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Comfort and pressure profiles of two auto-adjustable positive airway pressure devices: a technical report

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Summary *Study objectives:* The purpose of this study was to compare comfort parameters and pressure profiles of the AutoSet™ (Resmed) and the SOMNOsmart™ (Weinmann), two auto-adjustable positive airway pressure (APAP) devices. *Setting:* The sleep disorders center of a university hospital. *Design:* A single-blind randomized trial protocol was applied. A split night procedure allowed each patient to be treated in a crossover fashion with both APAP devices during one overnight study. *Patients and methods:* Fifty consecutive obstructive sleep apnea (OSA) patients were recruited. Each patient filled out an evaluation form for both devices after the study night. Visual analogue scales were used to score four comfort measures. Three CPAP outcomes generated by the devices (P_{50}, P_{95} and P_{max}) were assessed, compared with each other and correlated with the individually predicted CPAP (P_{pred}). *Results:* Forty-five males and 5 females, mean age 53.0 years, body mass index 31.0, were included. The mean apnea-hypopnea index was 58.7, the mean arousal index was 54.3. Mean CPAP-compliance before the titration study was 4.9 h per night. Comparison of the two devices regarding the effect on the subjective sleep quality parameters showed no differences. The AutoSet™ pressure outcomes correlated significantly better with P_{pred} in comparison with the SOMNOsmart™. The P_{50} and P_{95} but not the P_{max} values were significantly lower in the SOMNOsmart™ as compared with the AutoSet™ (P_{50}: 5.1 ± 1.3 vs 7.1 ± 1.9 mbar, $P < 0.0001$; P_{95}: 7.8 ± 3.0 vs 9.6 ± 1.9 mbar, $P < 0.0005$; P_{max}: 10.0 ± 3.4 vs 10.8 ± 1.8 mbar, NS). *Conclusion:* While the subjective tolerance of the two APAP machines was comparable, these devices were characterized by different pressure profiles. The pressure parameters of the AutoSet™ correlated better with P_{pred} than those of the SOMNOsmart™.

Abbreviations: AHI, apnea-hypopnea index; APAP, auto-adjustable positive airway pressure; BMI, body mass index; COPD, chronic obstructive pulmonary disease; CPAP, continuous positive airway pressure; FEV_1, forced expiratory volume in one second; FVC, forced vital capacity; FL, flow limitation; FOT, forced oscillation technique; mbar, cm H_2O; NC, neck circumference; OSA, obstructive sleep apnea; P_{50}, median positive airway pressure; P_{95}, 95th percentile of positive airway pressure; P_{max}, maximum positive airway pressure; P_{pred}, predicted CPAP; SD, standard deviation; UPPP, uvulopalatopharyngoplasty

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Introduction

Ever since the landmark publication by Sullivan et al. two decades ago,[1] nasal continuous positive airway pressure (CPAP) has been the mainstay for treatment of patients suffering from moderate to severe obstructive sleep apnea (OSA). In recent years, several new devices have been developed that are designed to deliver auto-adjustable positive airway pressure (APAP) meeting the patient's

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instant pressure needs.[2] These devices have the theoretical advantage of stabilizing the upper airway during changing physiological conditions, which require different CPAP levels.[3]

Although different algorithms for driving APAP are used by different manufacturers, APAP devices in general have been shown to be useful in the assessment of CPAP requirements both in the sleep laboratory and at home.[4] We elected to study two devices whose operation is based on pro-active pressure augmentation following the detection of incipient upper airway obstruction. The operational characteristics of the AutoSet™ (ResMed, Sydney, Australia) feature detection of flow limitation (FL) of inspired air and subsequent pressure adaptation.[5] The SOMNOsmart™ (Weinmann, Hamburg, Germany) measures upper airway impedance using the forced oscillation technique (FOT). Pressure adjustments are based on changes in the impedance values.[6]

The aim of this study was to compare both devices in terms of subjective tolerance and pressure parameters. From a theoretical point of view, one should obtain comparable figures regarding tolerance and pressure output, if both devices prove to perform equally well. In addition, one would expect to find a correlation between the pressure generated by these devices and individually predicted pressure (P_{pred}), which has been shown to be significantly related to manually titrated CPAP.[7]

Methods

Subjects

The target population were OSA patients who demonstrated an apnea-hypopnea-index (AHI) >20/h plus an arousal-index >30/h (i.e. Belgian criteria for reimbursement of nasal CPAP). All consecutive patients who underwent polysomnography in our sleep laboratory from January till September 2001 and who fulfilled these inclusion criteria, were asked to participate in the study. Exclusion criteria included a history of prior UPPP, signs of severe nasal obstruction, excessive sleep fragmentation due to nonrespiratory causes and COPD (i.e. $FEV_1/FVC < 65\%$). None of the selected individuals refused to take part in the trial and none met the exclusion criteria. The participants gave written informed consent to the trial, which was approved by the Ethical Review Board of our institution.

