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A model of quality assessment in patients on long-term oxygen therapy

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Summary
Background: The difficulty of implementing guidelines for long-term oxygen therapy (LTOT) has been recognized. We performed this analysis to evaluate the impact of a national quality assurance register on the quality of LTOT and to suggest indicators with levels for excellent quality LTOT.
Methods: Based on national register data on Swedish LTOT patients in 1987–2005, we measured nine quality indicators and the achievement levels of the participating counties in fulfilling these treatment criteria.
Results: There were improvements in the following eight quality indicators: access to LTOT, $PaO_2 \leq 7.3$ kPa without oxygen, no current smoking, low number of thoracic deformity patients without concomitant home mechanical ventilation, >16 h of oxygen/day, mobile oxygen equipment, reassessment of hypoxemia when LTOT was not started in a stable state of chronic obstructive pulmonary disease (COPD) and avoidance of continuous oral glucocorticosteroids in COPD. There was decline in the quality indicator $PaO_2 > 8$ kPa on oxygen. After improvements, three criteria were fulfilled by ≥80% of the counties in 2004–2005.
Conclusions: We found improvements in eight of nine quality indicators. We suggest these indicators with levels for excellent quality for use in quality assurance of LTOT based on our results.

Introduction

Long-term oxygen therapy (LTOT) doubles survival time in chronic obstructive pulmonary disease (COPD) complicated by severe hypoxemia ($PaO_2 \leq 7.3$ kPa)[1,2] but not by moderate hypoxemia (PaO_2 7.4–8.7 kPa).[3,4] These findings led to

Abbreviations: COPD, chronic obstructive pulmonary disease; HMV, home mechanical ventilation; kPa, kilopascal; LTOT, long-term oxygen therapy; PaO_2, arterial oxygen tension.

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recommendations for LTOT from the Swedish Association of Chest Medicine in 1985, revised in 1993, and the American Thoracic Society together with the European Respiratory Society, among many others.[5,6] It is recognized that it is difficult to implement guidelines for the management of LTOT.[7] Adherence to the LTOT guidelines varies in different countries and different parts of these countries.[8–12]

No beneficial effects of LTOT on survival time have been demonstrated in conditions other than COPD causing respiratory failure. One unpublished, randomised, controlled trial showed no effects on survival with interstitial lung disease.[13] LTOT is, however, assumed to have beneficial effects, such as the alleviation of dyspnoea and a reduction in the negative effects of hypoxemia on the internal organs. Consequently, there are recommendations for LTOT in idiopathic pulmonary fibrosis and pulmonary arterial hypertension.[5,14,15]

The overall benefits of LTOT vary with access,[5] the appropriate selection of patients with regard to levels of chronic hypoxemia,[3,6,16,17] smoking avoidance[8,18–20] and provision of home mechanical ventilation (HMV) to patients with thoracic deformity.[21–23] Furthermore, the indication for LTOT should be re-evaluated if the therapy is started during an exacerbation of COPD.[6,16,17]

The benefits of LTOT also depend on performance in terms of reaching the recommended oxygenation during oxygen therapy,[1,2] length of oxygen therapy per day[1,2,8] and access to mobile oxygen equipment when needed.[1,24,25] It can be assumed that avoidance of long-term oral glucocorticosteroids in COPD supports the treatment goals in patients receiving LTOT.[26–28]

To facilitate the implementation of guidelines, a national register provides a basis for evaluation and subsequent improvements.[8]

The purpose of this evaluation was to investigate the feasibility and the possible impact of a national quality assessment register as a benchmarking tool for improved LTOT and to suggest levels of excellent quality for indicators based on such impact at national and regional levels.

Methods

Oxygen Register

The national register of patients undergoing LTOT in Sweden was started on 1 January 1987, with registration of patients already receiving LTOT for chronic respiratory failure and prospective registration of new patients starting LTOT.[5] The LTOT was based on guidelines from the Swedish Society of Chest Medicine, agreed on in 1985 and subsequently revised in 1993. In November 2004, the register was merged with the register of home mechanical ventilation to create the Swedevox national quality assurance register, an Internet-based register with on-line presentations of the quality assessment results for the individual participating centres, compared with national results.[23]

All adults receiving LTOT for chronic hypoxemia were eligible for registration and were followed prospectively for a minimum of one year. The coverage of the register was assessed by repeated questionnaires to the participating responsible respiratory physicians, and was found to be approximately 85%. Patients receiving LTOT for short periods as part of palliative treatment for lung cancer, whether primary or secondary, were not included.

