The importance of process variables analysis in the assessment of long-term oxygen therapy by concentrator

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The aim of the present study was to evaluate process variables and intermediate outcomes involved in long-term oxygen therapy (LTOT) by concentrator with the purpose of identifying which of those factors would be the most influential in the final health outcome of the therapy. A cross-sectional survey was carried out on a random sample of 111 patients receiving LTOT by concentrator in Catalonia (Spain). Patients were interviewed and assessed at home by a trained physician, and the variables collected were arterial oxygen saturation, performance of the concentrators, and patient compliance. Sixty-two patients participated in the study. Overall, LTOT was appropriately prescribed in 36 patients, of whom only 29 were able to correct their level of hypoxaemia. Patient compliance with treatment was considered adequate in 19 of those 29 patients. Thus, only 19 of 62 patients (31%) fulfilled those criteria needed to achieve the expected clinical benefits. Strategies for improving the effectiveness of medical interventions or technologies ought to consider those factors of the therapeutic process which might influence the expected health outcomes in a specific health-care context.

Introduction

Technology assessment activities include the evaluation of the efficacy, safety, effectiveness and appropriateness of emerging and established health technologies (1,2). Randomized control trials have proved the efficacy of long-term oxygen therapy (LTOT) as survival rates of patients with chronic obstructive pulmonary disease (COPD) and chronic respiratory failure were shown to increase due to the effect of therapy (3,4). However, the effectiveness of any therapy is dependent, in average clinical practice, on the achievement of the different intermediate outcomes implied in the therapeutic process, along with its appropriate indication and use. In LTOT, those process variables are the diagnosis of chronic hypoxaemia, the correction of the hypoxaemia which depends on correct prescription of oxygen flow rate and proper functioning of the device, and patient compliance with the treatment. All those intermediate factors should be met simultaneously in each treated patient in order to get the expected health benefit of the therapy. Therefore, the effectiveness of LTOT depends initially on the appropriateness of the therapeutic process.

The aim of the present study was to evaluate process variables and intermediate outcomes involved in LTOT by concentrator with the
purpose of identifying which of those factors would be the most influential in the final outcome of the therapy. The questions include: are the patients, enrolled in a public financed programme, being prescribed oxygen correctly?, are they complying with its use?, are they reporting compliance accurately? and, finally, is the equipment functioning well?

Patients and Methods

In Catalonia (Spain), the total number of patients included in the public financed LTOT programme was 3910 in 1991 (prevalence rate 65/100 000). Overall, 534 patients (14%) of those patients were receiving LTOT by concentrator. A random sample of 111 patients was selected from the census of all patients who had received this therapy via concentrator during 1991. A cross-sectional survey of the 111 patients was carried out from March to April 1992. Patients who died during the time interval from the census to the survey (n=21) or were no longer receiving treatment (n=14) were excluded from the study. All patients were assessed at home by the same trained physician, who was not a member of the research team. Each patient provided informed consent before participating in the study.

Data regarding gender and place of residence of members of the programme were collected from the Catalan Health Service information system. A questionnaire was also specifically designed to obtain the following information: age, smoking habits, main diagnosis, and type and hours of concentrator utilization. Level of percentage saturation of haemoglobin with oxygen in arterial blood ($\text{SaO}_2$) at rest was measured using a pulse oxymeter (Ohmeda Biox IVA, U.K.), firstly whilst breathing room air for 30 min and, secondly, whilst breathing oxygen at the prescribed flow rate for more than 30 min. The percentage of oxygen delivered by concentrator was measured at a flow rate of 2 l min$^{-1}$ when the device was working for more than 15 min using an Ohmeda 5120. Oxygen Monitor (U.K.) indicated oxygen concentrations from 0 to 100% (drift range ±1%; monitor linearity ±1% of full scale).

