

**PERFORMANCE OF MECHANICAL VENTILATORS AT THE PATIENT'S HOME.
A MULTICENTER QUALITY CONTROL STUDY.**

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ABSTRACT

A multicenter quality control survey of home mechanical ventilation (HMV) based on testing the ventilator at the patient's home was carried out. The study, which was performed at the home of 300 patients included in the HMV programs of 4 hospitals in Barcelona, consisted of three steps. First, we compared the prescribed ventilation settings, the actual settings in the ventilator control panel and the actual performance of the ventilator measured at home. Second, the different ventilator alarms were tested. Finally, we ascertained whether disagreement between the prescribed settings and the actual performance of the ventilator had an impact on non-programmed readmissions of the patient. Considerable differences (mean and limit of agreement) were found between actual, set and prescribed values of ventilator variables, these differences being similar in volume- and pressure-preset ventilators. The percentage of patients with a discrepancy between the prescribed and actually measured main ventilator variable (minute ventilation or inspiratory pressure) greater than 20% and 30% was 13% and 4%, respectively. The number of ventilators with built-in alarms for power-off, disconnection or obstruction was 225, 280 and 157, respectively. These alarms did not work in 2 (0.9%), 52 (18.6%) and 8 (5.1%) ventilators, respectively. The number of non-programmed hospital readmissions in the year prior to the study did not correlate with the index of ventilator error. This study illustrates the current limitations of the quality control of HMV and suggests that improvements should be made to ensure adequate ventilator settings, correct ventilator performance and ventilator alarm operation.

INTRODUCTION

Home mechanical ventilation (HMV) is a chronic care respiratory treatment whose application has progressively increased in the last years, as recently documented by a European survey [1]. This report also showed that the quality control procedures vary considerably among the different HMV providers, probably because of the sharp increase in the number of clinical groups using HMV in the last decade and the consequent short training period [2]. According to this survey, some of the procedures for the equipment follow-up reported by the HMV providers suffer from inadequate quality control. In addition to the lack of standardization of HMV quality control, there are no data on the actual performance of ventilators at home and on the potential clinical effects of ventilator dysfunction. Although HMV is generally a safe procedure [3], data from a pilot study in a limited number of patients suggest that the home ventilators could not perform in accordance with their settings [4]. Moreover, it has been found that ventilator settings at home may differ from the settings prescribed by the physician in charge of the patient [4].

The aim of the present study was to carry out an extensive multicenter quality control survey based on testing the settings and performance of ventilators at the patient's home. First, we compared the prescribed ventilation settings, the actual settings in the ventilator control panel and the actual performance of the ventilator measured at home. Second, the different ventilator alarms were tested. Finally, we ascertained whether disagreement between the prescribed settings and the actual performance of the ventilator had a major clinical impact as reflected by increased non-programmed hospital readmissions.

METHODS

The study was carried out at the homes of 300 patients (54% women; age: 54 yr (15 yr), mean (SD)) selected at random from the 561 patients included in the HMV programs of the 4 main University hospitals in the metropolitan area of Barcelona. The random selection was constrained to maintain the proportion of patients from each hospital (44%, 33%, 17% and 6%). The Public Health Service of Catalonia provides free HMV (ventilators, consumables and maintenance) to all those requiring it through registered prescription hospitals and in accordance with common HMV regulations. At the time of the study HMV was supplied by four commercial companies in the Barcelona area. Ten patients were excluded from the quality control study because of technical reasons (incomplete data obtained in the home measurement procedure).

