

Home Nebulized Therapy for Patients with COPD*

Patient Compliance With Treatment and Its Relation to Quality of Life

Zoë M. Corden, BSc; Catherine M. Bosley, MBBS; Peter John Rees, MD; and Gordon McLellan Cochrane, MBBS, BSc

Study objectives: To assess compliance with home nebulized therapy in patients with COPD.
Design: Patients' home nebulizers were replaced with nebulizers that recorded the date and time of each treatment over a period of 4 weeks. Poor compliance was defined as taking <70% of the prescribed dose (or <60% for those prescribed treatments five or more times daily).
Setting: Patients were seen at the hospital COPD outpatient clinic. The compliance data obtained were recorded while they were at home.
Patients: Ninety-three patients aged 44 to 76 years (mean, 64.9 years) were recruited from the hospital nebulizer database.
Measurements: Patients completed a self-reported quality of life scale, the St. George's Respiratory Questionnaire (SGRQ), both before (SGRQ1) and after (SGRQ2) the 4-week study period to look at whether quality of life was either predictive of or subsequent to level of compliance.
Results: Data were obtained from 82 patients. Mean compliance was 57% (range, 0 to 124%). Thirty-six (44%) patients were compliant and 46 (56%) were poorly compliant. There was no difference between the two groups in age or sex distribution. Compliance was negatively correlated with the total score on the SGRQ2 ($p=0.03$).
Conclusion: The study shows that levels of compliance with nebulized therapy are low in a large proportion of patients with COPD and that patients with low levels of compliance report greater impairment in their quality of life. (CHEST 1997; 112:1278-82)

Key words: COPD; home nebulized therapy; patient compliance

Abbreviations: SGRQ=St. George's Respiratory Questionnaire

Compliance with medical advice in chronic respiratory disease has not been widely investigated. Most studies have concentrated on compliance with inhaled β -agonists and corticosteroid treatment using devices such as the Chronolog (Advanced Technology Products Corp; Lakewood, Colo) and the turbo-inhaler computer^{1,2} (Astra Draco; Lund, Sweden) but have largely ignored nebulized therapy. At Guy's Hospital, large numbers of COPD patients whose symptoms are not controlled by inhaled medication regularly use home nebulizers to administer β -agonists, anticholinergics, and corticosteroids. Prescribed regimens range from twice to six times daily. The cost of purchasing and upkeep of these nebulizer-compressor units is consid-

erable. Before prescription, patients undergo a clinical assessment of reversibility to establish that they will benefit from their use. Given that the patient's condition is severe enough to warrant the use of regular nebulized therapy and considering the expense, it is important that the actual use of these units be assessed and efforts made to ensure that they are used as prescribed. In addition, Bosley et al³ have previously shown that patients with poor compliance have a tendency to be depressed and feel unsupported. This study aimed to find out how and when patients use their home nebulizers. It also looked at whether people use them in relation to the severity of their symptoms and/or the impact of their chest disease on their lifestyle and activities.

*From the Departments of Allergy and Respiratory Medicine (Ms. Corden and Drs. Rees and Cochrane), and Psychiatry (Ms. Bosley), United Medical and Dental Schools, Guy's Hospital, London, United Kingdom.

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MATERIALS AND METHODS

Patients

Patients were recruited from a database at Guy's Hospital of patients using regular nebulized therapy at home. All patients

had previously been assessed as to their suitability for nebulized therapy and had been prescribed a nebulizer on the basis of at least 10% reversibility being achieved as well as subjective improvement. All patients with a diagnosis of asthma, emphysema, or chronic bronchitis between the ages of 40 and 75 years were approached by letter followed by a telephone call. A total of 129 patients were contacted. Ninety-three patients (72%) agreed to take part in the study. The mean (SD) age of this group was 64.9 years (7.7) [range, 44 to 77 years]. Most participants were suffering from chronic obstructive bronchitis with varying degrees of emphysema (74%). Nineteen patients had asthma, one had bronchiectasis, and one had fibrosis (rheumatoid arthritis). Eleven patients (12%) were using inhaled corticosteroids.

Thirty-six (28%) refused to take part: 16 were male and 20 were female. The mean age of this group was 65.3 years (7.9) [range, 42 to 75 years]. Twenty-one (58%) gave no reason or were not interested, 10 (28%) said they were not well enough, and 2 (6%) did not like the idea of questionnaires and interviews. There was no difference between those who accepted and those who refused to take part in terms of age and gender. Three of the thirty-six patients (8%) initially accepted but did not attend the appointment and were thus included in the refusals.

