ORIGINAL ARTICLE

Randomised short-term trial of high-span versus low-span APAP for treating sleep apnoea

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Abstract

Purpose Auto-titrating continuous positive airway pressure (APAP) devices were developed to improve treatment efficacy and compliance in patients with obstructive sleep apnoea syndrome (OSAS). Since there are insufficient data on the optimal pressure range setting, we aimed to compare the adherence, efficacy and tolerability of treatment with high-span versus low-span APAP.

Methods Seventy-six newly diagnosed OSAS patients fulfilling the treatment criteria were randomised to receive high-span (HS, range 4–15cmH$_2$O, n=38) or low-span (LS, range 8–12cmH$_2$O, *n*=38) APAP. Patients were assessed at 1 and 3 months.

Results Median Epworth sleepiness scale (ESS) was 13 (IQR, 6–16) and median apnoea-hypopnoea index (AHI) was 35.9 (IQR, 27.6–56.3). There were no significant differences in baseline demographic and clinical characteristics between groups. Overall, no significant differences were found at the first month assessment. After 3 months of therapy, we found again no differences in residual AHI or ESS. However, the group HS proved less adherent than group LS, respectively, with median 87 % (IQR, 60.5–97.5) versus 94 % (IQR, 80.0–98.3) of the nights using ≥4 h (*P*=0.014) and mean (±SD) usage 5.7±1.6 versus 6.4±1.2 h/night (*P*=0.049). The group HS reported more frequently nasal congestion, excessive oronasal dryness and nocturnal awakenings of at least moderate intensity, the latter with statistical significance (*P*=0.005).

Conclusions Both pressure ranges appear to be equally effective to correct AHI and to improve symptoms. Though, patients with high-span APAP were less compliant to treatment, raising issues about the tolerability of wide pressure range settings of these devices.

Keywords Obstructive sleep apnoea · Auto-titrating positive airway pressure · Pressure range · Treatment compliance

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Introduction

Obstructive sleep apnoea syndrome (OSAS) is a common and potentially serious disorder affecting nearly 4 % of adult population [1]. The hallmark of this condition is the excessive daytime sleepiness, caused by sleep fragmentation due to repetitive episodes of partial or complete upper-airway obstruction [2]. It is frequently associated with neurocognitive deficits, hypertension, myocardial infarction and stroke [3, 4]. The standard treatment is nocturnal continuous positive airway pressure (CPAP), which has been shown to improve quality of life, reduce the risk of road traffic and occupational accidents, and decrease cardiovascular morbidity and mortality [5–8].

Traditionally, after a patient is diagnosed with OSAS, an attended polysomnography (PSG) is performed, during which positive airway pressure is manually titrated throughout the recording period to determine the minimal pressure that maintains the upper airway patency. Auto-titrating positive airway pressure (APAP) devices were developed to allow for a lower average pressure over the course of the night, through continuously adjusting the applied pressure to the optimal level, in that way improving the patient comfort and compliance [9–12]. The rationale for this treatment modality was based on the observations that the pressure required to eliminate obstructive respiratory events varies over a night depending on several factors, like alcohol or hypnotic agent use, body position, nasal obstruction and sleep state [13–15]. Additionally, APAP devices seem to be more cost-effective, since there is no need for PSG to titrate pressures and, despite scarce data on objective clinical outcomes, its effectiveness in reducing the apnoea-hypopnoea index (AHI) and symptoms appears to be similar to that of fixed-pressure CPAP therapy [16, 17]. However, the American Academy of Sleep Medicine does not recommend APAP titration or treatment in patients with congestive heart failure, significant lung disease, obesity hypoventilation syndrome, non-snoring patients and in patients with associated central sleep apnoeas [18].

At present time, there is insufficient evidence regarding the optimal APAP pressure range. Most APAP devices have default settings ranging from 4 to 20 cmH_2O, values thought to be tolerable and effective for the majority of patients. However, studies that compare different pressure ranges are still lacking and it is not clear whether rapid pressure augmentations induce sleep fragmentation.

