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# Adherence to entry criteria and one year experience of long-term oxygen therapy in Poland

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**ABSTRACT: The adherence to entry criteria and results of one year long-term oxygen therapy (LTOT) in Poland were analysed.**

**Four hundred and seven patients with advanced respiratory failure due to chronic lung diseases qualified for LTOT were observed for one year in 12 regional LTOT centres. There were 315 patients with chronic obstructive pulmonary disease (COPD) and 92 with other chronic lung diseases. In 270 patients the prescription of oxygen was based on the single criterion of stable arterial oxygen tension ($Pao_2$) ≤55 mmHg (7.3 kPa); and in the remaining 137 with less severe stable hypoxaemia ($Pao_2$ 56–65 mmHg) (7.4–8.6 kPa), on concomitant signs of cor pulmonale and/or of tissue hypoxia.**

**Of 407 patients who started LTOT, 95 (23%) died during the first year of treatment. The mortality rate was 21% for COPD patients and 33% for patients with other lung diseases. After one year of LTOT 312 patients survived: 250 COPD patients and 62 with other lung diseases. Of these, 19 COPD patients (8%) and 9 with other chronic lung disease (15%) who had $Pao_2$ ≤55 mmHg (7.3 kPa) when oxygen was prescribed, presented with $Pao_2$ >55 mmHg (7.3 kPa). From the 137 patients (106 with COPD and 31 with other lung diseases) who qualified with less severe hypoxaemia, 10 COPD patients (10%) and 5 (16%) with other lung disease had $Pao_2$ >65 mmHg (8.6 kPa). On further follow-up of these patients (1 to 34 months later), of the 28 patients accepted to LTOT with $Pao_2$ ≤55 mmHg (7.3 kPa) 13 died and 11 remained severely hypoxaemic, whereas of the 15 patients accepted with moderate hypoxaemia, 3 died and $Pao_2$ remained >65 mmHg (8.6 kPa) in 10.**

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Long-term oxygen therapy (LTOT) in patients with advanced chronic respiratory failure has become a routine treatment in many countries. The high costs of such treatment and restrictions imposed on patients' daily lives call for adherence to strict qualification criteria. If such criteria are not met, domiciliary oxygen is unnecessarily prescribed [1–4].

LTOT was introduced in Poland in 1986 and is steadily expanding from large agglomerations to the provinces. The system is part of the chest clinics in the National Health Service. The source of oxygen is the oxygen concentrator Healthdyne BX-5000 assembled in Poland. Concentrators are purchased by provincial chest clinics and given free of charge to patients. Only patients with chronic lung diseases are accepted for LTOT.

The LTOT centre at the Institute of Tuberculosis and Lung Diseases in Warsaw is a reference centre helping to create provincial centres and supervising their activities. LTOT is prescribed by chest physicians trained in the Warsaw centre according to uniform criteria. The criteria are as follows: partial arterial oxygen tension ($Pao_2$) ≤55 mmHg (7.3 kPa) or $Pao_2$ 56–65 mmHg (7.4–8.6 kPa) if at least one of the following additional criteria is present:

1. Haematocrit (Hct) ≥55%;
2. Radiological signs of pulmonary arterial hypertension [5–7];
3. Electrocardiograph signs of right ventricular hypertrophy [8].

The patient is advised to stop smoking and oxygen therapy is prescribed if the carboxyhaemoglobin level is <3%. Oxygen therapy is recommended for at least 17 h daily.

The aim of this study was to evaluate the adherence to the entry criteria for LTOT in 12 regional centres. Also, to assess the diagnoses of patients accepted for LTOT and the results of the one year treatment.

## Material and methods

The patient is accepted for LTOT after 3 weeks observation, at the beginning and end of which blood

gases on air and spirometry are performed. When $Pa_{O_2}$, during the observation period, increases more than 5 mmHg (0.7 kPa) and/or spirometric indices more than 20%, the patient is observed for a further 3 weeks until a steady-state of the above mentioned variables is achieved. At this stage, around one third of the referred patients do not meet the entry criteria and are refused oxygen therapy.

Oxygen is prescribed for at least 17 h daily. Patients are regularly, at least once a month, visited at home by a nurse and once in 3 months examined by a physician from the LTOT centre in an out-patient clinic. At these visits clinical status is assessed, lung function tests and blood gas are measured and hours on oxygen controlled.

A questionnaire including personal data of qualified patients, the main diagnosis, variables used in qualification procedure at the beginning and at the end of the observation period, as well as the results of blood gas analysis, spirometry and Hct after the first year of treatment, was sent to all participating centres. They were asked to fill in data for all patients accepted for LTOT at least 12 months before the study started. The number of patients who died before one year of treatment had also to be reported. Out of the 411 questionnaires returned, 407 were accepted for evaluation.