Study Design

Patients' home nebulizers were exchanged for data loggers for a period of 4 weeks; they were advised that this was only a different compressor system and not that it had any special features such as recording of their compliance. Patients were given a demonstration on how to use the data logger and provided with written instructions. The patient's prescribed regimen was checked against medical notes and confirmed with the patient. Each patient completed the St. George's Respiratory Questionnaire (SGRQ) at the beginning and the end of the 4-week study period.

Measurement of Compliance

The data loggers were supplied by Medicaid (West Sussex, UK). Each comprised a compressor (CR50) and a nebulizer (Ventstream) to which had been connected a data collection system. The system consists of a processor that collects pressure data from the nebulizer mouthpiece via a sensor and an analogue-to-digital converter. The system also has an input from a pressure switch on the output of the compressor which checks that the nebulizer is connected to the system. The data logger recorded the date and time of each treatment as well as the duration of treatment (length of time the machine was switched on). Inhalation time (time spent actually inhaling treatment) was recorded via the pressure sensor on the mouthpiece which trips in at about 15 L/min. The data loggers had a downloading facility so that data could be read from the unit into a computer (IBM; Rochester, Minn). Patients used the data loggers for 4 weeks after which data were downloaded and their compliance assessed. Whereas the treatment normally takes around 5 min, a valid dose was taken as at least 2 min duration with evidence of inhalation of treatment. This served to exclude instances in which the patient "tried out" the compressor by switching it on and off and then returning to it a few minutes later to actually take the treatment. Measurement of compliance was calculated as follows:

$$\% \text{ compliance} = \frac{\text{number of doses taken}}{\text{number of doses prescribed}} \times 100$$

Poor compliance was defined as taking <70% of prescribed treatment (or <60% for those prescribed treatments five or more times daily).

Measurement of Quality of Life

The SGRQ is a 76-item self-completed questionnaire for measuring health in chronic airflow limitation.⁴ A total score is obtained along with scores for three subscales: symptomology (including questions on levels of coughing, wheezing, breathlessness, and sputum production); activity (questions about activities which either bring about or are limited by breathlessness); and impact (questions about aspects of daily life, for example, employment, stigma). Each item of the questionnaire is weighted and scores for each subscale, as well as the total score, range from 0 to 100 with 0 indicating no quality of life impairment. The original questionnaire asks questions relating to the previous year of the patient's life; this was adapted so that it referred only to the previous 4 weeks.

Statistical Analysis

The χ^2 test was used to compare demographic data of "compliant" and "poorly compliant" patients. Correlation between percent compliance and quality of life measures were analyzed using Pearson's correlation. Values are reported as mean \pm SD, unless otherwise noted.

Ethical Approval

To get as accurate a picture of compliance as possible, patients were not told that their compliance was being monitored but were told that they were trying out a new, faster type of compressor. Approval was granted by the local Ethics Committee and all patients completed written consent forms.

RESULTS

Withdrawals

Eleven patients withdrew from the study: 7 female and 4 male. The mean age of this group was 64.4 years (± 7.5). Four patients experienced worsening symptoms and felt safer using their own machine, four found the nebulizer hard to use, and the remaining three patients dropped out due to a hospital admission, diagnosis of lung cancer, and a nebulizer recording malfunction.

Patient Details

Eighty-two patients (88%) completed the study. Forty-four (54%) were male and 38 (46%) were female. The mean age of the group was 64.9 years (± 7.65). Duration of illness ranged from 1 to 66 years, with a mean of 15.9 years (± 15.09). The mean FEV₁ for this group at the start of the study was 0.87 L (range, 0.45 to 1.85 L) and the mean FVC was 1.99 L (range, 1.15 to 3.45 L). Most patients (56%) had been prescribed use of the nebulizer four times a day, 13% three times a day, 17% twice a day, and 1% once a day. Twelve percent of patients were using the nebulizer more than four times a day.

Compliance Data

The mean compliance of the whole group was 57% ($\pm 34.3\%$) with individual compliance ranging

Table 1—Mean Scores of SGRQ Subscales and Correlation With Percentage Compliance

Subscale	SGRQ1		SGRQ2	
	Mean	SD	Mean	SD
Symptoms	71.39	17.81	68.03 [†]	18.00
Impact	57.10	15.61	54.47 [†]	15.46
Activity	81.47	17.37	81.67	16.45
Total	67.01	12.99	64.86*	13.42

*Correlation coefficient = -2.477, $p=0.03$.

[†]Correlation coefficient = -2.213, $p=0.053$.

