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Comparison of results of sequential home oxygen therapy in patients using stationary or portable oxygen sources

Porównanie wyników domowego leczenia tlenem u chorych leczonych sekwencyjnie za pomocą stacjonarnego i przenośnego źródła tlenu

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Abstract

Introduction: Home-based oxygen therapy (long-term oxygen therapy, LTOT) uses two sources of oxygen: stationary oxygen concentrator (OC) or portable liquid oxygen system (LO). Polish National Healthcare System reimburses only stationary oxygen sources for home therapy.
The aim of the study was to analyse the effects of switching from OC to LO in patients on LTOT.
Material and methods: The study involved 30 patients qualified for home-based LTOT. Analysed parameters included degree of dyspnoea (MRC, Borg scale), exercise tolerance (6MWT), physical fitness, duration of daily oxygen therapy use, peripheral blood status, lung function tests, number of exacerbations and health-related quality of life (SGRQ). Analyses were performed before initiation of LTOT, after 6 months of therapy using OC and 6 months later, following switch to LO.
Results: During the first six months of therapy, a decrease in red blood cell count (RBC) from 5.4 to 5.1 ($p<0.0001$) and in haematocrit value (Ht) from 50.1% to 47.8% ($p< 0.0001$) was observed, alongside an increase in 6MWT distance from 337.7 m to 378.7 m ($p< 0.0001$) and improved SGRQ score from 72.1 to 64.4 points ($p< 0.0001$).
Liquid oxygen therapy resulted in further improvement of the analysed variables: RBC reduction from 5.1 to 4.8 ($p< 0.0001$), Ht decrease from 47.8% to 44.3% ($p< 0.0001$), prolongation of 6MWT distance from 378.7 m to 413 m ($p< 0.0001$), and improvement in SGRQ score from 64.4 to 54.9 points ($p< 0.0001$). A significant increase in daily oxygen breathing hours, from 13.7 to 18.9 hours ($p< 0.0001$), was also observed.
Results: Portable liquid oxygen sources facilitate oxygen therapy both at home and outdoors, increasing the number of oxygen breathing hours and thus improving blood cell counts, exercise tolerance, and health-related quality of life.

Key words: liquid oxygen, LTOT, oxygen therapy, respiratory insufficiency, quality of life, 6-minute walk test, COPD
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Introduction

Home-based long-term oxygen therapy LTOT) is an established and life-prolonging treatment method in patients with chronic respiratory insufficiency. Two types of oxygen sources may be used for LTOT: oxygen concentrator (OC) and liquid oxygen source (LO). Oxygen concentrators are inexpensive but stationary, thus limiting the patient's daily mobility range. Liquid oxygen is a more expensive but much more convenient oxygen source from a patient's perspective, as it is silent, does not require an external power supply system, permits application of high oxygen flow (of over 5 L/

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min), and can be used outdoors, when using portable containers.

Oxygen therapy in outdoor conditions is believed to improve the patient's self-sufficiency and facilitate professional activity and participation in family life and social activities [1]. It also increases duration of daily oxygen breathing periods, as suggested by studies of small patient groups [2, 3]. Big population studies in national patient cohorts, however, did not confirm these results [4].

The Polish healthcare system reimburses only OC therapy [5]. In 2001, the Centre for LTOT in Bydgoszcz was the first institution in the country to introduce liquid oxygen therapy systems for selected patients on LTOT as part of the current national reimbursement system. The Kujawy-Pomeranian region is at present the only one in Poland to offer selected patients liquid oxygen systems as part of LTOT. The authors intended to present in the current study their own experience of LO in LTOT patients.

The aim of the study was to analyse the impact of oxygen therapy using liquid gas sources upon the intensity of dyspnoea, exercise tolerance, self-dependence, duration of out-of-home activity, peripheral blood status, functional lung tests, number of disease exacerbations, and compliance to recommendations concerning the number of oxygen breathing hours. Increased duration of oxygen breathing periods and the possibility of staying outdoors was supposed to improve the quality of life of patients with chronic respiratory insufficiency who were qualified for LTOT.