CPAP habituation

Before carrying out the APAP procedure, patients were tried out on home CPAP treatment. The CPAP was empirically set at a predicted pressure value (P_{pred}), which is derived from a formula published by Miljeteig et al.[8] This formula takes into account the AHI, neck circumference (NC) and the body mass index (BMI) [$P_{pred} = 0.13\,BMI + 0.16\,NC + 0.04\,AHI - 5.12$]. Patients may habituate this way to CPAP for some months before being restudied in the sleep laboratory. They were, however, instructed to contact our service for further help and CPAP adjustment whenever necessary, e.g. when snoring or sleep disruption persisted at P_{pred}.

Trial protocol

After the habituation period, the patients were hospitalized for one night to carry out a crossover study in which the APAP devices were used during half of the night in randomized order. The patients had no previous experience with these appliances and were unaware of the operational features. By covering the devices in identical boxes, true blinding to the intervention was assured. They were instructed to breathe normally and not to talk, cough or swallow during a settling period of 5 min prior to starting the actual titration procedure. After the participants had been using the first APAP device for 3.5 h, the mask was disconnected and switched to the hose of the next machine, which was then used for another 3.5 h. The 5 min adaptation procedure as described above was repeated.

The pressure data of the APAP devices were obtained for further analysis. During operation, these devices continuously log the pressure curve and store the data into electronic memory. After downloading the memory to a computer, the dedicated software computes statistical indices, including the median (P_{50}), 95th percentile (P_{95}) and maximum pressure (P_{max}) over the timespan during which the machine was being used. These indices are important because they summarize the overall level of pressure requirements and fluctuations around this level in individual patients.

The patients were requested to fill out a questionnaire upon awakening in the morning. Visual analogues scales ranging between 0 (best score) and 10 (worst score) were used to answer four questions pertaining to the first and last used APAP machine separately: (a) Did the pressure changes disturb my falling asleep? (b) Did the pressure changes cause awakenings? (c) How did

the APAP device affect my sleep quality? (d) Did the noise of the device disturb my sleep? In addition, the patients were asked to indicate their preference for one of the APAP machines as if they would have to choose between them for continued use at home.

Technical settings of the APAP devices

The AutoSet™ was programmed to a pressure range between 4 and 14 cm H_2O. The AutoSet™ long air tube was used. The following settings were applied: "standard" mask setting; mask fitting feature not used; ramp: off; settling time: 5 min; humidifier: off; leak alert: off; smart start: on.

The SOMNOsmart™ was also set to a pressure range between 4 and 14 cm H_2O. The default settings of the device were kept. A standard Weinmann hose was used.

Each patient wore the same type of mask (Respironics Profile Light™) and air exhaust (Respironics Whisper Swivel™). While ResMed does not recommend the use of non-ResMed masks with the AutoSet™, we checked the compatibility with Respironics Profile Light™ mask and found no inconsistencies in pressure delivery.

The concordance between the pressure indicated on the APAP devices and the recorded pressure levels was verified and found to correspond within limits of ± 0.5 mbar.

Statistical analyses

In keeping with the crossover design, the Wilcoxon matched pair test was applied for evaluating differences between identical groups. The concordance between groups was evaluated using Spearman's correlation. *P*-values less than 0.05 were considered to indicate statistical significance.

Results

Forty-five males and 5 females were included in the study. The age (mean $\pm$ SD) was 53.0 ± 10.6 years, the body mass index was 31.0 ± 5.3 kg/m^2, the neck circumference was 43.5 ± 3.9 cm. The apnea-hypopnea-index was 58.7 ± 34.9, the arousal-index was 54.3 ± 24.2. The number of days of CPAP habituation prior to the study was 97.7 ± 82.4. The CPAP-compliance during that period was 4.9 ± 2.4 h per night. P_{pred} was 8.2 ± 2.0 mbar.

