Eur Respir J
1991, 4, 227–231

TECHNICAL NOTE

Home controls of a sample of 2,414 oxygen concentrators

Sous-Commission Technique ANTADIR

Home controls of a sample of 2,414 oxygen concentrators. Sous-Commission Technique ANTADIR.
ABSTRACT: In France, 12,000 patients receive long-term oxygen therapy at home supplied by oxygen concentrators (OCs) which are provided by a non-profit organization, the National Home Treatment for Respiratory Insufficiency Association (ANTADIR - 31 regional associations). OCs are regularly checked at home by technicians from the associations. Technical data, oxygen fraction (Fo_2) supplied at working flow-rate and working duration, were recorded by technicians only during the planned home controls. Data were collected from January 15th to February 15th, 1988. Twenty three associations taking care of more than 10,000 OCs participated in the study. 2,414 machines of six different brands were controlled in the study. 77.5% of OCs had a working duration of less than 15,000 h (about 3 yrs). Working flow-rate of OCs was equal to or lower than 2 $l \cdot min^{-1}$ in 79.2% of cases. Mean Fo_2 of the 2,414 measurements was equal to 92±6%. Three quarters of OCs had an Fo_2 equal to or higher than the Fo_2 predicted by the manufacturers. Less than 0.3% of machines were out of order ($Fo_2 \leq 50\%$). We observed a significant progressive decrease in measured Fo_2 in relation to flow-rate and working duration (analysis of variance (ANOVA) 2: $p<0.001$): the higher the flow-rate and the longer the working duration, the lower the Fo_2. We conclude that supply of used OCs has to be avoided when the prescribed flow-rate is high, and that systematic technical checks are essential to keep OCs in good working order.
Eur Respir J., 1991, 4, 227–231.

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Keywords: Home care; long-term oxygen therapy; oxygen concentrator; performance.

Received: October 9, 1989; accepted after revision June 28, 1990.

It is well documented that long-term oxygen therapy (LTOT), with more than 15 h administration a day, improves survival of patients with chronic obstructive pulmonary disease [1–3]. Nowadays, alternative solutions to hospitalization allow patients to be treated at home. Gradually, oxygen gas cylinders were replaced by oxygen concentrators (OCs). The main advantages of this oxygen source are its low cost and easy handling. However, it is necessary to perform regular maintenance controls to ensure effective treatment. Indeed, the quality of oxygen therapy provided by OCs depends not only on flow-rate, but also on oxygen fraction (Fo2) available at the machine outlet. Normally, Fo_2 must not be lower than 90% for a flow-rate equal to or lower than 2 $l \cdot min^{-1}$. In fact, a recent study performed in Switzerland showed that, for 12 OCs checked over one year, Fo_2 was lower than the 92% expected value, in 97 out of 102 measurements [4].

Currently in France, 12,000 patients receive LTOT at home. They are taken in charge by The National Home Treatment for Respiratory Insufficiency Association (ANTADIR) which includes 31 regional associations in France. LTOT is provided by OCs in 96% of these patients. Regular maintenance checks of the machines are performed by the technicians of regional associations.

Considering the increasing number of LTOT prescriptions, we thought it was necessary to evaluate the quality of treatment provided by a source liable to failures. To our knowledge, no large sample of OCs was ever studied.

Material and methods

Technicians of regional associations regularly check whether the machines are in proper working order and overhaul the different parts according to the manufacturers' instructions. If there is a problem, the OC is repaired either on the spot or at the regional association workshop. In between visits, if a patient detects a breakdown, a technician will immediately come and repair the machine or exchange it for another one in less than 24 h.