The register is intended to contribute to gradual improvements in LTOT by annual distribution of the results.

The effective units in this process are the counties with their responsible physicians.[5] These physicians are the contact persons for the Oxygen Register. They are responsible for the organisation of LTOT in their counties and reporting to the Oxygen Register. In each unit, specially trained nurses participate in the treatment. These nurses, or technicians at a few units, perform home visits to LTOT patients. In 1987, there were oxygen nurses in some counties and, by approximately 10 years later there were oxygen nurses in all counties. Sweden was divided into 24 counties in 1987. In 2005, the division was changed to 20 counties; this division has been used in our calculations over the entire observation period. The populations of the counties varied between 1,606,157 and 133,389 in 1987 and between 1,889,945 and 127,028 in 2005. There were university hospitals in six of the counties. The number of hospitals in each county varied between one and 10. There was a pulmonary division or pulmonary outpatient department at 96% of the hospitals. The overwhelming majority of the LTOTs was prescribed by physicians with special training in COPD and respiratory failure, either pulmonologists or internists.

The quality indicators and their levels were discussed in annual national reports and at meetings of the register, with the participation of physicians and nurses involved in LTOT, as well as continuously via mail and e-mail.

LTOT indications and performance

According to the guidelines from the Swedish Society of Chest Medicine, LTOT was indicated for patients with

- chronic hypoxemia due to COPD or other diseases,
- a stable disease course on optimum medical therapy for at least three weeks,
- arterial oxygen tension (PaO_2) when still breathing room air of less than 7.0–7.5 kPa ($\leq$7.3 kPa after 1993) or signs of cor pulmonale or haematocrit $>$50% plus room air PaO_2 of around 7.5 kPa (7.4–8 kPa after 1993).

Arterial blood gas samples were taken at rest after breathing air or the prescribed flow of oxygen for a minimum of 20 min. The prescribed flow of oxygen was defined using pulse oximetry in patients without hypercapnia and with repeated adjustment and arterial blood gas samples in hypercapnic patients.

Smoking habits were checked by questions to the patients and their relatives and caregivers. From 2002 and onwards, the register stated whether or not LTOT was initiated during an exacerbation of COPD. An exacerbation was defined as a deterioration of COPD serious enough to require hospitalization and associated with respiratory failure.

Every regional ethics committee in Sweden, the National Board of Health and Welfare, and the Data Inspection Board approved the evaluation. All of the patients gave their informed consent prior to inclusion.

Our quality indicators

Patient selection criteria
From 1987 onwards:

- access to LTOT as the number of LTOT patients per 100,000 inhabitants,
- percentage of patients with $PaO_2 \leq 7.3$ kPa when breathing air, daytime at rest,
- percentage of patients who are not current smokers.

From 1993 onwards:

- a small number of patients with thoracic deformity without concomitant HMV.

Performance of LTOT
From 1987 onwards:

- percentage of patients with $PaO_2 > 8$ kPa when breathing oxygen,
- percentage of patients with prescribed dosage of oxygen >16 h per day.

From 1989–2004:

- percentage of patients with access to mobile oxygen equipment, registered at follow-up after one year.

From 2002 onwards:

- percentage of COPD patients with reassessment of hypoxemia when breathing air if LTOT was not started in a stable state, registered at follow-up after one year.

Concomitant treatment
From 1987–1989 and from 1995 onwards:

- percentage of COPD patients without continuous oral glucocorticosteroids.

Data analyses

Data from the questionnaires were compared with data in the Swedish Causes of Death Register kept by the Swedish National Board of Health and Welfare. Both registers use the Swedish census registration numbers, which secures follow up on vital status for all Swedish citizens. In COPD patients starting LTOT between 1987 and 2004, we measured the crude survival rate during LTOT. We also analysed the change in age and sex-adjusted first year and overall survival rates according to the year of starting LTOT in COPD patients starting LTOT between 1987 and 2004.

Use of quality indicators

As basic criteria, evidence from the literature was used.[1–3,6,8,15,16,18–22,24–29] Early experience from the register, identifying major differences in access between counties as a serious shortcoming, led to development of an access criterion.[5] Our early results showing impaired survival in current smokers and poor compliance with the prescribed hours of oxygen in patients with a good performance status also encouraged us to two criteria.[8] For each quality indicator, the counties level of achievement was given for comparison with the national level achieved by all participating centres. With the individual levels obtained by these centres as guidance, a recommended level of achievement was chosen as a marker of excellent quality, e.g., XX% of patients have $PaO_2 > 8$ kPa when breathing oxygen (Table 1).