While the results of the subjective evaluation scores varied between very good (0) and very bad (10) for all parameters under consideration, the median values were between 1 and 2, and the interquartile ranges were <5, indicating that the overall comfort of both devices was satisfactory to most patients. No significant differences were found between the devices in any of the subjective parameters. The patients' first choice corresponded with the AutoSet™ in 25 cases, with SOMNOsmart™ in 20 and remained indifferent in 5.

The SOMNOsmart™ produced significantly lower values (mean $\pm$ SD; 95% confidence intervals) regarding P_{50} (5.1 ± 1.3; 4.8–5.5 mbar) and P_{95} (7.8 ± 3.0; 6.9–8.6 mbar) as compared with the AutoSet™ (7.1 ± 1.9; 6.6–7.7 and 9.6 ± 1.9; 9.1–10.1 mbar, respectively) ($P<0.0001$ and $P<0.0005$, respectively). P_{max} values, on the other hand, were not significantly different (SOMNOsmart™: 10.0 ± 3.4; 9.1–11.0 mbar; AutoSet™: 10.8 ± 1.8; 10.2–11.3 mbar; NS).

Figure 1 illustrates the distribution characteristics of the pressure parameters in comparison with the predicted pressure. P_{pred} was mostly found in the 6.5–7.5 mbar range. While P_{pred} and the P_{50} of the AutoSet™ matched a normal distribution pattern, the P_{50} of the SOMNOsmart™ remained close to the lowest preset limit (4.5 mbar) in 36 patients. P_{95} was most prevalent at about 4.5–5.5 mbar in the SOMNOsmart™ and around 10.0–12.0 mbar in the AutoSet™. The SOMNOsmart™ was also remarkable for a large number of P_{max} values equal to 14.0 mbar. The different pressure outcomes of the AutoSet™ correlated better with P_{pred} than those of the SOMNOsmart™ (Fig 2).

Discussion

Although the application of APAP devices has been the subject of recent investigation in sleep disordered breathing, this is—to our knowledge—the first study to compare two such devices in a clinical setting. It was shown that APAP machines that are driven on different measurements of upper airway obstruction and that operate on different pressure-adjusting algorithms yield different pressure outcomes. Nonetheless, the devices under study, namely the AutoSet™ and the SOMNOsmart™, received for the most part satisfactory comfort scores by the patients and no differences in subjective tolerance could be demonstrated.

While P_{50} and P_{95} values were distinctly lower in the SOMNOsmart™ as compared with P_{pred} and the AutoSet™, more patients were exposed to maximum pressure levels when using the SOMNOsmart™. This finding would indicate that the pressure generated by the SOMNOsmart™ tends