## Statistical analysis

Average values of spirometry, arterial blood gas and haematocrit at entry for both dead and surviving patients and values after one year of LTOT were compared using Student's t-test or Wilcoxon's rank sum test. Differences were considered significant at $p<0.05$.

## Results

There were 135 women and 272 men among the 407 patients entered for LTOT. The mean age was 59±11 yrs. Patients with chronic obstructive pulmonary disease (COPD) predominated. Among 315 patients with COPD there were 233 males and 82 females. Other chronic lung diseases were present in the remaining 92 patients. In this group more females (53) than males (39) were observed. The diagnoses appear in table 1.

The mean observation period before the treatment was prescribed was 31.5 days. The mean baseline measurements of blood gas, spirometry and Hct are shown in table 2. Patients with COPD were older and had slight hypercapnia as compared to patients with other chronic lung disease. The other parameters were similar. In 254 patients with COPD, radiological evidence of pulmonary hypertension was present, and in 240 ECG signs of right ventricular hypertrophy. Of 92 patients with other lung diseases, 58 presented with radiological signs of pulmonary hypertension and 61 with ECG signs of right ventricular hypertrophy. All patients qualified for LTOT fulfilled the entry criteria.

Table 1. – Diagnoses of 407 patients qualified for LTOT in 12 regional centres in Poland

| Diagnosis | Patients n | % Total |
|---|---|---|
| COPD | 315 | 77 |
| Interstitial lung fibrosis | 36 | 9 |
| TB sequelae | 15 | 4 |
| Bronchiectasis | 14 | 3 |
| Kyphoscoliosis | 13 | 3 |
| Pulmonary thromboembolic disease | 3 | 1 |
| Silicosis | 3 | 1 |
| Primary pulmonary hypertension | 4 | 1 |
| Other | 4 | 1 |

LTOT: long-term oxygen therapy; COPD: chronic obstructive pulmonary disease.

Table 2. – Entry criteria for LTOT: blood gas, spirometry and haematocrit in 407 patients with COPD or other lung disease (mean±SD)

| Variable | COPD (n=315) | Other (n=92) |
|---|---|---|
| Age yrs | 62±8 | 50±15 |
| $Pa_{O_2}$ mmHg | 51±8 | 52±8 |
| kPa | 6.8±1.1 | 6.8±1.1 |
| $Pa_{O_2}/O_2$ mmHg | 66±11 | 67±10 |
| kPa | 8.8±1.5 | 8.9±1.3 |
| $Pa_{CO_2}$ mmHg | 51±10 | 46±10 |
| kPa | 6.8±1.4 | 6.1±1.3 |
| pH | 7.37±0.05 | 7.39±0.08 |
| VC *l* | 1.86±0.71 | 1.74±1.11 |
| $FEV_1$ *l* | 0.79±0.31 | 1.24±0.22 |
| Hct % | 49±6 | 49±7 |

$Pa_{O_2}$: partial arterial oxygen tension; $Pa_{CO_2}$: partial arterial carbon dioxide tension; $Pa_{O_2}/O_2$: partial arterial oxygen tension on oxygen; VC: vital capacity; $FEV_1$: forced expiratory volume in one second; Hct: haematocrit. For further abbreviations see legend to table 1.

Most of the patients accepted for the treatment (270 out of 407, 66%) had severe hypoxaemia ($Pa_{O_2}$ ≤55 mmHg (7.3 kPa). The remaining 137 (34%) patients entered into the study with less severe hypoxaemia ($Pa_{O_2}$ 56–65 mmHg (7.4–8.6 kPa)).

The daily oxygen use and carboxyhaemoglobin level at one year were recorded in 130 patients. The mean oxygen usage evaluated by reading the meter was 14.9 $h \cdot day^{-1}$. About 13% of patients resumed smoking as assessed by a carboxyhaemoglobin level >3%.

Ninety five patients (23%) died during the first year of treatment. Of 312 patients who survived, 271 (87%) had measurements performed after one year of LTOT. In the remaining 41 (13%) some measurements were lacking.

Of 315 COPD patients who entered the study, 65 (21%) died before one year of treatment. Of the 250 survivors, 224 (90%) had measurements performed after one year of LTOT. In the remaining 26 (10%) some data were missing (table 3).