The present study was designed to compare the impact of high-span versus low-span APAP pressures on tolerability, effectiveness and compliance to treatment in ventilation naive patients with OSAS.

Methods

Subjects

Cases were recruited from the patient population attending the Respiratory Sleep Disorders Unit at Centro Hospitalar de São João (Porto, Portugal). Patients were eligible to participate if they had a confirmed diagnosis of moderate to severe OSAS (AHI >15 events/h), met the criteria for APAP treatment and had not been on positive airway pressure (PAP) therapy previously. Exclusion criteria were as follows: hypercapnia (all patients with pulse oxygen saturation lower than 94 % or body mass index >30 kg/m^2 had an arterial blood gas analysis), forced expiratory volume in 1 s/forced vital capacity (FEV1/FVC) ratio <0.7, or FEV1 <70 % predicted, and if >50 % of the events were central apnoeas. We also excluded

patients with malignant disease and psychiatric disorder or cognitive disability.

The diagnosis of OSAS was based on an overnight sleep study by home portable cardiorespiratory polygraph (Embletta™ Gold Portable Testing Device, Broomfield, USA), which included monitoring of heart rate, nasal airflow, chest wall and abdominal excursion, and oxygen saturation. All sleep studies were manually scored by and experienced sleep technician and apnoea and hypopnoea were defined according to the criteria of the American Academy of Sleep Medicine [19]. We only considered the cases with an adequate record of polygraphic sleep study >80 % of the night and/or >6 h.

Criteria for APAP therapy were as follows: AHI≥30 events per hour; AHI≥15 events per hour with associated symptoms, that included unintentional sleep episodes while awake, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, gasping or choking and loud snoring, or associated with cardiovascular comorbidities [20].

All patients recruited provided written informed consent. The study protocol was approved by our institution's Ethics Committee (approval number 284-12).

Study design

All patients were examined by a pulmonologist with expertise in sleep medicine. After establishing the diagnosis and the inclusion criteria, patients were randomised into two different treatment arms in a 1:1 ratio, according to a random computer-generated single block allocation sequence: group HS—high-span APAP, with pressure range from 4 to 15 cmH_2O; and group LS—low-span APAP, with pressure range from 8 to 12 cmH_2O (Fig. 1).
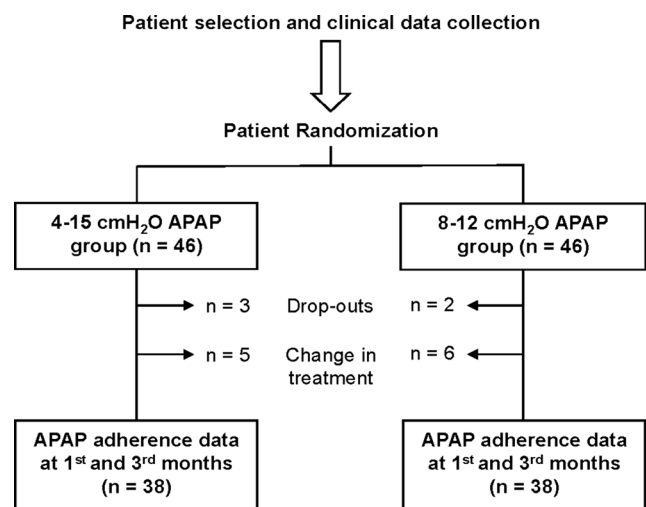

Fig. 1 Study design: patients were enrolled to high-span APAP (4–15 cmH_2O, group HS) or low-span APAP (8–12 cmH_2O, group LS) treatment; drop-outs were cases that lost follow-up or had no compliance data available; patients that had changes in pressure settings or that switched to bi-level PAP were also excluded from the analysis

At enrollment, we collected demographic data, information on smoking habits and medical background. Subjective sleepiness was measured using the Epworth sleepiness scale (ESS) [21]. Height, weight, neck circumference, arterial blood pressure, cardiac rate and oxygen saturation were measured, and simple spirometry was performed.

