LONG-TERM DOMICILIARY OXYGEN THERAPY — THE JOHANNESBURG HOSPITAL EXPERIENCE

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Objectives. To assess the clinical and demographic characteristics of patients attending an oxygen clinic, to assess the relevance of the current clinical criteria determining the need for domiciliary oxygen, to assess the cost-effectiveness of an oxygen clinic and to assess compliance with the oxygen prescription.

Design. Descriptive study with a retrospective review of data.

Setting. Tertiary-level academic hospital.

Subjects. All patients attending a newly established oxygen clinic.

Results. Data were analysed for 679 patients (361 male and 318 female), of whom 543 were ex- or current smokers, and 136 were non-smokers. Of the total number, 576 had chronic obstructive pulmonary disease. Oxygen was given to 425 patients and denied to 254. Forced expiratory volume in 1 second (FEV_1) is probably not of value in determining requirement for oxygen as there was no correlation between severity of lung disease and partial arterial oxygen pressure (PaO_2). There was also no correlation between PaO_2 and litres of oxygen prescribed. Compliance with the oxygen prescription was 39%. Cost savings to the State from the oxygen that was not prescribed was in the region of R125 000 per month.

Conclusions. Each patient should be assessed individually using clinical parameters to classify the disease severity and to assess the degree of tissue hypoxia. Oxygen clinics are of value and should be established more widely within each province. Compliance is suboptimal and continued follow-up to motivate patients to use the oxygen as prescribed should be instituted.

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The goal of therapy in chronic obstructive pulmonary disease (COPD) is to improve quality of life by minimising symptoms, preventing acute exacerbations and preserving optimal lung function.[1] COPD is a largely irreversible, progressive disease and management includes smoking cessation, bronchodilation and oxygen therapy.[2]

Oxygen supplementation is life-saving during acute exacerbations and has also been proven to be of benefit in those with hypoxic COPD.[3] In a British Medical Research Council study,[4] oxygen administered via nasal cannulas at a flow rate of 2 l/min for at least 15 hours per day, reduced mortality at 3 years from 66.7% to 45.2%. Similarly, the Nocturnal Oxygen Therapy Trial[5] (NOTT) randomised hypoxic COPD patients into a control group that received 12 hours of supplemental oxygen at night and a study group that received continuous oxygen therapy. Mortality within the study group was 11.9% at 12 months and 22.4% at 24 months compared with 20.6% and 40.8% respectively in the controls. The conclusions of these studies were that oxygen can prolong life if used for a period of more than 12 hours per day, and that pure oxygen utilised for relief of symptoms only was not cost-effective in the long run.

Until recently, hospital services in Gauteng have provided oxygen in a random fashion without regard to underlying disease or degree of hypoxaemia. Consequently, an oxygen clinic was established at the Johannesburg Hospital with the intention of providing oxygen in a more scientific manner. This study represents a review of data from patients who attended this clinic from January 1996 to November 1996.

METHODS

All patients already receiving long-term domiciliary oxygen therapy (LTDOT), as well as new referrals from hospitals, clinics, district sisters, private practitioners and the Johannesburg Hospital Pulmonology Unit, were assessed at the oxygen clinic.

Lung function tests

All patients were subjected to spirometry on the Compac II vitallograph according to American Thoracic Society (ATS) criteria.[6] Arterial blood gas analysis was performed on a sample of blood drawn from the radial artery of each individual; all patients had been breathing room air for a period of at least 30 minutes before this.

Eligibility for LTDOT

Patients were subsequently assessed for eligibility for LTDOT by the consultants of the Pulmonology Unit of the Jhb Hospital. The criteria for eligibility were:

1. Abstinence from smoking for a period of at least 6 weeks (historical information).

2. Moderate COPD (forced expiratory volume in 1 second (FEV_1)% < 50%) with hypoxaemia (partial arterial oxygen pressure (PaO_2) < 55 mmHg) with or without hypercapnia (partial arterial carbon dioxide pressure ($PaCO_2$) > 45 mmHg) and with or without cor pulmonale.
3. A compassionate group that included: (*i*) COPD patients with a PaO_2 between 55 and 60 mmHg and evidence of tissue hypoxia (plethora, pedal oedema, altered mental state); (*ii*) patients with severe dyspnoea on effort, relieved by low-flow oxygen, who reported an improved effort tolerance or functional ability on LTDOT; (*iii*) patients with respiratory failure from diseases other than COPD; and (*iv*) patients with malignancies with pulmonary involvement.

