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Impact of a controlled heated breathing tube humidifier on sleep quality during CPAP therapy in a cool sleeping environment

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ABSTRACT: There are conflicting data on the effect of adding a heated humidifier to nasal continuous positive airway pressure (CPAP) therapy for patients with obstructive sleep apnoea syndrome (OSAS). The effects of heated humidification on sleep quality and treatment side-effects for patients who prefer a cold bedroom environment have not been studied.

A randomised, controlled crossover trial involving 19 patients with a first-ever diagnosis of OSAS measured the effect of conventional heated humidification added to CPAP compared with a controlled heated breathing tube humidifier (ThermoSmart®; Fisher and Paykel Healthcare, Auckland, New Zealand) on sleep quality.

During the night in the sleep laboratory at a mean room temperature of 14°C, less condensation formed with the controlled heated breathing tube humidifier (1.9 mL *versus* 35.3 mL) in the delivery system. In addition, the total sleep time, time spent in sleep stages 3 and 4, and rapid eye movement sleep phases were significantly longer and the overall side-effect score was lower than with conventional heated humidification.

Patients on nasal continuous positive airway pressure desiring a cool bedroom temperature could benefit from controlled heated breathing tube humidification technology (with inputs from ambient temperature, set pressure and flow).

KEYWORDS: Continuous positive airway pressure, heated humidification, obstructive sleep apnoea, side-effects

Continuous positive airway pressure (CPAP) is the preferred treatment for obstructive sleep apnoea syndrome (OSAS). However, >60% of patients complain of symptoms in the nose and pharynx [1–3]. One option for reducing such side-effects is the additional use of a heated humidifier, but few data are currently available on the effectiveness of this measure and the indications for its use have not been adequately defined [4–9]. In addition, the humidification systems presently available consist only of a heating plate and water chamber and a control setting, which changes the temperature of the heater plate to raise or lower the humidity output from the chamber. These conventional humidifiers are limited in the level of humidity that can be delivered to the patient, owing to the ambient room temperature. Cool room temperatures can affect the delivery of humidity to the patient by cooling the temperature of the air travelling within the delivery tube, thereby reducing the maximum level of moisture the air can hold. The result is an accumulation of water in the breathing tube, or condensation, and consequentially, a level of humidity delivered to the patient's mask that is lower than that desired. During the winter months, many patients who require a heated humidifier to counter nasal/oral or pharyngeal problems complain of condensation forming in the tube of the CPAP device: a problem that has so far not been systematically investigated. It is conceivable that the condensation reduces effective CPAP pressure due to the reduction of the CPAP delivery tube's effective lumen [10].

A new CPAP device (ThermoSmart®; Fisher and Paykel Healthcare, Auckland, New Zealand) incorporating new controlled heated breathing tube humidifier technology comprises an integrated humidifier consisting of a heater plate and water chamber in addition to a heated breathing

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tube. The internal algorithm of the humidifier takes into consideration a number of inputs, such as set pressure, ambient temperature and flow, and using these inputs adjusts the power to the heated breathing tube in order to maintain the individually adjustable heat and humidity all the way from the chamber output to the patient's mask.

The aim of the present study was to compare the effectiveness of CPAP with conventional heated humidification with that of a controlled heated breathing tube humidifier at a cool ambient temperature <20°C.

In addition to sleep quality, the incidence and amount of condensation forming in the system overnight were measured during polysomnography (PSG).

METHODS

During the winter season January–March 2005, all patients referred to the sleep laboratory (Klinik Ambrock, University of Witten-Herdecke, Hagen, Germany) with suspected OSAS were asked to fill in a questionnaire about their usual sleeping habits. Patients who preferred a bedroom temperature <20°C, or who habitually slept with a window open, were invited to participate in the study. The study was approved by the internal review board of the clinic. Patients were fully informed about the study aims and the need to give their written consent, and 19 patients (14 males and five females) with mean age 55±10.4 yrs and mean body mass index (BMI) 33±6.3 $kg \cdot m^{-2}$ agreed to be enrolled. All patients underwent PSG. Patients were investigated during the winter months and only on days with an outside temperature <15°C, so that unheated rooms had a temperature <18°C. One inclusion criterion was an apnoea/hypopnoea index (AHI) of >20 h^{-1}. Exclusion criteria were: more than five central apnoea episodes per hour of sleep; an acute infection; decompensated cardiac insufficiency (New York Heart Association level 3 or 4); acute pulmonary embolism; acute coronary syndrome; and severe malignant illness. Patients with signs of respiratory insufficiency were also excluded.

