

Long-term home care programmes may reduce hospital admissions in COPD with chronic hypercapnia

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Long-term home care programmes may reduce hospital admissions in COPD with chronic hypercapnia. E. Clini, M. Vitacca, K. Foglio, P. Simoni, N. Ambrosino. ©ERS Journals Ltd 1996.

ABSTRACT: Long-term oxygen therapy (LTOT) has been shown to improve survival in chronic obstructive pulmonary disease (COPD) patients. The clinical effectiveness of long-term home mechanical ventilation (HMV) is still discussed, nevertheless both LTOT and HMV are often included in the home care programmes of these patients.

To evaluate the effectiveness of home care programmes including either HMV or LTOT, 34 COPD patients were studied. They were admitted to either HMV (Group A: 12 males and 5 females, aged 62 ± 5 yrs), or LTOT (Group B: 9 males and 8 females, aged 62 ± 8 yrs). They were compared to a historical group (Group C: 19 males and 10 females, aged 67 ± 16 yrs) performing only their usual standard LTOT during the same period. Spirometry, maximal inspiratory pressure and arterial blood gas values were assessed at baseline and at 6, 12 and 18 months of follow-up. Mortality rate and number of hospital and intensive care unit (ICU) admissions and days of hospitalization were also assessed.

Four out of 17 (23%) patients in Group A, 3 out of 17 (18%) in Group B, and 5 out of 29 (17%) in Group C died within 18 months. Of the lung function tests, only maximal inspiratory pressure in Group A showed a significant increase in the 18th month (50 ± 4 to 56 ± 7 cmH₂O; $p<0.01$). In comparison to 18 months prior to the study, hospital admissions (from 2.2 ± 0.6 to 1.3 ± 1.1 and from 2.0 ± 0.7 to 1.0 ± 0.9 for Group A and B, respectively; $p<0.005$ for both), and days of hospitalization (from 60 ± 34 to 34 ± 40 and from 55 ± 23 to 18 ± 20 days in Group A and B, respectively; $p<0.005$ for both) significantly decreased only in the two groups submitted to the home care programme.

We conclude that home care programmes may be effective in the long-term treatment of chronically hypercapnic chronic obstructive pulmonary disease patients in reducing hospital admissions.

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Long-term oxygen therapy (LTOT) has been shown to improve survival in chronic obstructive pulmonary disease (COPD) [1, 2]. Long-term mechanical ventilation through tracheostomy is performed in ventilator-dependent patients with chronic respiratory insufficiency from restrictive and obstructive diseases [3]. Although several studies have reported a favourable effect on daytime gas exchange using nocturnal noninvasive home mechanical ventilation (HMV) in restrictive pulmonary diseases [4–8], the long-term effectiveness of such a modality in COPD is still discussed and only uncontrolled trials have been performed [9–11].

Recently, hospital-based home care programmes have been proposed in the long-term treatment of COPD patients with chronic respiratory insufficiency, with the aim of improving quality of life and reducing hospitalization and cost/benefit ratio, but few data from studies in this field are available [12–16]. Furthermore, few data are available on the relative role of HMV and LTOT in home care programmes.

The aim of this study was, therefore, to assess the effectiveness of a new home care programme including, either long-term HMV added to LTOT, or LTOT alone in chronically hypercapnic COPD patients.

Methods

Patients

We studied 34 patients with severe COPD as defined by American Thoracic Society (ATS) criteria [17], who were recruited from December 1991 to September 1992 by our department and proposed for a controlled prospective study evaluating the effectiveness of home care programmes including either HMV and LTOT, or LTOT alone. All the patients met the criteria for LTOT [18] and had been on LTOT for at least 18 months. Inclusion criteria were: 1) chronic hypercapnia (arterial carbon

dioxide tension (P_{a,CO_2}) >6.7 kPa (50 mmHg)); 2) at least one hospital admission due to severe exacerbation in the preceding 18 months; 3) willingness to participate in a home care programme; 4) evidence of family support or availability of a care-giver; and 5) geographic location allowing easy reach.

