

Original Article

Impact of heated humidification with automatic positive airway pressure in obstructive sleep apnea therapy*

Impacto da umidificação aquecida com pressão positiva automática em vias aéreas na terapia do síndrome de apneia obstrutiva do sono

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Abstract

Objective: To study the impact that heated humidification instituted in the beginning of automatic positive airway pressure (APAP) therapy has on compliance with and the side effects of the treatment. **Methods:** Thirty-nine treatment-naïve patients with obstructive sleep apnea were randomized into two groups to receive APAP using one of two modalities: with heated humidification (APAPwith group); and without heated humidification (APAPw/o group). Patients were evaluated at 7 and 30 days after APAP initiation. The following parameters were analyzed: compliance with treatment (mean number of hours/night); side effects (dry nose or mouth, nasal obstruction and rhinorrhea); daytime sleepiness (Epworth sleepiness scale score) and subjective comfort (visual analog scale score). Patients were also evaluated in terms of residual apnea-hypopnea index (AHI), as well as mean pressures and leaks registered in the ventilators. **Results:** There were no differences between the two groups in terms of mean age (APAPwith: 57.4 ± 9.2 ; APAPw/o: 56.5 ± 10.7 years), AHI (APAPwith: 28.1 ± 14.0 ; APAPw/o: 28.8 ± 20.5 events/hour of sleep), baseline Epworth score (APAPwith: 11.2 ± 5.8 ; APAPw/o: 11.9 ± 6.3) and initial nasal symptoms. Compliance was similar in both groups (APAPwith: 5.3 ± 2.4 ; APAPw/o: 5.2 ± 2.3 h/night). There were no differences in any of the other parameters analyzed. **Conclusions:** The introduction of heated humidification at the beginning of APAP therapy provided no advantage in terms of treatment compliance or side effects of treatment.

Keywords: Humidity; Positive-pressure respiration/adverse effects; Patient compliance.

Resumo

Objetivo: Avaliar o impacto da umidificação aquecida introduzida no início da terapia com pressão positiva automática em vias aéreas (APAP, do inglês *automatic positive airway pressure*) na adesão e efeitos secundários. **Métodos:** Foram randomizados 39 doentes com síndrome de apneia obstrutiva do sono sem terapia prévia em dois grupos de tratamento com APAP: com umidificação aquecida (grupo APAPcom); e sem umidificação (grupo APAPsem). Os doentes foram avaliados 7 e 30 dias após a colocação de APAP. Os parâmetros analisados foram a adesão ao tratamento (número médio de horas/noite), efeitos secundários (secura nasal ou da boca, obstrução nasal e rinite), sonolência diurna (escala de sonolência de Epworth) e o conforto subjectivo (escala visual analógica). Foram ainda avaliados o índice de apneia-hipopneia (IAH) residual, pressões e fugas médias registados nos ventiladores. **Resultados:** Os dois grupos de doentes estudados eram semelhantes no que respeita à média etária (APAPcom: $57,4 \pm 9,2$; APAPsem: $56,5 \pm 10,7$ anos), IAH (APAPcom: $28,1 \pm 14,0$; APAPsem: $28,8 \pm 20,5$ eventos/hora de sono), Epworth basal (APAPcom: $11,2 \pm 5,8$; APAPsem: $11,9 \pm 6,3$) e sintomas nasais iniciais. A adesão foi semelhante nos dois grupos (APAPcom: $5,3 \pm 2,4$; APAPsem: $5,2 \pm 2,3$ horas/noite). Não se verificaram diferenças nos outros parâmetros avaliados. **Conclusões:** A introdução inicial da umidificação aquecida na terapia com APAP não demonstrou vantagem no que diz respeito à adesão e efeitos secundários.

Descritores: Umidificação; Respiração com pressão positiva/efeitos adversos; Cooperação do paciente.

