

A heated humidifier reduces upper airway dryness during continuous positive airway pressure therapy

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Upper airway dryness is a frequent side-effect of nasal continuous positive airway pressure (nCPAP) therapy in obstructive sleep apnoea (OSA). In this situation, heated humidification is often used. Alternatively, oily nose drops are frequently applied to relieve dryness. The present study aimed to investigate the efficacy of a heated humidifier in comparison with oily nose drops.

Twenty-four OSA patients complaining of serious nCPAP-related upper airway dryness were randomized to 6 weeks of treatment either with heated humidification (HC 100[®], Fischer & Paykel, Inc., Auckland, New Zealand) or oily nose drops (Colda-Stop[®], Desitin, Inc., Germany). The patients completed questionnaires on the degree and frequency of upper airway dryness, compliance with nCPAP, intention to terminate nCPAP and comfort during the nCPAP therapy.

All 12 patients treated with heated humidification improved in terms of the degree and frequency of upper airway dryness, and reported greater comfort when using the nCPAP device. All patients in the heated humidification group intending to terminate nCPAP therapy because of upper airway dryness persisted with nCPAP on addition of humidification. In contrast, only five out of 12 patients (42%) in the oily nose drops group reported their degree of upper airway dryness to be improved ($P=0.003$), only three patients (25%) reported an improvement in the frequency of upper airway dryness ($P<0.001$), and only five patients (42%) reported greater comfort when using the nCPAP device with oily nose drops ($P<0.001$). In the group using oily nose drops none of the three patients who intended to terminate nCPAP therapy persisted with nCPAP.

Heated humidification is highly effective and superior to oily nose drops in reducing the symptoms of upper airway dryness during nCPAP.

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Introduction

Obstructive sleep apnoea syndrome (OSA) occurs in about 4% of middle-aged men and 2% of middle-aged women (1). Sullivan *et al.* introduced nasal continuous positive airway pressure (nCPAP) therapy in 1981 (2) and this therapy has since become the treatment of choice for OSA. Numerous studies have demonstrated the efficacy of nCPAP therapy in terms of reducing symptoms (e.g. daytime sleepiness), improving long-term survival, and preventing such sequelae of OSA as cardiovascular complications (3–6). However,

there is a high frequency of troublesome side-effects under nCPAP.

Among the most frequently reported side-effects of nCPAP is dryness of the nose, mouth and throat, which is experienced by 30–66% of patients on nCPAP (5,7–11). To deal with this problem, heated humidification of the inspired air is often added to nCPAP therapy (11). Although the therapeutic efficacy of heated humidification has been estimated to be high (5,11–13), it has not yet been investigated in a prospective, randomized study. Alternatively, oily nose drops, which are much cheaper, are employed for the same purpose, but their efficacy has not yet been studied.

The main purpose of our investigation was to examine the therapeutic efficacy of heated humidification in comparison with oily nose drops in terms of the reduction of nCPAP-related upper airway dryness. A further aim was to determine whether patient tolerance of nCPAP can be increased by either of these measures.

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TABLE 1. Questionnaires

Pre- and post-study questions

1. How would you evaluate the dryness of nose/mouth/throat during the past 14 days?	None (1)	Mild (2)	Moderate (3)	Severe (4)
2. How often did you discontinue nCPAP during the past 14 days?	Never (1)	1 day (2)	1-7 days (3)	8-14 days (4)
3. How often did you suffer from dry nose/mouth/throat during the past 14 days?	Never (1)	1-4 days (2)	5-10 days (3)	11-14 days (4)
4. Would you terminate nCPAP because of nose/mouth/throat dryness?	Yes	No		

Post-study questions

5. How would you evaluate the effect of the study treatment on dryness?	No improvement (1)	Some improvement (2)	Considerable improvement (3)	Complete elimination (4)
6. Did you find nCPAP more acceptable using the study treatment?	No (1)	Yes, somewhat (2)	Yes, definitely (3)	Yes, considerably (4)
7. Did you experience any side-effects of the study treatment?	No	If yes, please describe		

