Predictive Factors for the Need for Additional Humidification During Nasal Continuous Positive Airway Pressure Therapy

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Predictive Factors for the Need for Additional Humidification During Nasal Continuous Positive Airway Pressure Therapy*

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Objective: **To identify potential risk factors for the need for an additional cold or heated humidifier in nasal continuous positive airway pressure (nCPAP) circuitry.**
Design: **A prospective cohort study.**
Setting: **University hospital sleep-disorders center.**
Patients: **Eighty-two consecutive patients with obstructive sleep apnea syndrome were followed up for a median of 347 days (range, 3 to 530 days) after the initiation of nCPAP therapy.**
Measurements and results: **In 46 patients (56%), the occurrence of upper-airway symptoms led to the addition of a cold humidifier after a median time of 39 days (range, 2 to 94 days). In 23 of the 46 patients, the persistence of the symptoms indicated the secondary use of a heated humidifier after a median time of 28 days (range, 5 to 70 days). nCPAP use (mean ± SD) was not influenced by cold humidification (4.58 ± 2.05 h/d vs 4.7 ± 2.48 h/d; $p = 0.75$), but it increased significantly with heated humidification (5.38 ± 2.26 h/d vs 3.51 ± 2.53 h/d; $p < 0.01$). Anthropometric characteristics, drying medications, clinical findings such as deformity of the nasal septum, symptoms of a chronic mucosa disease (CMD), a previous uvulopalatopharyngoplasty (UPPP), and polysomnographic parameters had no significant effect on the need for a cold humidifier. Age > 60 years (odds ratio [OR], 5.58; 95% confidence interval [CI], 1.69 to 18.43), drying medications (OR, 6.59; 95% CI, 1.29 to 33.51), presence of CMD (OR, 4.11; 95% CI, 1.24 to 13.58), and previous UPPP (OR, 4.56; 95% CI, 1.18 to 17.6) were found as significant risk factors for the addition of a heated humidifier.**
Conclusion: **Our results demonstrate that heated humidification significantly improves the nCPAP daily rate of use and that its need may be predicted.** ***(CHEST 2001; 119:460–465)***

Key words: humidification; nasal continuous positive airway pressure; obstructive sleep apnea syndrome

Abbreviations: AHI = apnea/hypopnea index; BMI = body mass index; CI = confidence interval; CMD = chronic disease of the nasal mucosa; ESS = Epworth sleepiness scale; nCPAP = nasal continuous positive airway pressure; NSD = deformity of the nasal septum; OR = odds ratio; OSAS = obstructive sleep apnea syndrome; rH = relative humidity; UPPP = uvulopalatopharyngoplasty

Nasal continuous positive airway pressure (nCPAP) is the first-line therapy for moderate-to-severe obstructive sleep apnea syndrome (OSAS).[1–3] Among the side effects described with this treatment, undesirable nasal symptoms, such as congestion, dryness, or sneezing, are particularly prevalent.[4–7] They may be so severe as to reduce compliance with therapy.[5,8] Several mechanisms may be potentially involved in the development of nasal discomfort with nCPAP. OSAS is an age-related disease, and an increased likelihood of nasal complaints is an age-related change in the nose.[9] Medical therapies are frequently prescribed in patients with OSAS; some therapies, such as antihypertensives or antidepressants, can promote nasal dryness. Increased nasal resistance due to a nasal disease or previous palatal surgery can promote mouth leaks during sleep.[10,11] Although these potential causes of undesirable nasal effects are mentioned in the literature, they have not been studied in any great detail in OSAS patients complaining of these effects.

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Anecdotal information indicates that a number of methods, with limited efficacy, have been used to try to minimize these nasal problems, including decongestants, topical nasal solutions containing steroids, and room vaporizers.[12] Recently, the use of a full face mask has been shown to completely prevent dehydration of the respiratory tract,[13] but long-term compliance is generally poor.[13,14] The method most commonly used is in-line humidification of inspired air. Air can be modified either by a cold passover humidifier or a heated water-bath humidifier. Experimentally, heated humidification is clearly more effective than cold humidification to lessen inspired air dehydration due to massive mouth leaks.[10,13] Recently, a randomized, crossover study[15] has shown that patients are more satisfied with nCPAP when it was used with heated or cold passover humidification than without humidification, and that only heated humidification resulted in an improvement in daily nCPAP use. In this controlled study,[15] the humidifier was added systematically during the titration night, and it is not possible from its results to identify the patients most likely to benefit from humidification. To our knowledge, there are no prescription guidelines concerning additional humidification when a clinician is faced with the problem of nasal discomfort in a patient treated with nCPAP.

