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Automatic Titration and Calculation by Predictive Equations for the Determination of Therapeutic Continuous Positive Airway Pressure for Obstructive Sleep Apnea*

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Background: It is unknown to what extent therapeutic continuous positive airway pressure (CPAP) levels obtained by various methods for the treatment of obstructive sleep apnea syndrome (OSAS) differ. This study aimed to explore the relationships among pressures titrated by an automatic CPAP (APAP) device and those calculated using different predictive equations, and to compare different ranges of calculated pressures with pressure values titrated by APAP.

Methods: In 140 OSAS patients, the 95th percentile pressure delivered by an APAP device (AutoSet T; ResMed; Sydney, NSW, Australia) during polysomnography, and pressures calculated by three equations (equation 1, Hoffstein and Miljetig [1994]; equation 2, Sériès et al [2000]; and equation 3, Stradling et al [2004]) were compared.

Results: Titrated and calculated pressures were weakly correlated. Significant differences were found between the mean (\pm SD) pressures (11.1 ± 1.6 , 8.3 ± 1.8 , 10.5 ± 1.6 , and 10.3 ± 1.3 cm H₂O, respectively) for 95th percentile APAP, and pressures calculated by equations 1, 2, and 3, except between values calculated by equations 2 and 3. Differences between the calculated and APAP-derived pressures were negative for the low calculated values, and were progressively attenuated, or became positive, for the high values. The differences were smallest for calculated pressures from 11 to > 13 cm H₂O, which were represented to a greater extent among the values calculated by equations 2 and 3 than by those calculated by equation 1.

Conclusions: Considerably different therapeutic CPAP levels may be determined using various methods. The differences between the calculated and APAP-derived pressures are largest for calculated values of < 9 or > 15 cm H₂O. The clinical consequences of these findings deserve further evaluation. Caution is still required before treating OSAS patients with calculated pressures.

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Key words: hypoxemia; positive-pressure breathing; sleep apnea

Abbreviations: AHI = apnea-hypopnea index; APAP = auto-continuous positive airway pressure; BMI = body mass index; CPAP = continuous positive airway pressure; NC = neck circumference; oAHI = obstructive apnea-hypopnea index; ODI = oxygen desaturation index; OSAS = obstructive sleep apnea syndrome; REM = rapid eye movement; TST = total sleep time

Continuous positive airway pressure (CPAP) is the treatment of choice for most patients with obstructive sleep apnea syndrome (OSAS). Its application is aimed at improving symptoms due to obstructed breathing during sleep, and at preventing possible related cardiovascular complications thanks to the restored patency of the upper airway due to the administration of an appropriate pressure level.^{1,2}

The therapeutic CPAP level has traditionally been identified with manual titration during assisted polysomnography. However, this is a time-consuming procedure, and contributes to the delay in the prescription of treatment. While assisted manual titration is usually still considered the reference method to identify therapeutic pressure,³ there is not a generally accepted “gold standard,” and in the last few

years there has been a search for simplified methods to replace it. Among the alternatives, automatic titration by auto-CPAP (APAP) devices and the calculation of therapeutic pressure by means of predictive equations have been proposed.

Titration with some APAP devices is a pragmatic approach that has been accepted by the medical

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community, at least when done during an assisted polysomnography.⁴ The 90th or the 95th nocturnal percentile pressure delivered by APAP devices is often chosen as the therapeutic level.⁵⁻⁷ Polysomnographic monitoring during APAP application allows us to verify cases of poor reliability of the titrated pressure, due to possible residual obstructive events or inadequate sleep,⁸ or to artifactual increases in pressure delivery.⁹

The experience with predictive equations is more limited. Such equations are based on parameters relevant to anthropometric characteristics and the severity of sleep respiratory disorders of patients, and were usually derived from relatively small sample sizes of obese patients with severe disease. The first equation was elaborated after manual titrations aimed at finding the lowest pressure that brought the apnea-hypopnea index (AHI) to below 10.¹⁰ Two later equations took as a reference therapeutic pressure, defined as the lowest pressure eliminating obstructive apneas, hypopneas, and snoring, identified manually^{11,12} or by one APAP device (Horizon; DeVilbiss; Somerset, PA).¹³