Patients were excluded if they had: a 15% or greater increase in forced expiratory volume in one second (FEV₁) after administration of an inhaled bronchodilator; suspicion of sleep apnoea as assessed by arterial saturation monitoring [19]; and co-existing medical conditions, such as uncontrolled coronary heart disease, malignancies or any other condition that could make them unsuitable to be included in long-term trials.

Patients were divided into two groups matched for anthropometric, functional and blood gas data: Group A (12 males and 5 females, aged 62 ± 5 yrs) was included in a home care programme involving HMV and LTOT; Group B (9 males and 8 females, aged 67 ± 7 yrs) was submitted to a home care programme carrying out LTOT alone.

Inclusion in the two groups was not random. Patients included in Group A followed the above criteria and had suffered from at least one episode of acute respiratory failure (ARF) needing noninvasive mechanical ventilation (NMV) [20] (11 patients) or had undergone at least two admissions to respiratory units for severe exacerbations not requiring ventilatory support in the previous 18 months (6 patients).

Seven of the 17 patients included in Group B had undergone intensive care unit (ICU) admissions needing mechanical ventilation but were not able to perform long-term HMV.

These two groups were compared with a historical control group of COPD patients (Group C) performing only LTOT (19 males and 10 females, aged 62 ± 8 yrs), retrospectively selected from our department, and comparable in terms of anthropometric data and severity of underlying illness. They had performed LTOT for at least 18 months prior to the beginning of observation, and were followed up for a further 18 months in the same periods as Group A and B.

Throughout the study, all patients continued their standard medical therapy, including theophylline, steroids and bronchodilators. Changes in medical therapy, when needed, were prescribed by physicians in our department or by the general practitioner who was not involved in the study.

Informed consent was obtained from all the patients of Group A and B at the beginning of the study, which was approved by the Ethics Committee of Salvatore Maugeri Foundation.

Home supervision programme

The home care programme consisted of a supervision programme planned during an in-hospital preliminary evaluation and included physical, occupational and dietary information, with a special trial for the families. After discharge, the programme was co-ordinated by our department and aimed to provide a link service between the hospital and the community health service by means of telephone contact with general practitioners and patients.

Home supervision was also ensured by a physician from our department by means of monthly visits, in which physical examination, functional status (assessment of spirometry, inspiratory muscle (IM) function, arterial blood gas (ABG) values), and correct performance of treatment was assessed. The visiting physician also gave the patients and family members a better insight into the possible disabilities and handicaps due to impairment of the lungs. Information was given about pulmonary disease, various strategies of treatment, how to use medication, how the patient could cope with the disease and the role of their specific treatment [21]. Control of equipment was also performed. The staff physician made clinical decisions about hospitalization during the periodical domiciliary routine or emergency calls.

Ventilatory assistance and long-term oxygen therapy

Noninvasive mechanical ventilation was initiated during a preliminary hospital trial when patients were in a stable state and was administered *via* a standard nasal mask (Respironics Inc., Monroeville, PA, USA) using a bilevel positive airway pressure (BiPAP®) ventilator (Respironics Inc., Monroeville, PA, USA) [22, 23]. After correct mask fitting, the ventilatory device was set with the minimal inspiratory positive airway pressure (IPAP) able to achieve an expiratory tidal volume (V_T) >8 mL·kg⁻¹ (this value ranged 10–16 cmH₂O). The expiratory positive airway pressure (EPAP) ranged 0–2 cmH₂O. A back-up respiratory frequency of 10 breaths·min⁻¹ was also set. The in-hospital trial was prolonged for at least 15 days, and patients were instructed to perform adequate HMV at night for a minimum of 8 h. The length of time patients used the ventilator was assessed by interviewing the patients and relatives and by controlling the device counter.