The APAP adherence data were collected at two different follow-up visits. The patients were firstly referred to a structured group education session at the sleep clinic in the pulmonology department approximately 1 month after initiating the APAP treatment. They were previously advised to bring their APAP device and interface. The education session was conducted by a pulmonologist, a psychologist, and a respiratory physiotherapist, as previously described [22]. Each patient's adherence reports were analysed after downloading usage data stored in the device. Under supervision of a respiratory physiotherapist, they were invited to put their interface on. The adequacy of the model and size of each patient's mask were assessed and, whenever necessary, the interface or the ventilator mode was changed.

The patients were again evaluated at the third month of APAP treatment in a follow-up group session conducted by a respiratory physiotherapist. The adherence reports were reassessed and treatment adjustments took place as needed.

The subjects were asked to complete the items of the ESS, to determine the degree of daytime sleepiness, and also the "treatment-related symptoms" domain (domain E) of Sleep Apnoea Quality of Life Index (SAQLI) questionnaire. This is an OSAS-specific questionnaire, which was already validated in Portuguese patients [23]. Patients selected the top five treatment side effects they experienced (from a list of 26). Each item was subjectively graded on a seven-point Likert scale, ranging from 1 (maximal impairment) to 7 (no impairment). Response values were reversed (7 to 0, 6 to 1, 5 to 2, 4 to 3, 3 to 4, 2 to 5, and 1 to 6), and the mean score was obtained by summing the scores for the five symptoms and dividing by five (even when the patient selected fewer than five symptoms).

APAP devices

The APAP device used in this study was S9 AutoSet™ (ResMed, North Ryde, Australia) that automatically delivers the combination of APAP with Easy-Breathe™ Expiratory Pressure Relief (EPR) to prevent the collapse of the upper airway during sleep. Patients were prescribed with nose or face masks, as appropriated for the facial structure of each individual, patient comfort and nasal or oral breathing predominance. Heated humidifiers were not prescribed to any patient at the beginning of the study. When necessary (complaints of oronasal mucosal dryness), heated humidifiers were added. All APAP devices carried a monitoring chip for adherence data collection and storage.

Adherence data

After 1 and 3 months of APAP therapy, usage data were downloaded by sleep technicians during a hospital visit, before the group education and follow-up session that patients routinely undergo in our centre, as described above. Adherence data, air leakage, air pressure delivered and residual AHI were recorded.

Adherence was analysed as a continuous and as a dichotomous variable. When analysed as a continuous variable, we recorded the percentage of days the APAP was used, the percentage of days with APAP usage >4 h/night and the mean effective use per effective day, defined as the cumulative time of effective use divided by the number of days APAP was actually used. When analysed as a dichotomous variable, we compared adherent versus non-adherent. Patients were defined as being adherent if they used APAP at least 4 h per night for at least 70 % of days [22, 24].

Statistical analysis

The Kolmogorov–Smirnov test was used to determine the normality of distribution of all continuous variables, and Levene's test was used to assess the equality of variance. Differences between means were analysed using t tests for normally distributed variables and Mann–Whitney U tests for non-normally distributed variables. The chi-squared test was used to compare frequencies and proportions between groups. All statistical analyses were performed using SPSS® software v. 22. A P value <0.05 was considered statistically significant.

The expected difference in the primary outcome variable (compliance) which might be clinically important and the pooled standard deviation were specified on the basis of previous published studies [25]. The required sample size to detect a difference of 1.0 h with 80 % power at the 5 % significance level, based on a pooled standard deviation of 1.7 h, was 38 subjects in each group.

Results

We recruited 92 patients according to the selection criteria and assigned 46 cases to each treatment arm. As shown in Fig. 1, three patients in group HS (4–15 cmH$_2$O) and two in group LS (8–12 cmH$_2$O) dropped out from the study (lost to follow-up or without compliance data available), and an additional five and six cases of each group, respectively, were withdrawn because of changing in treatment conditions (changes in pressure settings or switch to bi-level PAP). The analysis was performed on the remaining 76 patients who completed the trial.