Material and methods

The study had a prospective design, and evaluation was done every 6 months. The analysed cohort included patients with chronic respiratory insufficiency treated between November 2001 and October 2011 in the Regional Centre for LTOT of the Kujawy-Pomeranian Regional Pulmonology Centre in Bydgoszcz. The institution had a contract with a company delivering LTOT devices, which enables them to provide some patients with liquid oxygen sources as part of the institutional contract with the regional branch of the National Healthcare System. A liquid oxygen system from CryopAL was used. The device includes two independent components which the patient receives for home use. These are: a 44-litre stationary oxygen container FREELOX 2, providing oxygen supply for 10–14 days of constant use, and a small portable 1.2 L FREELOX container, providing oxygen supply for outdoor use for several hours, depending on the gas flow rate. The portable 1.2 L container can provide oxygen supply for 9 hours, with 1.5 L/min flow, 7 hours with 2 L/min, and 4 hours 30 minutes if the oxygen flow is 3 L/min. When filled up with liquid oxygen, the FREELOX 1.2 L portable container had a weight of 3.5 kg. It has an oxygen gauge meter, which permits the patient to control the duration of the outdoor activities. The FREELOX system uses controlled evaporation of liquid oxygen, and transforms liquid oxygen stored in isolated containers into breathable gas of temperature close to room conditions, ready for patient use, and delivers oxygen at a constant and adjustable flow rate.

All the patients were qualified for LTOT according to current criteria, and were provided with an oxygen concentrator [5]. The following concentrators provided by Invacare Corporation were used: Invacare 5 Sens O2 version RC5LXAQ and RC5LXO2AQ as well as Platinum S versions 5LX02AWQ, 5LXAW, and 5LX02AW.

The qualification criteria for liquid oxygen therapy established in the Centre for LTOT in Bydgoszcz are presented in table 1.

Morante et al. [6] showed that the 6-minute walk test (6MWT) is a good method of detecting desaturation (blood saturation decrease) during daily activity. Therefore, desaturation was measured using this test in the presented group of patients.

Table 1. Eligibility criteria for the use of liquid oxygen

Inclusion criteria	Exclusion criteria
Outdoor activity ≥ 2 hours/day	Outdoor activity < 2 h/day
Patient motivated for increasing outdoor activity	Lack of motivation for increasing outdoor activity
Patient's consent to use oxygen source outdoors	Patient ashamed of showing his/her disability; lack of consent to oxygen therapy outdoors
Adherence to the program of respiratory rehabilitation programme with out-of-home oxygen therapy according to given schedule	Patient with PaO_2 > 55 mm Hg, no desaturation on exertion
Desaturation on exertion	

Following 6 months of OC therapy, patients fulfilling the inclusion criteria but not having any exclusion criteria were qualified for switching to liquid oxygen source-based treatment.

During hospitalization in the Department of Lung Diseases and Respiratory Insufficiency, all investigations required by the NHS for qualification to LTOT were performed in each patient [7]. Those included: peripheral blood analysis, arterial blood gasometry when breathing atmospheric air, ECG, antero-posterior and left lateral chest X-ray, and spirometry. Spirometric tests were performed using devices from Medical Graphics (USA), Lung 1000-type from the MES company (Cracow), or MasterScreen device (CareFusion), in adherence to recommendations of the Polish Respiratory Society [8]. Furthermore, gasometry of arterial blood was also performed when patients were breathing oxygen at a constant predetermined flow rate so as to reach SpO_2 of more than 90%.