The purpose of this prospective, controlled study was to define predictive factors for the need for additional humidification in OSAS patients starting nCPAP therapy.

Materials and Methods

Over a 12-month period, 82 consecutive patients suffering from OSAS (defined as an apnea/hypopnea index [AHI] > 10 events per hour of sleep) were prospectively included into the present study. All of them lived in Paris or its near suburb. The pressure setting of the machine was adjusted during full-night polysomnography at the pressure level associated with the lowest incidence of breathing irregularities and sleep arousals.

Humidification and Patient Follow-up Protocol

The patients were instructed in the use of nCPAP during the daytime before starting home therapy. They were particularly encouraged to immediately report by phone the occurrence of significant nasopharyngeal symptoms (*ie*, nasal obstruction, sneezing, nasal drainage, or dryness of the oral cavity) sufficiently bothersome to limit or even prevent use of the device. In addition, these symptoms were systematically looked for at the end of the first month, the third month, and the 12th month of treatment.

When the patient developed significant nasal discomfort, a cold passover humidifier (ResMed; Sydney, Australia) was added to the nCPAP circuitry in a first attempt. The follow-up visits were then scheduled at the end of 3 months and 12 months after changing the circuit.

If these nasal symptoms persisted despite cold humidification, the equipment was replaced by a new nCPAP device that was fitted with a water bath supported by a plate (CP95; Taema; Antony, France), delivering 8 mL/h/10 cm H_2O.

The humidifier was installed by the medical-device provider (LVL Medical; Paris, France) within 24 h following the patient's report of appearance or persistence of the nasal problem. The person responsible for deciding whether a patient needed added humidification was a nurse blinded to the objectives of the study.

Data Collection

On inclusion in the study, all patients completed a questionnaire and underwent an otolaryngologic examination to identify any symptoms of chronic disease of the nasal mucosa (CMD; *ie*, subjective chronic nasal obstruction, chronic sneezing, nasal discharge and postural drip, abnormal appearance of the turbinate mucosa, and polyposis); previous uvulopalatopharyngoplasty (UPPP); and/or fixed obstruction of the nasal cavities due to a deformity of the nasal septum (NSD).

Age (in years), sex, body mass index (BMI; in kilograms per meter squared), concomitant drying medications, Epworth sleepiness scale (ESS) score, AHI, effective level of positive airway pressure, and the season when nCPAP therapy began were also recorded.

The follow-up period was defined as the number of days from the date of the start of nCPAP therapy to the date of stopping treatment (decided by the patients themselves), or to the date of death, or to the end date of the study (at least 6 months after inclusion of the last patient into the study).

During the follow-up period, the time elapsed between the beginning of treatment and the first report of nasal symptoms was recorded. When applicable, the time elapsed between addition of a cold humidifier and the report of persistent significant nasal problems was also recorded.

The mean daily rate of use was chosen as the index of compliance with nCPAP. It was calculated by dividing the difference between two successive readings of the in-built time counter of the nCPAP device by the number of days elapsed. In the group of patients reporting nasal symptoms, this information was obtained at the time of addition of the heated and/or cold humidifier, 3 months after modification of the circuitry, and at the end of the follow-up period. In the patients who did not report nasal discomfort, data were systematically collected during follow-up visits that were systematically scheduled at the end of the third month of treatment and at the end of the follow-up period.

Statistical Analysis

Statistical analysis was performed with SAS software (SAS Institute; Cary, NC).[16] Values are expressed as mean ± SD and median (range). We used Student's unpaired or paired t test to compare cross-classified continuous variables, and Fisher's Exact Test to compare differences between groups for discrete variables.