Materials and Methods**PATIENTS**

Between November 1996 and March 1997 we recruited 24 consecutive OSA patients (22 men, two women, mean age 57.58 ± 9.78 years, body mass index (BMI) $29.92 \pm 3.98 \text{ kg m}^{-2}$) complaining of serious upper airway dryness caused by nCPAP therapy. In all cases the diagnosis of OSA and the manual titration of the nCPAP pressure had been made by full-night polysomnographies (CNS-SleepLab, Jaeger and Toennies Inc., Germany) performed in our sleep laboratory using standard methods, as recommended by the American Thoracic Society (ATS) (14,15) and the German Sleep Society (DGSM) (16). While on nCPAP therapy all patients underwent periodical follow-up in our outpatient department. Only patients with an apnoea-hypopnoea index of at least 10 h^{-1} were admitted to the study. The patients included had been on nCPAP therapy for a mean period of 14.75 ± 14.85 months (2-51 months). The mean pressure used during home treatment was 7.21 ± 2.19 mbar. All patients employed the nCPAP device Somnotron 2[®] (Weinmann Inc., Hamburg, Germany).

Excluded from the study were patients older than 75 years, those with a central sleep apnoea syndrome, Cheyne-Stokes respiration, significant daytime nasal obstruction, severe upper airways infection (e.g. febrile sinusitis) or chronic obstructive lung disease, and patients who had already been treated with a humidifier or with oily nose drops.

STUDY DESIGN

All patients were asked to complete a questionnaire (see later) in our outpatient department to provide information about the degree and frequency of dryness, and discontinuation of nCPAP (Table 1). With the aid of a randomization list the patients were randomized to a humidification group

(12 patients) or to an oily nose drops group (12 patients). The patients in the humidification group were treated for 6 weeks with nCPAP added heated humidification, while those in the other group were given oily nose drops instead. At the end of the 6-week period the patients were again asked to complete the same questionnaire and to answer additional questions aimed at determining the results of treatment and possible side-effects (Table 1). The study protocol was examined and approved by the local Ethics Committee of the Friedrich-Alexander-University Erlangen-Nuremberg.

STUDY TREATMENT

For humidification we employed the heated humidifier HC 100[®] (Fischer & Paykel, Inc., Auckland, New Zealand), which was attached to the tube of the nCPAP device in accordance with the manufacturer's recommendations. The air was humidified by heating boiled tap-water on the hot-plate of the humidifier. The temperature of the hot-plate can be set in steps between 1 and 9. Throughout the study the temperature setting of the hot plate was fixed at 5 for each patient. The patients were instructed to employ the humidifier whenever they used the nCPAP system.

As oily nose drops we used Colda-Stop[®] (Desitin, Inc., Germany) containing alkyl fatty acid ester, peanut oil, orange oil, lemon oil, terpineol, isopropyl myristate, α -tocopherol acetate and retinol palmitate. We prescribed a dose of 3 drops to be applied three times a day in each nostril.

QUESTIONNAIRE

All patients completed a questionnaire (Table 1) before and after the study period. When designing the questionnaire we made every effort to make it uncomplicated and easy for the patient to understand. To this end we created seven simple items in the form of analogue visual scales (questions 1-3

TABLE 2. Characteristics (mean \pm SD) of patients by treatment group

	Humidification (<i>n</i> =12)	Oily nose drops (<i>n</i> =12)	
Male/female	11/1	11/1	
Age (years)	58.33 \pm 9.77	56.83 \pm 10.15	n.s.
BMI (kg m ⁻²)	28.50 \pm 1.78	31.33 \pm 5.05	n.s.
Pressure (mBar)	7.00 \pm 2.49	7.42 \pm 1.93	n.s.
AHI	37.58 \pm 17.09	39.00 \pm 21.11	n.s.
Duration of CPAP (months)	16.08 \pm 14.75	13.42 \pm 15.48	n.s.

AHI=apnoea-hypopnoea index; duration of CPAP= months receiving CPAP prior to the study; n.s.=not significant.

and 5-6), and two 'yes' or 'no' questions (questions 4 and 7).

When completing the pre- and post-study questionnaires the patients were unaware of the aim of the study and the rationale of the study therapy.