The 290 patients under study were subjected to HMV because of lung and airway diseases (9.5%), neuromuscular diseases (24.7%), thoracic cage abnormalities (53.0%) or hypoventilation-obesity syndrome (12.8%). The duration of ventilation ranged from 1 yr to 16 yr (52% of the patients were on home ventilation for a period exceeding 4 yr). The patients were ventilated with an assist mode by means of 22 different models/versions of conventional home ventilators used in the routine HMV programs of the hospitals participating in the study. Volume-preset ventilators were used in 153 patients and pressure-preset ventilators in 137 patients. A 64% of the ventilators allowed locking the ventilation settings in the control panel to avoid patient manipulation. Assisted ventilation was applied through a customised nasal mask (47.2%), commercially available nasal masks (46.2%), full face masks (2.3%) or via tracheostomy (4.3%). In 56.7% of the patients, ventilation was applied only during the night, 40.7% of the patients were ventilated during the night plus a few-hour daily periods at the patient's request, 1.3% of the patients were ventilated more than 18 h per day, and in 1.3% of patients, ventilation was applied continuously.

A especially trained nurse visited the homes of all the patients during a four-month period. The patients were not previously informed that a ventilator check will be carried out during the visit of the nurse. The quality control protocol followed during the home visits consisted of three steps. First, the ventilation parameters set in the control panel of the ventilator were recorded. Second, the corresponding values actually provided by the ventilator were measured by a portable system designed to test ventilators (Ventest, Soderel Medical, Heillecourt, France). The ventilator was connected to a standard resistance (5 cmH₂O·s/l) – compliance (0.05 l/cmH₂O) lung model (European Standards NF-EN-794-2) included in the ventilator testing system. Inspiratory and expiratory flow and pressures during the ventilator operation were recorded by a computerized unit which yielded the actual values generated by the ventilator. Third, the ventilator alarms were tested during the normal functioning of the ventilator when connected to the lung model. To test the power-off alarm, the ventilator was disconnected from the mains power supply. The disconnection alarm and the obstruction alarm were tested by disconnecting the lung model from the ventilator or by completely occluding the tubing at the entrance of the lung model, respectively.

The ventilator variables analyzed were minute ventilation (V_E), frequency (f) and inspiratory/expiratory time (I/E) for volume-preset ventilators (153 patients) and

inspiratory (P_{ins}) and expiratory (P_{exp}) pressures for pressure-preset ventilators (137 patients). The differences between the ventilation variables prescribed to the patient (obtained from his/her clinical record), the values set on the ventilator panel control and the values actually measured during the ventilator test were compared by a Bland-Altman analysis [5]. To define an index of ventilator error for each patient we used the data from V_E or P_{ins} since these can be considered to be the main variables in volume- and pressure-preset ventilators, respectively. The index of ventilation error was defined as the positive value of the percent difference between the actually measured value yielded by the ventilator at home and the prescribed setting (V_E or P_{ins} , depending on the ventilator type). For instance, if in a pressure-preset ventilator the prescribed P_{ins} was 14 cmH₂O and the measured value at home was 6 cmH₂O, the index of ventilator error was 57% ($57=100 \cdot ABS(6-14)/14$). ANOVA was used to ascertain whether the index of ventilator error depended on the hospital, the company that serviced the ventilator, the respiratory disease or on the duration of ventilation (less or more than 4 yr). The data stored in the patient clinical records were used to assess the relationship between the index of ventilator error and the number and length of non-programmed hospital readmissions in the 12 month period prior the study.

This multicenter study was carried out under the auspices of the Catalan Agency for Health Technology Assessment and Research. Approval was obtained from the relevant Ethics Committee. The different companies involved in HMV in the metropolitan area of Barcelona were informed about the study six months before the start of data collection. Each participating patient was informed of the aim of the investigation by his/her attending clinical team and his/her written consent to participate was obtained.

RESULTS

Considerable differences were observed between the settings prescribed to the patient and the actual settings in the ventilator control panel, both in volume- and pressure-preset ventilators. Figure 1 shows the results corresponding to a representative variable in each type of ventilator (V_E and P_{ins}). Although the mean value of the differences was not significantly different from zero, the limits of agreement between the set and prescribed values, computed as the mean \pm 2 \cdot SD of the difference between variables [5], were considerable (Table 1). This table also shows the wide range of the actual differences observed. These data illustrate the existence of marked discrepancies between prescribed and set values within the 5% of data which, according the theoretical prediction, are outside the limits of agreement. As shown in Table 1, similar results were found in the other ventilation variables (f , I/E and P_{exp}) between the settings prescribed and the actual settings in the ventilator control panel. Interestingly, the difference (in V_E or P_{ins}) between prescribed and set values was 4.8 % (13.7%) in the ventilators allowing locking the control panel settings and 8.1% (8.6%) in the ventilators where such locking was not possible. The dependence of the discrepancy between prescribed and set values on the existence of the locking option in the ventilator was significant ($p=0.046$; t-test).