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Introduction

The treatment of choice for severe and mild to moderate obstructive sleep apnea syndrome (OSAS) in symptomatic patients or patients with associated heart or cerebrovascular diseases is nasal continuous positive airway pressure (CPAP).^(1,2) However, despite its efficacy, treatment compliance is limited, ranging from 46 to 85%, due principally to the side effects associated with the use of nasal CPAP and to the lack of perception of its benefit.⁽³⁻⁵⁾

Humidification, especially heated humidification, has been used to relieve secondary nasal symptoms, thereby improving comfort with the ventilator and increasing compliance.^(3,4,6-10) However, the effect of humidification on compliance with nasal CPAP therapy has yet to be clarified, and the results of the studies conducted to evaluate its effect present no consensus.^(3,4,6,7,9,11,12) Among such studies, three have aimed at evaluating the effect that humidification applied at the onset of therapy with nasal CPAP has on compliance and on side effects, but none recommends its initial use as a routine.^(4,11,12)

As to the choice of the CPAP modality in the OSAS treatment, CPAP versus automatic positive airway pressure (APAP), most studies have found no differences between the two modalities in terms of efficacy, compliance or side effects, even though some studies report higher tolerance and preference for the use of APAP, possibly related to the lower mean pressure observed with this modality.⁽¹³⁻¹⁸⁾

Since the pattern of compliance with CPAP tends to be established early,⁽¹⁹⁾ and confronted with the lack of a consensus, we proposed to study the benefit of the initial use of humidification in nasal APAP therapy, determining its impact on compliance, comfort and side effects.

Methods

A prospective randomized study was carried out, involving 50 patients with OSAS in whom CPAP therapy was indicated.^(1,2) Patients were sequentially selected during visits for the treatment of sleep disorders, after polysomnography with electroencephalography or cardiorespiratory monitoring. Patients with a history of uvulopalatopharyngoplasty, medical therapy for rhinitis, long term oxygen therapy or previous therapy with CPAP were excluded, as were those who declined to participate in the protocol.

Patients were randomized, over an eight-week period, into two groups: nasal APAP with heated humidification (APAPwith group) and nasal APAP without humidification (APAPw/o group).

Oral informed consent was obtained from all participating patients.

We used AutoSet Spirit® ventilators (ResMed Corp., Poway, CA, USA) and Remstar® Auto nasal masks (Respironics, Cedar Grove, NJ, USA). The parameters for the initial pressure were, for all patients, a maximum of 16 cmH₂O and a minimum of 4 cmH₂O.

The patients were evaluated on the day of APAP introduction and, subsequently, in two follow-up appointments.

On the day of APAP introduction, age, gender, baseline apnea-hypopnea index (AHI) and daytime sleepiness (calculated using the Epworth sleepiness scale)⁽²⁰⁾ were recorded. In addition, nasal obstruction was evaluated using a questionnaire that included a visual analogue scale (VAS) and an objective evaluation. All patients were submitted to an OSAS education program and were instructed on how to maintenance the APAP equipment, the mask and the humidifier. The adaptation to the mask and to the ventilator was performed by a technician specializing in cardiology and pulmonology.

In the two subsequent evaluations, at 7 and 30 days after the installment of the APAP equipment, the following parameters were evaluated: compliance; residual AHI; mean leakage and pressure; and daytime sleepiness. Side effects were determined using a questionnaire that addressed complaints of rhinorrhea, nasal obstruction, dry nose/mouth, epistaxis, eye irritation, earache, marks on the face, noise and abdominal distension. Nasal obstruction was reevaluated. The VAS was also used, with a score of 0 to 5, for subjective evaluation of comfort with the APAP equipment.