STATISTICAL METHODS

All figures are expressed as arithmetic means \pm SD. For the statistical analysis of questions 1-3 the patients were classified as 'improved' or 'unchanged/worse' and the two study groups were compared using Fisher's exact test. Group comparisons for the analysis of questions 5 and 6 were performed using the Mann-Whitney *U*-test. Group comparisons of patient characteristics, age, BMI, CPAP pressure, apnoea-hypopnoea index and duration receiving CPAP before the study, were carried out using the Student's *t*-test. The statistical calculations were performed with the aid of SPSS (Version 6.0.1, SAS Institute, Inc., Cary, NC, U.S.A.). For differences between groups a two-tailed *P*-value of less than 0.05 was considered significant.

Results

PATIENTS

For all 24 participants, the study was carried out in accordance with the protocol.

Patient characteristics are summarized in Table 2. There were no statistically significant differences between the two groups in terms of age, sex, BMI, apnoea-hypopnoea index, nCPAP pressure and duration of nCPAP treatment prior to the study.

EFFICACY OF THE STUDY TREATMENT

The answers to the questions 1-3 are shown in Figs 1-3. Significantly more patients in the heated humidification

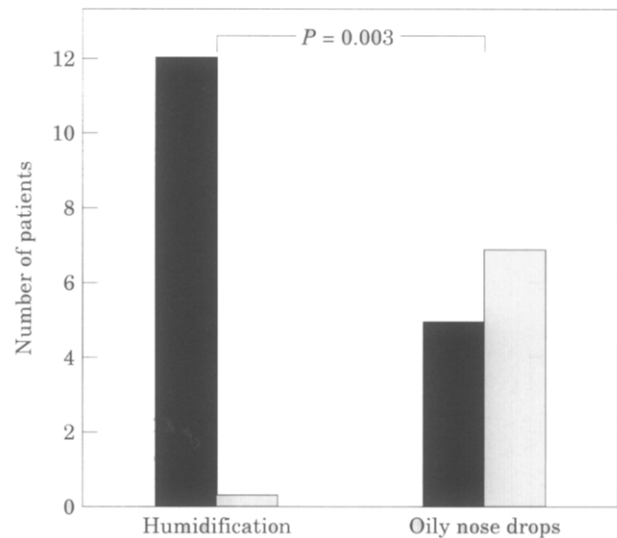


FIG. 1. Question 1: 'How would you evaluate the dryness of nose/mouth/throat during the past 14 days?'. End-of-study dryness in comparison with pre-study: ■, improved; □, no change/worse.

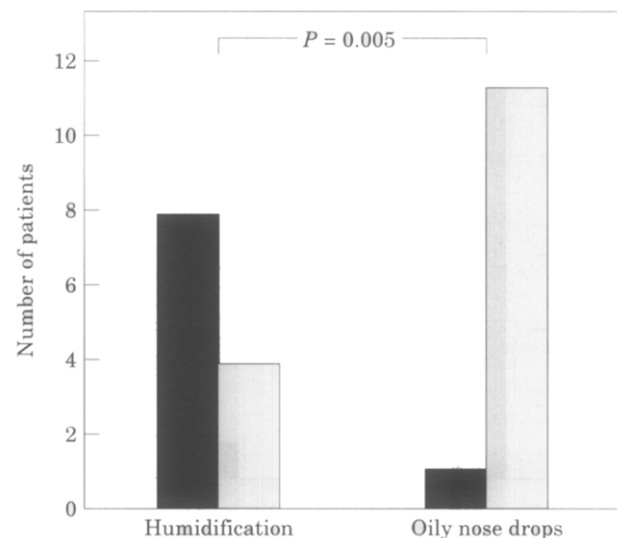


FIG. 2. Question 2: 'How often did you discontinue nCPAP during the past 14 days?'. Change in the number of nCPAP discontinuations during the study: ■, fewer; □, unchanged/more.

group reported a decrease in the severity of upper airway dryness (100 vs. 42%, $P=0.003$), in the number of nCPAP discontinuations (66 vs. 8%, $P=0.005$) and the number of days suffering from dryness (100% vs. 25%, $P<0.001$) than in the oily nose drops group.

The responses to questions 5 and 6 are shown in Figs 4 and 5. In comparison with the patients in the oily nose drops group, those in the heated humidification group indicated significantly better results in terms of upper airway dryness ($P<0.001$) and improvement in comfort when using nCPAP ($P<0.001$).