To evaluate the working order of the OCs, technical data recorded by technicians during the planned home controls only, were collected from January 15th to February 15th, 1988. The study only concerned the 25 regional associations managing their own technical service. Associations subcontracting maintenance were excluded. The following information was taken into account: brand and type of OC, reading of working flow-rate (prescribed O_2 flow-rate - accuracy of OCs flow-meter: ±10%), Fo_2 measured at working flow-rate before any technical intervention, time (time meter) of visit and of molecular sieve and/or compressor change (the most important parts of the OC) if these parts were changed. The OC must work for a least 30 min before measurements were taken. Fo_2 of OC was checked by using oxygen analysers (galvanic oxygen sensor) which were very frequently calibrated with medical O_2 gas. The oxygen analyser was connected to the end of the machine tubing and the measurement of Fo_2 was taken 10 min after stabilization. OCs associated with another machine (another OC or respirator) were excluded from the study. Technical checks performed by non-specialized staff (physicians, nurses and physiotherapists) were not taken into account in the study.

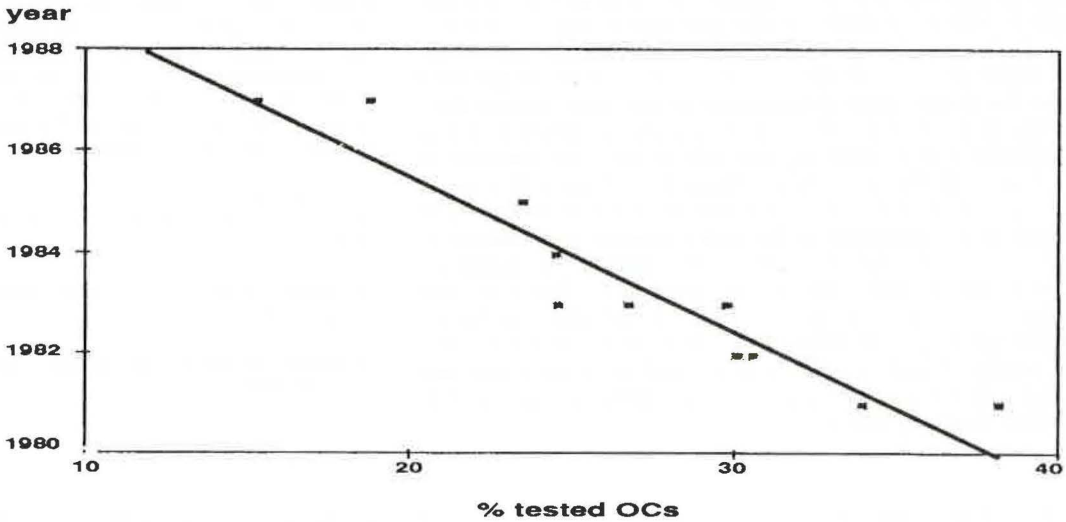

Fig. 1. – Relationship between the year of introduction on the market and the sample size of each type of oxygen concentrator (OC). Total number of OCs tested=2,414.

OCs were considered in good working order if measured Fo_2 was equal to or higher than predicted Fo_2; the latter is stated by the manufacturers for every flow-rate with a precision of ±2%. OCs were considered out of order if measured Fo_2 was equal to or lower than 50% [5]. Other OCs were considered "not in optimal order".

Results are presented as mean±SD. Statistical analysis included the chi-squared test (χ^2), the one-way analysis of variance (ANOVA) and two-way (ANOVA 2), and linear regression analysis. Statistical significance was taken as $p<0.05$.

Results

Twenty three associations out of 25 running their own technical service participated in the study. Two associations did not wish to conduct this survey. Within one month, 2,414 OCs, *i.e.* 20.3% of ANTADIR's OCs were checked at patients' homes.

Eleven OC types, of 6 brands, were controlled. (Kinox 2 and Zéfir (AIR LIQUIDE), Boras and Delox (DELHOMME), $DeVO_2$ 44, $DeVO_2$ 955 and MC 29 (DEVILBISS), Permox (DRAGER), ARP 110 and Briox 2100 (PIERRE), Companion 492 (PURITAN-BENNETT). The distribution of OC types in the sample was not representative of that in the stock of the 23 associations (χ^2: $p<0.05$). In fact, there was a correlation between the sample size of each OC type and the year the OC was put on the market ($r=0.99$, $p<0.001$) (fig. 1): The older the OCs, the greater the number of checks. On average OCs were controlled every 4 months (range: 2.6–6.6). There is a relationship between this number and the year the OC was put on the market ($r=0.96$, $p<0.001$).