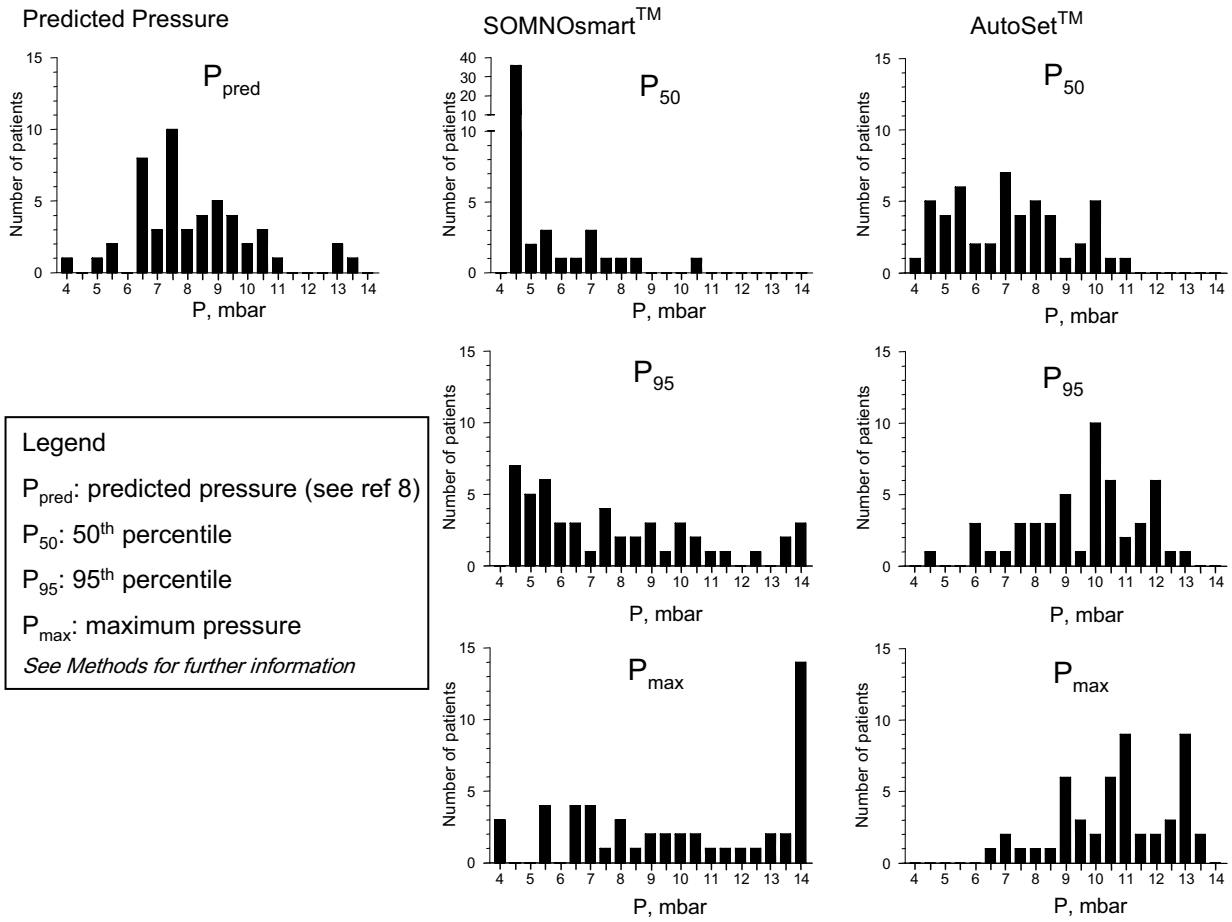

Figure 1 Frequency distribution of predicted pressure, SOMNOsmart™ and AutoSet™ pressure profiles

to vary more between extreme levels and that the pressure output of the AutoSet™ tends to cluster more around intermediate values. Although this observation could be explained by different patient-related conditions that determine the status of upper airway obstruction, such as wakefulness, sleep state and body position, the potential effect of such confounders should have been limited by the randomized and crossover design of the study. Indeed, we believe that the technical characteristics of the devices account for most of the observed differences.

An important dissimilarity between the two APAP devices, is the reaction times ($\Delta P/\Delta t$) that determine the rate at which the pressure adjustments are to be made. The slope of adaptation is steeper in response to certain respiratory events in the SOMNOsmart™. In response to elevated impedance, the pressure is increased with 0.2 mbar/s or 12 mbar/min (adjustable to 0.4 or 0.6 mbar/s). When no elevated impedance is detected, the pressure is lowered within a time channel between 16 and 120 s at a 0.05 mbar/s rate. After 120 s the device decreases the pressure at a 0.1 mbar/s rate. Pressure adaptation is much slower in the AutoSet™. Significant FL will induce CPAP increments of 0.2 mbar/tidal volume ($\pm$2 mbar/min), whereas the CPAP will remain unchanged with mild FL. Unobstructed breathing, which is characterized by absence of FL, will cause an exponential decline in CPAP, using a time constant of 20 min.[9]

The present study has several limitations. Of most importance is the fact that the efficacy of the devices was not assessed in terms of their capability to reduce sleep disordered breathing events. Since sleep was not recorded and AHI not computed, we cannot conclude from this study which device is better than the other. On the other hand, the large number of subjects included, the blinding and the randomized trial design add credits to the strength of the study. We elected to use P_{pred} as reference outcome, since it was shown that P_{pred} corresponds closely to the manually titrated effective CPAP in 63% of patients and that the two measures are within $\pm$2 mbar in 83% of patients.[7] Accordingly, we found that all