Statistical analyses

Each quality indicator was analysed by comparing data from 1987 and 2005, or at some other start and end year, as specified in the text. Statistical analyses of survival rates were performed using Kaplan–Meier and Cox's regression analysis. The calculations were made with the STATA 9 statistics package.

Results

Patients

Data on start of LTOT
During the period 1987–2005, 12,070 patients (49% male), 8379 (69%) of whom had COPD were registered when they started LTOT (Fig. 1). The mean age of COPD patients when starting LTOT increased from 66 to 74 years over the period 1987–2005. In 2005, 18% of the LTOT for COPD patients was initiated during an exacerbation. In COPD, the mean values of PaO_2 and $PaCO_2$ when breathing air were 6.6 ± 0.9 and 6.3 ± 1.2, respectively, and $PaCO_2$ was above 6.0 kPa in 58% of the COPD patients.

Survival in COPD

First year survival rate was 0.74 (95% confidence interval 0.73–0.75). There was no significant change in first year survival rate according to starting year of LTOT.

Second year survival rate was 0.54 (95% confidence interval 0.53–0.55) and five-year survival was 0.20 (95% confidence interval 0.19–0.21%). In COPD patients, overall survival was stable in LTOT from 1987 to 2004 after account was taken of age and sex.

Quality indicators at national level

Table 1 shows the figures at national level at the start and end of the observation period in the nine quality indicators, divided into three categories. There were improvements in eight quality indicators. The achievement of adequate oxygenation ($PaO_2 > 8$ kPa) when breathing oxygen has declined.

Access to therapy increased in terms of the number of patients on LTOT. The prevalences in the separate counties varied between 1.3 and 19.6 per 100,000 on 1 January 1987 and between 21.0 and 76.0 per 100,000 on 31 December 2005 (variations by a factor of 15 and 3.6, respectively) (not shown in the Table 1). At national level, the prevalence of

Table 1 Quality indicators, proposed levels for excellent quality, and achieved performance level for the first and last year cohort, respectively.

Quality indicator	Proposed excellent quality level	Achieved performance level first year cohort and last year cohort	
		Year	Level
Patient selection criteria			
1. Access to LTOT (patients/100,000 inhabitants)	>30	1987	7
		2005	31
2. $PaO_2 \leq 7.3$ kPa (% of patients)	>85	1987	76
		2005	85
3. Non-smokers (% of patients)	≥95	1987	96
		2005	99
4. LTOT patients with thoracic wall deformity without HMV (*n*)	None	1993	30
		2005	5
Performance of LTOT			
5. $PaO_2 > 8$ kPa on oxygen (% of patients)	>90	1987	86
		2005	80
6. More than 16 h a day (% of patients)	>95	1987	91
		2005	97
7. Mobile oxygen equipment (% of patients)	>50	1989	48
		2004	65
8. Reassessment of LTOT 1–3 months after initiation during a COPD exacerbation (% of patients)	>95	2002	0
		2005	30
Concomitant treatment			
9. Avoidance of continuous oral glucocorticosteroids in COPD (% of patients)	≥80	1987	54
		2005	81

LTOT: long-term oxygen therapy; PaO_2: arterial oxygen tension; HMV: home mechanical ventilation; and COPD: chronic obstructive pulmonary disease.

LTOT increased from 565 on 1 January 1987 to 2871 on 31 December 2005. The dominant underlying diseases were COPD and pulmonary fibrosis (Fig. 1).

County quality achievement

At the end of the evaluation period, all counties had achieved our proposed quality level for the prescription of oxygen for more than 16 h a day. Ninety per cent achieved this level in terms of LTOT to non-smokers and 80% in terms of providing the patients with mobile equipment (Table 2). Conversely, only 25% of the counties managed to achieve the quality levels for the reassessment of LTOT 1–3 months after initiation during a COPD exacerbation, and only 25% of the counties achieved the proposed quality level for $PaO_2 > 8$ kPa on oxygen, a decline in achievement in comparison with 2002 and 1987, respectively.