Every six months, all patients were revaluated, and the following tests were performed: tolerance of exertion by 6MWT (6MWD, 6-minute walk distance) with measurement of walked distance according to the 2002 ATS recommendations [9], and assessment of dyspnoea according to the modified Medical Research Council (mMRC) scale [10] and Borg scale [11], assessment of physical fitness using Katz scale to evaluate basic activities of daily living (ADL) [12], Lawton scale for assessment of activities necessary for independent functioning (Instrumental Activities of Daily Living, IADL) [13] as well as physical activity assessment according to the British Thoracic Society [14] (1 — normal unlimited physical activity, 2 — limited tolerance of strenuous activity, retained possibility of non-strenuous work, 3 — limited physical activity, retained self-dependence, 4 — limited physical activity, limited self-dependence, 5 — bed/armchair immobilization, patient requiring constant care).

The ADL or Katz scale measures a patient's ability to clothe, eat meals, walk, use the toilet, and take care of personal hygiene as basic elements of their daily routine. One point is given for each activity that the patient is able to perform, thus the overall score ranges from 0 to 6 points. A total score of 6 points means that the patient is self-dependent regarding daily basic activities, 4 points means partial dependence on other persons, and a score of 2 points represents a patient completely dependent on others on a daily basis.

The IADL scale is used for assessment of capability of doing shopping, managing personal finances, maintaining own household, doing laundry, preparing meals, using public transportation, using a telephone, and taking drugs prescribed by a physician. The subject's ability to perform these activities on their own is assessed in a three-tiered scale, with 3 points awarded if the patient can perform the activity independently, 2 points if some assistance is needed, and 1 point given to a person not capable of performing the activity on his/her own. Overall score ranges from 8 to 24 points. The higher the score, the greater the patient's ability to exist independently. The IADL scale is used mainly to assess in detail a patient's functioning as well as to monitor the course of the disease and treatment results.

The patient's mood as well as the presence and intensity of depression symptoms during the last month were assessed using Beck Depression Inventory (BDI) [15]. A score of over 11 was an important indicator that the patient suffers from mood disturbances or is at risk of becoming depressed. For evaluation of health-related quality of life, the St. George's Respiratory Questionnaire (SGRQ) [16] was used. The questionnaire consists of 50 questions grouped in three areas: symptoms (S), activity (A), and impact on life (I). Based on the answers to respective questions, scores are assigned and used to calculate a result representing the patient's quality of life (QoL). The total score (T) from the SGRQ assessment and scores in respective areas can range between 0 (least impairment of QoL) and 100 (greatest impairment of QoL).

Patients filled in the SGRQ on their own, Beck Depression Inventory was analysed by a clinical psychologist, and the other scales were assessed by a qualified nurse. Analyses were performed before initiation of LTOT, after 6 months of LTOT with the use of OC, and 6 months after switching to LO.

Each patient was given a list of physical exercises, with instructions on how to perform them and encouragement to start daily walks. The list included exercises aimed at general fitness improvement, exercises increasing mobility of the chest wall, and respiratory exercises, developed in accordance with recommendations concerning respiratory rehabilitation [17]. The duration and intensity of training was individually adjusted for each patient, depending on his or her physical capabilities. Most patients were recommended to exercise for 15 minutes, twice a day.

When qualified for liquid oxygen system use, patients and their families were trained by a nurse and a representative of the device deliverer to use the FREELOX System and to fill the small portable 1.2 L FREELOX container using a 44-litre stationary FREELOX 2 oxygen repository. Once every three months, each patient was visited at home by a tra-

ined nurse, who controlled compliance to the physician's recommendations and orders, adherence to physical exercise programme, motivated the patients to adhere to the recommended duration of daily oxygen breathing regime, and calculated the number of LTOT hours based on OC meter readings.

Total number of hours on LTOT and number of hours with oxygen source spent outdoors were noted by each patient in respective logs. The patients visited the Centre for LTOT every 3 months to perform of the above-mentioned analyses and for a doctor's visit. Each episode of disease exacerbation was recorded on a separate chart, including both episodes treated on an outpatient basis (as reported by the patient's GP in their patient record) and episodes of hospitalization, as described in hospital discharge charts.

