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Evaluation of Quality of Life Indicators of Patients with Arterial Hypertension and Comorbid Chronic Obstructive Pulmonary Disease

Iryna Vysochyna, Tetiana Burtniak

Department of Family Medicine FPE, Dnipro State Medical University, Dnipro, Ukraine

Email address:

taniaburtniak@gmail.com (T. Burtniak)

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Abstract: The purpose of this study to analyze the quality of life (QoL) of patients in accordance with a personalized approach in the complex drug treatment of patients with hypertension and comorbid chronic obstructive pulmonary disease (COPD). Materials and methods: the analysis of two groups of male patients. The presence of left ventricular remodeling with preserved ejection fraction (≥ 50%) – Group 1 with antihypertensive therapy of valsartan with amlodipine, or mid-range (45-49%) – Group 2 with combination of candesartan and nebivolol. The general clinical examination was performed using international clinical scales and validated SF-36 and SGRQ questionnaires. Comparison of QoL parameters according to the SF-36 questionnaire revealed a significant difference between pre- and post-treatment parameters in Groups 1 and 2 ($p < 0.05$). In conclusion, a comprehensive approach is recommended in patients with hypertension and comorbid COPD, which provide long-term antihypertensive and bronchodilator effects and are recommended for use in patients. After 6 months of comprehensive combination therapy, the condition of patients has significantly improved, as evidenced by changes in QoL according to the SF-36 and SGRQ questionnaires. All indicators of mental and physical components of the SF-36 questionnaire significantly increased and the values of the categories of the specific respiratory questionnaire SGRQ decreased.

Keywords: Quality of Life, Arterial Hypertension, Chronic Obstructive Pulmonary Disease, Antihypertensive Therapy

1. Introduction

Monitoring and treatment of patients with arterial hypertension (AH) is currently performed according to the Order of the Ministry of Health of Ukraine № 384 of 24.05.2012, which protocol is current [1]. The purpose of these measures is to improve the quality of medical care, as well as to improve the efficiency of treatment methods and rationalize treatment costs [2]. The main task in treatment of patients with combined pathology is to achieve the maximum reduction of long-term risk of cardiovascular mortality and morbidity in bronchoobstructive states, preservation of arterial blood pressure (BP) indices within the "target level" range and control of external respiratory function (RF) indices [3, 4].

Difficulties in treating patients with AH in combination with chronic obstructive pulmonary disease (COPD) are a serious problem, as the combination of these diseases leads to significant mutual burdening and increased drug load. The pathophysiological basis for the correction of disorders of the cardiorespiratory system in patients with AH in combination with COPD is the development of modern approaches to the treatment of both hypertension and COPD, which are safe and effective [9]. Antihypertensive drugs and bronchodilators in some cases have side effects, and the wrong choice of drug, inappropriate dosage, lack of synergy of treatment and adherence to it - are the main disadvantages of patient management. Therefore, the doctor is faced with the question of prescribing effective therapy, which, above all, must be safe in comorbid conditions [3, 5-8].

Despite the relevance of this problem, today we have not any multidisciplinary protocol for the management of patients with AH and comorbid COPD, which makes it difficult to treat them in practice, especially in the primary level.

Objective: to analyze the quality of life (QoL) of patients in

accordance with a personalized approach in the complex drug treatment of patients with hypertension and comorbid COPD.

2. Materials and Methods

The analysis of both Groups of male patients, which were formed depending on the presence of left ventricular (LV) remodeling with preserved (≥50%) – the Group 1, or mid-range ejection fraction (EF) (45-49%) – the Group 2.

The Group 1 included 30 men with stage II hypertension with diastolic dysfunction and comorbid COPD. The Group 2 included 30 men of similar profile with asymptomatic dysfunction with mid-range EF.

The general clinical examination was performed using international clinical scales and validated SF-36 and SGRQ QoL questionnaires.

Antihypertensive therapy in patients of Group 1 consisted of valsartan in combination with amlodipine and in Group 2 by candesartan in combination with nebivolol. The last combination is based on the Chronic Heart Failure (CHF) Manual 2021 of the European Heart Association, which, through retrospective meta-analysis, provided a favorable effect of nebivolol, candesartan, and spironolactone on prognosis in mid-range of EF LV (41-49%).