Oxygen prescription

The patient's oxygen requirements were determined on dual-prong nasal cannulas according to the dose required to achieve arterial oxygen saturation (SaO_2) of ≥ 90%. This was determined by pulse oximetry, which in general correlates well with SaO_2.[27] Patients were instructed to use oxygen for at least 15 hours per day. If nasal cannulas could not be utilised, then an oxygen mask was prescribed using the conversion of 1 l/min via cannulas = a 3 - 4% increase in the fractional concentration of inspired oxygen (FiO_2). Oxygen was provided for the first 3 months via cylinders and thereafter Newlife Airsep oxygen concentrators were supplied and serviced by a company contracted to the State.

Statistical analysis

Statistical analysis of the entire group and the COPD subgroup was performed by the Institute of Biostatistics of the Medical Research Council. The demographics, the descriptive statistics and the correlates were analysed using the univariate procedures, Student's *t*-test and Pearson's correlation coefficients. COPD was defined as an FEV_1/FVC (forced vital capacity) ratio of < 70%. Severity was defined in terms of FEV_1% predicted.

Ethics Committee approval was obtained from the Human Research Division of the University of the Witwatersrand before embarking on this analysis.

RESULTS

During the period January 1996 to November 1996, 940 patients were assessed at the oxygen clinic. Complete data were available for 679 patients. Those for whom complete data were not available included paediatric patients, patients who were unable to perform lung function tests (because of tracheostomies, dementia, mental retardation) and a small number of patients without arterial blood gas analysis.

Demographic data

Of the 679 patients who were analysed, 361 were male and 318 female. The mean age was 66.8 years. Five hundred and forty-three patients had either smoked or were current smokers, and 136 had never smoked. Oxygen was given to 425 patients and denied to 254.

Subanalysis of the group revealed that 576 patients had COPD; 320 were male and 256 female. The mean age of those with COPD was 67.19 years and 493 of these patients were current or ex-smokers. The other causes for COPD included exposure to organic dusts, cystic fibrosis, long-standing poorly controlled asthma, bullous lung disease and tuberculosis. Oxygen was given to 387 patients in the COPD subgroup and denied to 189 (Table I).

Table I. Demographic data of patients attending the oxygen clinic and those with COPD irrespective of aetiology

	Entire group	COPD subgroup
Males	361	320
Females	318	256
Mean age (yrs)	66.85	67.19
SD	12.18	11.06
Smokers	543	493
Non-smokers	136	83
O_2 prescribed (%)	425 (62.7)	387 (67.1)
O_2 refused (%)	254 (37.3)	189 (32.9)

Descriptive data

The mean number of pack-years smoked by the whole group was similar to that of the COPD subgroup (36.5 versus 39.3). However, male patients had a significantly greater smoke burden than females, with a pack-year history of 45.8 compared with 26.18 ($P < 0.001$).

Male patients had a significantly higher FEV_1 than females (1.08 l v. 0.86 l), as did non-smokers when compared with current and ex-smokers (1.2 l v. 0.92 l). Notably, males had a significantly lower FEV_1% than females (39.31 v. 48.46), and predictably, smokers had a significantly lower FEV_1% than non-smokers (39.87 v. 58.57).

Despite the difference in clinical parameters, male and female patients had a similar PaO_2. Smokers had a significantly lower PaO_2 than non-smokers (51.97 mmHg v. 61.47 mmHg) (Table II).

The COPD subgroup was analysed as a separate entity with specific reference to those who were given oxygen and those who were not. Some bias may exist because some of those who were denied oxygen were severely hypoxic but were still smoking. This group as a whole had a mean FEV_1 of 0.87 l, a mean FEV_1% of 38.55 and a mean PaO_2 of 52.41 mmHg. Those who received oxygen had a mean FEV_1 of 0.76 l, a mean FEV_1%

Table II. Descriptive statistics of all patients and those with COPD attending the oxygen clinic. Males are compared with females, and current and ex-smokers with non-smokers

	All patients	Males	Females	Current and ex-smokers	Non-smokers	COPD subgroup
Mean No. pack-years	36.53	45.8*	26.18*	45.56	0.00	39.34
SD	37.85	42.28	28.91	37.15	0.00	37.13
Mean FEV_1 (l)	0.98	1.08*	0.86*	0.92†	1.20†	0.87
SD	0.54	0.60	0.44	0.49	0.67	0.42
Mean FEV_1%	43.62	39.31*	48.46*	39.87†	58.57†	38.55
SD	24.45	21.02	27.02	22.84	25.17	20.40
Mean PaO_2 (mmHg)	53.89	54.39‡	53.30‡	51.97†	61.47†	52.41
SD	13.33	13.05	13.63	12.48	13.80	12.26

*$P < 0.001$ (comparison between males and females).
†$P < 0.001$ (comparison between current and ex-smokers and non-smokers).
‡$P = 0.28$ (comparison between males and females).
SD = standard deviation.

of 34.7 and a mean PaO_2 of 47.18 mmHg. These were all significantly lower than the mean values in the group that was denied oxygen (mean FEV_1 of 1.11 l, mean FEV_1% of 46.43 and mean PaO_2 of 63 mmHg (all $P < 0.001$) (Table III).

