggests that they have little effect on the decrease in lung function that is characteristic of the disease, at least in patients with no evidence of concomitant asthma. Barnes P. suggest that inhaled corticosteroids do not slow down FEV1 decline in COPD so they cannot modify the natural history of the disease, characterized by an accelerated decline in FEV1. [14] On the other hand bronchodilatators are an important form of treatment for reducing the symptoms, but there is also no convincing evidence that these drugs alter the natural history of the disease. [15, 16, 17, 18] Our study also showed lower values of FEV1 at the end, after the treatment, in both groups, and we concluded that long-term therapy did not have an influence on decline of FEV1. Also in our study the data suggest that lower values of FEV1 are associated with a higher SGRQ total score (Pearson's coefficient $r = -0.49$, ($p < 0.05$) in group I and $r = -0.35$ (0.05) in group II).

An majority of patients with COPD lose body weight and suffer from malnutrition, as the association between underweight and increased mortality risk has been established in numerous retrospective studies. Landbo C. *et al*. suggest that although it is not fully understood why these patients become underweight, weight loss and specifically loss of fat mass is generally the result of negative energy balance and appears to be more prevalent in patients with emphysema. [4]

Several studies show increased resting energy requirements linked to low-grade systemic inflammation in some COPD patients. Furthermore, some studies have reported an increased oxygen cost of respiratory muscle activity due to lung hyperinflation. The body weight loss is also a result of musculature loss. Malnutrition, especially muscle loss, affects the respiratory muscles even in health, so its presence may aggravate respiratory muscle dysfunction, and this may result in increased airway obstruction and hyperinflation. This is the way that body weight loss in COPD patients influences breathlessness. [4, 6, 8] In our study patients with BMI < 21kg/m^2 were older, they had lower values of

FEV1 and higher SGRQ scores both at the start and at the end of the examination, so we can see that patients with malnutrition have lower values of lung function and a worse quality of life before and after the therapy.

Conclusion

It can be concluded that regular use of therapy for controlling the disease leads to improved quality of life in COPD patients which is not associated with improvement in lung function. Patients with malnutrition (BMI < 21kg/m^2) have lower values of FEV1, and they have higher SGRQ scores of quality of life, both at the start of our study and at the end of the study after the treatment. High levels of SGRQ scores are associated with lower values of FEV1.

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Р е з и м е

КВАЛИТЕТОТ НА ЖИВОТОТ, ФОРСИРАНИОТ ЕКСПИРАТОРЕН ВОЛУМЕН ВО ПРВАТА СЕКУНДА И BMI (BODY MASS INDEX-ОТ) КАЈ ПАЦИЕНТИТЕ СО ХОББ, ВО ТЕКОТ НА ТЕРАПИЈА ЗА КОНТРОЛИРАЊЕ НА БОЛЕСТА

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Пациентите со хронична опструктивна белодробна болест (ХОББ) се карактеризираат со нарушена белодробна функција и намалена толеранција на напор. Медикаментите и рехабилитирачките програми главно се насочени кон ослободување од симптомите и подобрување на белодробната функција и толеранцијата на напор.

Вклучивме 130 пациенти во испитувањето со дијагностицирана хронична опструктивна белодробна болест, стабилна форма, 114 мажи и 16 жени, од кои 121 беа пушачи а 9 непушачи. Инклусивни критериуми беа FEV1 < 50% од предвиденото (со среден и тежок степен на болеста), FEV1/FVC < 70%, со бронходилататорен тест на реверзибилност помала од 15%. Пациентите беа следени 18 месеци. Тие беа евалиуирани на почетокот и на крајот од испитувањето. За време на испитувањето 9 пациенти беа исклучени бидејќи не ги почитуваа препораките на испитувањето, а тројца починаа во текот на испитувањето. На крајот од студијата беа евалуирани 77 пациенти во првата група, 66 мажи и 11 жени и 41 пациент во втората група, 35 мажи и 6 жени. Тие беа поделени во две групи врз основа на BMI (bodi mass index-от), првата со BMI од 21 до 28 kg/m^2 и втората со BMI помал од 21 kg/m^2. Средната возраст на пациентите беше 63 ± 7,2 години кај првата и 68 ± 8,3 кај втората група. Вредностите на FEVl на почетокот беа 1,33 ± 0,35 L (43 ± 8,1) кај првата група и 0,89 ± 0,27 L (28 ± 7,9) кај втората група. Тие се сигнификантно пониски кај втората група ($p < 0,001$). На крајот од испитувањето вредностите на FEV1 беа пониски кај двете групи во однос на почетокот (слика 1).

На почетокот на студијата SGRQ скоровите кај првата група беа сигнификантно пониски кај првата група ($p < 0,001$) во однос на втората група. Ова укажува на подобар квалитет на животот кај првата група, која е со BMI од 21 до 28 kg/m^2.

SGRQ скоровите на крајот од студијата исто така беа сигнификантно пониски кај првата група ($p < 0,001$). Тие исто така кај двете групи беа пониски отколку на почетокот што укажува на подобрување на квалитетот на животот кај пациентите со ХОББ по 18 месеци редовна употреба на терапијата (слика 2).

Pearson-овиот коефициент на линеарна корелација r = -0,49 ($p < 0,05$) кај првата група и r = -0,35 ($p < 0,05$) покажа индиректна односно негативна корелација помеѓу вредностите на FEV1 и SGRQ тоталниот скор, што значи дека пониски вредности на FEV1 се асоцирани со повисоки вредности на SGRQ тоталниот скор.

Според тоа можеме да заклучиме дека редовната употреба на терапијата за контрола на болеста, доведува до подобрување на квалитетот на животот кај пациентите со ХОББ, што не е асоцирано со подобрување на белодробната функција. Пациентите со малнутриција (BMI < 21kg/m^2) имаат пониски вредности на FEV1, а исто така имаат повисоки SGRQ скорови на квалитет на живот. Високи вредности на SGRQ скорови се асоцирани со ниски вреднисги на FEV1.

Клучни зборови: ХОББ, терапија, квалитет на животот, форсиран експираторен волумен во првата секунда, body mass index.

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