Bronchodilator therapy was the same in both groups and was based on the supportive use of an inhaled combination bronchodilator in one inhaler, which consists of the long-acting cholinolytic umeclidinium bromide and the long-acting β2-agonist vilanterol. We justified the choice of this bronchodilator therapy with the available evidence base on cardiovascular safety [10-13]. Our goal was to reduce as much as possible the number of prescribed medications in order to prevent malpractice and increase treatment adherence. The effectiveness of treatment was evaluated by comparison with baseline data using the Wilcoxon criterion to compare dependent samples.

In Group 1, the daily dose of valsartan ranged from 80–160 mg (an average dose of 120 (40.6) mg/day) and amlodipine 5–10 mg (mean dose 7.50 (2.50) mg /day). In Group 2, the daily dose of candesartan was 8–16 mg (mean dose 11.6 (4.9) mg/day) and nebivolol 2.5–5.0 mg (mean dose 3.75 (1.25) mg/day). The daily dose of umeclidinium bromide with vilanterol in both Groups was 55/22 mcg.

Comprehensive assessment of treatment results was carried out after 6 months from the start of treatment, which is reasonable in terms of the possibility of establishing a medical effect on the course of AH and COPD. Dynamical monitoring was performed monthly by office visits or by computerized interrogation. We did not observe any lethal effects or adverse drug reactions during the monitoring period.

Also, all patients with high and very high cardiovascular risk (CVR) were prescribed rosuvastatin at a dose of 20 mg. According to the indications, thiazide or loop diuretics were periodically prescribed. Inhaled corticosteroids (budesonide) were taken by 16 (26.6%) patients with severe course as part of triplet inhalation therapy in accordance with the Order of the Ministry of Health of Ukraine dated 27.06.2013 № 555 [15].

3. Results

We conducted a comparative assessment of changes in QoL during treatment using a validated non-specific SF-36 questionnaire and a validated SGRQ respiratory questionnaire. The results are shown in Table 1.

Table 1. *Change in QoL values according to the SF-36 questionnaire in the examined patients during 6 months of treatment.*

№	Concepts	Groups of respondents					
		1 (n=30)		p	2 (n=30)		p
		Before treatment	After treatment		Before treatment	After treatment	
1.	Physical function (PF), бали	55 (40; 75)	70 (70; 80)	<0,01*	57,5 (40; 72,5)	72,5 (65; 80)	<0,01#
2.	Role-Physical (RP), points	25 (0; 50)	50 (50; 75)	<0,01*	25 (0; 50)	75 (50; 75)	<0,01#
3.	Bodily pain (BP), points	41 (41; 52)	52 (51; 62)	<0,01*	46,5 (41; 62)	55 (52; 74)	<0,01#
4.	General health (GH), points	45 (30; 50)	52 (47; 62)	<0,01*	45 (32,5; 53,5)	51 (35; 57)	<0,01#
5.	Vitality (VT), points	40 (30; 45)	55 (50; 60)	<0,01*	40 (30; 50)	55 (50; 60)	<0,01#
6.	Social Functioning (SF), points	50 (37,5; 62,5)	75 (62,5; 75)	<0,01*	62,5 (50; 62,5)	75 (62,5; 75)	0,04#
7.	Role-Emotional (RE), points	66,6 (16,6; 100)	100 (66,6; 100)	0,02*	66,6 (33,3; 100)	100 (66,6; 100)	0,01#
8.	Mental health (MH), points	60 (56; 64)	72 (68; 76)	<0,01*	60 (56; 64)	74 (68; 76)	<0,01#
9.	Physical Component (PC), points	34,6 (31,4; 41,7)	41,9 (41; 47,6)	<0,01*	37,4 (30,2; 41)	44,4 (38,4; 46,8)	0,01#
10.	Mental Component (MC), points	38 (32,3; 44,9)	47,7 (47,4; 50,9)	<0,01*	39,8 (35; 45,1)	49 (47,2; 51,6)	<0,01#

1. * - statistically significant differences in group 1 before and after treatment;
2. # - statistically significant differences in group 2 before and after treatment;
3. comparison of indicators was performed using Wilcoxon test.

Comparison of QoL parameters according to the SF-36 questionnaire revealed a significant difference between pre- and post-treatment parameters in Groups 1 and 2 ($p < 0.05$). It was found that the PF index in Groups 1 and 2 increased 1.27 and 1.26 times, respectively. A significant difference was found between the indicator of RE in Group 1, which after treatment improved 2 times and in Group 2 - 3 times, which indicates positive changes in the daily physical activity of patients.