In these follow-up appointments, the patients' questions were clarified and side effects were treated. In both groups, nasal corticosteroid therapy (fluticasone propionate) was introduced in patients with nasal obstruction complaints. Marks on the face, skin irritation and mask leakage were treated with mask adjustments, change of mask and dermatological treatment (moisturizer or topical corticosteroid in case of exacerbation of seborrheic dermatitis). Leakage through the mouth was corrected with the introduction of a chin support. Complaints of

Table 1 – Characteristics of the patients.*

Characteristic	APAPwith (n = 17)	APAPw/o (n = 22)
Age (years), mean \pm SD	57.4 \pm 9.2	56.5 \pm 10.7
AHI (events/h), mean \pm SD	28.1 \pm 14.0	28.8 \pm 20.5
Epworth, mean \pm SD	11.2 \pm 5.8	11.9 \pm 6.3
Gender (female/male)	4/13	6/16
Previous nasal obstruction, n	5	6

APAPwith: automatic positive airway pressure with heated humidification; APAPw/o: APAP without humidification; AHI: apnea hypopnea index; and Epworth: score on the Epworth sleepiness scale. *p non-significant in comparisons between groups.

excessive pressure, earache or abdominal distention were met with the introduction of a ramping up of the APAP or a decrease in its maximum pressure.

Patients were allowed to contact the distributor, technician or physician if any problem occurred during the study.

Statistical analysis was performed using the Statistical Package for the Social Sciences, version 11.5 (SPSS Inc, Chicago, IL, USA). The Student's t-test (or its nonparametric equivalent, the Mann-Whitney test, and the chi-square test were used in order to compare differences among the groups for continuous and categorical variables, respectively. Values of $p < 0.05$ were considered significant.

Results

Of the total of the patients, 39 completed the study, 17 in the APAPwith group and 22 in the APAPw/o group. Eleven patients were lost of follow-up.

We observed that the studied population was homogeneous, and no differences ($p > 0.05$) regarding age, gender, AHI and Epworth score were found between the groups at baseline. Nor were there any differences in nasal symptoms prior to therapy (Table 1).

As to the study variables, we found no differences between the two groups. In both evaluations, compliance was similar (APAPwith: 5.3 ± 2.4 ; APAPw/o: 5.2 ± 2.3 h/night), as well as the Epworth scale, residual AHI, leakage, mean pressures and patient comfort (Table 2).

In relation to the questionnaire for side effects and nasal obstructions, there were also no significant differences between the two groups (Table 3).

Of the procedures most frequently performed during the scheduled appointments, the following are of note: pressure reduction (9 patients), use of chin support (7 patients), substitution of the initial mask for a gel mask (7 patients) and treatment with nasal corticosteroids (6 patients). In addition, there were no differences in procedures performed in the two groups were observed as well.

Regarding the previous existence of nasal obstruction, according to Table 1, both groups were identical (29% in the APAPwith group and 27% in the APAPw/o group).

In the APAPwith group (with humidification), the previous presence of this symptom did not condition compliance, comfort or the appearance of side effects. In contrast, when only patients with previous nasal obstruction were analyzed, no differences were observed between the group with humidification and the control group, concerning compliance (Table 2) or the other variables.

Table 2 – Parameters evaluated in the follow-up appointments.

Parameter	Follow-up on day 7*		Follow-up on day 30*	
	APAPwith	APAPw/o	APAPwith	APAPw/o
Compliance (h/night), mean \pm SD	4.9 \pm 2.6	5.2 \pm 2.3	5.3 \pm 2.4	5.2 \pm 2.3
Compliance in patients with previous nasal obstruction, mean \pm SD	5.2 \pm 3.1	4.3 \pm 2.1	5.4 \pm 3.2	4.7 \pm 2.6
>4 h use/night, n (%)	12 (70.6)	16 (72.7)	13 (76.5)	16 (72.7)
Leakage (L/s), mean \pm SD	0.2 \pm 0.2	0.2 \pm 0.2	0.2 \pm 0.3	0.37 \pm 0.2
Pressure (cmH ₂ O), mean \pm SD	10.8 \pm 1.4	10.4 \pm 1.3	11.1 \pm 1.9	10.2 \pm 1.4
Residual AHI (events/hour of sleep), mean \pm SD	6.3 \pm 5.8	5.8 \pm 4.3	4.6 \pm 5.2	4.7 \pm 3.4
Residual Epworth, mean \pm SD	7.5 \pm 5.7	7.2 \pm 6.0	6.9 \pm 5.4	6.7 \pm 5.3
Subjective comfort (VAS), mean \pm SD	2.3 \pm 1.0	2.2 \pm 1.1	2.1 \pm 1.0	1.9 \pm 1.2