The criteria established to define the appropriateness of the therapeutic process were:

1. Diagnosis of chronic hypoxaemia at the time of the survey ($\text{SaO}_2 \geq 88\%$ at rest while breathing room air) (5);
2. Oxygen flow rate capable of raising arterial oxygen tension ($\text{PaO}_2$) at rest ($\text{SaO}_2 > 90\%$ at rest whilst breathing oxygen) (6);
3. Proper functioning of the concentrator (percent of oxygen delivered >90% at a flow rate of 2 l min$^{-1}$) (7); and

The latter was measured by a clock fitted to every device in order to record hours of electricity used for a period of at least 7 days. Adequate compliance was defined as concentrator utilization for at least 80% ($\geq 12 \text{ h day}^{-1}$) of the previously defined appropriate utilization time ($\geq 15 \text{ h day}^{-1}$).

Data are expressed as mean ± SD. Differences between self-reported and measured compliance were examined using the McNemar test. A $P$ value $<0.05$ was considered to be significant.

Results

Overall, 76 patients were considered eligible, although only 62 participated in the study (82%). Reasons for non-participation were change of address (nine patients) and hospitalization at the time the survey took place (five patients). The average age of the participate patients was 68 ± 9 years, 76% were male, 11% of the surveyed patients were active smokers at the time of the study, 60% were ex-smokers, and 29% had never smoked. The most frequent diagnosis reported was chronic obstructive pulmonary disease (70%). In 87% of cases, the therapy had been prescribed by chest physicians.

Inclusion in the LTOT programme was considered to be appropriate for only 36 of the 62 patients assessed at the time of the survey ($\text{SaO}_2$, 81.0 ± 5.8%), while this therapy was considered to be inappropriate in the remaining 26 patients ($\text{SaO}_2$, 92.1 ± 2.1%). The latter group of patients was, therefore, excluded from the therapeutic process analysis. In addition, 12 of the 62 devices (19%) were found not to work properly. Defective devices were observed mainly in the group in which the therapy was inappropriately prescribed (10 of 12 devices). Table 1 includes the list of concentrator models used.
Table 1. Concentrator models

<table>
<thead>
<tr>
<th>Model</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Companion 208 (U.S.A.)</td>
<td>17</td>
</tr>
<tr>
<td>Bunn 3001 (U.S.A.)</td>
<td>16</td>
</tr>
<tr>
<td>DeVilbis (U.S.A.)</td>
<td>13</td>
</tr>
<tr>
<td>Bunn Rx02 (U.S.A.)</td>
<td>9</td>
</tr>
<tr>
<td>Forlip (U.S.A.)</td>
<td>4</td>
</tr>
<tr>
<td>Bunn Lite (U.S.A.)</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
</tr>
</tbody>
</table>

Patients participating in study \( (n = 62) \)

Satisfactory Unsatisfactory
19/29 10/29

Appropriate process of LTOT by concentrator

![Diagram](image)

Fig. 1. Process variables analysis of long-term oxygen therapy (LTOT) via oxygen concentrator.

Compliance with the therapy was reported as adequate by 54 patients (87%), although measured compliance was found to be adequate in only 38 of those patients (67%). The latter group were patients who had used the concentrator for an average of 18.1 ± 4.0 h day \(^{-1}\). The group who misreported their compliance \( (n = 16) \) had used the therapy for an average of 8.4 ± 3.4 h day \(^{-1}\). The difference between self-reported and measured compliance with the therapy was significant \( (P<0.05) \).

Figure 1 summarizes the results of the global assessment of the process associated with the indication and use of LTOT by concentrator in the present series. Key factors of the therapeutic process which might modify the effectiveness of the therapy were identified and analysed. Overall, 29 of the 36 patients in whom LTOT had been appropriately prescribed were able to correct their level of hypoxaemia \( (\text{SaO}_2 94.0 \pm 2.0\%) \) using the device at the prescribed flow rate. Of those 29 patients, 19 received oxygen for more than 12 h day \(^{-1}\) as measured by the device's clock. Therefore, the therapy was prescribed and used appropriately in only 19 of the 62 patients.