The index of BP increased significantly compared to baseline in Groups 1 and 2 - 1.5 times and 1.33 times, respectively, indicating a decrease in pain intensity due to treatment. The rate of GH in the background of treatment in groups 1 and 2 increased by 1.21 and 1.13 times, respectively.

The greatest changes were in the RP index, which characterizes the reduction of physical problems in the

patient's activity after the treatment and problems related to the physical state. The analysis revealed a significant change in the physical parameters of QoL in both Groups, which indicates the effective use of the proposed combination of drugs. The rate of VT significantly increased in both Groups by 1.43 times, while the rate of SF in Group 1 increased by 1.52 times, and in Group 2 by 1.20 times, respectively, indicating improved social contacts and increased vital activity in patients with hypertension and comorbid COPD.

The rate of RE in Groups 1 and 2 increased 1.50 times, which indicates an improvement in the emotional state of patients. The HF indicator reliably increased by 1.21 and 1.23 times, respectively, and indicated a decrease in anxiety. The increase of PC in groups 1 and 2 by 1.21 times and 1.19 times means improvement of the physical state on the whole, and the increase of MC index after treatment in Groups 1 and 2 - by 1.26 and 1.23 times respectively, proves that the psychological state has improved. There were no significant differences between Groups 1 and 2 after treatment, indicating a rational and effective choice of drugs depending on the course of AH and comorbid COPD.

Analysis of QoL indicators on the SGRQ respiratory questionnaire is shown in Table 2.

Table 2. *Changes in QoL values according to the SGRQ respiratory questionnaire in patients with stage II hypertension and comorbid COPD during treatment.*

№	Concepts	Groups of respondents					
		1 (n=30)		p	2 (n=30)		p
		Before treatment	After treatment		Before treatment	After treatment	
1.	"Symptoms," points	86,3 (65,9; 97,5)	69,4 (58,0; 85,2)	<0,05*	72,5 (56,0; 85,1)	60,3 (51,0; 75,7)	<0,05#
2.	«Activity, points	47,7 (29,5; 60,3)	35,4 (35,4; 41,4)	<0,05*	53,6 (41,7; 60,7)	44,3 (37,1; 49,3)	<0,05#
3.	«Impact», points	45,4 (40,0; 65,4)	34,9 (29,7; 41,5)	<0,05*	42,9 (36,2; 54,7)	33,8 (27,5; 26,6)	<0,01#
4.	«Amount», points	52,9 (42,5; 65,3)	39,9 (36,0; 48,7)	<0,01*	48,1 (42,2; 60,6)	35,4 (31,2; 44,8)	<0,01#

1. * - statistically significant differences in group 1 before and after treatment;
2. # - statistically significant differences in group 2 before and after treatment;
3. comparison of indicators was performed using Wilcoxon test.

Values on the "symptoms" scale in patients of Groups 1 and 2 after therapy decreased by 24.3 and 20.2%, respectively. The indicators of the scale of "activity" in Groups 1 and 2 after treatment decreased by 34.7 and 20.9%, respectively. In Groups 1 and 2, the indicators of the scale of "impact" decreased significantly by 30.0 and 26.9%, and the values of the scale "amount" - by 32.5 and 35.8%, respectively, indicating a rational choice of drugs in Groups 1 and 2. Thus, an integrated approach to the treatment of patients in Groups 1 and 2 had a significant impact on the components of mental and physical life of patients. There was a significant increase in the SF-36 questionnaire and a decrease in the SGRQ questionnaire, indicating an improvement in social adaptation and a reduction in complaints of patients with QoL.

4. Conclusion

A comprehensive approach is recommended in patients with hypertension and comorbid COPD, including the proposed combination of valsartan with amlodipine or candesartan with nebivolol and umeclidinium bromide with vilanterol, which provide long-term antihypertensive and bronchodilator effects and are recommended for use in patients with AH and comorbid COPD.

After 6 months of comprehensive combination therapy, the condition of patients has significantly improved, as evidenced by changes in QoL according to the SF-36 and SGRQ questionnaires. All indicators of mental and physical components of the SF-36 questionnaire significantly increased and the values of the categories of the specific respiratory questionnaire SGRQ decreased.

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