APAPwith: automatic positive airway pressure with heated humidification; APAPw/o: APAP without humidification; AHI: apnea hypopnea index; and VAS: visual analog scale. *p non-significant in comparisons between groups

Table 3 - Side effects of the automatic positive airway pressure therapy, 7 and 30 days following therapy onset.

Side effects	Follow-up on day 7*		Follow-up on day 30*	
	APAPwith	APAPw/o	APAPwith	APAPw/o
Rhinorrhea, n	3	3	1	4
Nasal Obstruction, n	5	6	3	9
Dry nose, n	2	3	1	4
Dry mouth, n	8	8	6	12
Epistaxis, n	0	0	0	2
Eye irritation, n	2	4	2	3
Earache, n	0	0	1	0
Marks on the face, n	6	11	4	2
Noise, n	1	4	2	2
Abdominal distension, n	0	1	0	3

APAPwith: automatic positive airway pressure with heated humidification; and APAPw/o: APAP without humidification. *p non-significant in comparisons between groups.

Discussion

In our study, the introduction of humidification at the onset of APAP therapy did not improve compliance, complaints or the degree of comfort associated with nasal APAP therapy. Therefore, we can conclude that there is no advantage in the initial introduction of humidification in nasal APAP therapy, as reported in previous studies conducted with CPAP.^(4,11,12) To our knowledge, this is the only study in which this comparison has been made using APAP rather than CPAP.

However, we can identify some limitations of our study. It is unknown to what extent the patients used the humidifier, since there is no objective record of its use, only patient reports. However, this criticism applies not only to our study, but to all studies of humidification. It would also have been ideal if only one type of APAP device had been used, and not two, as in our case; However, this choice resulted from the effective availability of APAP devices at our hospital. Although this was a randomized study, it was not a blind study, since it would have been difficult to hide the humidification from the responsible physicians and technicians, as well as from the patients themselves.

In relation to the other factors that might interfere with APAP compliance,⁽²¹⁾ namely OSAS severity, the types of interfaces chosen and education could hardly have interfered with the results of our study, since our population was homogeneous, the mean baseline AHI being similar in both groups, and the same type of interfaces, follow-up and support

was provided, subsequently adjusted to individual needs.

As to the nasal complaints, there were no significant differences between the two groups, although the group receiving humidification seemed to present a tendency toward a decrease (Table 3). This negative finding might have resulted from a type II error, that is, from the small sample size. This tendency, also observed in previous studies,^(3,4,12) together with small sample size, call for further studies involving larger patient samples. These larger samples would also take into account the exact proportion of each nasal complaint in the population with OSAS. For the treatment of these complaints, we always took pharmacological measures in both groups in our study, not using humidification in the control group.

A history of nasal obstruction also had no influence on compliance, side effects or comfort in the group with humidification. In turn, since no differences related to these evaluations have been found among patients with previous nasal obstruction in either group, we concluded that the initial introduction of humidification in patients with previous nasal obstruction is unjustified.

Our study is also the first to evaluate the comfort of the treatment, and no differences were found between the two groups. There has been only one study evaluating quality of life during treatment.⁽⁴⁾ In that study, no differences were found between the patients receiving humidification and those not receiving humidification in terms of quality of life.

In conclusion, the initial introduction of heated humidification in APAP therapy provided no benefit concerning compliance or side effects. Therefore, heated humidification should be reserved for symptomatic treatment of nasal complaints. Patient education and support remain the only initial interventions that increase compliance.

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