Considering that the mean working duration of an OC is 5,000 $h \cdot yr^{-1}$, *i.e.* 13–15 $h \cdot day^{-1}$, 28.9% of machines had worked for <1 yr, 26.1% for 1–2 yrs, 22.5% for 2–3 yrs, and 22.5% >3 yrs.

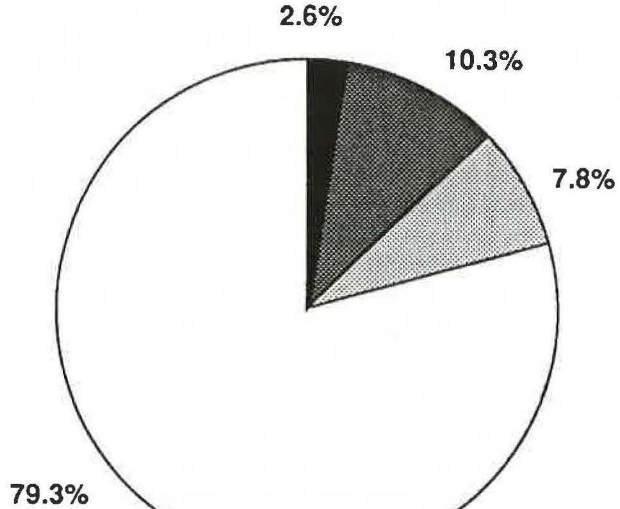

Fig. 2. – Distribution of oxygen concentrators related to working flow-rate (n=2,414). ■: ≥3.5 $l \cdot min^{-1}$; ▩: 3.0 $l \cdot min^{-1}$; ▨: 2.5 $l \cdot min^{-1}$; □: ≤2.0 $l \cdot min^{-1}$.

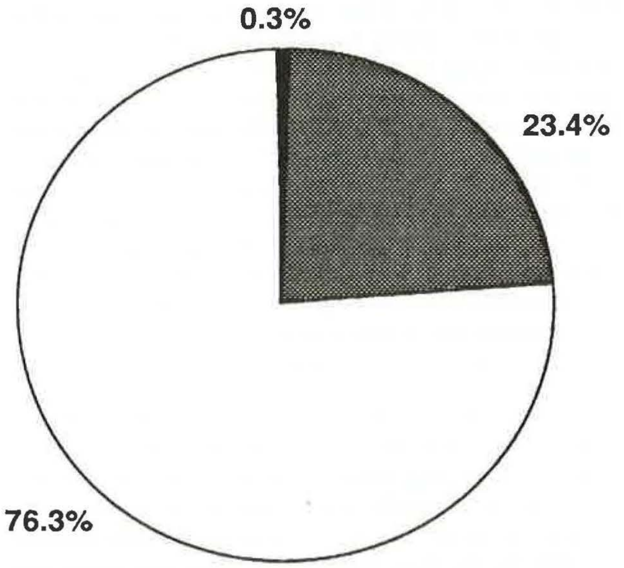

Fig. 3. – Distribution of the oxygen concentrators (OCs) related to Fo_2 supply (OCs out of order ■ : measured Fo_2 <50% (n=7); OCs not in optimal order; ▩ : 50% ≤measured Fo_2 <predicted Fo_2 (n=565); OCs in good working order □: measured Fo_2 ≥predicted Fo_2 (n=1,842). Fo_2: oxygen fraction.