Table 1 shows the demographic and clinical characteristics of the patient sample. Patients were as expected for a group with moderate-to-severe OSAS, being predominantly male, middle-aged and obese. Baseline features did not differ between groups. There was no significant weight change during follow-up.

The adherence was high among all patients, with overall APAP usage in 92.8±16.5 % (mean±SD) of the days at 1 month and 93.1±15.2 % at 3 months of follow-up. At 1 month, the percentage of nights with APAP usage for at least 4 h and the mean hours of use per night were similar between groups (Fig. 2). However, at 3 months of follow-up, only 66.7 % patients in the group HS were using APAP ≥4 h for at least 70 % of nights, compared with 88.9 % of patients of group LS (P=0.025). In the former group, participants used APAP ≥4 h in 87 % (IQR, 60.5–97.5) of the nights, while in the latter participants used in 94 % (IQR, 80.0–98.3), as shown in Fig. 2 and Table 2 (P=0.014). In fact, patients at group LS used APAP on average more 42 min per night (6.4±1.2 h/night or mean 6 h, 24 min), than patients at group HS (5.7±1.6 h/night or mean 5 h, 42 min, P=0.049). Air leakage did not differ significantly between groups at both 1 and 3 months of treatment. As already mentioned, heated humidifiers were not prescribed at the beginning of the study. During follow-up, three (7.9 %) in group HS and three (7.9 %) in group LS started humidification due to complaints of oronasal mucosal dryness.

When assessing APAP therapy effectiveness, both groups reported a significant improvement of subjective daytime sleepiness measured with the ESS. Similarly, we found no differences in residual AHI between groups during follow-up (Fig. 3 and Table 2).

Since there were differences in pressure range and 95th percentile pressure delivered (Fig. 2), we went to assess the symptoms related to treatment in SAQLI domain E. Although

patients in group LS reported a lower score, the difference between treatment arms did not reach statistical significance (Table 2). Nevertheless, after analysing the six most frequent side effects of at least moderate intensity (scoring 3 or more in the reversed 0 to 6 Likert scale), we found that patients treated with high-span pressure reported more often nasal congestion, excessive oronasal dryness, discomfort from the mask, facial marks or rash and repeated nocturnal awakenings, than patients of low-span group (Fig. 4). However, only the latter was significantly different (P=0.005).

Discussion

The effectiveness of CPAP depends largely on its regular use. After three decades of experience since CPAP therapy was first proposed for treating OSAS [26], and extensive work published stating its efficiency in the long-term treatment [27], sleep clinicians are still challenged to find solutions that improve adherence. By delivering pressure that is continuously adapting to changes in airflow resistance, APAP is thought to improve the breathing synchrony with the PAP device and, therefore, to increase patient comfort and enhance its compliance. The APAP devices are particularly thought to have an advantage relatively to fixed pressure CPAP in patients requiring high pressures.

The present study aimed to compare the efficacy, adherence and tolerability between low-span and high-span APAP settings. Both pressure ranges appear to be equally effective to correct AHI and to improve subjective sleepiness. Though, patients with high-span APAP were less compliant to treatment at the end of the trial, raising issues about the tolerability of wide pressure range settings in these devices. We believe that the difference of 0.7 h/night (a 12.3 % improvement) in APAP usage observed in the group LS is clinically significant,

Table 1 Baseline demographics and clinical characteristics in group HS (high-span APAP) and group LS (low-span APAP): continuous variables are presented as mean±SD or median (25th–75th percentile)