The differences between the mean calculated and titrated pressures in the patient groups were small, but a large disagreement was observed in some cases.^{13,14} Besides, a preliminary investigation¹⁵ has suggested that differences between the pressure calculated with one equation and titrated manually varied depending on the calculated pressure value. Differences between the results of equations have received little attention. Possible large disagree-

ments in the prescribed CPAP level may importantly affect the outcomes of treatment.

In the present study, in a representative sample of OSAS patients requiring CPAP treatment, therapeutic CPAP was determined as the 95th percentile pressure administered by one widely used APAP device the application of which determines the elimination of snoring and inspiratory flow limitation, and as pressure levels calculated by three predictive equations. The purposes of the study were to assess the relationships among therapeutic pressures determined with the application of the APAP device and with calculation using the predictive equations, and to evaluate how calculated pressures, separately at different intervals, differed from pressures titrated with APAP.

MATERIALS AND METHODS

One hundred ninety consecutive white patients, who had previously been subjected to polysomnography for the diagnosis of OSAS and were candidates for CPAP treatment, underwent a standard attended polysomnographic study for CPAP titration. An APAP device was applied during polysomnography (AutoSet T; ResMed; Sydney, NSW, Australia). The polysomnography device reacts to flow limitation, snoring, and apneas. The lowest pressure was set at 4 cm H₂O, and the highest pressure was set at 18 cm H₂O. Patients with respiratory or sleep disorders in addition to OSAS were not included in the study. All patients gave written informed consent for the anonymous treatment of their data. The study was approved by the institutional review board.

After the sleep study, the APAP device was downloaded; the 95th percentile pressure delivered by the device, and the median air leak during the APAP application, were taken into account. Polysomnographic studies were analyzed. Sleep was scored according to standard rules.¹⁶ Apneas and hypopneas were manually evaluated following published indications.¹⁷ Total AHI was calculated as the number of apneas and hypopneas per hour of total sleep time (TST). Central apneas were subtracted from the total number of events to calculate the obstructive AHI (oAHI). The oxygen desaturation index (ODI) was calculated as the number of oxyhemoglobin saturation falls of $\geq 4\%$ per hour of TST.

Only patients with successful titration were included in the study. The criteria for unsuccessful titration were as follows: TST of < 4 h; TST in supine posture of < 1 h; rapid eye movement (REM) sleep duration of < 10 min; excessive overshoots of delivered pressure associated with sleep disruption⁹; insufficient correction of obstructive events, not allowing us to recognize a therapeutic pressure; median nocturnal air leak of > 0.4 L/s.

In the included patients, three predictive equations were used for the retrospective calculation of therapeutic pressure:

$$0.16 \times \text{BMI} + 0.13 \times \text{NC} + 0.04 \times \text{AHI} - 5.12 \text{ (Hoffstein et al)}^{10} \quad (1)$$

$$0.193 \times \text{BMI} + 0.077 \times \text{NC} + 0.02 \times \text{AHI} - 0.611 \text{ (Sériès et al)}^{11} \quad (2)$$

$$0.048 \times \text{ODI} + 0.128 \times \text{NC} + 2.1 \text{ (Stradling et al)}^{13} \quad (3)$$

where BMI is body mass index and NC is neck circumference. All values are reported as the mean \pm SD. The 95th percentile

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Table 1—Baseline Characteristics of the Patients*

Characteristics	Included Subjects	Excluded Subjects
Gender, No.		
Male	115	42
Female	25	8
Age, yr	53.5 ± 10.1	56.7 ± 11.5
BMI, kg/m ²	34.4 ± 6.2	36.4 ± 6.5
NC, cm	43.5 ± 3.9	44.1 ± 4.5
AHI, events/h	56.1 ± 22.2	57.5 ± 22.5
ODI, events/h	54.7 ± 21.9	56.7 ± 24.6