Significant differences were found between the ventilator parameters set in the control panel of the ventilator and the actual measured values. Figure 2 shows the

difference plots corresponding to V_E and P_{ins} , and Table 2 provides the results corresponding to all the variables studied. Most of the investigated variables showed significant differences. As in Table 1, the limits of agreement were wide and the range of actual differences was considerable.

The index of ventilator error, computed as defined in the methods section, was similar in volume- and pressure-preset ventilators: 9.6% (13.2%) (range: 0 – 133%) and 10.5% (11.7%) (range: 0 – 54%), respectively. Figure 3 shows the cumulative percentage of all patients as a function of the index of error of his/her ventilator. In 70% of the patients, the index of ventilator error was lower than 10%. The percentage of patients with an index of ventilator error exceeding 20% was 13%. The index of ventilator error exceeded 30% in 4% of the patients. The ventilator error index did not significantly depend ($p>0.05$) on the hospital, the company that serviced the ventilator or on the respiratory disease of the patient. The index of ventilator error was significantly ($p=0.036$) greater for the patients on HMV for a period exceeding 4 yr (11.6%) than for those receiving the treatment for a shorter time (8.4%).

The number of ventilators with built-in alarms for power-off, disconnection or obstruction was 225, 280 and 157, respectively. These alarms did not work in 2 (0.9%), 52 (18.6%) and 8 (5.1%) ventilators, respectively. All the alarms worked correctly in the patients subjected to 24 h ventilation.

The number of non-programmed hospital readmissions in the last year prior to the study did not correlate with the index of ventilator error, as shown in Figure 4. A similar result was found when the number of total days of non-programmed readmission was compared with the ventilator error index.

TABLE 1. Comparison between the ventilation values prescribed and those set on the control panel of the ventilator

Variable	Difference	Difference	Difference
Value prescribed (mean (SD))	Mean (SD)	Limits of agreement	Actual range
V_E (L/min) (11.09 (2.53))	-0.12 (1.38) p=0.298	-2.88 / 2.64	-5.00 / 6.40
f (cycles/min) (17.99 (2.66))	0.02 (1.30) p=0.854	-2.58 / 2.62	-4.00 / 12.00
I/E 0.852 (0.152)	-0.00 (0.19) p=0.822	-0.38 / 0.38	-0.48 / 0.37
P_{ins} (cmH ₂ O) (17.57 (3.05))	-0.23 (1.52) p=0.079	-2.77 / 2.32	-4.00 / 6.00
P_{exp} (cmH ₂ O) (5.10 (1.76))	-0.32 (0.89) p<0.001	-2.10 / 1.46	-4.00 / 4.00

V_E : minute ventilation; f: frequency; I/E: inspiratory/expiratory time; P_{ins} : inspiratory pressure; P_{exp} : expiratory pressure. V_E , f and I/E were measured in the 153 patients on volume-preset ventilators. P_{ins} and P_{exp} were measured in the 137 patients on pressure-preset ventilators.