Factors associated with mortality	All (n=76)	HS group (n=38) 4–15 cmH₂O	LS group (n=38) 8–12 cmH₂O	P value
Age (years)	56.6±11.2	54.7±12.3	58.6±9.9	0.129
Male gender, n (%)	58 (76.3 %)	28 (73.7 %)	30 (78.9 %)	0.589
BMI (kg/m²)	32.8±5.0	33.0±4.9	32.6±5.2	0.704
Cervical perimeter (cm)	43 (40–46)	43 (39–46)	43 (40–47.9)	0.673
Present or former smoker, n (%)	38 (50 %)	19 (50 %)	19 (50 %)	0.948
Alcohol consumption, n (%)				
No	33 (43.4 %)	17 (44.7 %)	16 (42.1 %)	0.887
<30 g/day	13 (17.1 %)	7 (18.4 %)	6 (15.8 %)	
≥30 g/day	30 (39.5 %)	14 (36.8 %)	16 (42.1 %)	
Use of sedatives	9 (11.8 %)	4 (10.5 %)	5 (13.2 %)	0.723
ESS	11.2±5.9	11.6±5.8	10.9±6.0	0.644
AHI (/h)	35.9 (27.6–56.3)	39.4 (30.2–61.6)	33.5 (26.8–48.7)	0.158

Fig. 2 Comparison of APAP use data between groups HS and LS: percentage of days using for at least 4 h, mean hours of APAP use per night, 95th percentile (P95th) pressure and air leak, and residual apnoea-hypopnoea index (AHI) under treatment. *NS* not significant
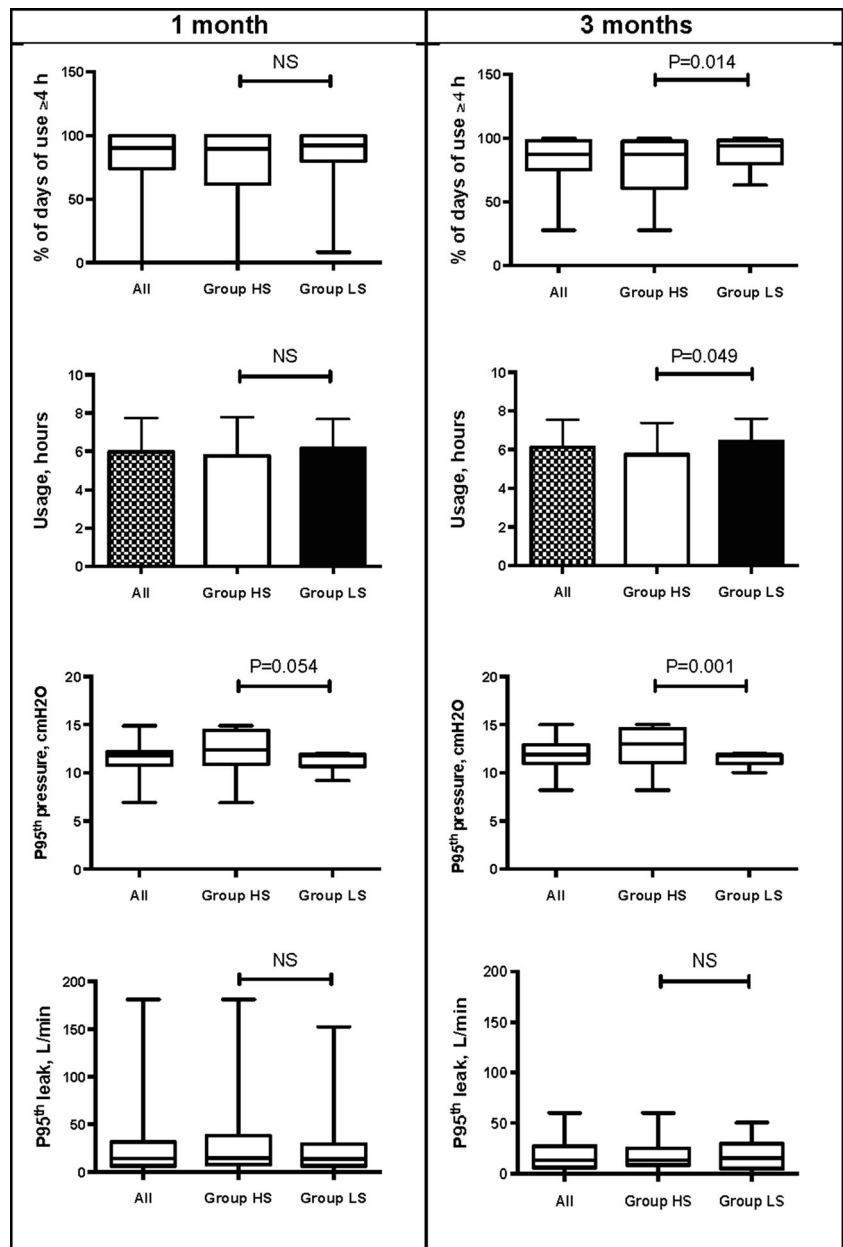