Study design

The degree of daytime sleepiness was established by means of the Epworth Sleepiness Scale (ESS) and a continuous attention test. All patients underwent a standardised CPAP training programme comprising group session instruction and practical CPAP training of ⩾4 h per day at a pressure of 5 cmH_2O (0.5 kPa). Nasal and full face masks from different manufacturers were fitted with extreme care. On the night following diagnostic PSG, CPAP titration was performed with CPAP pressure increased from 6 cmH_2O (0.6 kPa) to up to 12 cmH_2O (1.2 kPa) in increments of 1 cmH_2O (0.1 kPa). The lowest CPAP pressure at which AHI was <5 h^{-1}, snoring was eliminated and respiratory arousals were normalised was taken to be the effective therapy pressure. For flow chart study design see figure 1.

On the following two nights in the sleep laboratory, the patients underwent treatment with the SleepStyle™ 600 CPAP device with ThermoSmart® (HC 602, software version 1.04; Fisher and Paykel Healthcare) with the heated breathing tube on setting 7, heater plate on setting 3 (recommended default settings by manufacturer) in treatment arm 1, and the SleepStyle™ 600 CPAP device with ThermoSmart® Humidification switched off but with an external conventional humidifier attached to the CPAP (HC100; Fisher and Paykel Healthcare) with the heater plate on setting 3 (commonly recommended default setting by manufacturer) in treatment arm 2, both at their respective titrated pressure, in randomised order. Standard PSGs were performed on both nights. Each morning, following the PSG, the patients were asked to complete a subjective questionnaire to record their sleep experience and side-effects.

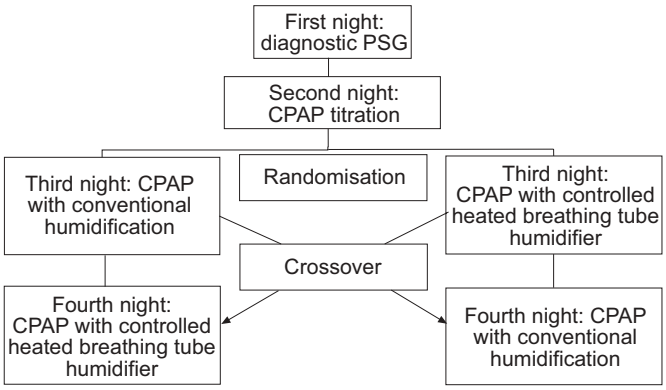

FIGURE 1. Flow chart study protocol. PSG: polysomnography; CPAP: continuous positive airway pressure.

The delivery tube system connecting the device to the patient was set up in a defined manner for each of the condensation measurements. Three tubing systems were prepared for each patient. If the patient was disturbed and woken up by water in the tubing system, the entire tubing system was replaced. Before the start of treatment, and in the morning after completion of the measurements, all breathing tubes were weighed and the differences in weight recorded. The water in the humidifier was also weighed immediately before treatment and again in the morning.

All measurements were made during the winter months January–April. The room in the sleep laboratory was not heated and ventilation was achieved by opening the window to simulate the home environment. For the measured data to be included in the study, the room temperature had to be <18°C. The room temperature was measured electronically and the signal fed into the PSG recordings.