Table III. Comparison of FEV_1, FEV_1% and PaO_2 in patients with COPD who were given oxygen and those denied oxygen

	COPD — given oxygen	COPD — denied oxygen
Mean FEV_1 (l)	0.76*	1.11*
SD	0.34	0.48
Mean FEV_1%	34.70*	46.43*
SD	21.08	16.58
Mean PaO_2 (mmHg)	47.18*	63.00*
SD	9.89	9.52

*P < 0.001.

Those with no evidence of COPD included normal individuals with anxiety disorders, asthmatics, and patients with terminal malignancies, interstitial lung disease, congenital cyanotic heart disease, angina and other disorders. Thirty-eight of these individuals were given oxygen and 63 were refused it. They had a mean number of pack-years of 20.58, a mean FEV_1 of 1.53 l, a mean FEV_1% of 72.12 and a mean PaO_2 of 62.13 mmHg.

Correlation between lung function, PaO_2, age and litres of oxygen prescribed

Analysis of the entire group revealed that there was no correlation between FEV_1 or FEV_1% with PaO_2.

Similarly, analysis of the COPD group as a whole, as well as those with COPD and a positive smoking history as a sub-category, revealed no correlation between FEV_1 or FEV_1% with either PaO_2, or pack-years.

There was also poor correlation between PaO_2 with litres of oxygen per minute required to increase the SaO_2 to ≥ 90% (Table IV).

Compliance

All patients on LTDOT were visited at monthly intervals by

Table IV. Pearson's correlation coefficients (significance > 0.6) comparing age, PaO_2 and pack-years

	Age		PaO_2		Pack-years
	All patients	COPD only	All patients	COPD only	(COPD only)
FEV_1	0.14	0.08	0.44	0.33	0.02
FEV_1%	0.13	0.15	0.39	0.27	0.07
PaO_2	0.10	0.16	–	–	0.08
Litres O_2 prescribed	–	–	0.61	–	–

health care workers to assess compliance with the oxygen prescription. Only 39% of patients on LTDOT were using oxygen for the prescribed period of 15 hours or more per day. Certain individuals had been hospitalised for a period of time and this distorted their averages. Others, however, reported various reasons for non-compliance that included a fear of addiction to oxygen, frequent power failures, increasing electricity bills, a dislike of the noise of the concentrator and a conviction that the requirement for LTDOT was confirmation of imminent death.

DISCUSSION

The cumulative survival of patients with hypoxic COPD who were given LTDOT in both the MRC and the NOTT trials[4,5] was 50 - 68% at 3 years and 32 - 53% at 5 years. This was significantly greater than the predicted survival of 32 - 53% at 3 years and 18 - 37% at 5 years that has been documented in the literature.[8]

The reason why LTDOT increases survival is uncertain, but it is probable that it may slow or halt the progression of pulmonary hypertension.[8] LTDOT does not change the spirometric indices or blood gas values significantly but does reverse polycythaemia, increase body weight, and improve exercise performance and quality of life.[1,2,6-10]

The aim of LTDOT is to alleviate tissue hypoxia by maximising oxygen delivery. Various criteria for the prescription of LTDOT have been established based on the MRC and NOTT trials[1,2] (and internal circular No. 21, 1997, from the Gauteng Department of Health) and have been influenced primarily by the effects of oxygen on survival in hypoxic patients with COPD. We have derived similar criteria for our clinic. A PaO_2 of 55 mmHg marks the point on the oxygen dissociation curve below which significant reduction in oxygen delivery to the tissues occurs.[8] Consequently, a PaO_2 of < 55 mmHg is an indication for supplemental oxygen provided that contraindications do not exist. However, there is no doubt that many patients with a PaO_2 of > 55 mmHg have decreased oxygen delivery, particularly on exercise, and although oxygen may not improve survival, it does improve functional ability and quality of life. Consequently, we found it difficult to deny oxygen to this category of patients.