Multiple logistic regression analysis was used to evaluate the impact of potential risk factors on the need for additional humidification, controlling for the remaining variables. When constructing the model, variables were selected with the backward stepwise method, assessing significance by means of the likelihood ratio test. A variable was eligible for entry into the logistic regression model when it was associated with humidification with a p value < 0.2 in univariate analysis. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated in accordance with standard methods. A p value < 0.05 was considered significant.

Results

Of the 82 patients included, 11 were women (13.5%) and 71 (86.5%) were men, with a mean age of 54 ± 11 years and a mean BMI of 30 ± 5.8 kg/m^2. Twenty-five percent of patients received systemic medication known to potentially act on the nasal mucosa. Fifty-nine percent of these patients were treated with psychotropic drugs (antidepressants, neuroleptics, hypnotics, anxiolytics), 32% with antihypertensives (diuretics, centrally acting antihypertensives, calcium channel blockers, β-blockers), and 9% with drugs designed to treat prostatic functional disorders. The mean ESS was 12 ± 5.5. CMD was reported in 34.1% of patients. UPPP had been performed unsuccessfully prior to nCPAP therapy in 20.7% of patients. Otolaryngologic examination found a NSD causing > 50% reduction in cross-section area of the nasal cavity in 32.9% of cases. The mean AHI was 74.5 ± 38.2, and the mean effective level of nCPAP was 9.6 ± 2.1 cm H_2O. Among the study population, 23.2% of patients started nCPAP therapy in spring, 40.2% in summer, 23.2% in autumn, and 13.4% in winter (Table 1).

We followed up the 82 patients for a median of 347 days (3 to 530 days). No patients were unavailable for follow-up or died during the follow-up period. Sixty-eight of these 82 patients (82.9%) were followed up for > 3 months, and 34 patients (41.5%) were followed up for > 12 months.

Thirty-six patients (44%) never complained of nasal problems and consequently did not require addition of a humidifier (group 1). Ten of these patients discontinued treatment because of claustrophobia, insomnia, noisy equipment, or family intolerance after a median treatment time of 44 days (3 to 118 days). The daily rate of use of nCPAP in these asymptomatic patients (the 10 patients who stopped treatment were not included in this calculation) was 5.46 ± 2.17 h/d at the third month and 6.28 ± 1.18 h/d at the end of the study.

Table 1—*Characteristics of the Study Population*

Variables	Mean (SD)*
Age, yr	54 (11)
Male/female gender, %	86.5/13.5
BMI, kg/m^2	30 (5.82)
ESS score	12 (5.5)
CMD (Y/N), %	34.1/65.9
UPPP (Y/N), %	20.7/79.3
NSD (Y/N), %	32.9/67.1
AHI, events/h	74.5 (38.2)
Minimum Sa_{O_2}, %	74.1 (11.7)
Stage 1 and 2, % TST	73.9 (17.6)
Stage 3 and 4, % TST	17.5 (13.9)
REM sleep, % TST	8.8 (8)
Sleep efficiency, % TST	71 (8.7)
nCPAP, cm H_2O	9.6 (2.1)
Season (spring/summer/autumn/winter), %	23.2/40.2/23.2/13.4

*Data are expressed as mean (SD) unless otherwise indicated. TST = total sleep time; Y = yes; N = no; REM = rapid eye movement; Sa_{O_2} = arterial oxygen saturation.

Forty-six patients (56%) reported of nasal symptoms after a median time of 39 days (2 to 94 days) from initiation of home therapy. Only age was significantly associated with the need for humidification ($p = 0.02$); otherwise, no significant difference was observed in terms of sex, BMI, medications, clinical findings, polysomnographic parameters, and season when the nCPAP therapy started in these patients requiring humidification compared to those of group 1.

In 23 of 46 patients (50%; group 2), nasal discomfort disappeared after initiation of the cold humidification, even in the 5 patients who stopped nCPAP therapy in this group. However, the daily rate of use of nCPAP was not significantly modified. It ranged from 4.58 ± 2.05 h/d on addition of the cold humidifier to 4.70 ± 2.48 h/d at the end of the follow-up period ($p = 0.75$) in the whole group (including the five patients who were not compliant), and from 5.11 ± 1.64 h/d on addition of the cold humidifier to 5.88 ± 1.11 h/d at the end of the follow-up period ($p = 0.50$), if the five patients who stopped nCPAP therapy were excluded.