Table 3. – Results of blood gas, spirometry and haematocrit in patients with COPD at entry and after one year of LTOT (mean±SD)

| Variable | Initial | | One year LTOT |
|---|---|---|---|
| | Dead (n=65) | Survivors (n=250) | (n=224) |
| Age yrs | 63±7 | 61±8 | |
| $Pao_2$ mmHg | 50±8 | 52±8 | 52±9 |
| kPa | 6.6±1.1 | 6.8±1.1 | 7.0±1.1 |
| $Pao_2/O_2$ mmHg | 64±9 | 67±12* | 66±10 |
| kPa | 8.5±1.2 | 8.9±1.6 | 8.7±1.4 |
| $Paco_2$ mmHg | 52±11 | 51±10 | 50±10 |
| kPa | 6.9±1.5 | 6.8±1.3 | 6.6±1.4 |
| pH | 7.38±0.05 | 7.37±0.05 | 7.37±0.05 |
| VC *l* | 1.67±0.52 | 1.90±0.74 | 1.97±0.73 |
| $FEV_1$ *l* | 0.72±0.23 | 0.81±0.31 | 0.80±0.32 |
| Hct % | 49±6.0 | 50±6.0 | 48±6$^+$ |

For further abbreviations see legend to table 2. *: $p<0.05$, differences between dead and survivor group; $^+$: $p<0.05$ differences between survivor initial and one year LTOT results. No other significant differences found.

Table 4. – Follow-up of patients with COPD and other lung diseases according to entry criteria

| Variable | COPD n=315 | | Other n=92 | |
|---|---|---|---|---|
| | Group 1 | Group 2 | Group 3 | Group 4 |
| Entry criteria | A | B | A | B |
| Number of patients | 209 | 106 | 61 | 31 |
| Dead before 1 year | 46 | 19 | 21 | 9 |
| $Pao_2$ improved at 1 year | 19 | 10 | 9 | 5 |

Group 1: COPD patients accepted to LTOT according to criterion A - $Pao_2$ ≤ 55 mmHg (7.3 kPa); Group 2: COPD patients accepted to LTOT according to criterion B - $Pao_2$ 56–65 mmHg (7.4–8.6 kPa); Group 3: patients with other lung diseases accepted to LTOT according to criterion A; Group 4: patients with other lung diseases accepted to LTOT according to criterion B.

The only significant difference between patients who died and those who survived was $Pao_2$ on oxygen. After one year a significant decrease of Hct was noted.

Of 92 patients with other lung diseases accepted for LTOT, 30 (33%) died before one year of treatment. Of 62 survivors, 47 (76%) had measurements performed after one year of treatment. In the remaining 15 (24%) data were missing.

The follow-up of patients with COPD and other lung diseases is presented in table 4. At entry 66% of patients with COPD presented with severe hypoxaemia (group 1, n=209), the remainder presented with moderate hypoxaemia (group 2, n=106). After one year 164 patients from group 1 and 60 patients from group 2 were re-examined. Spontaneous improvement in blood gas values was observed in 9% of patients from each group.

At entry 61 patients with other lung diseases (66%) presented with severe hypoxaemia (group 3), the remainder presented with moderate hypoxaemia (group 4, n=31) (table 4). Of the 21 patients from group 3 who died before one year of treatment there were 7 with tuberculosis sequelae (TB), 5 with interstitial lung fibrosis (IPF), 5 with bronchiectasis, 2 with pulmonary thromboembolic disease (PTED), 1 with primary pulmonary hypertension (PPH) and 1 with kyphoscoliosis. Of the 9 patients from group 4 who died there were 2 with TB, 1 with IPF, 2 with bronchiectasis, 2 with silicosis and 2 with PPH. After one year an improvement in blood gas measurements was observed in 15% of patients from group 3 and in 16% of patients from group 4.

Of the 270 patients from groups 1 and 3, 67 (25%) died before one year of treatment and at one year 28 (10%) had a $Pao_2$>55 mmHg (7.3 kPa). Of the 137 patients from group 2 and 4, 28 (20%) died before one year of treatment and at one year 15 (11%) had a $Pao_2$>65 mmHg (8.6 kPa).

Follow-up, data are now available for 26 patients out of 28 from group 1 and group 3 who improved

Table 5. – Follow-up (1–34 months later) of patients spontaneously improving after one year of LTOT

| Variable | COPD | | Other | |
|---|---|---|---|---|
| | Group 1 | Group 2 | Group 3 | Group 4 |
| Number of patients | 19 | 10 | 9 | 5 |
| Dead | 9 | 2 | 4 | 1 |
| Returned to entry criteria | 9 | - | 2 | - |
| Remained improved | 1 | 7 | 1 | 3 |
| No data | - | 1 | 2 | 1 |

Groups as described in table 4.

spontaneously; 13 died, 11 returned to severe hypoxaemia and in only 2 $Pao_2$ remained >55 mmHg (7.3 kPa). For 13 out of 15 patients from group 2 and group 4 who improved spontaneously after first year of treatment; 3 died and 10 maintained $Pao_2$>65 mmHg (8.6 kPa) (table 5).