Statistical analysis

Statistical analysis was performed using Statistica 7.1 (StatSoft) software.

Variables were reported as mean values, standard deviation (SD), and median values and were depicted on histograms (empiric distribution graphs). In order to verify statistical hypotheses, the following tests were used: Shapiro-Wilk's test for variables with non-normal value distribution, Wilcoxon non-parametric pair rank test, and non-parametric U Mann-Whitney test. In order to assess the significance of QoL changes during oxygen therapy, a hypothesis was made (and verified) that the mean changes in scores differ significantly from the zero value (baseline). For this purpose, Student's t parametric test for related groups was used with the assumption of normal value distribution. The adopted level of significance was p ?0.05, and critical values for p = 0.05 were taken from respective distribution tables.

Results

The studied group of 30 patients included 22 men (73.3%) and 8 women. Mean patient age was 49 ± 10.4 years. Mean age of male patients was 50.5 years, and of females — 48 years.

The main disease leading to respiratory insufficiency was chronic obstructive pulmonary disease (COPD) in 20 patients (66.7%), bronchiectases in 4 patients (13.3%), interstitial lung disease in 3 patients (10%), and other lung diseases (mucoviscidosis (cystic fibrosis), kyphoscoliosis, LAM) in the remaining 3 patients (10%). Seven patients in the group (23.3%) never smoked tobacco, and 23 persons (76.7%) admitted a past smoking habit. Tobacco exposure in former smokers was 37 ± 17 pack-years on average. Median duration of abstinence from smoking until qualification for LTOT was 2.83 ± 3.63 years. The main disease duration was 13.42 ± 7.32 years. The period from disease diagnosis and initiation of LTOT was 9.01 ± 8.61 years on average. The characteristics of the patient population before onset of LTOT is presented in table 2.

Spirometry and blood gasometry

There were no significant changes in spirometry or blood gasometry results under oxygen therapy with OC or LO.

Dyspnoea and physical fitness

Oxygen therapy applied using liquid oxygen during daily activity reduced dyspnoea and improved tolerance of exertion. There was significant

Table 2. Characteristics of the study group, including anthropometric features, spirometry, blood gasometry, blood counts, 6MWD, MRC, Borg Scale, BDI, and number of exacerbations in the year preceding initiation of DLT

Parameter	Mean value	SD
Body height [cm]	168.72	7.98
Body mass [kg]	82.72	20.47
BMI [kg/m2]	28.67	6.15
PaO_2 (–) O2 [mm Hg]	52.15	3.87
$PaCO_2$ (–) O2 [mm Hg]	50.01	6.24
pH	7.40	0.03
O_2 saturation (%)	85.83	3.65
FVC [l]	2.12	0.65
FVC (% predicted)	56.37	15.06
VC [l]	2.29	0.72
VC (%)	57.25	14.10
FEV_1 [l]	0.97	0.31
FEV_1 (%)	31.59	12.05
FEV_1/VC (%)	44.58	15.68
Hb (g%)	15.89	2.34
Ht (%)	50.18	7.75
RBC [106/iL]	5.40	0.70
6MWD [m]	337.72	116.81
Dyspnoea according to Borg scale (0–10) (points)	4.83	0.91
mMRC (0–4) (grade)	3.63	0.49
BDI (0–63) (points)	14	8.15
Number of exacerbations per year	3.67	2.01

BMI — body mass index; O2 saturation — oxygen saturation in arterial blood; FVC — forced vital capacity; FEV1 — forced expiratory volume in one second; RBC — red blood cell count; 6MWD — 6-minute walking distance test; mMRC — modified intensity of dyspnoea Medical Research Council scale; BDI — Beck Depression Inventory; SD — standard deviation

improvement in feeling of dyspnoea as assessed by patients using the mMRC scale (mean decrease from 3.53 to 3.17 grade, p <0.001) and Borg scale (mean decrease from 4.83 to 3.8 points, p <0.0001). Physical fitness also improved, as assessed by ADL scale (increase from 5.1 to 5.6 points, p <0.0001), IADL scale (increment from 18.27 to 20.4 points, p < 0.0001) and degree of fitness according to BTS (mean decrease from 3.2 to 2.5 grade), p <0.0001).