Table 2 Comparison between groups HS and LS of APAP use data, subjective sleepiness and symptoms related to treatment at the end of the trial: values are presented as mean±SD or median (25th–75th percentile)

	All ($n=76$)	HS group ($n=38$) 4–15 cmH$_2$O	LS group ($n=38$) 8–12 cmH$_2$O	P value
Percentage of days using ≥4 h	87.0 (75.0–98.0)	87.0 (60.5–97.5)	94.0 (80.0–98.3)	0.014[a]
Mean use (h/night)	6.1±1.4	5.7±1.6	6.4±1.2	0.049[a]
P95th PAP (cmH$_2$O)	11.9 (10.9–12.9)	13.0 (11.1–14.6)	11.7 (10.9–11.9)	0.001[a]
P95th leak (L/min)	13.2 (6.0–27.0)	13.2 (8.7–24.9)	15.0 (5.1–29.4)	0.953
Residual AHI (/h)	1.9 (0.9–3.2)	2.1 (1.0–3.8)	1.7 (0.8–2.6)	0.211
ESS	5.0 (1.7–6.2)	5.0 (2.0–6.0)	4.5 (1.0–7.2)	0.780
SAQLI domain E	1.9±1.4	2.1±1.8	1.8±1.1	0.542

P95th 95th percentile

[a] Statistically significant results

Fig. 3 Effectiveness of APAP therapy
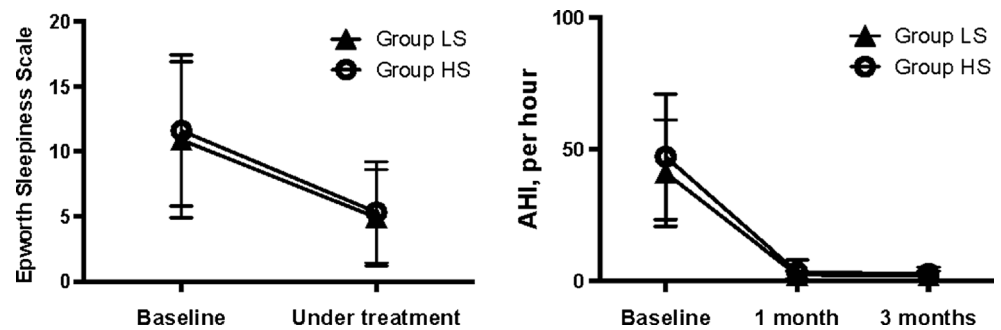
since it transposes the target time of 6 hours of use per night. Several studies have indicated that better outcomes are associated with more hours of nightly PAP use [22] and the use for at least 6 h per night was found to optimise memory performance [28]. One should notice that we are comparing two groups with high adherence levels, which makes the difference achieved with low-span treatment even more striking. The overall good adherence reflects the close follow-up that patients had during the first months of treatment, with compliance reinforcement in group education sessions occurring at both time points. We have previously published the impact of a structured education session in enhancing APAP adherence in certain groups of patients [22, 29].