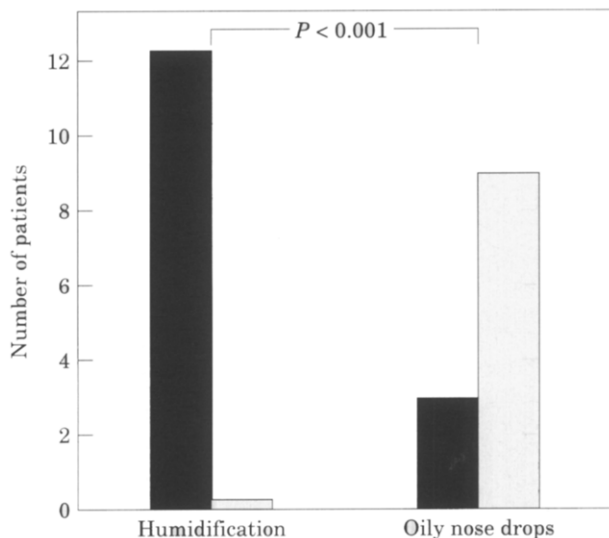


FIG. 3. Question 3: 'How often did you suffer from dry nose/mouth/throat during the past 14 days?'. Difference between pre- and post-study number of days suffering from upper airway dryness: ■, fewer; □, unchanged/more.

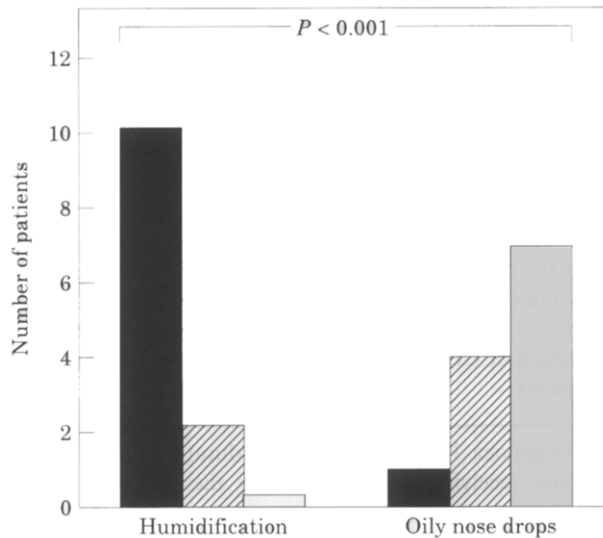


FIG. 5. Responses to question 6: 'Did you find nCPAP more acceptable for you using the study treatment?'. ■, Yes, considerably or yes, definitely; ▨, yes, somewhat; □, no.

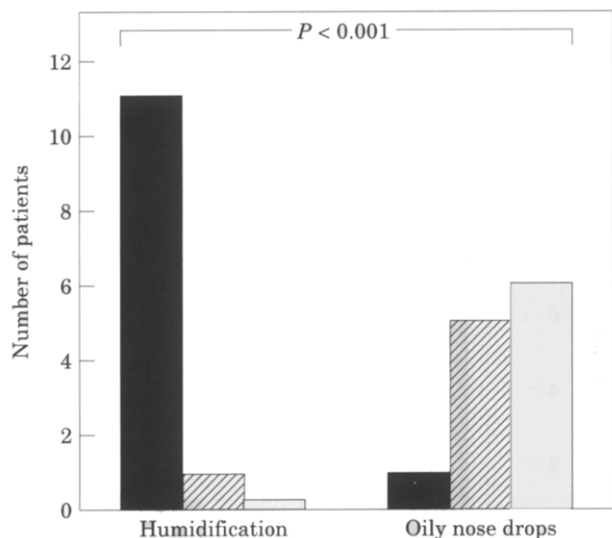


FIG. 4. Responses to question 5: 'How would you evaluate the effect of the study treatment on dryness?'. ■, Considerable improvement or complete elimination; ▨, some improvement; □, no improvement.

SIDE-EFFECTS

None of the patients in either group reported any severe side-effects of the study treatment, but there was a low rate of mild adverse reactions (oily nose drops group 8%; heated humidification group 33%). One patient in the oily nose drops group reported experiencing an unpleasant taste of oranges after using the nose drops. In the heated humidification group, four patients reported that condensed water collected inside the tube between the nCPAP device and the nasal mask, and one of these patients noted that his face under the mask was wet in the morning.