Figure 1 presents the impact of LO therapy on patients' mood, the presence and intensity of depression symptoms as measured by BDI, intensity of dyspnoea according to MRC and Borg scale, daily activity measured by ADL and IADL scale, as well as degree of fitness according to BTS when compared to results under therapy with OC.

Unfortunately, only 14 (46.7%) patients demonstrated compliance to the physical exercise training programme; the other patients did the exercises only sporadically. There was no difference in regularity of training between different sources of oxygen for therapy. On the other hand, all patients using liquid oxygen increased their daily activity and duration of out-of-home stay when using an oxygen source.

Peripheral blood parameters, daily duration of LTOT, duration of out-of-home stay, number of exacerbations

During the first six months of therapy with OC, patients demonstrated a significant decrease in red blood cell count from 5.40 ± 0.70 to 5.15 ± 0.49 (p <0.0001), haematocrit from 50.18 ± 7.75% to 47.78 ± 5.62% (p <.0.0001), and haemoglobin from 15.89 ± 2.34 to 15.1 ± 1.68 g% (p <0.0001). During the following 6 months of LO therapy, all the patients used oxygen therapy daily for >15 hours/day, with a significant increase of therapy duration from the mean value of 13.73 ± 2.10 to 18.93 ± 1.84 hours/day (p <0.0001), increased number of hours of out-of-home stay on average from 3.10 ± 1.45 to 4.60 ± 1.22 (p <0.0001), and further improvement of blood parameters as reflected by a decrease in RBC from 5.15 ± 0.49 to 4.80 ± 0.38 (p <0.0001), decrease in haematocrit from 47.78 ± 5.62 % to 44.32 ± 4.10% (p <0.0001), and in haemoglobin from 15.1 ± 1.68 to 14.28 ± 1.25 g% (p <0.0001). Furthermore, there were fewer episodes of disease exacerbation, a mean decrease from 1.53 to 0.57 (p <0.0001), and lesser intensity of depression symptoms according to BDI, from mean score of 13.27 points to 9.1 points (p <0.0001). The greatest improvement in haemoglobin, haematocrit, and red blood cell count was observed in 11 patients, which at baseline had features of polyglobulia (with parameters before initiation of LTOT, after 6 months of OC and after further 6 months on LO, respectively — Hb: 17.72, 15.33, 15.22g%; Ht: 56.26, 51.65, 47.05%; RBC: 5.88, 5.43, 4.99 × 10^6/UL).

The impact of LO treatment on blood morphology as compared to OC is depicted in figure 2. Figure 3 shows the correlation between source of oxygen and number of therapy hours per day, and between duration of out-of-home stay and number of exacerbations.

Six-minute walking test

After six months of LO therapy, mean walking distance during 6MWT increased by 34.31 ± 15.45 m (p <0.0001). In 18 patients with COPD and bronchiectases, who at baseline had 6MWD >350 m, there was a mean improvement of 42.29 ± 6.84 m.

Mean walking distance values in 6MWD test before initiation of LTOT and under oxygen therapy with OC or LO are demonstrated in figure 4.

Quality of life

A significant improvement in health-related quality of life measured by SGRQ was observed under oxygen therapy with OC, with further amelioration in all areas of SGRQ when using LO.

Figure 5 depicts the impact of oxygen therapy with OC or LO upon patients' quality of life measured by SGRQ, with its respective areas (symptoms, S; activity, A; impact on daily life, I) and global QoL measure.

