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Home Mechanical Ventilation through Mask: Monitoring Leakage and Nocturnal Oxygenation at Home

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Key Words
Noninvasive mechanical ventilation · Home noninvasive mechanical ventilation · Home monitoring · Leaks in noninvasive ventilation

Abstract

Background: Leakage is common in patients receiving home mechanical ventilation (HMV) via a face mask. Although pressure ventilators have partial compensatory capacity, excessive leakage can compromise the effectiveness of treatment. Home ventilators are equipped with built-in software which provides information on leakage. However, the values of leakage and their effects in routine clinical practice are currently little known. ***Objective:*** To measure leakage in stable patients on nocturnal HMV and its impact on treatment effectiveness. ***Methods:*** Consecutive outpatients on HMV were recruited. Nocturnal pulse oximetry was performed at home and leakage was measured using the ventilator's built-in software. We measured: mean SpO_2, percentage of time with SpO_2 <90% (T90), mean leakage (meanL), maximum leakage (maxL), and minimum leakage (minL) during the ventilation session. We estimated ventilator capacity to compensate for leakage according to inspiratory positive airway pressure and divided the patients into two groups: those with leak compensation and those without. ***Results:*** The study included 41 patients [mean age, 64 years (SD 11.9); 23 (56%) women]. Nocturnal pulse oximetry showed an SpO_2 of 94% (±2.9) and a T90 of 10% (±21.7). Leakage (in l/min) was: meanL, 32.2 (±15.3); maxL, 64.8 (±28.5), and minL, 18.8 (±10.6). Seven cases (17%) had leakage greater than the ventilator compensatory capacity, but no significant difference in SpO_2 or T90 was observed between patients with or without leak compensation. ***Conclusions:*** A wide variation between maxL and minL was observed in our series; 17% of cases had higher leakage values than the compensatory capacity of the ventilator, but this did not affect nocturnal oxygenation.

Introduction

Leakage is highly frequent in patients on home mechanical ventilation (HMV) using a nasal or oronasal mask interface. It can be of two types: controlled leak through a leak port, the amount of which is calibrated by the manufacturer and intended to prevent rebreathing, and uncontrolled leakage which occurs through the mouth or the contour of the interface. Excessive leakage

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may decrease the effectiveness of or patient tolerance for treatment. Rabec et al. [1] and Borel et al. [2] in bench studies found that leaks during noninvasive ventilation could worsen the effectiveness of treatment. Other authors [3–5] have demonstrated the negative impact of leaks on the quality of sleep.

Monitoring patients on HMV allows the clinician to verify compliance, comfort, adverse effects, and treatment effectiveness. Although there are no consensus documents on the most appropriate method to carry out this monitoring, clinical interview together with diurnal arterial blood gas (ABG) analysis and nocturnal pulse oximetry seem to be the most widely used tools in practice [6, 7].

The latest generation of home ventilators are equipped with built-in software which provides the clinician with potentially useful information, including estimated leakage. However, the values and variability of leakage and its impact on therapeutic effectiveness in real conditions are not well known, and consensus criteria for interpreting this information have not been established [8, 9]. Since excessive leakage can affect the quality of ventilation, our hypothesis was that quantification of leakage in patients on HMV would allow assessment of the quality of treatment. Our objective was to measure leakage in stable patients undergoing HMV and evaluate its impact on treatment effectiveness. A secondary objective was to investigate factors possibly related to the presence of leaks.

Method

Design and Population

We performed a cross-sectional observational study in a cohort of patients in stable condition recruited consecutively from an outpatient clinic specifically for HMV patients. Inclusion criteria were: HMV treatment with a pressure ventilator (Vivo 30/40; Breas, Mölnlycke, Sweden) for a minimum of 4 months. All were ventilated with single circuit tubing and masks that incorporate a leakage port. The patients were in stable condition defined as the absence of exacerbations and the need for ventilation therapy adjustments in the previous 4 weeks.