TABLE 2. Comparison between ventilator values actually measured and set on the control panel of the ventilator

Variable	Difference	Difference	Difference
Value set in the ventilator (mean (SD))	Mean (SD)	Limits of agreement	Actual range
V_E (L/min) (11.22 (2.74))	-0.47 (1.31) p<0.001	-3.09 / 2.15	-3.65 / 6.05
f (cycles/min) (18.01 (2.52))	0.07 (0.66) p=0.160	-1.25 / 1.39	-2.83 / 3.75
I/E 0.844±0.171	-0.04 (0.11) p<0.001	-0.26 / 0.18	-0.37 / 0.52
P_{ins} (cmH ₂ O) (17.47 (3.27))	1.71 (1.95) p<0.001	-2.19 / 5.61	-1.66 / 9.98
P_{exp} (cmH ₂ O) (4.72 (1.64))	0.12 (0.87) p=0.110	-1.62 / 1.86	-3.49 / 2.69

V_E : minute ventilation; f: frequency; I/E: inspiratory/expiratory time; P_{ins} : inspiratory pressure; P_{exp} : expiratory pressure. V_E , f and I/E were measured in the 153 patients on volume-preset ventilators. P_{ins} and P_{exp} were measured in the 137 patients on pressure-preset ventilators.

DISCUSSION

In this study on the settings and performance of mechanical ventilators at the patient's home we observed considerable differences between the settings prescribed, the values set at the control panel of the ventilator and the ventilation values effectively yielded by the equipment. We also found underperformance in the ventilator alarms. As the errors in the ventilators did not depend on the hospital or on the company servicing the equipment, the deficiencies observed must be attributed to limitations of the quality control procedure followed at the centres studied. The fact that the index of ventilator error was greater in the patients in whom HMV started earlier is consistent with a poor quality control. Indeed, the probability that the ventilator settings were changed in an uncontrolled way and that their clinical records were not adequately updated is increased in these patients. Given that the quality control of equipment at the centres included in this study was similar to the average in Europe [2], the results found in the present study may be regarded as representative.

To the best of our knowledge, this is the first extensive multicenter study to test the actual performance of normally operating ventilators at the patient's home. An earlier study on ventilator dysfunction covering a wide patient population was retrospectively based on a register of incidents and, hence, the results did not come from the inspection of ventilators at homes randomly selected from the general HMV population [3]. During the ventilator home test we recorded the parameter settings on the ventilator control panel and we measured the actual ventilation provided by the device. Since home visits require a portable system, the standardised lung model used was passive. Therefore, data such as ventilator triggers which might also affect patient comfort and compliance were not tested. However, given that we found similar results in all the parameters studied the settings involved in the active response of the ventilator could be affected by the same level of deficiencies.

One interesting finding from this study was that the parameter values set in the control panel of the ventilator did not coincide with the settings prescribed to the patient (Figure 1 and Table 1). Such a difference, which cannot be attributed to equipment malfunction, could be due to the fact that changes in setting prescription during the HMV follow-up had not been adequately registered in the patient's clinical record or to the fact that the patient had in/voluntarily modified the ventilator settings. Although manipulation of the control panel by the patient is not possible in modern ventilators, a non negligible number of ventilators in current use still allow an easy modification of the settings. The fact that the patient modifies the ventilator settings is not necessarily detrimental. In some cases it is possible that the patient adapts the ventilator settings to improve his/her comfort. In fact, it should be borne in mind that while the setting titration is carried out at patient discharge, the pathophysiological status of the patient evolves with the result that some months after discharge the ventilation that the patient needs could not coincide with the one titrated at discharge. It is also possible that the patient adapts the settings to counterbalance the unintentional leak level from the mask, which can change as the patient rearranges the mask to improve comfort. Accordingly, this action could be interpreted positively as a sign of patient empowerment. However, in some cases the patient could wrongly modify the ventilator settings with the result that the beneficial effects of the treatment are minimized. In any case, the fact that the patient is ventilated with settings that are different from the ones prescribed to him/her should be regarded as a quality control

deficiency. Indeed, to adequately monitor the normal clinical evolution of the patient and to interpret potential acute incidents, the physician in charge of the patient follow-up must be aware of how the patient is actually ventilated.