Measured Fo_2 of the 2,414 controls was on average equal to 92±6%. For reasons relating to the design of the machine, measured Fo_2 was inversely correlated to flow-rate: the higher the flow-rate, the lower the Fo_2 (ANOVA: $p<0.001$). Even if OCs are regularly checked, and defective parts are repaired or changed, we observed a significant progressive decrease in measured Fo_2 in relation to working duration (ANOVA: $p<0.001$). With both factors (flow-rate and working duration) taken into account, we found a significant decrease in measured Fo_2 (ANOVA 2: $p<0.001$): the higher the flow-rate and the longer the working duration, the lower the Fo_2 (fig. 4).

Out of 2,414 OCs checked, 6.1% had a molecular sieve changed, 5.1% a compressor and 6.5% both. The molecular sieve was changed after a mean duration of 10,000 h and the compressor after a mean duration of 11,000 h for compressor but in both cases, the disparity of the results was wide (SD about 5,000 h). After 4 yrs of working (over 20,000 h), 95% of machines had at least one of their parts changed.

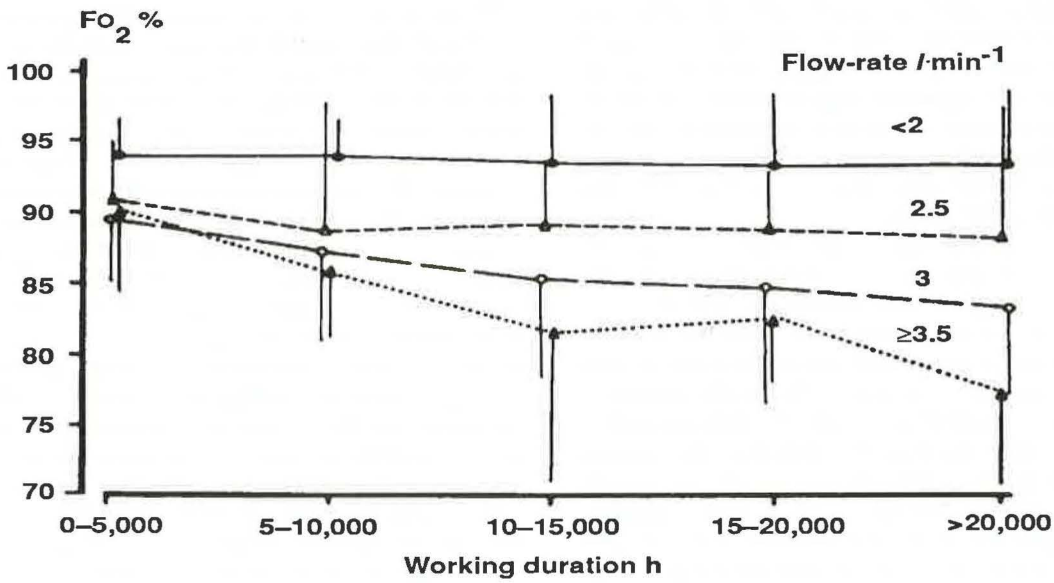

Fig. 4. – Oxygen fraction (Fo_2) supplied by the oxygen concentrators (OCs) related to working duration and flow-rate: the higher the flow-rate and working duration, the lower the Fo_2 (analysis of variance (ANOVA) 2: $p<0.001$). Flow-rate ≤2 $l{\cdot}min^{-1}$ ● : for every working duration (0–5,000 to >20,000 h), number of OCs (n) was 556, 506, 424, 270 and 157, respectively; flow-rate = 2.5 $l{\cdot}min^{-1}$ Δ: n=48, 45, 45, 32 and 19, respectively; flow-rate = 3 $l{\cdot}min^{-1}$ O: n=78, 60, 55, 37 and 19, respectively; flow-rate >3.5 $l{\cdot}min^{-1}$ ▲: n=16, 19, 18, 4 and 6, respectively.

Working flow-rate of OCs was equal to or lower than 2 $l{\cdot}min^{-1}$ in 79.2% of the cases, and equal to or higher than 3.5 $l{\cdot}min^{-1}$ in only 2.6% of the cases (fig. 2).