## Discussion

We have evaluated the entry criteria and diagnoses of patients qualified for LTOT in 12 regional centres in Poland. Most were COPD patients (77%), and in the rest, chronic respiratory failure was due to other lung diseases. Although the latter group was heterogeneous, the entry variables (except for the type of ventilatory impairment) were similar to those in patients with COPD. The death rate, however, in those patients was higher than in COPD patients.

In contrast to other studies [9–12], all of our patients fulfilled the entry criteria. This could be explained by the fact that in Poland patients are qualified for LTOT exclusively by chest physicians, specifically trained in this field, and using standard criteria. In some countries domiciliary oxygen may be prescribed by general practitioners. For that reason, the prevalence of incorrect admissions for this treatment may be substantial. It reached 48% in Liverpool [13] and 43% in a survey from Sheffield [9]. Dilworth *et al.* [11], from Bristol, observed that the number of inappropriately treated patients is much higher if LTOT is prescribed by a general practitioner (66%) as compared with a chest physician (16%).

In our patients, qualified with either single or combined entry criteria, about 10% ceased to fulfil these criteria after one year of LTOT. Follow-up of these patients revealed that of those who were accepted for LTOT on the basis of severe hypoxaemia, half died and all who survived remained severely hypoxaemic, as demonstrated by further arterial blood gas determinations. Only 2 out of 28 continued to present with $Pao_2$ >55 mmHg (7.3 kPa) (table 5).

Contrary to these findings, in the group accepted to LTOT with mild hypoxaemia, who ceased to fulfil entry criteria, 20% died and the rest did not present with hypoxaemia on further examinations, and so, in fact, did not need oxygen (table 5).

Analysis of our data suggests that qualification of patients for LTOT based on severe hypoxaemia was in almost all cases correct. Even patients, who on a single blood gas examination after a year of treatment presented with $Pao_2$ >55 mmHg (7.3 kPa), needed oxygen since half of them died within 1–34 months and others remained severely hypoxaemic on follow-up.

However, the qualification of patients with less severe hypoxaemia accompanied by the signs of chronic cor pulmonale and tissue hypoxia was less accurate. After one year of treatment, 9% of COPD patients, and 16% with other chronic lung diseases, did not fulfil the entry criteria for LTOT. On further follow-up, 80% no longer needed LTOT.

It seems that in patients with $Pao_2$ ≤55 mmHg (7.3 kPa) an extension of the observation period over three weeks, before LTOT is prescribed, is not necessary. Although Levi-Valensi *et al.* [14], observed a spontaneous improvement of blood gas, after an exacerbation of COPD, up to 3 months later, the improvement in the second and the third month occurred only in patients with $Pao_2$ >55 mmHg (7.3 kPa) after the first month of the probationary period.

In patients with $Pao_2$ between 56–65 mmHg (7.4–8.6 kPa), the qualification should be more cautious and based on a longer observation period. The proposed 3 months seems to be adequate.

One fifth of our COPD patients and one third of those with other lung diseases died before one year of treatment. The high mortality rate in COPD was also observed in other studies [1, 2, 15]. In our patients with other chronic lung diseases, a high mortality rate was observed in PPH, TB sequelae and bronchiectasis, and the lowest in kyphoscoliosis. In a recent study from Sweden, the lowest mortality rate was also observed in kyphoscoliosis [12]. We noted a higher mortality raten patients as compared to patients accepted to LTOT with mild hypoxaemia. Dubois *et al.* [16] recently observed that 46% of COPD patients, qualified with $Pao_2$ <55 mmHg (7.3 kPa), died before 2 yrs of treatment.

The frequency of spontaneous improvement of blood gas during LTOT in our patients, suggesting an incorrect qualification, was similar to that observed in the recent study from Sweden. After 18 months of follow-up 4% of the patients did not need oxygen and 12% did not fulfil the entry criteria [12, 17].

In patients with less severe hypoxaemia ($Pao_2$ around 60 mmHg (8.0 kPa)) additional qualification criteria should also be taken into consideration. Measurements of arterial blood oxygenation during sleep are advisable. An increasing number of studies suggest that pulmonary hypertension and right ventricular hypertrophy not only result from permanent hypoxaemia but are also observed in patients desaturating at night only [18, 19]. Oxygen treatment during sleep protects against increases of pulmonary hypertension and long-term oxygen treatment decreases pulmonary vascular resistance [20].

Recently FLETCHER *et al.* [21] observed that patients with COPD with daytime $Pao_2$ >60 mmHg (8 kPa), who desaturate during sleep, have a shorter survival than patients who do not have such episodes. Analysis of our own material [22] seems to support such an hypothesis. For this reason, in patients with less advanced hypoxaemia an overnight monitoring of blood oxygenation should be performed as an additional criterion of eligibility for LTOT.

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