Polysomnography

Respiratory effort was measured by recording the patients' abdominal and thoracic movements by means of induction plethysmography. In addition, snoring sounds were recorded by means of a laryngeal microphone (Alice®; Respironics, Murrysville, PA, USA) and oxygen saturation by means of a pulse oximeter (Nonin, Plymouth, MN, USA). In diagnostic PSG, respiratory flow was measured by nasal prongs and a flow pressure monitor (Heinen und Lowenstein, Bad Ems, Germany). During CPAP therapy, a pressure signal from the mask was recorded and fed into the PSG. The following additional parameters were recorded: electroencephalogram C4A1 or C3A2; submental and pretibial electromyogram; and electrocardiogram. The PSG recordings were evaluated by an experienced physician. The sleep stages and arousals were

categorised in accordance with the criteria of RECHTSCHAFFEN and KALES [11] and the recommendations of the American Sleep Disorders Association [12]. Arousals were classified as respiratory if they occurred at the beginning of, or within 2 s of, an apnoea or hypopnoea. If the flow signal was reduced by >50% *vis-à-vis* the initial signal, for >10 s, the episode was classified as hypopnoea; if the amplitude of the flow signal was <20% of the initial value, the episode was classified as apnoea. PSG was carried out using the Alice® system (Respironics).

Questionnaire

The patients' subjective experiences and side-effects with each humidification treatment arm were recorded in the morning after the treatment nights using a questionnaire. The questionnaire was developed internally and has been used in a previous study [13]. The questionnaire consisted of 13 items, each scored on a five-point Likert scale ranging from 0 (very good) to 5 (very poor).

Sleepiness

The subjective sleepiness was evaluated using the ESS.

Statistics

The Wilcoxon test was used to identify possible significant differences between PSG results of the different study groups, condensation levels (data from the sleep laboratory), subjective side-effects (results of the questionnaire after the first and second night and after the home treatment phase), and compliance data (home treatment).

Power analysis

Based on previous experience of patients and examination results, a reduction of sleep quality was expected when condensation formed in the tube. As a consequence, the parameter wake time after sleep onset (WASO) was chosen as the primary parameter indicative of sleep quality. A difference of 20 min of WASO was decided to be clinically relevant. Based on the results of the previous examination, an SD of 20 min was expected. This is why in a one-sided test the study group comprises 17 patients. A p-value <0.05 was regarded as significant.

Randomisation

The study was randomised *via* blinded envelope prior to the beginning of the study.

RESULTS

After undergoing physical examination and diagnostic PSG, and having their medical history recorded, 19 patients gave their written consent to participate in the study. Their mean$\pm$SD age was 55 ± 10.4 yrs, BMI 33 ± 6.3 kg·m^{-2}, AHI 53 ± 27.6, minimal oxygen saturation 76 ± 12.4% and ESS 11 ± 5.0. According to the randomisation list, 10 patients were treated with the conventional humidification first; the other nine were treated with the controlled heated breathing tube humidifier.

Room temperature

The mean nocturnal room temperature, monitored electronically, was 14.2 ± 1.8°C when the conventional humidification was used and 13.8 ± 1.8°C on the nights when the controlled heated breathing tube humidification technology was applied. The difference was not significant. The individual data of room temperature in each night are shown in table 1.

The ambient relative humidity was not measured. However, air conditioning and central heating were switched off. Temperature and ambient relative humidity were adjusted by means of natural ventilation.

Delivery system

An average of 2.4 ± 0.8 mask/tube systems were used during treatment with conventional humidification, while treatment with controlled heated breathing tube humidification technology required only 1.1 ± 0.2 mask/tube systems. The difference was statistically significant ($p=0.0003$).

Condensation

Measurement of the weight of the delivery systems prior to, and on the morning after, therapy, reflecting the amount of condensation formed in the tubing, revealed an average volume for all 19 patients of 35.3 ± 16.0 mL under treatment with conventional humidification, and 1.9 ± 1.3 mL with controlled heated breathing tube humidification technology. The difference between the two therapy modes was significant ($p=0.001$). The individual measurements of condensation in the tubing, as well as the difference between the humidifier's quantity of water for the evening and following morning, can be seen in table 1.