All baseline characteristics were similar between the two groups, meaning that a good randomisation was achieved. The only difference at the starting point was the prescription of treatment, which included a wider range and a higher P95th PAP in the high-span treatment arm (Fig. 2). We hypothesise that when PAP provokes nasal congestion, it will, in turn, drive the device to increase pressure to the available span. The higher pressure (15 cmH$_2$O in group HS) again worsens the nasal obstruction and other PAP-related symptoms, in a vicious cycle. One study showed that greater air leak levels

Fig. 4 Frequency of the six most prevalent side effects reported as at least of moderate intensity by patients treated with high-span (group HS) and low-span (group LS) APAP: nasal congestion, excessive oronasal dryness, waking up frequently during the night, air leakage from the mask, discomfort from the mask and marks or rash on the face

during APAP therapy were associated to poor adherence [30]. However, contrarily to expected, the disparity of compliance could not be attributed to increased air leakage in group HS, since there were no significant differences in this parameter. In fact, when we assessed the symptoms related to treatment, air leaks were one of the most frequent side effects reported in both groups, but with comparable severity (Fig. 4). Conversely, nasal congestion, excessive oronasal dryness and nocturnal awakenings, which may be directly imputable to high PAP, were reported more frequently as clinically relevant (at least of moderate intensity) by patients in high-span group. Of these, only nocturnal awakenings were significantly more important in this group, suggesting that the wide pressure range can induce arousals, which if meaningful, may cause patients to spend more time awake during the night without PAP. Of note, there is an overall low incidence of symptoms related to treatment at the end of the trial, probably due to the early detection and management of side effects at the first month follow-up visit after treatment initiation. We believe that SAQLI domain E score could have a wider and significant difference between groups if no intervention was employed during group sessions to minimise complaints.

As mentioned, a higher P95th PAP was observed with the high-span treatment. However, low-span APAP was equally effective in a population with the same characteristics, suggesting that most patients can be treated with PAP up to 12 cmH$_2$O. If we check the number of patients removed from the study during follow-up because they needed to increase the upper level of PAP or switched to bi-level PAP, we find a similar proportion in both groups (Fig. 1). In practice, the optimal PAP level is a trade-off between pressure-related side effects and effectiveness in preventing upper airway obstruction during sleep. Our data suggests that patients newly diagnosed with OSAS can be initially treated with a trial of low-span APAP 8 to 12 cmH$_2$O and early reassessed to determine the effectiveness of treatment with those settings.

To our knowledge, this is the first study comparing the tolerability, effectiveness and compliance of different APAP range settings. In the future, a prospective study could be designed to compare nocturnal PSG, performed during high-span and low-span APAP use, in order to assess if sleep fragmentation is different in the two treatment arms.
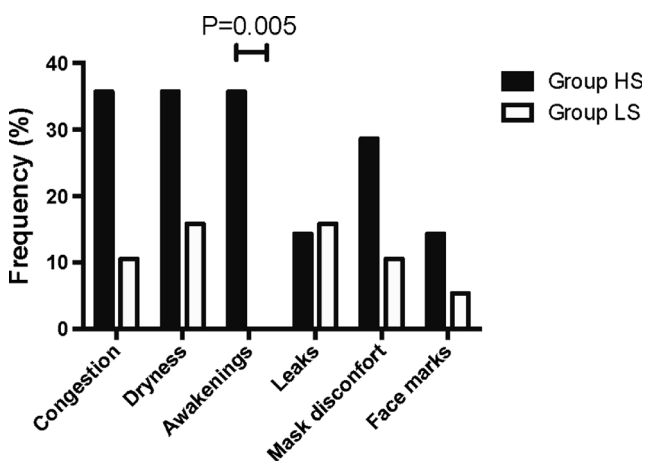
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Comment

In the era of increasing long-term auto-titrating positive airway pressure (APAP) device use for OSA treatment, this study helps sleep physicians improve adherence without substantive effects on OSA control. This randomised controlled trial evaluates the effect of high-span (4–15 cm water) and low-span (8–12 cm water) APAP initial settings on efficacy and adherence over a 3-month time span. The authors find that there is no difference in efficacy between the treatment arms and improved adherence with the low-span APAP settings. These findings indicate that there may be significant differences in long-term adherence based on initial PAP therapy settings. Long-term studies are needed to further clarify the issue; however, it may be prudent in selected patients at the start of therapy to do a trial of low-span APAP with short-term follow-up.

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