The effect of LTDOT on mortality in other pulmonary disorders has not been studied other than in a small group of patients with cystic fibrosis, for whom it had no effect.[11] We did not deny oxygen to this category of patient if the degree of hypoxia warranted it and if the patient felt symptomatically improved.

The rationale for the use of absolute FEV_1 of < 1.51 l/min[1] is that it is an indicator of the severity of COPD. However, there is a wide variation in normal FEV_1 values that depends on gender, age, height and ethnicity, and our analysis has revealed no correlation between FEV_1 and PaO_2. The FEV_1%, which is a better indicator of disease severity, also did not correlate with PaO_2 and the need for LTDOT. We therefore feel that FEV_1% in conjunction with FEV_1/FVC could be used as a diagnostic tool but should be abandoned as inclusion criteria because ventilation/perfusion (V/Q) mismatch can be severe in a subgroup of patients with only moderately reduced lung function. We believe that clinical status and functional needs should be the most important considerations.

The lack of a correlation between PaO_2 and litres of oxygen prescribed indicates that each patient should be titrated on an individual basis. Many oxygen policies prescribe the same amount of oxygen to every patient but it is unlikely that benefits will accrue without correlation of hypoxaemia. In this study, for logistical reasons, we did not perform blood gas analysis after the administration of oxygen. Although there is a concern that some patients may develop CO_2 narcosis, we believe that this is unlikely as the hypercapnia of COPD is usually due to V/Q mismatch rather than respiratory centre depression.[3] No patient in this group developed a deterioration in mental status or complained of hypersomnolence at home.

The poor compliance noted in this study is cause for concern but concurs with figures reported in the literature.[12] This indicates a need for ongoing education as to the benefits of LTDOT and how these are best achieved. We have not yet removed oxygen for reasons of non- compliance because it is hoped that we may still increase correct oxygen usage.

Smokers who were new referrals were given a 3-month period to stop smoking before being reassessed for eligibility for LTDOT. Smokers who were already receiving LTDOT were also given a 3-month period to stop smoking, with the threat of oxygen removal as an incentive. Smoking does attenuate the beneficial effect of oxygen[13] and is probably a rational exclusion criterion. However, given the nature of the addiction, we are uncertain whether one can ethically withhold oxygen from smoking hypoxic patients, given that we do prescribe oxygen for compassionate reasons to individuals who do not have a proven survival benefit.[13]

Patients who are assessed during or after an acute exacerbation should be reassessed after a 3-month period on medication as approximately 30% of patients will no longer require LTDOT.[2,8] The majority of patients in our clinic are cold referrals who are stable and these individuals should continue oxygen for life irrespective of any improvement that may occur.[9] Patients who are referred to us following an acute exacerbation are not always reassessed at 3 months because of logistical problems with transport or because of the patient being too ill. There is ongoing supervision by the 'oxygen sisters' who regularly supply us with clinical and compliance data, and as such these patients are maintained on LTDOT despite the lack of a formal reassessment at the oxygen clinic.

Oxygen is prescribed as a panacea for a variety of clinical conditions and is perceived as a life-saving measure by many individuals. The removal of oxygen from those individuals

assessed as not warranting LTDOT caused a tremendous amount of distress and anxiety to both the patients and the doctors concerned. The need to do this made the oxygen clinic an emotionally exhausting experience.

Despite our relatively lenient criteria, 252 of the 679 patients who had either been receiving oxygen or who would have received oxygen before the establishment of the clinic, were refused LTDOT. This represented a saving to the province in the region of R125 000 per month, and it is expected that 30 - 40% of all new referrals will also not be issued with oxygen, representing an enormous cost reduction for the future.

CONCLUSIONS

Managing COPD requires the maximisation of lung function, the prompt treatment of bronchopulmonary infections, the treatment of heart failure and the correction of tissue hypoxaemia.[2] LTDOT is a definite therapeutic option for hypoxic COPD.

Our analysis suggests that FEV_1 should be abandoned as a criterion for eligibility for LTDOT and that FEV_1% should be used in conjunction with FEV_1/FVC as a diagnostic tool. An absolute PaO_2 of < 55 mmHg as an inclusion criterion does a disservice to a group of individuals who demonstrate evidence of tissue hypoxia despite having a PaO_2 of > 55 mmHg. The patient and his needs should be individually assessed. Each individual must be titrated as no correlation exists between PaO_2 and litres prescribed. The poor compliance suggests that an improved support and education network should be established in an attempt to encourage the correct use of LTDOT.

The correct prescription of oxygen will save the State a large amount of money and will prevent the emotional trauma of oxygen removal at a later stage.

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