Patients of both groups continued LTOT as previously prescribed. Oxygen supplementation in Group A was also continued during HMV *via* a cannula attached to a port on the nasal mask, when necessary, to achieve an arterial oxygen tension (S_{a,O_2}) $>92\%$. This value was also the target of LTOT.

Lung function tests

In all groups, baseline measurements of dynamic and static volumes were obtained from a body plethysmograph (1085 Medical Graphics, USA). In Group A and B, baseline and follow-up measurements of FEV₁, forced vital capacity (FVC) and FEV₁/FVC ratio were obtained using a portable spirometer (Pocket Monitor Micro Medical Ltd, Rochester, UK).

Monitoring of lung function and ABG values was performed at home (Groups A and B) or during ambulatory control (Group C) after 6, 12 and 18 months. Inspiratory muscle strength was evaluated only in Group A and B, by assessment of maximal inspiratory pressure (MIP) using a portable manometer (NIF Markos, Monza, Italy; range 0–150 cmH₂O) during a maximal static inspiratory effort against an occluded airway from functional residual capacity (FRC) [24]. Predicted values were those of BRUSCHI *et al.* [25]. The best of five measurements was recorded.

Table 1. – Baseline demographic, anthropometric and functional data of the COPD patients

	Group A (n=17)	Group B (n=17)	Group C (n=29)	p-value*
Age yrs	62±5	67±7	62±8	NS
Gender M/F	12/5	9/8	19/10	NS
Weight kg	67±11	60±7	63±20	NS
Height cm	167±6	164±7	162±8	NS
Pulmonary function				
FEV ₁ L	0.8±0.3	0.8±0.2	0.8±0.3	NS
FEV ₁ % pred	31±10	33±10	31±12	NS
FVC % pred	51±12	54±13	51±14	NS
FEV ₁ /FVC %	50±18	49±12	50±18	NS
TLC % pred	103±17	108±10	107±13	NS
RV % pred	155±21	141±22	139±21	NS
FRC % pred	115±19	110±11	114±21	NS
MIP cmH ₂ O	48±8	50±4	NA	NS
Arterial blood gas levels#				
P _a O ₂ kPa	7.2±0.9	6.6±0.6	6.8±0.6	NS
P _a CO ₂ kPa	6.4±1.4	6.4±0.5	6.7±0.6	NS
pH	7.38±0.03	7.37±0.01	7.38±0.03	NS

Values are presented as mean±SD. #: breathing room air; *: by analysis of variance. Group A: included in home care programme involving home mechanical ventilation and long-term oxygen therapy (LTOT); Group B: included in home care programme involving LTOT only; Group C: historical control group performing only LTOT. COPD: chronic obstructive pulmonary disease; M: male; F: female; FEV₁: forced expiratory volume in one second; FVC: forced vital capacity; % pred: percentage of predicted value; TLC: total lung capacity; RV: residual volume; FRC: forced residual capacity; MIP: maximal inspiratory pressure; P_aO₂: arterial oxygen tension; P_aCO₂: arterial carbon dioxide tension; NA: not available; NS: nonsignificant.

ABG values were assessed at home (Group A and B) taking blood samples from the radial artery whilst breathing room air, cooling them at 0–4°C and sending them to the hospital to be analysed by means of an analyser (ABL 300 Radiometer, Copenhagen, Denmark) within 30 min. The accuracy of the measurement after prolonged storage has been reported previously [26, 27].

Table 2. – Pulmonary function in patients completing the study

Month Subject (n)	Group A				Group B				Group C			
	0 (17)	6 (15)	12 (13)	18 (13)	0 (17)	6 (17)	12 (16)	18 (14)	0 (29)	6 (28)	12 (26)	18 (24)
FEV ₁ % pred	31±10	30±8	30±9	31±12	33±10	32±11	29±10	32±13	31±12	32±8	29±12	28±13
FVC % pred	51±12	52±11	50±11	51±13	54±13	53±12	54±11	54±12	51±14	51±12	48±13	44±14**
FEV ₁ /FVC %	50±18	50±11	49±14	49±14	49±12	50±9	45±18	45±12	50±18	50±18	51±17	49±15
MIP cmH ₂ O	50±4	52±5	52±6	56±7*	48±8	47±9	49±12	49±13	NA	NA	NA	NA

Values are presented as mean±SD. For definitions and explanation of groups see legend to table 1. **: p<0.005 (within group C by analysis of variance (ANOVA)); *: p<0.01 (within group A by ANOVA).