TERMINATION OF NCPAP THERAPY

Prior to the start of the study, four patients randomized to the heated humidification group (33%) and three patients randomized to the oily nose drops group (25%) indicated that they would terminate nCPAP therapy because of upper airway dryness. In the heated humidification group all four patients indicated that they would continue nCPAP with humidification after the study. In contrast, the treatment with oily nose drops had no influence on the decision by the three patients to terminate nCPAP use.

Discussion

In summary, heated humidification was highly superior to oily nose drops in terms of the reduction of the severity and frequency of upper airway dryness under nCPAP. All patients treated with heated humidification reported an improvement. These results are in accordance with the postulates of many authors (5,17). The reduction in the number of nCPAP discontinuations in the heated humidification group was higher than that in the oily nose drops group. This illustrates the fact that side-effects under nCPAP may result in noncompliance, whilst the elimination of side-effects may improve compliance with nCPAP therapy. Our investigation also showed that symptoms of upper airway dryness in particular may lead to definitive termination of nCPAP therapy. All patients intending to terminate nCPAP because of upper airway dryness continued to use it under heated humidification. In contrast, the use of oily nose drops had no such effect.

Heated humidifiers are superior to cold pass-over humidifiers since hot air can carry a higher maximum absolute humidity than cold air (13). The cheaper, cold pass-over humidifiers might nevertheless suffice for clinical

purposes. This point needs to be studied in further clinical trials. Currently, we regard heated humidification as standard therapy for upper airway dryness under nCPAP. The present study was therefore designed to establish the therapeutic efficacy of a heated humidifier.

For use in the present study we chose the most widely used heated humidification device in Germany, the HC 100[®] (Fischer & Paykel, Inc., Auckland, New Zealand). Since the degree of moisturization obtained with other devices may differ from that of the HC 100[®], the results of this study may not apply unreservedly to other such devices.

Oily nose drops are often used to treat symptoms of dryness in the nose, particular by specialists in otorhinolaryngology. A positive effect on the symptoms of nose dryness by oily nose drops has been described in patients with rhinitis sicca, ozena, drug-induced rhinopathy and during the postoperative period in patients undergoing surgery on the nose (18). This positive effect was explained by postulating the formation of a lipid layer on the nasal mucosa that protects it from drying out. No systemic effect of such nose drops has been described to date. This means that a positive effect on the symptoms of dryness in the nose, but not in the mouth or throat, may be expected with the nose drops used in our study. Negative effects of such drops, for example on the symptoms of upper airway dryness, have not so far been described and would seem extremely unlikely.

For the patients, of course, the alternatives, heated humidification or oily nose drops, are quite different. Thus a blind study design could not be employed.

Although we did not find any serious side-effects of heated humidification, the study does not rule out the possibility that significant side-effects may arise from the long-term use of heated humidification. One might expect, in particular, an increased incidence of infections of the airways, since the humidification chamber offers good conditions for colonization by micro-organisms. Bacterial and fungal colonization of similar devices, such as oxygen concentrators and inhalers, has repeatedly been demonstrated (19). This fact underlines the importance of proper and frequent cleaning of heated humidifiers. With regard to the HC 100[®] humidifier, a microbiological study done in 13 patients showed significant bacterial and fungal colonization of the humidification chamber and the mask (20) when boiled tap-water was used for humidification, as in our case. However, none of the 13 patients developed infection of the upper or lower respiratory system, which is in accordance with our own observation that no patient showed symptoms of upper or lower airway infection under heated humidification.

The only adverse reaction from heated humidification reported by our patients during the study period was condensation of water within the tube and mask, resulting from hot moist air cooling down within the tube. In our study the incidence of this adverse reaction was particularly high because no change in the hot-plate temperature was allowed. By decreasing the temperature of the hot plate, condensation could have been reduced or avoided.

Heated humidification has been shown to be an effective and safe treatment of the symptoms associated with nCPAP-related upper airway dryness in OSA patients, thus preventing termination of nCPAP therapy. Heated humidification is superior to oily nose drops. We suggest heated humidification as standard treatment of upper airway dryness due to nCPAP.

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