*Values are given as the mean ± SD, unless otherwise indicated.

pressures and the pressures calculated by each equation were compared by analysis of variance for repeated measures, and were correlated by linear regression analysis. Then, differences between the calculated pressures and 95th percentile pressure were evaluated for intervals of calculated pressures spanning 2 cm H₂O, and were compared by a factorial analysis of variance. The Student-Newman-Keuls test was used for *post hoc* multiple comparisons. A p value of < 0.05 was considered to be significant.

RESULTS

Among the recruited patients, 50 were excluded, as follows: 2 patients requested interruption of the recording (*ie*, TST of < 4 h); 8 patients showed a REM sleep time of < 10 min; 8 patients slept in the supine position for < 1 h; and 8 patients had an insufficient correction of obstructive events (all with an oAHI of > 20 events per hour). These patients repeated a nocturnal monitoring with other devices for positive-pressure delivery or declined to be re-studied. Twenty-four patients showed repeated pressure overshoots associated with sleep disruption. These patients were prescribed a pressure lower than the 95th percentile APAP pressure, based on indications obtained with analysis of the polysomnographic study. All of the remaining patients fulfilled all criteria for inclusion in the study. The median air leak never exceeded 0.4 L/s. Eventually, 140 patients were included in the study. The characteristics of included and excluded patients did not differ significantly (Table 1).

Table 2—Characteristics of the Titration Polysomnography

Values	TST					Median Air Leak, L/s
	TST, min	Supine, min	REM, min	AHI, events/h	oAHI, events/h	
Mean	343.5	265.2	71.5	5.1	3.7	.09
SD	43.1	97.8	32.7	4.6	3.6	.11

The 95th percentile APAP pressures had the highest mean value (11.1 ± 1.6 cm H₂O), followed by pressures calculated by equation 2 (10.5 ± 1.6 cm H₂O), equation 3 (10.3 ± 1.3 cm H₂O), and equation 1 (8.3 ± 1.8 cm H₂O); differences between the means were all significant (p < 0.01) except those between equations 2 and 3.

The pressures calculated by each equation were strongly correlated between each other (r² = 0.561