At the time of the outpatient visit, the following variables were recorded: age, sex, diagnostic reason for HMV, time on HMV (weeks), ventilator mode and settings [inspiratory positive airway pressure (IPAP), expiratory positive airway pressure (EPAP), respiratory rate], type of mask (nasal or oronasal), and diurnal ABG breathing ambient air. The study was approved by the hospital ethics committee, and informed consent was obtained from all patients participating in the study.

Measurements

Nocturnal home pulse oximetry (NHPO) was used to assess therapeutic effectiveness. It was carried out with a Nellcor-Covidien N-560 pulse oximeter on two consecutive nights. We then examined the ventilator record with specific software and obtained the following data: percentage of recording time with Sp_{O_2} below 90% (T90) and the mean Sp_{O_2} value.

For measurement of leakage, data from the ventilator memory using specific software (PS Live software 3.0) was recorded on two consecutive nights (coinciding with NHPO), including: hours of treatment, mean leakage value (meanL), and a complete graphic record of leakage for the entire session. This graph was analyzed by two of the authors (R.F.A. and G.R.C.) independently to obtain the maximum (maxL) and minimal leakage (minL) per patient. We calculated the amplitude of the leak (Amp) as the difference between maxL and minL. The value of leakage measured was the total (intentional plus unintentional) leakage taking into account that the software incorporated in the Vivo 30 and 40 ventilators measures the amount of the leak during the expiratory phase.

We then estimated the following variables for each patient: (1) maximum leakage compensation (MLC), i.e. the maximum leakage that the ventilator could compensate for, according to the programmed IPAP, established in accordance with information provided by the manufacturer; (2) intentional leakage (intL), obtained from information provided by the manufacturer of the interface used, according to the programmed IPAP; (3) uncompensated leakage (uncL) (yes/no), referring to situations in which the leakage exceeded the value of MLC at any time during the session, and (4) the uncL index, i.e. the percentage of uncL time divided by the total duration of the session.

The manufacturer provided the authors with a table showing the maximum leak compensatory capacity in liters per minute for each IPAP value. The ventilator (Vivo 30/40) measures leakage by comparing air flow at a certain IPAP with a known reference flow value for the same pressure. The leak compensatory capacity for a system is calculated (the reference value being 4 respiratory cycles) to establish a baseline flow to activate the inspiratory trigger and cycling (Breas patent WO-2006/137784).

For the analysis of the results we divided the patients into two groups: those who had episodes of uncL and those who did not.

All patients were asked about subjective sleep quality and possible problems on the nights when measurements were made, to determine the validity of the recordings. We excluded recordings of less than 4 h in duration and those in which the patient reported poor subjective quality or disrupted sleep.

Statistical Analysis

Data are presented as means (SD) and medians (range) for quantitative variables, and as percentages for qualitative variables. For comparison of quantitative variables we used Student's t test and correlation coefficients. Differences with a p value <0.05 were considered statistically significant.

Results

Of the 50 patients included in the study, valid records for analysis were obtained in 41 cases [mean age, 64 years (11.9); 23 (56%) women]. The median time on HMV was 27 months (range 5–120). Diagnoses were: obesity-hypoventilation syndrome (OHS) (n = 15; 37%), chest wall disease (n = 13; 32%), COPD (n = 7; 17%), and neuromus-

Table 1. Leakage and oxygenation values recorded in two consecutive nocturnal sessions of HMV

	Nocturnal session 1	Nocturnal session 2	p value
meanL, l/min	32.2 (15.3)	32.5 (13.1)	NS
maxL, l/min	64.8 (28.5)	66.0 (28.1)	NS
minL, l/min	18.8 (10.6)	19.4 (11.4)	NS
Amp, l/min	44.8 (22.5)	46.4 (22.6)	NS
T90, %	10.3 (21.7)	9.6 (20.1)	NS
Mean SpO_2, %	94.2 (2.9)	94.4 (3.0)	NS

cular disease (n = 6; 14%). In 23 cases (56%) an oronasal mask was used; 4 patients (9%) used a humidifier, and 9 (22%) received supplementary oxygen therapy. The mean time per day on HMV was 7.1 h (1.3).