The greatest benefit was observed in the area of "impact on daily life" after switching from OC to LO (–14.8 points), which improved overall quality of life measures (–9.47 points). The least difference was noted in the sphere of "activity", with a difference of less than 4 points (–3.51).

Discussion

The presented study is most likely the first Polish publication reporting the impact of switching oxygen source (from concentrator to liquid oxygen) upon physical activity, quality of life, and general condition of patients requiring home-based oxygen treatment. Usage of liquid oxygen gives a patient the benefit of receiving therapy when staying outside of home. The United States has become a pioneer of LO treatment, as one third of almost a million of patients requiring home-based oxygen therapy is using LO [18]. The presented study confirmed earlier observations [19] stating that LO permits longer oxygen therapy during the day. The authors also showed a significant increase in number of oxygen breathing hours (from

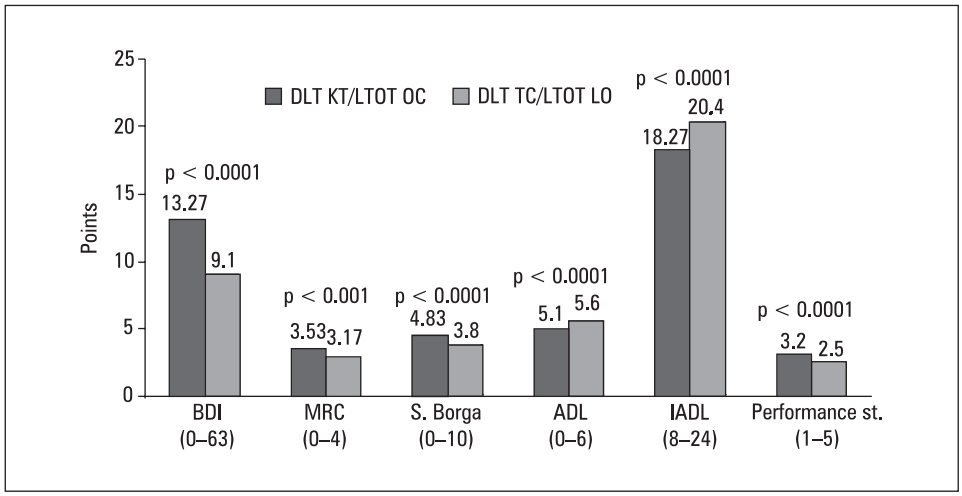

Figure 1. Mean values of BDI, MRC, Borg scale score, ADL, IADL, and performance status according to BTS in patients under oxygen therapy with OC and LO; abbreviations explained in the text above

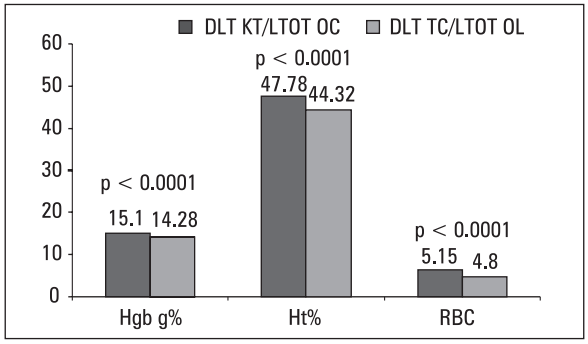

Figure 2. Mean values of Hb, Ht, and RBC in patients under oxygen therapy with OC and LO; abbreviations explained in the text above