In 23 of 46 patients (50%; group 3), the symptoms persisted after addition of a cold humidifier, and a heated humidifier was added after a median time of 28 days (5 to 70 days) elapsed from the start of cold humidification. The symptoms disappeared in all but three patients after addition of the heated humidifier; two patients stopped treatment each night for 3 to 5 h after sleep onset because of severe nasal obstruction, and one patient permanently stopped his treatment because of persistent severe nasal discomfort. In contrast with the lack of improvement in the daily rate of use observed with cold humidification, from 3.51 ± 2.53 h/d without humidifier to 3.84 ± 2.08 h/d with cold humidifier ($p = 0.36$), the daily rate of use increased significantly to 5.38 ± 2.26 h/d with heated humidifier at the end of the study (*ie*, a 40% increase [$p = 4.10^{-4}$]).

No significant difference was observed in terms of anthropometric characteristics, medications, clinical findings, and polysomnographic parameters in group 3 compared to group 2.

Predictive Factors for the Need of Heated Humidification

Table 2 summarizes the main elements of comparison of the patients in groups 1 and 2 and the patients in group 3. Female gender ($p = 0.005$) and

Table 2—*Univariate Analysis for Requiring a Heated Humidifier (Group 3): Variables With a p ≤ 0.20 Included in the Logistic Regression Model*

Variables	Groups 1 and 2 (n = 59) No.	%	Group 3 (n = 23) No.	%	p Value
Age, yr					
≤ 60	46	78	11	47.8	0.008
> 60	13	22	12	52.2	
Gender					
Male	55	93.2	16	69.6	0.005
Female	4	6.8	7	30.4	
CMD					
Yes	17	28.9	11	47.8	0.10
No	42	71.1	12	52.2	
UPPP					
Yes	10	16.9	7	30.4	0.17
No	49	83.1	16	69.6	
NSD					
Yes	17	28.9	10	43.5	0.20
No	42	71.1	13	57	
Medications, No.					
≤ 1	55	93.2	18	78.2	0.06
> 1	4	6.8	5	21.8	

age > 60 years were significantly associated with the need for heated humidification (p = 0.008) on univariate analysis. NSD, CMD, UPPP, and the use of drying medications also tended to be overrepresented in these patients. These variables, associated with p ≤ 0.2 on univariate analysis, were examined by stepwise logistic regression, using "requiring a heated humidifier" as the dependent variable.

The final model (Table 3) identified age > 60 years (OR, 5.58; 95% CI, 1.69 to 18.43), drying medications (OR, 6.59; 95% CI, 1.29 to 33.51), presence of CMD (OR, 4.11; 95% CI, 1.24 to 13.58), and previous UPPP (OR, 4.56; 95% CI, 1.18 to 17.60) as significant risk factors for addition of a heated humidifier. No significant interaction was observed between these variables. In this model, we assumed that the 10 patients who discontinued nCPAP (after a median of 40 days) did not require a humidifier. Anyway, even excluding these 10 patients from the study, the multiple logistic regression analysis led to the same results.

Table 3—*Summary of Multivariate Analysis to Identify Variables Independently Associated With a Heated Humidifier**

Variables	OR	95% CI
Age (≤ 60 yr/> 60 yr)	5.58	1.69–18.43
Medications, No. (≤ 1/> 1)	6.59	1.29–33.51
CMD (N/Y)	4.11	1.24–13.58
UPPP (N/Y)	4.56	1.18–17.6

*See Table 1 for abbreviations.

Discussion

This prospective study confirms that nasal discomfort occurred in a majority of unselected OSAS patients starting home nCPAP therapy. In all but one of our patients, in-line humidification was associated with resolution of the symptoms or reduction to a level allowing continuation of treatment. Heated humidification was necessary in 50% of the patients complaining of nasal discomfort after failure of cold humidification.