All patients were ventilated with pressure support as follows: IPAP, 18.5 cm H_2O (4.3); EPAP, 6.3 cm H_2O (2.8), and rescue frequency, 16.1 breaths/min (5.1). The mean values of intL and MLC for the entire series were 36.8 l/min (6.0) and 89.5 l/min (10.5), respectively.

In the study of oxygenation, NHPO showed SpO_2 values of about 94% and T90 was 10%. Measurement of leakage showed meanL values very close to the expected IntL values, with no significant differences between the two, but with significant variations between minL and maxL, reflected in an Amp of over 40 l/min. There were no significant differences in any variable between the first and second night (table 1). Seven patients (17%) had uncL, with a mean uncL index of 31.4%. There were no significant differences in mean SpO_2, T90, pO_2, pCO_2, pH, and HCO_3 between those with and those without uncL (table 2). We found no significant differences in the amount of leakage between patients with different underlying diseases (OHS, neuromuscular disease, chest wall disease, and COPD) as shown in table 3. Likewise, we observed no significant differences in the amount of leakage between patients receiving oxygen supplementation [meanL, 33.1 l/min (17.1); maxL, 72.0 l/min (24.3)] and those not receiving oxygen supplementation [meanL, 30.8 l/min (13.4); maxL, 61.7 l/min (26.8)], or between patients using oronasal masks [meanL, 30.9 l/min (15.4); maxL, 63.3 l/min (27.9)] and those using nasal masks [meanL, 32.7 l/min (12.9); maxL, 65.3 l/min (26.3)].

The correlation coefficients between the leakage variables measured (meanL, maxL, Amp, and uncL index) and nocturnal oxygenation (mean SpO_2 and T90) were not statistically significant (table 4).

Table 2. Comparison between HMV patients with and without leak compensation

	Compensated leakage (n = 34)	Uncompensated leakage (n = 7)	p
Age, years	64.5 (10.9)	61.0 (21.2)	NS
Time on HMV, months	28.7 (21.2)	9.2 (5.1)	<0.01
Time per day	7 h 6 min	7 h 28 min	NS
IPAP, cm H_2O	18.5 (4.6)	18.5 (2.6)	NS
EPAP, cm H_2O	5.5 (2.9)	7.1 (1.8)	0.04
T90, %	9.2 (15.5)	15.8 (22.3)	NS
	9.7 (12.7)	12.2 (9.3)	
SpO_2	94.4 (2.3)	93.2 (3.0)	NS
	95.9 (3.3)	94.4 (2.3)	
pO_2, mm Hg	72.8 (11.6)	67.7 (9.4)	NS
pCO_2, mm Hg	44.5 (5.1)	47.8 (4.5)	NS
pH	7.42 (0.03)	7.41 (0.02)	NS
HCO_3, mmol/l	30.0 (4.4)	30.0 (2.3)	NS
meanL, l/min	27.1 (10.5)	54.5 (16.1)	<0.0001
	28.8 (10.4)	48.0 (12.4)	
Amp, l/min	37.4 (13.4)	81.0 (23.5)	<0.0001
	38.5 (11.4)	85.6 (24.6)	

Table 3. meanL and maxL measured during two consecutive nocturnal sessions of HMV, according to underlying disease

Underlying disease	n	meanL, l/min	maxL, l/min	p value
OHS	15	37.6 (18.0)	67.7 (30.2)	NS
CWD	13	28.2 (10.5)	63.5 (18.3)	NS
COPD	7	31.3 (12.7)	64.4 (41.8)	NS
NMD	6	29.8 (10.6)	69.1 (34.1)	NS

CWD = Chest wall disease; NMD = neuromuscular disease.