Figure 3 shows, for our sample of OCs, the distribution of machines related to their working order: out of order, not in optimum order, good working order. There is a correlation between the percentage of not in optimal order or out of order OCs, and the year of introduction on the market ($r=0.82$, $p<0.01$).

Discussion

The justification of our study was the fact that the proper functioning of OCs is an essential although not sufficient, condition of a good LTOT service. The sample was not representative of the various machines used in the associations and of the different types of OCs because the study reflects the actual activity of the technical services. Indeed, the older the OCs, the greater the number of checks. Despite the lack of representation, results were of interest because of the large number of machines which were controlled in real conditions of use (2,414 OCs, *i.e.* about 1/5 ANTADIR's OCs). To our knowledge, in all other studies, the number of OCs checked was always lower than 20 [4–7].

Our data showed that regular maintenance ensures proper functioning in 75% of our OC sample. Our results are in line with those of EVANS *et al.* [5] who checked 14 OCs over 1 year. On the other hand, in the study of BONGARD *et al.*, [4] the percentage of OCs in good working condition was very low: 5%. It was all the more worrying since this situation was confirmed several times for every machine. The results of JOHNS *et al.* [6] and GOULD *et al.* [7] were very satisfactory. However, their studies were not performed under routine conditions, but in a laboratory and took into account only 6 and 4 machines, respectively.

Concerning the number of OCs out of order, our results are better than those of BONGARD *et al.* [4] and of EVANS *et al.* [5]. Only six OCs were out of order, *i.e.* less than 0.3%, while, respectively, 22 and 14% of OCs were inefficient in the studies BONGARD *et al.* [4] and EVANS *et al.* [5]. Despite the small sample of machines tested in the above-mentioned studies of, it is unlikely that an "unlucky" selection could justify the difference between their results and ours. In fact, the planning of control visits could explain the good condition of our OCs checked: we organized regular home checks by specialized technicians and in some associations by visiting nurses also: both can record a breakdown by simply measuring Fo_2 before any complaint is voiced by the patient regarding the machine.

Nevertheless, despite regular maintenance, nearly 25% of our OCs had displayed an Fo_2 lower than predicted. If it is understandable that patients do not feel any decrease in Fo_2 when lower than 10%, it is more worrying that patients fail to call and notify a dysfunction when Fo_2 decreases by at least 15%. In the studies of BONGARD *et al.* [4] and EVANS *et al.* [5], there seemed to be the same observation [4, 5]. Whatever the reasons for not calling the technical service (no sensation, unnecessary oxygen prescription *etc.*), such a number of unrecognized defective OCs must be avoided. One possible solution would be to increase the frequency of regular home checks, particularly for old OCs because the older the OCs, the greater the number not in optimal order. It is likely that the number of defective machines could be reduced but not totally suppressed. For this reason, it would be sensible to introduce or to improve the alarm system on such devices, waiting for home-automation.

In the second part of the study, we showed how the performances of the machines were affected by the working duration. It is well known that they can be disturbed by the surroundings (moisture, pollution, *etc.*) [8, 9]. This holds even more when the OC is working to the limits of its capacity (*i.e.* at a high flow-rate). To our knowledge, former studies on OC reliability did not analyse the time factor or only tested new machines [4, 5, 7]. In a first ANTADIR study [10], on a sample of 139 OCs, we showed that a significant decrease in Fo_2 in relation to working duration was only observed for flow-rates equal to or higher than 3 $l \cdot min^{-1}$. The present study extends the observed decrease in Fo_2 also to low flow-rates ($\leq$2.5 $l \cdot min^{-1}$). If the difference between mean measured Fo_2 for "new" OCs (<5,000 h) and "old" OCs (>20,000 h) for low flow-rates is acceptable (2.4%), on the other hand, the major decrease between mean measured Fo_2 for higher flow-rates is worrying (13.4%). Therefore, supplying of old OCs has to be avoided when the prescribed flow-rate needs to be high. In fact, we had expected that changes of molecular sieve and compressor could prevent the gradual decrease in Fo_2. Out of 2,414 OC controls, only 17.6% had a change of at least one of those elements. Does it mean that this percentage is too low to maintain the mean measured Fo_2 to the level of predicted Fo_2 or do machines unavoidably wear out? A study on this topic would be interesting because our survey reveals no close relationship between Fo_2 and the working duration of molecular sieve and compressor.