Another result of this study was that the ventilators did not perform in agreement with the settings in the control panel (Figure 2 and Table 2). Specifically, the minute ventilation provided by the device progressively worsened as the set value increased. The fact that home ventilators tended to underperform when subjected to high-level requirements has already been documented [6]. However, recent data indicate that the performance of modern ventilators has improved [7]. To adequately interpret the importance of the results reported in Figure 2 and Table 2, it should be stressed that the lung model used in the home test featured the resistance and elastance of a normal respiratory system. According to the literature, a greater underperformance is expected if a lung model with high resistance/elastance mimicking patients with increased impedance is used [6]. The fact that the normal servicing of the ventilators did not detect the observed underperformance indicates that the quality control carried out by the companies could be improved.

In this study we also focused on ventilator alarms. A significant proportion of the ventilators did not incorporate alarms. Moreover, the alarms did not work when subjected to an effective in a non negligible number of ventilators with built-in alarms because these were not activated or because they failed. Although the alarms operated correctly in all the patients subjected to 24 h ventilation, our results highlight the problem of quality control. Specifically, the question of adapting the alarms to the needs of different patients. In any case, it seems reasonable that if the ventilator is equipped with an alarm it should be activated and work properly even if the patient is not fully dependent on the ventilator.

Although the results found in this study could raise significant concerns about the quality control of home ventilators, it should be noted that the equipment dysfunctions detected were not correlated with major indices of treatment failure such as non-programmed readmissions. However, we did not ascertain whether ventilator malfunction could affect other parameters describing the clinical impact in greater detail (patient compliance, tolerance, side effects, or quality of life). Although all the patients remained stable while receiving HMV, it cannot be ruled out that improving the HMV performance could in some cases enhance patient comfort, treatment compliance and clinical effectiveness [8]. The finding that safe and effective treatment is compatible with some ventilator errors could be attributed to the fact that in most patients subjected to HMV the required “dose” of treatment is not critical in terms of patient comfort and physiological effects [9, 10]. According to this interpretation, most stable patients on HMV need ventilatory support, but the amount of support to ensure adequate treatment of the patient falls within a relatively wide range of settings [9, 10]. The question of whether the HMV settings should be titrated in terms of patient comfort or physiological improvement remains open to date [11, 12].

In conclusion, this study illustrates the current limitations of the quality control of HMV in a representative clinical context. The results suggest that HMV quality control can be upgraded to ensure adequate ventilator settings, correct ventilator performance and ventilator alarms operation. In addition to reducing the risk of possible accidents, an improved HMV quality control will provide the patient with a ventilatory support

closer to the one prescribed to him/her and will reassure both the patient and the physician about the adequacy of the patient's treatment.

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FIGURE LEGENDS

Figure 1. *Top:* Comparison between minute ventilation set in the volume-preset ventilator control panel (SET) and minute ventilation prescribed for the patient (PRESCRIBED) for the 157 patients on volume-preset ventilation. The differences between the two minute ventilation values are plotted as a function of the prescribed values. Dashed lines correspond to the mean differences in each plot. Dotted lines correspond to mean \pm 2-SD (limits of agreement). *Bottom:* Same for inspiratory pressure in pressure-preset ventilators (137 patients). The number or distinguishable symbols is lower than the number of cases because some symbols are the superposition of data from several patients.

Figure 2. *Top:* Comparison between actually generated minute ventilation (MEASURED) and minute ventilation set in the volume-preset ventilator control panel (SET) for the 157 patients on volume-preset ventilation. The differences between the two minute ventilation values are plotted as a function of the set values. Dashed lines correspond to the mean differences in each plot. Dotted lines correspond to mean \pm 2-SD (limits of agreement). *Bottom:* Same for inspiratory pressure in pressure-preset ventilators (137 patients). The number or distinguishable symbols is lower than the number of cases because some symbols are the superposition of data from several patients.

Figure 3. Cumulative percentage of patients as a function of the index of error of his/her ventilator. The ventilator error was assessed as error in minute ventilation or in inspiratory pressure for volume- and pressure-preset ventilators, respectively.

Figure 4. Relationship between the number of non-programmed hospital readmissions in the last year and the index of error of the home ventilator.