[‡]Correlation coefficient = -2.201, $p=0.054$.

better to consider a level of compliance that will maintain the patient in good health, which is the required outcome of treatment. Eighty to 100% has been suggested as a standard for full compliance.⁵ In this investigation, patients were considered to be "poor compliers" if they took <70% of the overall treatment prescribed for them during the 4-week period. The physicians involved in the study (P.J.R., G.M.C.) considered that therapeutic efficacy of the nebulizer therapy would be compromised beyond this point.

Studies of compliance in asthma and COPD show a noticeable variation in adherence to medical advice, with results ranging from 48 to 103%.⁵ Much of this variation can be attributed to differences in experimental design, the way in which compliance is assessed, and the number of times treatment must be taken. Frequency of drug administration has been reported to affect compliance with treatment, greater frequency being associated with poorer compliance.⁶ For this reason, patients instructed to use the nebulizer more than four times a day were considered poorly compliant if they took <60% of prescribed treatment. However, the results of this study showed no correlation between compliance and dose frequency. This may be due to the fact that nebulizers might be regarded to some extent as "as occasion requires" treatment. This study showed that levels of compliance in COPD patients are low and correspond to those found in other chronic illnesses.⁷ The mean compliance found was 57% with 36 patients (44%) being compliant with their prescribed regimen and 46 (56%) being poorly compliant, taking <70% of their treatment. Compliance levels were unrelated to demographic variables such as age, gender, duration of illness, and socioeconomic group, as widely reported elsewhere.⁷

If patients increase their compliance in response to severity of symptoms and the impact on their quality of life, we would expect percent compliance to correlate with the score on the SGRQ1. This was not the case; percent compliance was not related to

quality of life measurements at the start of the study, suggesting that the patient's experience in the 4 weeks prior to the study had no effect on the patient's subsequent use of the nebulizer. This contrasts with the finding by Turner et al⁸ that nebulizer-adherent patients complain of more breathlessness than nonadherent patients. There are two possible explanations for the finding that percent compliance correlates with the total score, symptom score, and the impact score on the SGRQ2: first, that patients who experience more respiratory symptoms and a greater impact of their illness on their lifestyle tend to be poorer compliers during a period of observation; second, poor compliance leads to a greater impairment in quality of life. While no causality can be implied, the second explanation is consistent with the results of the SGRQ1 finding that patients' use of the nebulizer is not related to the symptoms they experience or the impact that COPD has on their quality of life.

The study by Turner et al⁸ of 985 patients using home nebulizers reported that 50.6% of patients were adherent and 49.4% were nonadherent with their prescribed regimen. They also reported that adherence was not related to the effects of illness on daily functioning. This finding may contrast with the present one as these patients were put into adherent and nonadherent groups according to whether they fell above or below the median of 25 min of treatment per day. Using the median as a cutoff, by definition, places 50% of patients in each group and patients who might be considered clinically to be taking sufficient treatment might therefore be classed as nonadherent. Furthermore, these patients were aware that their compliance was being monitored and behavior is likely to be modified in response to observation. Improvement in compliance while being observed returns to baseline when intervention is over.⁹ In the present study, patients were unaware that compliance was being monitored and, in addition, information was available on whether the nebulizer was used when it was switched on.

The recording of no inhalation while a nebulizer is switched on may be due to the patient switching on a nebulizer and subsequently not using it, ineffective use of the mouthpiece (by nose-breathing), or failing to connect the mouthpiece to the compressor. The latter is unlikely as the same patients showed good inhalation data on other occasions and most patients tended to leave the connection tube in place between treatments.

From the day-by-day use of the nebulizer, it was found that a substantial proportion of patients (21%) took no treatment at all for half of the study period. This is surprising in view of the severity of illness of this group of patients. Only eight patients (10%)

used their nebulizer as prescribed for >80% of the days. This compares with studies of medication taken via inhalers in asthma. Bosley et al¹ found that only 14% of patients taking inhaled bronchodilators and corticosteroids took the correct dose on 80% of days (on a twice daily regimen). Mawhinney et al¹⁰ found that only 1% of patients used their inhalers correctly for >75% days (on a four times daily regimen).

Poor compliance in patients with COPD has been associated previously with increased levels of morbidity.^{11,12} The present finding that patients using regular nebulized medication are no more likely to take their treatment as prescribed than other patient groups is of particular concern. This is because the levels of morbidity for this group are already high and these patients also report high levels of impairment in their quality of life. In addition, since the cost of prescribing and maintaining these machines is high, it is important that efforts are made to improve patients' responses to their illness.

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