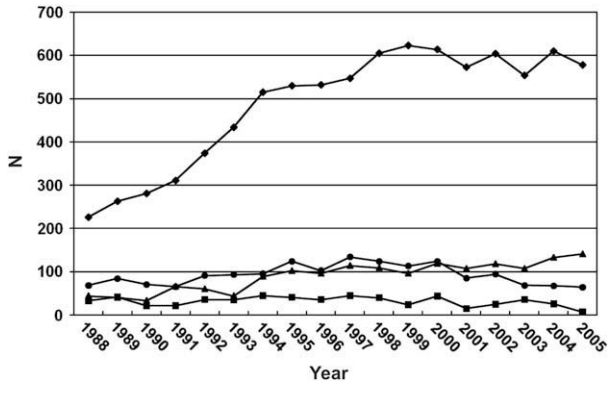

Figure 1 Number of new patients (*n*) with long-term oxygen therapy in 1987–2005 divided into causes of hypoxemia. ◆: chronic obstructive pulmonary disease; ▲: pulmonary fibrosis; ■: thoracic cage deformity; ●: other diseases.

Discussion

We found considerable improvements in most quality indicators after the initiation of the register in 1987, suggesting that the register does function as a benchmarking tool for quality assurance. There was substantial improvement in access to LTOT and the adherence to treatment criteria in terms of an increasing percentage of patients with severe hypoxemia and a decreasing percentage of current smokers. In spite of this, at national level, two of the nine quality indicators were poorly fulfilled even in 2005, including the percentage of patients reaching adequate oxygenation when breathing oxygen, which actually diminished during our observation period.

The annual reports and meetings for the personnel responsible for LTOT focused on access, patient selection and concomitant treatment. Likewise, attention has been focused on appropriate equipment selection, including lightweight mobile equipment, and reassessments of hypoxemia. In this area, we observed improvements,

Table 2 Achievement among the counties (%) of excellent quality levels by quality indicator, first and last year of use of indicator.

Proposed excellent quality level	Counties achieving excellent quality level first and last year of use of indicator	
	Year	%
Patient selection criteria		
1. Greater than 30 patients/100,000 inhabitants with access to LTOT	1987	0
	2005	60
2. Greater than 85% of patients with $PaO_2 \leq 7.3$ kPa	1987	35
	2005	65
3. Greater than or equal to 95% of patients who were non-smokers	1987	90
	2005	90
4. No thoracic wall deformity patients without HMV	1993	30
	2005	75
Performance of LTOT		
5. Greater than 90% of patients with $PaO_2 > 8$ kPa on oxygen	1987	50
	2005	25
6. Greater than 90% of patients with more than 16 h a day	1987	70
	2005	100
7. Greater than 50% of patients with mobile oxygen equipment	1989	60
	2004	80
8. Greater than 95% of patients with reassessment of LTOT one to three months after initiation during a COPD exacerbation	2002	0
	2005	25
Concomitant treatment		
9. Greater than or equal to 80% of COPD patients without continuous oral glucocorticosteroids	1987	25
	2005	50

LTOT: long-term oxygen therapy; PaO_2: arterial oxygen tension; HMV: home mechanical ventilation; and COPD: chronic obstructive pulmonary disease.

although we are still far from reaching our goal for excellent quality. The importance of oxygenation during oxygen breathing was not addressed until 2003, which may have influenced the apparent deterioration in quality before the time attention was paid to that indicator. We observed an improvement in the quality indicators after they were highlighted, and believe that continuous education and repeated focus on results are necessary prerequisites for a quality register, with the aim of achieving these desired improvements.

The gradual and considerable increase in the number of initiated LTOTs is probably a result of both the increasing attention that has been paid to LTOT and the time course of smoking habits in Sweden rather than a widening of the indications for LTOT. This assumption is supported by the decline in the percentage of patients with mild to moderate hypoxemia. An increase in the prescription of LTOT has also been demonstrated in Denmark, where COPD patients with LTOT increased from 27 per 100,000 inhabitants in 1994 to 42 per 100,000 in 2000.[29] The incidence of LTOT prescriptions in our material varied fourfold between the counties in 2005, which could very well reflect the regional differences in smoking related respiratory diseases, since it also corresponds to the fourfold variations in lung cancer among Swedish counties according to the Cancer Register of the National Board of Health and Welfare.[30]

Patients with thoracic wall deformity as a cause of chronic hypoxemia, especially those with concomitant respiratory disorders, often receive LTOT,[23] despite that the superior survival effects of HMV in these patients and some of them actually manage well on HMV alone.[21–23] We found a substantial decrease in the prescription of LTOT without concomitant HMV in patients with thoracic wall deformity.