Discussion

The results of this study indicate that LTOT via oxygen concentrator was prescribed and used appropriately in only 31% of the patients who were enrolled in the programme. Therefore, the overall effectiveness of the therapy might have been affected by a non-appropriate prescription, an incorrectly prescribed flow rate, an improper performance of the device, and/or a low patient compliance. Some studies have analysed the influence of all these factors independently \( (8-11) \). However, this is the first time that these factors have been considered simultaneously in a single sample of patients. The first therapeutic factor to be considered in the assessment of the therapeutic process was the appropriateness of the prescription. Pulse oximetry does not replace arterial blood gas measurements in the indication of LTOT; however, since the error in the accuracy and the precision in most pulse oximeters is smaller than 3% \( (12) \), it is acceptable to consider that patients with a \( \text{SaO}_2 \) of 81.0 ± 5.8% have a sufficient level of hypoxaemia to justify home oxygen therapy. One of the indications for home oxygen therapy accepted by Medicare is \( \text{SaO}_2 \leq 88\% \) \( (13) \). The results of the present study showed that LTOT by concentrator were not prescribed in accordance with well-established prescription criteria \( (14) \) in 42% of the study patients.

A second factor that might have influenced the appropriateness of the process was the capability of the device to correct the baseline level of hypoxaemia. Only 29 of 36 patients who fulfilled
established criteria for the appropriate prescription of the therapy were able to correct their hypoxaemia levels. Failure to raise PaO₂ to therapeutic levels may have been a consequence of either an incorrectly prescribed oxygen flow rate (n=5) or a poor device performance (n=2). Overall, concentrators did not work properly in 19% of the entire sample, a figure which is similar to that observed in France (15). Concentrators have been used in Catalonia as an oxygen source since 1984 (16). At the time of the present study, there was a regulation from the local health authorities which aimed to ensure the periodical control of home oxygen therapy compliance (by checking the concentrator timer), but it did not explicitly oblige the providers to make periodical inspections of the device functioning. The fact that almost 20% of all devices did not work properly can be used to support the notion that oxygen concentrators should be equipped with alarms to detect failures in the delivery of oxygen concentration. Also, quality control strategies to detect these failures must be implemented. The number of patients using concentrators in Catalonia has progressively increased. One year after the present study was undertaken, 23% of the patients on LTOT used this oxygen source, and the percentage of patients using concentrators fulfilling the indication for LTOT was higher than the population of patients with LTOT supplied by cylinders (17).

The last factor related to the therapeutic process that should be considered is patient compliance with therapy. According to different published studies, the percentage of non-complaints can range from 36 to 62% (18,19). In the present study, measured compliance (61%) was lower than self-reported compliance (87%).

The results of the present study showed that only one out of three patients who were enrolled in the LTOT programme via concentrator might have received its expected clinical benefits. Inappropriate prescription appears to be a key factor on the inappropriateness of the therapeutic process in Catalonia. Nevertheless, appropriateness might also be improved if faulty concentrators were detected and patient adherence to the therapy was increased. This study was part of a preliminary effort (20) to reorganize the prescription of LTOT in Catalonia.

The objective of this work was not to decide whether LTOT was to be maintained or not; this should be made by the physician in charge. The authors' aim was to generate objective information, regarding the environment, to be used to elaborate recommendations for clinicians, health-care providers and administrators.

In patients with underlying chronic conditions, factors related to the therapeutic process must be re-assessed periodically if the effectiveness of the therapy is to be guaranteed (21). This study showed how therapeutic process variables, which might be more easily controlled in a randomized control trial but not in average clinical practice, might distort the true effect of the therapy and, therefore, modify its expected effectiveness. The present results indicate that, in the context of the Catalan Health Service, efforts directed towards improving adherence to well-designed clinical practice guidelines for the appropriate prescription of the therapy might have more effect on the overall effectiveness than efforts directed to improve patient compliance alone. The latter might be the implementation of quality control measures to detect faulty devices.

This type of technology assessment study can provide the objective information needed to design strategies to improve the therapeutic process and, thereby, the effectiveness of LTOT in COPD patients.

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References