Table 3. – Blood gas analysis levels in patients completing the study

Month Subject (n)	Group A				Group B				Group C			
	0 (17)	6 (15)	12 (13)	18 (13)	0 (17)	6 (17)	12 (16)	18 (14)	0 (29)	6 (28)	12 (26)	18 (24)
pH [†]	7.38±0.03	7.37±0.02	7.37±0.01	7.36±0.02	7.37±0.01	7.37±0.01	7.38±0.01	7.37±0.01	7.38±0.03	7.38±0.01	7.38±0.02	7.38±0.02
P _a O ₂ kPa	6.4±1.4	6.3±1.4	6.2±1.1	6.3±1.2	6.4±0.5	6.3±1.1	6.3±0.4	6.5±0.5	6.7±0.6	6.6±1.2	6.6±1.0	6.5±0.9
P _a CO ₂ kPa	7.2±0.9	7.1±1.2	7.1±0.8	7.2±0.9	6.6±0.6	6.5±0.8	6.5±0.5	6.5±0.5	6.8±0.6	6.8±0.9	6.9±0.6	7.0±0.6

[†]: breathing room air at rest. For definitions and explanation of groups see legend to table 1.

Clinical data

Deaths, hospital admissions, ICU admissions and days of hospitalization were recorded by hospital registers, interviewing relatives or the general practitioner, and comparing the 18 months of the study period to a similar period prior to institution of the home care programme (Groups A and B). In Group A, days spent in the hospital when in stable state for HMV training were not taken into account. In Group C, two consecutive periods of 18 months while on LTOT were considered when calculating these parameters.

Statistics

Data are presented as mean±SD. Differences in baseline values were tested by analysis of variance (ANOVA). ANOVA was also applied among groups at the time considered and for the recorded parameters. A p-value of less than 0.05 was considered to be statistically significant.

Results

Characteristics of patients in the study are shown in table 1. Patients of all groups suffered from a severe airway obstruction with hyperinflation as assessed by reduction in FEV₁ and increase in residual (RV). There were no differences between groups in previous duration of LTOT (23±6, 22±5 and 22±4 months for patients of Groups A, B and C, respectively). ABG values on air indicated severe hypoxaemia with hypercapnia. MIP was reduced in all Group A and B patients. No significant differences in ABG values or in dynamic and static volumes were recorded between the three groups at baseline.

During the 18 month follow-up, 4 out of 17 (23%) Group A patients died, three due to acute respiratory failure (ARF). The other patient died 6 months after the beginning of HMV following a car crash. In group B, 3 out of 17 (18%) patients died due to ARF. In group

Table 4. – Hospital and ICU admissions and days of hospitalization, per patient, before and after beginning the clinical study

	Group A			Group B			Group C		
	Before	p-value	After	Before	p-value	After	Period 1	p-value	Period 2
Hospital admissions	2.2±0.6	<0.005	1.3±1.1	2.0±0.7	<0.005	1.0±0.9	1.5±0.7	NS	1.5±1.1
ICU admissions	0.6±0.6	<0.05	0.2±0.4	0.3±0.5	NS	0.2±0.5	0.2±0.4	NS	0.4±0.5
Days in hospital	60±34	<0.005	34±40	55±23	<0.005	18±20	47±25	NS	38±29

For explanation of groups see legend to table 1. ICU: intensive care unit; NS: nonsignificant.

C, 5 out of 29 (17%) patients died due to respiratory causes in the last 18 months. Eighteen month mortality rates in all groups were, therefore, not significantly different.