In Sweden, it is recommended not to initiate LTOT in current smokers, and adherence to this recommendation increased during our observation period. The reason for this recommendation is the assumed interference with the treatment results[8] and the risk of fire.[18–20] Despite an increase in mortality among current smokers,[8] it is possible that LTOT has a positive effect on survival rate in these patients. This problem was recently addressed at the NHLBI workshop on LTOT as an ethical issue to be included in future studies of LTOT.[31] In our patients, as many as 99% were non-smokers at the end of the observation period, as compared with 86% of Scottish patients and 79% of Danish patients with LTOT, for example.[9,12]

In respiratory failure during exacerbation of COPD, there is a chance of improvement of oxygenation during the recovery.[16] When initiating LTOT under these circumstances, the indication should, therefore, be reassessed after 1–3 months.[6] This recommendation has been a quality indicator in our register since 2002. Despite education in this area, its introduction on a wide scale has been slow, probably because recovery from COPD exacerbations are generally not expected to last as long as three months and because the reassessment calls for an extra visit by the oxygen nurse. Register data show that the proportion of LTOTs started during exacerbation in Sweden has increased since 2002. Shorter inpatient times due to the 75% decline in the national number of hospital beds from

1987 to 2005 has probably contributed to this, and to the diminished proportion of patients reaching adequate oxygenation at the start of LTOT.

One of the reasons for the eight-year increase in mean age for start of LTOT is probably the time course of smoking in the population. Smoking has decreased since the 1970s in Sweden. Another reason might be improvement in the overall care of patients. The higher age at the start of LTOT has an impact on survival rates during LTOT, which also vary with the changes in diagnosis and sex distribution.[32,33]

We have studied prescribed, rather than achieved, daily time of oxygen therapy. Compliance is a difficult issue, which we have not addressed in any detail in this evaluation.[11,34,35] In our experience, the assessment of compliance is too complicated to include as an indicator in a quality register.[8] When oxygen cylinder use and concentrator meter readings were checked in the Swedish register, approximately 70% of patients were found to use oxygen for a minimum of 15 h or more per day.[8]

The main goal of LTOT in COPD patients is to improve survival. The effect of LTOT on survival rates depends on the treatment time per day.[1,2] Lightweight portable oxygen equipment is important for compliance with the prescribed hours of oxygen in patients who are active outside the home.[11] Using portable oxygen equipment may also have a positive effect on health status.[24,34,36] This assumption was not supported by a recent study of ambulatory oxygen,[37] which found no impact on health status, as well as fairly poor compliance. The prescription of portable oxygen equipment to mobile patients (quality indicator 7 in Table 1) is clearly a quality debatable indicator until new trials elucidate the question.[31] To date, our recommendation has been to try to reach a continuous adequate level of oxygenation for the best impact on survival and health status.

It is possible that the common prescription of oxygen for a minimum of 16 h per day resulted in many patients not striving to use oxygen for up to 24 h per day, and thus not taking full advantage of their LTOT.

The survival rate among our register patients was lower than in the NOTT and MRC studies.[1,2] Compared with those studies, patients in our evaluation were older, and patients with very poor performance status or concomitant disease were not excluded, as they were in the NOTT and MRC studies. We found similar survival rate as Crockett et al.[38] Their first-year survival rate was 75% in an unselected patient group, like our patients. In Denmark, the first-year survival rate among COPD patients with LTOT has been found to be even lower, 55%.[29] It is believed that the high proportion of patients starting LTOT in an unstable state of COPD has contributed to this low first year survival rate in Danish patients. In our COPD patients, the majority started LTOT in a stable phase of their disease. A decreasing proportion of patients with PaO_2 when breathing air of above 7.3 kPa, and a diminished proportion of patients reaching adequate oxygenation when breathing oxygen, might have contributed to our absence of improvement in survival rates. However, we believe that the most important reason for the failure to improve survival rates was the higher age and more compromised performance status of patients initiated on LTOT during the latter part of the period 1987–2004.

There are no existing recommendations for levels of excellent quality in indicators for the care of patients on LTOT. Our choice of quality indicators was guided by published evidence (quality indicator 2,[1–3] 4,[21–23] 5,[1–3] 6,[1,2,8] 8[6,16,17] and 9[26–28] in Table 1), and our early results (quality indicator 1,[5] 3[8] 7[26] in Table 1). Our suggested levels are based on the observed county results. The latter three quality indicators and levels for excellent quality based on our experience are of a temporary nature and will have to be changed according to new knowledge and guideline revisions.[30] This applies particularly to the access indicator which will have to be adjusted to match the changing epidemiology of COPD over time in the area where it is used.

In conclusion, we found improvements in eight of nine quality indicators over 19 years of quality registration. We propose a model for the quality assurance of LTOT, using indicators with levels for excellent quality, based on our estimation of current knowledge.

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