CPAP pressure

The arithmetic mean of the pressure measured at the mask with heated humidification was 0.3 ± 0.1 cmH_2O (0.03 ± 0.01 kPa) lower than the set CPAP pressure. The mean with the heated humidification controlled by the heated breathing was 0.3 cmH_2O (0.03 kPa) lower at the mask than the set CPAP pressure. The difference between both forms of therapy was not significant.

The PSG data, diagnostic and under respiratory humidification treatment, with conventional humidification and controlled heated breathing tube humidification technology are presented in table 2 and figure 2.

Heated conventional humidification was associated with significantly shorter total sleep time (TST) and significantly reduced sleep efficiency, and a significantly higher proportion of light sleep (sleep stage 1); in addition, the proportions of slow-wave and rapid eye movement (REM) sleep were also significantly lower *vis-à-vis* controlled heated breathing tube humidification technology.

Side-effects

The questionnaire data on the patients' side-effects in the first two therapy nights are shown in table 3.

Sleepiness

After 3 weeks of treatment, the median ESS was reduced from 10.8 to 6.4 ± 2.9 in the conventional humidification group and 6.2 ± 3.2 in the controlled heated breathing tube humidification technology group (difference not significant).

TABLE 1 Condensate in the breathing system, mean room temperature and absolute humidification

Patient	Pressure cmH_2O	Mean room temperature °C		Water in mask/tube mL		Absolute humidification# mL	
		Conventional humidifier	Controlled heated breathing tube humidifier	Conventional humidifier	Controlled heated breathing tube humidifier	Conventional humidifier	Controlled heated breathing tube humidifier
1	7	17.3	11.9	34	0	145	229
2	8	15.6	14.0	34	2	131	136
3	8	14.6	11.6	16	0	130	143
4	12	13.6	14.0	63	2	222	158
5	9	10.8	13.6	29	2	143	92
6	7	15.3	13.6	54	1	76	119
7	7	12.6	12.9	36	5	114	154
8	10	16.2	16.6	26	2	151	149
9	10	14.6	16.0	40	2	145	229
10	7	11.7	11.1	69	2	103	138
11	8	11.0	10.9	27	0	120	137
12	7	15.4	12.2	13	2	178	170
13	7	13.2	14.7	49	2	123	134
14	7	14.1	14.2	22	3	153	85
15	7	13.0	12.0	37	4	113	140
16	7	16.3	15.5	35	1	142	116
17	9	15.1	15.0	7	2	159	203
18	9	13.7	16.1	33	3	125	200
19	7	15.3	15.7	46	2	116	158
Mean±SD	8.1±1.4	14.2±1.8	13.8±1.8	35.3±16.0	1.9±1.3	136.3±30.9	152.1±40.0
p-value		0.52		0.0001		0.12	

#: difference of water in the heating chamber between evening and morning minus water in the mask/tube system. 1 cmH_2O=0.0978 kPa.

DISCUSSION

The results of the present study show that, in a cool ambient temperature, conventional heated humidification is associated with a considerable amount of condensation in the CPAP mask and tubing system. This can be reliably avoided through the use of an auto-adjusted humidifier with a heated breathing tube. The difference between the two humidification modes with regard to sleep quality and subjective experience was significant. Controlled heated breathing tube humidification technology (ThermoSmart®) with a heated breathing tube significantly reduced light sleep (stage 1 sleep) and WASO. Conversely, the time spent in deep sleep (sleep stages 3 and 4),

TABLE 2 Polysomnography data for the 19 study patients

	Diagnostic night	CPAP with conventional humidification	CPAP with tube heating humidification	Comparison of both treatments
Sleep efficiency %	89±7	80±9	85±7	0.0269
WASO % SPT	7±5	13±10	7±6	0.0079
S1 %	17±7	19±10	14±8	0.0050
S2 %	56±9	53±10	51±9	NS
S3/4 %	14±11	11±9	13±11	NS
REM %	12±7	17±6	21±6	0.0141
Arousal index events·h^{-1} TST	32±21	15±8	13±9	NS
Central apnoea n	6±14	4±8	4±7	NS
Obstructive apnoea n	132±125	0±0	2±5	NS
Mixed apnoea n	24±61	0±1	3±10	NS
Hypopnoea n	162±94	31±19	39±34	NS
Total AHI events·h^{-1}	53±28	6±3	8±8	NS
Minimal Sa,O_2 %	76±12	90±3	89±3	NS