Tables 2 and 3 show the time-course of lung function and ABG values. Dynamic flows showed no differences over time in groups undergoing the home care programme. After 18 months, MIP showed a significant increase only in Group A. No change in ABG values was observed in any group.

Differences in the number of hospital admissions, ICU admissions and days of hospital stay due to respiratory illness between 18 months before and following the beginning of the home care programme are shown in table 4. Institution of the home care programme was followed by a significant reduction in hospital admissions and days of hospital stay in patients from Groups A and B, while no change in clinical data was observed in the two periods of observation in patients submitted to LTOT alone (Group C). Before institution of the home care programme, ICU admissions were slightly but significantly ($p<0.05$, in comparison to other groups) greater in Group A, and a significant reduction was observed over time only in this group.

Percentage of time (%*tot*) spent in hospital throughout the study is shown in figure 1. %*tot* significantly decreased

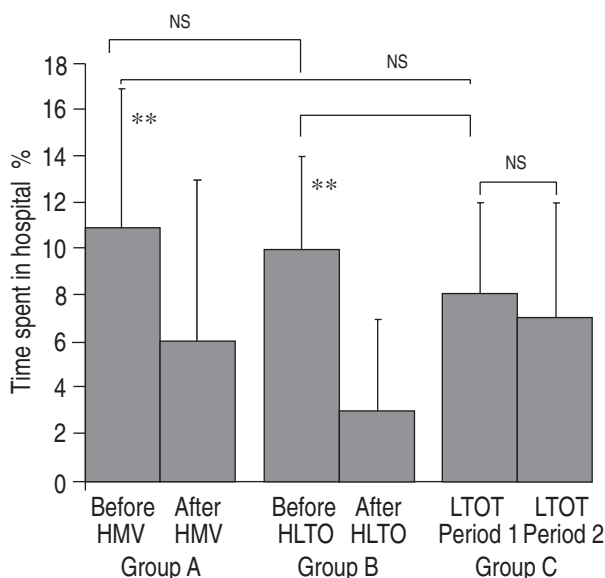


Fig. 1 – Difference in percentage of time spent in hospital before and after beginning the home care programme for Group A and B and between two consecutive periods of long-term oxygen therapy (LTOT) for Group C (Controls). Group A: included in home care programme involving home mechanical ventilation and LTOT (HMV); Group B: included in home care programme involving LTOT only (HLTO); Group C: historical control group performing only LTOT. **: $p<0.005$, before vs after home care programme. NS: nonsignificant.

both in Group A and B after institution of the home care programme HCP. No significant change was observed in the two consecutive observation periods in Group C.

Discussion

This is a preliminary report of a new programme for home care, integrating long-term treatment for hypercapnic COPD patients. Our study showed that COPD patients undergoing long-term home supervision programmes, including either noninvasive mechanical ventilation and LTOT or LTOT alone, were similarly successful in maintaining stability of lung function and ABG values, and in improving clinical conditions as assessed by reduction in number of respiratory and ICU admissions.

The severity of functional impairment of our COPD patients was shown in this study from the lung function tests performed in the stable state. They suffered from a severe airway obstruction as assessed by a mean FEV₁ <1 L. Stable ABG values showed that the patients of all groups were chronically hypoxaemic and hypercapnic. The role of chronic hypercapnia in the prognosis of COPD patients is still debated. BEGIN [28] considered hypercapnia as a means to avoid overloading of the inspiratory muscles. Hypercapnia *per se* has not been demonstrated to be associated with a higher mortality risk [29], but the rate of deterioration over time in PaCO₂ was found to be related to the necessity for ICU admission [30]. Similarly, the role of reducing the level of hypercapnia by means of HMV and its generalized use in COPD patients remains controversial.