Whatever the response, the most important fact is to evaluate the consequences for the patients of a decrease in Fo_2 in order to define when an OC is in good working order and when it is out of order. In fact, it is very difficult to estimate the impact of Fo_2 reduction on arterial oxygen tension (Pao_2) as it depends on different parameters: ventilation ($\dot{V}E$), arterial carbon dioxide tension ($Paco_2$), cardiac output, arterial-alveolar oxygen tension difference. However, we calculated a patient's expected inspired oxygen tension (PIo_2) with the measured Fo_2 corresponding to different working duration (see fig. 4). For this, $\dot{V}E$ of the patient at rest was assumed to be equal to 8 $l \cdot min^{-1}$. When the O_2 flow-rate equals 2 $l \cdot min^{-1}$, whatever the OC's working duration the decrease in Fo_2 has no impact on PIo_2. On the other hand, when O_2 flow-rate equals 4 $l \cdot min^{-1}$, the decrease in Fo_2 in relation to the working duration involved a fall in PIo_2 of about 45 mmHg. At such high O_2 flow-rate, the impact on Pao_2 could be very important. A further study would be of interest to measure the effect of the decrease in Fo_2 on Pao_2 in individual patients.

In conclusion, although 75% of the OCs of regional associations function properly according to manufacturers' data, the proportion of machines in poor working conditions is unacceptable. For this reason, OCs must be equipped with warning devices to detect failures sooner.

Acknowledgements: The authors are grateful for the helpful comments of B. Hannhart who reviewed the manuscript and for the technical assistance of M.C. Rohrer.

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Contrôle à domicile de 2,414 oxygène concentrateurs. sous-Commision Technique ANTADIR.
RÉSUMÉ: En France, 12000 malades sont traités par oxygénothérapie au long cours à domicile. La source d'oxygène est dans 96% des cas un concentrateur d'oxygène (CO) qui est fourni par une organisation à but non lucratif (ANTADIR - 31 associations régionales). Les CO sont régulièrement vérifiés à domicile par les techniciens d'associations. Les données techniques, fraction d'oxygène (Fo_2) délivrée par les appareils au débit de fonctionnement habituel et la durée totale de fonctionnement, sont recueillies par les techniciens. Les résultats, relevés uniquement pendant les visites régulièrement programmées, ont été collectés entre le 15 Janvier et le 15 Février 1988. Vingt-trois associations, prenant en charge plus de 10,000 CO, ont participé à l'étude. Deux mille quatre cent quatorze CO de 6 marques différentes ont été contrôlés pendant la période de l'étude. Pour 77.5% des CO le compteur horaire marquart moins de 15,000 heures (environ 3 ans d'utilisation). Le débit de fonctionnement était égal ou inférieur à 2 $l{\cdot}min^{-1}$ pour 79.2% des appareils. La Fo_2 moyenne sur les 2,414 mesures était de 92±6%. Les trois quarts des co avaient une Fo_2 égale ou supérieure à la Fo_2 théorique indiquée par les constructeurs. Moins de 0.3% des CO étaient totalement deficiente (Fo_2 <50%). Il existait une diminution significative de la Fo_2 mesurée en fonction du débit et de la durée totale de fonctionnement (ANOVA 2: $p<0.001$): plus le débit et cette durée étaient élevés, plus la Fo_2 était basse. En conclusion, il est conseillé d'éviter de fournir de "vieux" CO lorsque le débit d'oxygène prescrit est élevé. Les contrôles techniques systématiques ont essentiels pour garder le parc de CO en bon état de fonctionnement.
Eur Respir J., 1991, 4, 227–231.