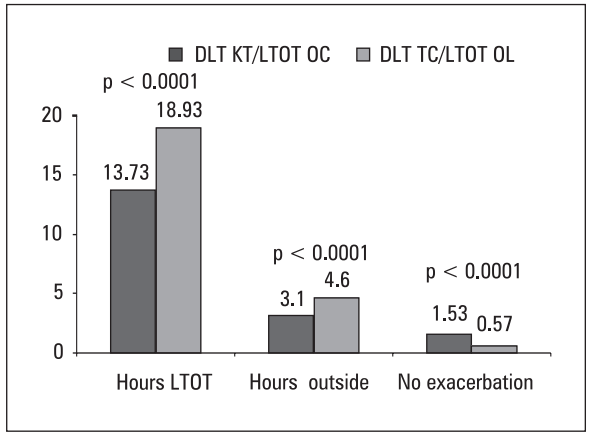

Figure 3. Mean number of hours of oxygen therapy, number of hours out-of-home stay, number of exacerbations in patients under oxygen therapy with OC and LO; abbreviations explained in the text above

13.73 to 18.93 hours/day, p <0.0001), greater than in other published reports [20]. Such a difference can probably be explained by stricter patient qualification. Katsenos et al. analysed a group of older patients (mean age of 75.4 ± 8.8 years), of whom most did not comply to physicians' orders, as demonstrated by usage of oxygen therapy for ≥ 15 hours/day by only 12.9% patients using OC and 42.5% patients with LO systems. Those patients had higher FEV1 values (mean of 42 ± 20.9% on OC and 39.1 ± 19.1% on LO) and blood saturation before treatment initiation (mean value 90.9 ± 4.51%). As many as 16% of patients with ongoing OC therapy and 20.5% of patients currently using LO were active smokers in the cited study. It can therefore be implied that the studied patients did not have a strong motivation to adhere to medical orders concerning their oxygen therapy. However, this study also demonstrated that patients using LO had a significantly longer daily duration of therapy (mean of 12.8 ± 5.6 hours/day) when compared to persons using a stationary oxygen source (7.6 ± 5.5 hours/day; p <0.001). Similarly to the results of the presented study, compliance to ≥ 15 hours/day of oxygen therapy was better when using LO than with OC systems (p <0.005).

The authors believe that the presented criteria can be applied when elaborating national recommendations for qualification for oxygen therapy using OC and LO. Inclusion of 6WMT distance can also be considered as patients with baseline 6MW distance >350 m experienced a greater improvement in tolerance of physical activity in the presented study.

Patients who qualified in the current study were young (with mean age 49 ± 10.4 years), and were more likely to execute professional activities, support families, and fully participate in family and social life despite their disease. The more ho-

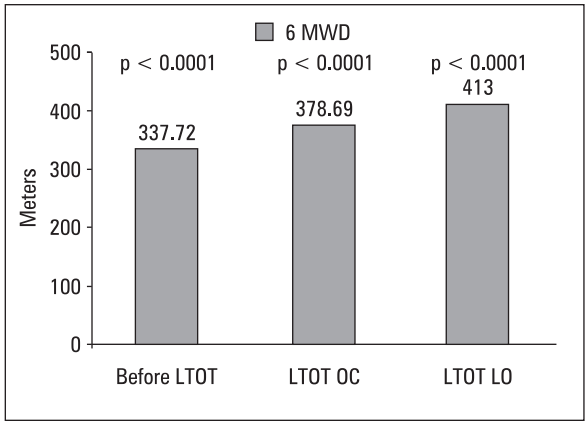

Figure 4. Mean values of 6MWD in patients under oxygen therapy with OC or LO; abbreviations explained in the text above

This is an important issue as no significant improvement of QoL was previously observed under therapy using a stationary oxygen source when using the same measurement approach [23].