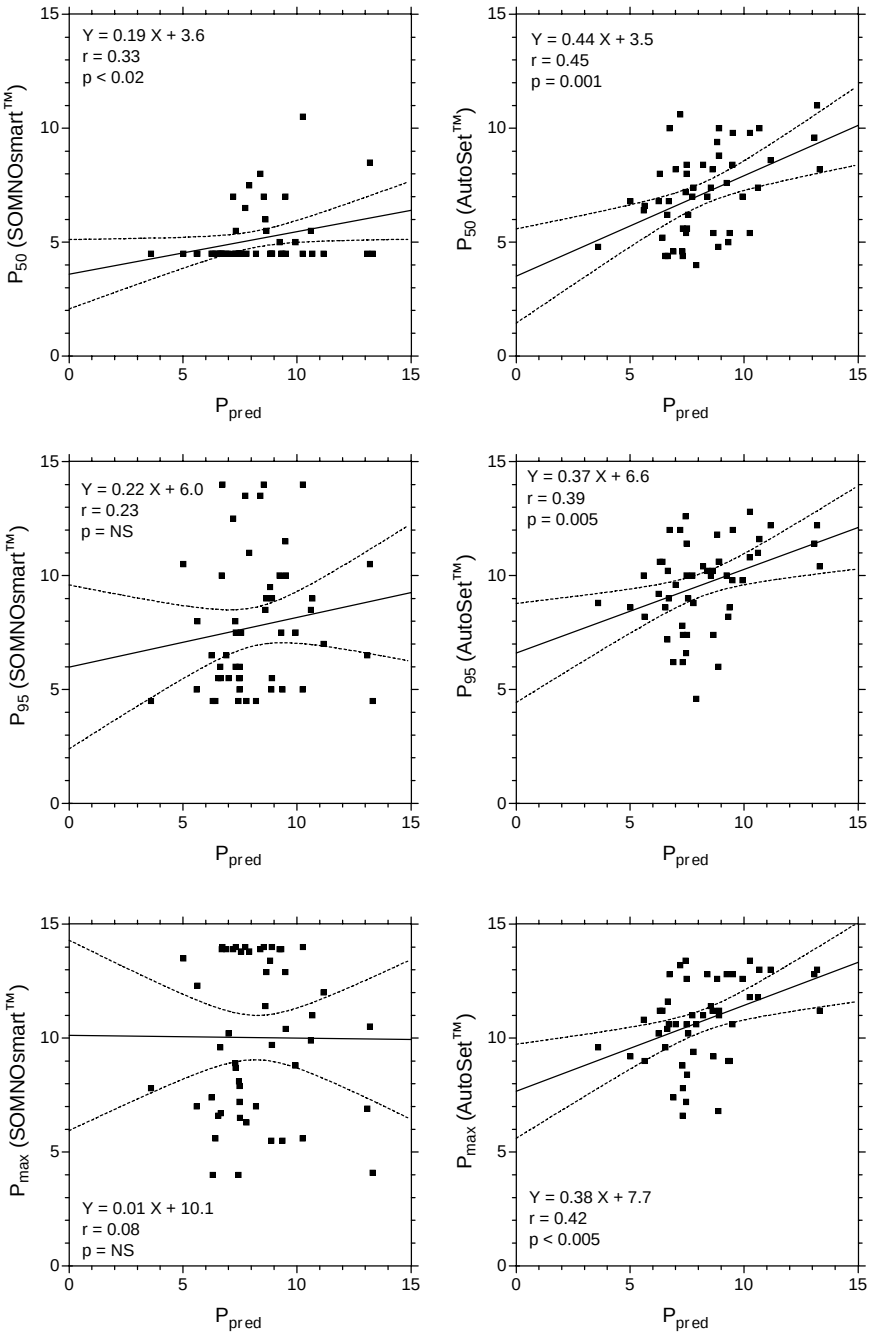

Figure 2 Correlation of SOMNOsmart™ and AutoSet™ pressure profiles, as compared with predicted pressure. All pressure values are mbar. *r*=Spearman's *r*.

pressure variables of the AutoSet™ correlated significantly with P_{pred}. Only the P_{50} of the SOMNOsmart™ showed a slightly significant concordance with P_{pred}, the other pressure variables were not significantly correlated. Though formal proof is lacking, this observation suggests that the Autoset™ is more suitable for determining a prescription pressure for fixed CPAP treatment. Since the Autoset™ is closer related to P_{pred}, one may assume that it might perform better in trials aimed at determining average effective CPAP values.

In conclusion, we have shown that the pressure profiles of the SOMNOsmart™ and Autoset™ are significantly different. Though we did not provide evidence that one device is superior to the other, our observation may at least cast some doubt on the contention that all APAP machines are equally effective in controlling sleep disordered breathing.

If so, one would expect a better concordance of the different pressure output variables. From the present study it is clear that the pressure outcomes of one device cannot be extrapolated to another. To address the question of efficacy, one has to await the results of trials that evaluate the effects of APAP machines on sleep and respiratory variables in a comparative protocol.

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