A large proportion (56%) of our patients, similar to the rates previously reported in the literature,[7,8] described the development of disabling nasal discomfort during nCPAP. It has been clearly established that airway dryness accounts for nasal discomfort during nCPAP therapy. We have previously reported that the relative humidity (rH) of the air delivered by the nCPAP device is, on average, 20% lower than the rH of room air and that this decrease is dramatically aggravated during mouth leak breathing.[13] Excessive drying of the nasal mucosa has been shown to induce the release of vasoactive leukotrienes[17] leading to increased nasal resistance[11] that in turn could induce mouth breathing, one of the powerful mechanisms of oropharyngeal dryness.[10] The superior efficacy of heated humidification to reduce the increase of nasal resistances generated by mouth leaks under nCPAP breathing was reported in normal subjects.[10] In sleeping OSAS patients, we have shown that heated humidification can prevent inspired air dehydration occurring under nCPAP, lower the dramatic decrease in air rH usually observed during mouth leak periods, and decrease the percentage of time spent with mouth leaks.[13] Heated humidification therefore appears to be able to break the vicious circle generated by mouth leaks.

At the end of our follow-up period (median of 347 days), 75% of patients were still treated with nCPAP. The reasons for discontinuation of treatment were similar to those usually reported in the literature.[4–7,18,19] Only one patient blamed nasal discomfort for discontinuation of treatment, despite the addition of a heated humidifier. Cold humidification improved comfort in one half of these patients, without considerably modifying their daily rate of use, which was satisfactory (> 4 h/d), but significantly lower than that of patients not requiring a humidifier or requiring heated humidification. No predictive factor of this subjective efficacy of cold humidification was demon-

strated in our study. Massie et al[15] reported that nCPAP with cold humidification was associated with a greater satisfaction of the patients than nCPAP without humidification. Identically to our results, they did not observe any improvement of the daily rate of use with cold humidification. As reported by these authors in their crossover study,[15] we observed that the use of nCPAP increased significantly after addition of a heated humidifier to the circuitry of patients who continued to complain of nasal dryness after addition of cold humidification.

In our study, as in clinical practice, we have voluntarily reserved humidification for patients who complained of upper-airway symptoms under treatment. Choosing this design, we were able to show that only half of the complaining patients (25% of the whole group) required a heated humidification. In addition, this step-by-step procedure allowed us to determine the predictive factors for the need of heated humidification.

One or several systemic drugs, whose known adverse effects include dryness of mucous membranes, were prescribed in addition to nCPAP in one quarter of patients in the study. In 44% of cases, two or more of these drying medications were associated in the same patient. This concomitant treatment appears to constitute a predisposing factor for addition of a heated humidifier (OR, 6.59). As far as possible, replacement of one or several of these molecules should therefore be proposed before considering addition of a humidifier.

Age was a strong predictive factor for the need for heated humidifier in our population (OR, 5.58). This is not surprising as the nose is an extremely dynamic organ that undergoes significant functional changes during aging. A number of specific age-related changes in the nose have been already identified, including an increased likelihood of nasal complaints,[9] an increased nasal resistance[9,20] and/or an impairment of the mucociliary function of the nose.[21]

UPPP is also a predictive factor for the development of nasopharyngeal dryness and the need for heated humidification (OR, 4.56). It has already been recognized to promote mouth leaks under treatment and is a potential cause of noncompliance with nCPAP therapy.[22]

CMD was predictive of the need for humidification in our patients (OR, 4.11). An abnormal allergic or nonspecific reactivity of the mucosa may potentially amplify its response face to excessively dry inhaled air. As it is often difficult to make a diagnosis of allergy on the basis of nasal symptoms in middle-aged patients,[9] and because these patients have a higher likelihood of nondiagnostic tests, we did not systematically investigate the allergic status of our patients.

In conclusion, in-line humidification is an effective form of treatment for the common nasal symptoms frequently occurring during nCPAP. On the basis of our results, heated humidification is needed in 25% of the patients. It should be proposed first in elderly subjects and/or patients with chronic nasal symptoms, previous UPPP, and/or taking drying medications. A prospective study should be conducted to investigate the impact of systematic use of heated humidification right from the start of treatment in patients presenting the predictive factors identified in the present study.

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