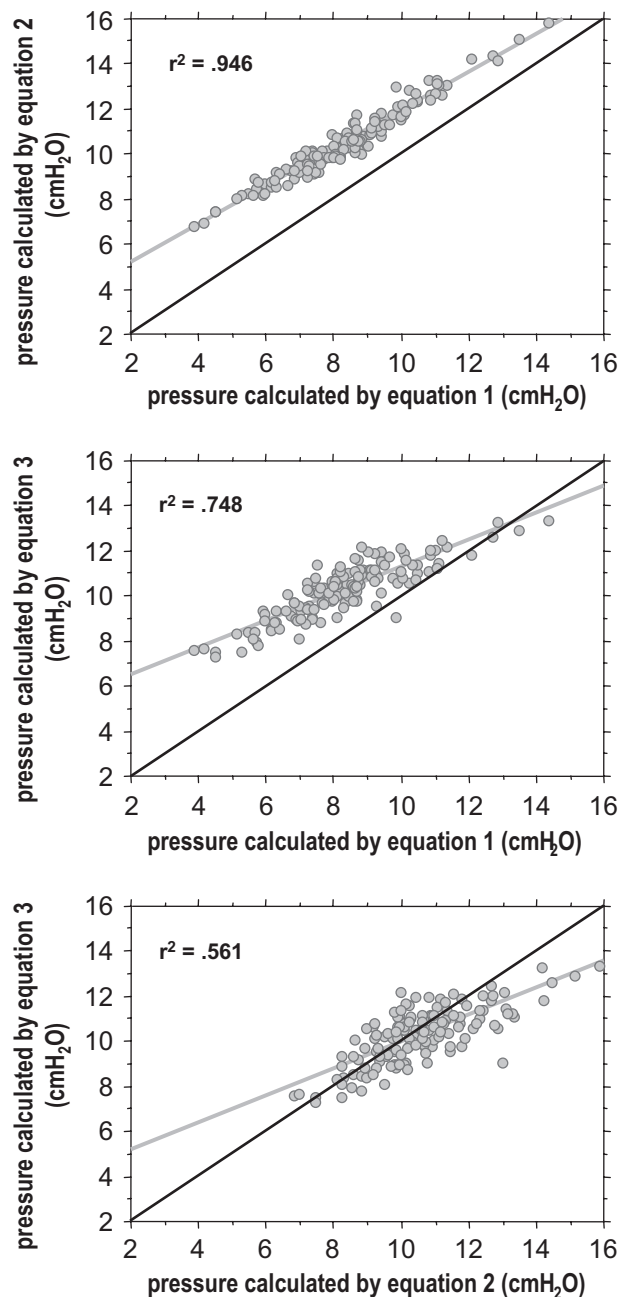


FIGURE 1. Correlations between pressures calculated by each equation. Regression lines are represented in gray. Identity lines are represented in black.

to 0.946; $p < 0.0001$). However, almost all pressures calculated by equation 1 were lower than those calculated by equations 2 and 3, while the pressures calculated by the latter equations were on average quite similar (Fig 1).

The titrated and calculated values were also significantly correlated ($p < 0.005$), but they were much more spread around the regression line, and correlation coefficients were very low. Values calculated by equation 1 were lower than the titrated values in the great majority of cases, while those calculated by equations 2 and 3 were more evenly distributed around the line of identity (Fig 2).

The differences between calculated pressures, at intervals of 2 cm H₂O, and 95th percentile APAP pressures were negative for the low calculated values, and progressively attenuated, or became positive, for the high values (Fig 3). Differences were lowest in the range of calculated

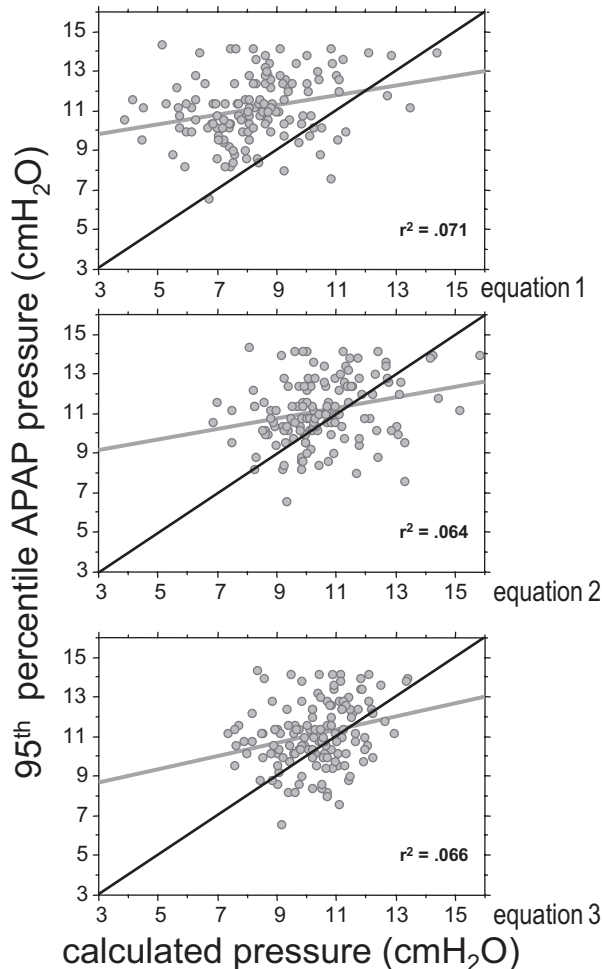


FIGURE 2. Correlations of pressures calculated by each equation with 95th percentile pressure delivered by the APAP device. Regression lines are represented in gray. Identity lines are represented in black.