Table 4. Correlation between leakage and nocturnal oxygenation parameters

		Mean SpO_2	p value	T90	p value
meanL	PCC	0.029	NS	0.007	NS
maxL	PCC	0.147	NS	0.024	NS
Amp	PCC	0.16	NS	0.16	NS
uncL index	PCC	–0.17	NS	0.14	NS

PCC = Pearson's correlation coefficient.

Discussion

The key findings of our study were that nocturnal monitoring of stable patients on HMV detected 7 cases (17%) with episodes of uncL and, for the whole sample, a mean uncL index of 31%. This would seem to indicate a low quality of care, but the presence of uncL did not significantly affect nocturnal oxygenation. In the absence of established criteria for interpretation, we characterized leakage during HMV using four parameters: meanL, minL, maxL, and Amp, taking into account the MLC and the intL which are related to IPAP and the mask used. Our results show that it is a variable phenomenon, with a great Amp with Fmax values that may exceed the buffer capacity at specific times of the fan, and minL values which may be less than the expected intL. Finally the value of meanL remained close to that of intL but rose significantly in cases with uncL.

We have not found similar work with which to compare our results, although Borel et al. [2] in a study of lung models found that a leak of less than 45 l/min for an IPAP of 14 cm H_2O did not induce problems of ventilation quality. In our series, the mean IPAP was 18 cm H_2O and the meanL in the group with uncL was higher than the value suggested by Borel et al. [2], with values close to 50 l/min. Up to 50% of our patients had leakage values above 60 l/min at some point during the session and, despite being within the compensatory capacity of the ventilator, such high values could have detrimental effects on cycling or triggering [10]. Moreover, in these cases the value of meanL was similar to intL, so that the isolated measurement of meanL may not be sufficient to characterize the leak in a particular patient.

In our subgroup of 7 cases (17%) with uncL, all were clinically well, all reported good subjective quality of sleep, and only 2 patients had T90 >10%. It may be that leak measurement and NHPO explore two distinct aspects of treatment with HMV, and perhaps accurate monitoring should include nocturnal respiratory polygraphy or transcutaneous capnography to measure the impact of leakage, but the cost-effectiveness of these procedures limits their use as home monitoring systems [8]. The use of NHPO is widespread and accepted as a measure of HMV effectiveness [6, 7]. It is a simple technique and easily performed at home but has the drawback of providing indirect information about ventilation. Perhaps this explains why we could not demonstrate the impact of leakage on T90 and mean Sp_{O_2}; this finding is consistent with that of another study [5], where no alteration in nocturnal pulse oximetry was found despite the presence of oral leaks. We also did not find significant differences in acid-base balance (ABG) between the two groups, but it must be said that these data were obtained at a subsequent outpatient visit, not at the time of nocturnal recording, and therefore this finding must be taken with caution.

To our knowledge this is the first study to propose an interpretation of leakage measured by HMV equipment as additional monitoring of outpatients on HMV. The method used has certain limitations: firstly, nocturnal monitoring did not include assessment of the quantity and quality of sleep. Secondly, our results are only valid for patients treated with a leak port incorporated into the mask and cannot be generalized to other circuits or to ventilators other than the equipment used (Vivo 30/40; Breas). Finally, these results should be interpreted with caution; a recent bench study [9] detected some bias in the reliability of leak measurement by HMV equipment. However, in the present study leakage was measured on two consecutive nights to reduce the possibility that isolated values might reflect a biased picture of the patient's condition [7]. No significant differences were detected between the two records.

In conclusion, ambulatory measurement of leakage in HMV provides useful information which complements that obtained by clinical interview, ABG, and NHPO, and allows the detection of a subgroup of patients receiving suboptimal treatment or requiring more sophisticated monitoring. Further studies are needed to test the reliability of leak measurement by ventilators used in HMV, and to establish tolerable leakage thresholds for each patient according to programmed levels of IPAP and the interface used.

Financial Disclosure and Conflicts of Interest

The authors declare no conflict of interest.

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