In the current study, patients experienced not only a significant improvement in daily activity as measured by ADL (from 5.1 points to 5.6 points; p <0.0001) and increased capability of activities necessary for independent functioning according to IADL scale (improvement form 18.27 points to 20.4 points; p <0.0001), but also improved fitness according to BTS (improvement from 3.2 to 2.5; p <0.0001). Most patients, when using a portable oxygen source, could actively take part in family life and perform non-strenuous work at home or in the

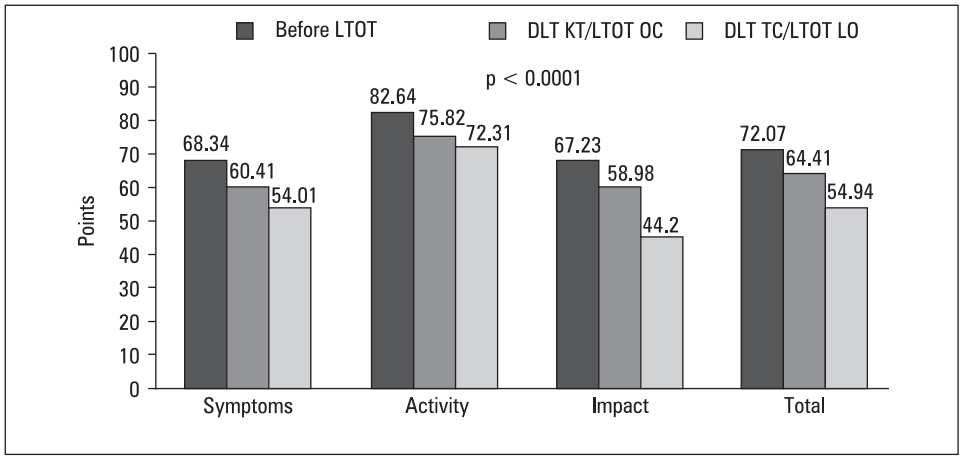

Figure 5. Impact of oxygen therapy with OC or LO upon patient quality of life measured by SGRQ; abbreviations explained in the text above

urs of oxygen breathing from LO source, the greater the possibility of spending more active hours outdoors.

Prolonged daily oxygen therapy resulted in fewer hours of tissue hypoxia, as reflected indirectly by progressive decrease in haematocrit and signs of polyglobulia. It was shown that secretion of erythropoietin, hormone stimulation erythropoiesis, increases when the partial pressure of oxygen in arterial blood drops under 60 mm Hg for more than 120 minutes [21]. This explains why patients using a stationary oxygen source and experiencing profound desaturation on exertion [22] have high haematocrit values. It can be suggested that liquid oxygen used by patients in the presented analysis protected them from prolonged hypoxia.

The greatest improvement in the presented study seems to concern patients' quality of life. Global improvement of health related quality of life was 9.47 points as measured by St. George's Respiratory Questionnaire.

garden (fig. 6). One patient could take part in occupational therapy meetings, and three others were able to continue their professional activities, which did not require physical exercise. Their ability to take part in family and professional life could have contributed to their improved quality of life, as reflected by global SGRQ score and especially when analysing the "impact on life" domain, where the improvement was on average 14.78 points. Effects such as better mood and lesser intensity of depression as assessed by BDI (from 13.27 to 9.1 points) can also be observed. These results can possibly be explained by a previous feeling of social isolation due to the necessity of using a stationary oxygen concentrator for more than 10 hours a day. Another factor that could explain the patients' improved quality of life in this study was the lower number of disease exacerbations during 6 months of oxygen therapy when using an LO source. Greater daily activity [24] and longer periods of outdoor stay [25] also contribute to a better prognosis.

Liquid oxygen sources became more widely used in Europe in the beginning of 1980s, when it was mainly intended to increase the number of oxygen breathing hours. Qualifications for this modality of treatment also included young age, heavy hypoxemia, and signs of right heart side failure [26]. Initial fears that carrying an oxygen tank can increase patient energy consumption proved ungrounded [27].

To sum up, the results of the current study confirm that use of a liquid oxygen source increases the duration of daily oxygen breathing therapy, reduces the risks of tissue damage by prolonged hypoxemia, and significantly improves the quality of life in patients with chronic respiratory insufficiency.

Figure 6. Patient breathing liquid oxygen from FREELOX 2 portable container while working in the garden

Conflict of interest

The authors have no conflicts of interests to declare.

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