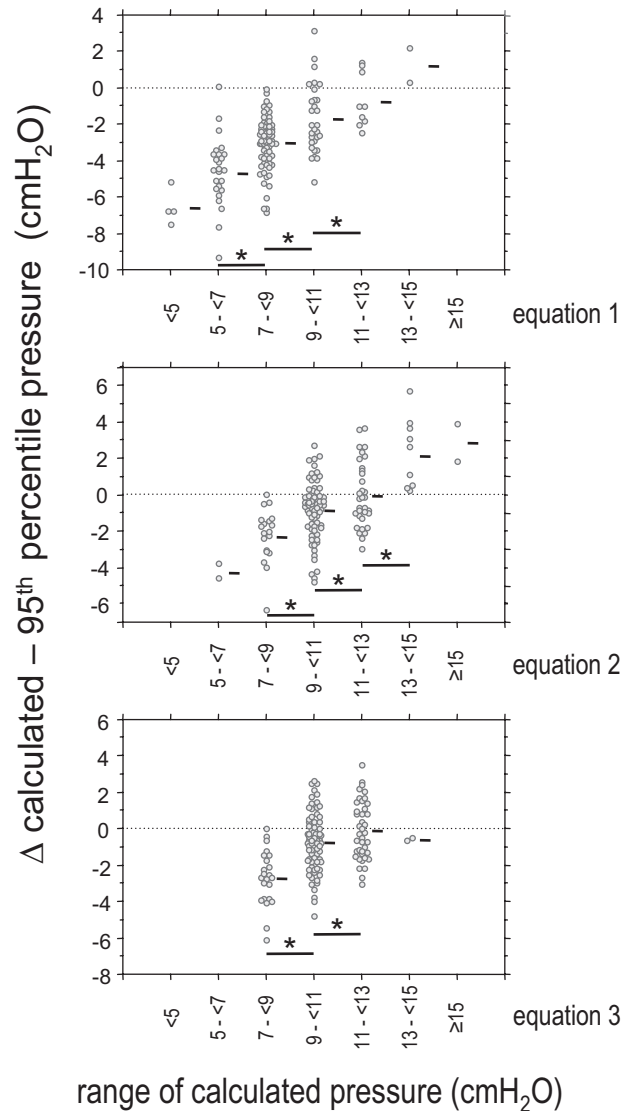


FIGURE 3. The difference, for each patient, between the pressure calculated by each equation, for intervals of 2 cm H₂O, and the 95th percentile pressure delivered by the APAP device. Mean values for each interval for the whole sample of patients is represented by a dash to the right of the circles. * = $p < 0.05$.

pressures from 11 to < 13 cm H₂O. Such values represented 6.4%, 23.4%, and 28.4%, respectively, of the values calculated by equations 1, 2, and 3. Calculated pressures of < 9 and > 15 cm H₂O, which showed the highest differences with titrated pressures, represented 70.7% of values for equation 1, and 16.4% of values for both equations 2 and 3. As regards the 95th percentile APAP pressures, values from 11 to < 13 cm H₂O represented 38.6% of total values, while values of < 9 and > 15 cm H₂O were 10% of total values (Fig 4).

DISCUSSION

Pressures determined with different methods were correlated between each other, but they often