Data are presented as mean±SD, unless otherwise stated. CPAP: continuous positive airway pressure; WASO: wake time after sleep onset; SPT: sleep period time; S1–S4: sleep stages 1–4; REM: rapid eye movement; TST: total sleep time; AHI: apnoea/hypopnoea index; Sa,O_2: arterial oxygen saturation; NS: nonsignificant.

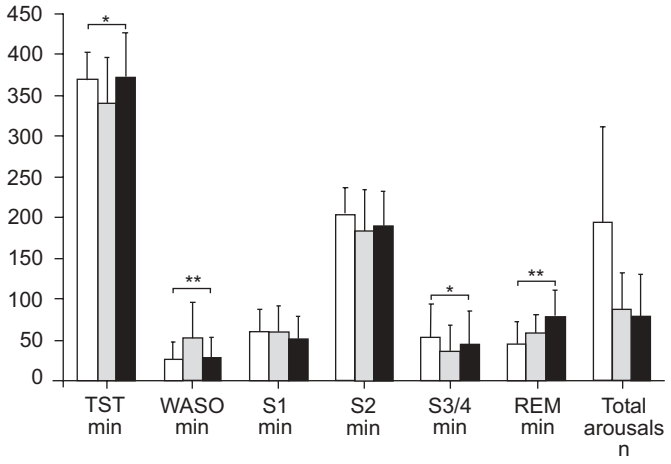

FIGURE 2. Comparison of the data of the diagnostic polysomnography with continuous positive airway pressure (CPAP) and conventional *versus* tube heating humidification. □: diagnostic night; ▒: CPAP with conventional humidification; ■: CPAP with tube heating humidification. TST: total sleep time; WASO: wake time after sleep onset; S1–S4: sleep stages 1–4; REM: rapid eye movement. *: $p<0.05$; **: $p<0.01$.

REM sleep and TST were significantly increased with controlled heated breathing tube humidification technology. Subjective disturbances with controlled heated breathing tube humidification technology were less frequent.

CPAP therapy is the preferred treatment for OSAS. However, it unfortunately often leads to bothersome symptoms in the nose and throat [1–3]. Experimental data [4, 5] have shown that if a mouth leak develops under nasal CPAP treatment, high unidirectional flow occurs in the nose, increasing both the blood supply to the nasal mucosa and nasal airway resistance. This can be avoided with heated humidification. Comparative studies have demonstrated that higher relative and absolute humidity levels are seen at the nose with heated *versus* cold humidification, such that any increase in nasal resistance will be less [6, 7]. Available data on the practical application of heated humidification differ. A prospective randomised study by MASSIE *et al*. [8] involving only patients receiving CPAP therapy for the first time showed an improvement in CPAP compliance under heated humidification, which proved to be superior to cold humidification. Another study found that heated humidification improved compliance in patients who had bothersome nasopharyngeal symptoms under CPAP [9].

In contrast, other studies have shown that neither the all-important initial acceptance of CPAP therapy nor the subjective side-effects experienced in the first treatment night were improved by heated humidification [14–17]. Many questions about humidification treatment thus remain unanswered, *e.g.* the level of absolute humidity required for optimal treatment results is not clear, nor is the identification of patients who need humidifier-assisted treatment nor heated breathing tube humidification.