In our study, no groups showed improvements in PaCO₂, whilst only the Group A patients undergoing home care programme and HMV showed an increase in MIP after 18 months of treatment. In contrast with our study, STRUMPF and co-workers [9] found no improvement in MIP in COPD patients after 3 months of nocturnal treatment with BiPAP®. Their patients were less severely affected than ours (FEV₁ 51% pred) and the duration of their study was too short to appreciate a real effect on a long-term basis. ELLIOTT *et al.* [31] found no relationship between changes in MIP and changes in PaCO₂ in COPD patients undergoing HMV. A similar period of domiciliary treatment with intermittent negative pressure ventilation (INPV) by means of a poncho-wrap was not able to improve inspiratory muscle strength in less severe COPD patients in the study by SHAPIRO *et al.* [32]. The difference from these studies might be related to the longer duration of treatment in our study, and might confirm the hypothesis that HMV may improve inspiratory muscle function by resting them [23, 33].

The patients included in the three groups did not differ in terms of baseline anthropometric and functional

data, while the number of ICU admissions was slightly greater in Group A patients. This clearly depends on patient selection and the criteria of institution of HMV, and may have influenced the results. The value of non-invasive ventilation in patients who have previously used it in exacerbations or who are frequent exacerbators has not been studied; previous studies having recruited stable hypercapnic patients [4, 9–11, 31, 32].

Mortality rate due to respiratory causes was similar in the different groups of patients in our study, suggesting a similar degree of severity in the disease at the time of admission as confirmed by functional measurements. Long-term prognosis of COPD patients surviving an episode of ARF remains controversial [34–39]. CORRADO *et al.* [39] showed that the overall survival rate during the first year after an episode of ARF treated with an iron-lung was 82%. Patients in their study underwent monthly visits. Comparison of mortality rates between studies is difficult, as the criteria for inclusion of patients, use of mechanical ventilation and medical treatment are different, especially for the oldest studies. As a whole, the prognosis for survival in COPD is considered to be similar for patients experience severe ARF or not, being related to the severity of the underlying disease [40]. Our preliminary data do not justify the generalized use of long-term noninvasive mechanical ventilation in stable hypercapnic COPD. A European long-term prospective, randomized, controlled study is being conducted to evaluate the real benefit of a long-term nasal mask ventilation vs LTOT in patients with severe COPD [41].

The main result in our experience over 18 months was the significant decrease in hospital admissions observed both in Groups A and B in comparison to the time before institution of the home care programme, whilst Group C patients showed a stable trend in days spent in hospital during the two consecutive 18 month periods evaluated (fig. 1). ICU admission significantly decreased only in Group A. This could be partly due to the difference in ICU admissions prior to the study. These findings in the two groups appear to be possibly related to the home care programme *per se* independent of whether or not long-term ventilatory support was given in addition to oxygen therapy. LEGER *et al.* [11] in their uncontrolled study also recorded a significant reduction in number of hospitalizations in mechanically-ventilated COPD patients over 3 yrs, but their patients also underwent a home supervision programme.

Reduction in hospital stay for COPD is consistent with cost-savings [3, 11], but is not necessarily related to the necessity for MV [13]. Analysis of costs has not been directly taken into account in our study. However, precise indications of costs-savings are difficult to draw as they are influenced by many factors besides hospitalization. In fact, differences in the design of the home care programme proposed and the selection of patients may explain different results [12, 13].

Our study had definite limitations. Historical comparison of different treatments must be interpreted with caution because treatment strategies may change with time and such studies are considered to favour the treatment group (Groups A and B) [42]. Furthermore, the retrospective analysis of data may be criticized, *e.g.* it limits further information, especially on some circumstances of the follow-up (*e.g.* quality of life or cost of treatment).

Groups A and B were also limited to those who could tolerate the technique. Nevertheless, a retrospective study gives information on a "real" operational setting.

In conclusion, our controlled study suggests that there is a reduction of hospital admission, within 18 months, for chronic obstructive pulmonary disease patients undergoing home supervision programmes with long-term oxygen therapy both alone and combined with long-term home mechanical ventilation.

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