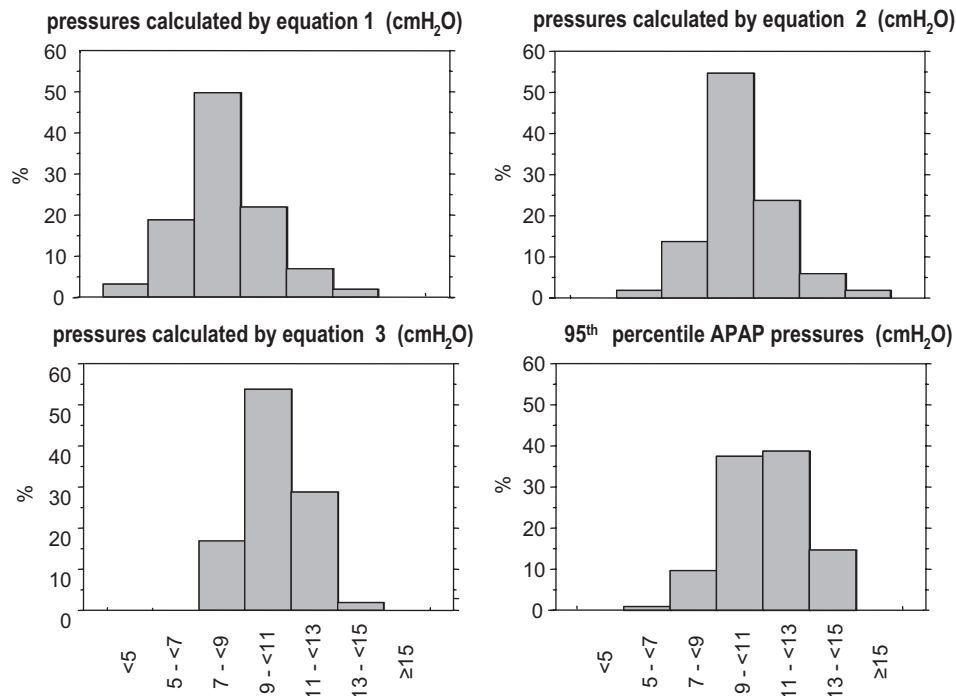


FIGURE 4. Distribution of pressure values calculated by each equation and titrated by the APAP device.

showed considerable differences. In particular, the average differences between calculated and titrated pressures changed for different calculated pressure ranges, as they were lowest for values from 11 to < 13 cm H₂O, and were highest for values of < 9 or > 15 cm H₂O. The latter values were rarely obtained with equations 2 and 3, while they were the most often obtained by equation 1.

Statistically significant differences were found among all calculated and titrated values, except between those calculated by equations 2 and 3. The pressures obtained by using equation 1 were the lowest, as expected, and differed considerably from the values of all other groups, which, in turn, showed small or negligible differences between each other. On average, titrated values were the highest. It is well-known that the pressure required to reduce AHI to < 10 events per hour, which was the target of equation 1, is lower than the pressure that eliminates snoring, which was the target of equations 2 and 3; in order to eliminate inspiratory flow limitation,¹⁸ as was done by the APAP device used in this study, a further slight pressure increase is often necessary.¹⁹ The mean differences between pressures obtained by each method could reflect the differences in CPAP required for various degrees of correction of upper airway obstruction.

These data suggest that the different methods of determination of the therapeutic CPAP analyzed in this study, sometimes lead to the prescription of

considerably different pressures, which should have a different efficacy. That apparently contrasts with previous reports,^{7,20-23} in which a good efficacy of predictive formulas was always claimed. However, a careful analysis of the reported data shows that there are some reasons for concern. Pressures calculated by the formulas were lower than the titrated pressures,^{7,23} and sometimes they left a higher number of residual respiratory disorders.⁷ An incomplete correction of respiratory disorders could result in a lack of benefit on OSAS-related cardiovascular risk, as has been demonstrated for BP.²⁴ Calculated pressures were sometimes corrected according to patients' or partners' symptoms and requests.^{7,20,22} That method may lead to an improvement of the performance of calculated pressures, but CPAP administration is associated with some placebo effect that may be difficult to recognize in clinical practice.²⁵⁻²⁷ Subjective reports or compliance with treatment were the only criteria used to evaluate the performance of calculated pressures in two studies.^{21,22} Finally, evaluations of the efficacy of calculated pressures were always performed on average results in population samples; the percentages of failure have not been mentioned.