To the current authors' knowledge, no studies have thus far been carried out to investigate the impact of heated humidification on sleep quality in a cool ambient environment. Under simulated conditions, BACON *et al.* [10] were able to show that condensation in the delivery tube caused the effective CPAP pressure in the mask to vary from 5.6 cmH_2O (0.55 kPa) below the set pressure during the inspiration phase to 3.5 cmH_2O

TABLE 3 Questionnaire: comparison of complaints after the first treatment night for the 19 study patients

Questions	CPAP with conventional humidification	CPAP with tube heating humidification	Comparison of both treatments
How did you sleep last night?	2.5±1.4	1.5±1.0	0.0288
How sleepy do you feel today?	1.5±1.1	1.7±1.2	NS
How would you rate your physical performance today?	1.6±0.8	1.5±0.8	NS
How would you rate your ability to concentrate?	1.7±0.9	1.4±0.7	NS
How would you rate your mood today?	1.4±0.6	1.3±0.7	NS
How would you rate the temperature of the air?	2.0±1.6	1.4±1.5	NS
How would you rate the humidity of the air?	1.9±1.7	1.3±1.6	NS
Were you bothered by pressure changes?	3.4±1.4	0.3±0.5	0.0001
Were you bothered by cold sensation on the face?	1.5±1.8	0.7±0.8	0.0414
Did you experience dryness of mouth as a side-effect?	0.8±1.1	0.8±1.4	NS
Did you experience eye watering as a side-effect?	0.7±1.0	0.5±0.8	NS
Did you experience sensation of cold on the face as a side-effect?	1.0±1.1	0.7±1.1	NS
Did you experience sensation of pressure in the chest as a side-effect?	0.6±0.8	0.5±0.8	NS
Total score	20.7±6.9	13.5±7.5	0.0069

Data are presented as mean±SD, unless otherwise stated. For all data n=19. CPAP: continuous positive airway pressure; NS: nonsignificant.

(0.34 kPa) above it during the expiration phase. The current authors found no pressure differences between the mask and the CPAP device. If a patient in the present study was disturbed and woken up by the noise associated with condensation, the mask/tube system was replaced so that no pressure reduction could occur. Therefore, it is possible that if the CPAP set-up was left untouched despite a build-up of condensation, transient variations in mask pressure may have been present and observable on the PSG system. However, it must be mentioned that the design of the study might have had an impact on the varying results regarding sleep stages and sleep quality, as the change of tubing and mask could have caused a prolonged wake time. However, the change was only made when the patient woke due to water in the tubing. New masks and tubing were ready, so emptying the system would have taken more time than a complete change. Given that both set-ups consisted of a heater plate and water chamber with the only differing component in the treatment arms being the heated breathing tube and algorithm (with inputs from ambient temperature, flow and set pressure), it appears likely that the addition of the heated breathing tube and algorithm allows the prevention of condensation.

Currently, the optimal level of humidification needed to reduce the side-effects of CPAP at the mucosa of the upper airways is still not known. For technical reasons, it was not possible to measure the level of humidity in the patients' upper airways. The fact that room temperature was not different in both groups and that a randomised crossover was given from night to night implies that room humidity and other ambient conditions were not different in either group.

It is essential to note that these results apply only under the conditions as stated. All patients preferred a cool bedroom. These ambient conditions were controlled during measurements in the sleep laboratory. For this reason, the results are only valid for these conditions and results cannot be generalised to all ambient temperature conditions. All patients underwent CPAP treatment for the first time, and nasopharyngeal symptoms were not a criterion for inclusion in the study. The humidifier setting was kept constant during the night in the sleep lab, which is not representative of the home setting, where patients might adjust their settings to prevent further condensation once experiencing a build-up of condensation for the first time. Consequentially, when doing so, a patient is sacrificing humidity output and the results of the present study are unable to provide any information on what effect this might have on comfort. Further CPAP investigations should examine the question of whether compliance would improve in all patients undergoing such humidifier treatment or only in patients with severe nasopharyngeal symptoms.

At the present time, there is no difference in cost between the controlled heated breathing tube humidifier investigated in the present study and a conventional CPAP device on the German market. The current authors consider the additional energy costs of heating the tube to be negligible. This means that economic considerations do not have to be taken into account in the selection of a CPAP device and form of humidification; medical arguments are the only factors to be taken into consideration.

In conclusion, the present authors suggest that patients requiring heated humidification and desiring a cool bedroom temperature might benefit from usage of the controlled heated breathing tube humidification technology.

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