Figure 4 shows that pressure values obtained with each method are always concentrated in a narrow range; this range was similar for values titrated by the polysomnography device (AutoSet T; ResMed) and for those calculated by equations 2 and 3. That may

explain why the application of such equations may lead to clinical outcomes that, on average, in a large population, may be satisfactory. However, that does not demonstrate the ability of the predictive formulas to identify the real therapeutic pressure in each patient. In fact, the correlations between titrated and calculated pressures were very weak, and the differences between calculated and titrated pressures increased as they diverged from the average levels, which were the most common ones. In a previous investigation,¹⁵ where equation 1 was studied, a similar progressive change in the difference between calculated and titrated pressures was observed, as in this study; however, the best agreement between calculated and titrated pressures was found for values from 6 to 9 cm H₂O. Such values are those most often found with equation 1. When that study was performed, the abolition of snoring and flow limitation were not yet considered a requirement of the therapeutic CPAP. That suggests that equation 1 most often results in values that are close to the therapeutic levels that may be found when the abolition of snoring and flow limitation are not required; however, even in that case, the equation fails to identify pressures that differ most from the mean pressure levels that are required.

Polysomnographic data of patients selected in this study indicated that the 95th percentile pressure delivered by the APAP machine adequately corrected upper airway obstruction during sleep. Strict criteria were adopted to exclude cases of possible inadequate titration, some of which were used and explained in a previous article.⁸ An additional exclusion criterion was a 95th percentile pressure substantially overestimating therapeutic CPAP due to wide pressure overshoots, sometimes occurring during APAP application, usually in association with arousals.⁹ Despite the elimination of these patients, other cases of overestimates of therapeutic pressure cannot be totally excluded, but the design of this study did not allow us to identify them. The selected threshold for acceptable air leaks was adopted in other studies.²⁸ However, this study is not based on the assumption that titrated pressure is better for treatment than the calculated pressure. Our aim was to compare therapeutic pressures that had been determined with different procedures. As far as APAP titration was concerned, we tried to select only the most accurate titrations. Before stating that APAP titration is more effective than predictive equations for the choice of the therapeutic CPAP, a long-term evaluation of clinical outcome and of polysomnographic variables during the application of a CPAP level determined by each method would be necessary. Anyway, the present data show that different methods lead to the identification of pressures

for treatment that may sometimes differ to a great extent, particularly when they are included in some pressure ranges. As the benefits of CPAP treatment are due to the correction of respiratory disorders consequent to the application of an appropriate pressure, these results could have important clinical implications, suggesting that the prescription of CPAP after titration or after calculation by different formulas cannot be always equally effective.

In summary, according to the available literature, pressures calculated by different predictive equations on average are efficient in the treatment of OSAS, but several considerations have suggested that their efficacy is less than that with traditional titration. Besides, their correlations with pressures obtained with the polysomnography device (AutoSet T; ResMed) are weak, which suggests that cases of failure may be frequent. Therefore, predictive equations should still be used with caution.

One limitation of this study is that most patients had severe OSAS, were frankly or morbidly obese, and belonged to one ethnic group only; therefore, we do not know whether the data may apply also to patients with different characteristics of the disease or to those of different ethnic groups. However, obese patients and patients with severe OSAS were also selected for the elaboration of the equations. Besides, the results of this study apply to predictive equations that were calculated using variables identified with the same definitions as those that we used. That may have partly affected the results. However, rather than strictly keeping to the definition of sleep-disordered breathing events adopted by all of the authors who elaborated the predictive equations, we preferred to use the definitions that are most often currently used,¹⁷ as they would be more likely to be adopted by possible users of the equations.

Future studies should assess, both on clinical grounds and on the basis of polysomnographic evaluations, the effectiveness of different titration methods and, in particular, of different predictive equations. Such studies should consider patients of different ethnic groups, as differences in somatic characteristics between races could have an important effect on the results. Besides, following the results of this study, it would be interesting to explore whether the effectiveness of different ranges of calculated pressures vary. At present, caution should be recommended before applying predictive equations for CPAP prescription.

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