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Reliability of automatic detection of AHI during positive airway pressure treatment in obstructive sleep apnea patients: A "real-life study"

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ABSTRACT

Introduction: Automatic event detection (AED) of residual apnea-hypopnea index (AHI) by ventilators is a current practice in sleep and mechanical ventilation Units but this methodology has not been validated in an unselected population of OSA patients. Aim of the present study was to assess in a "real-life" condition the reliability of AED during PAP therapy by the in-built software compared to full polysomnography during follow-up.
Methods: We enrolled 300 OSA patients (105 F; AHI 45.3 ± 27.8) already on Positive airway pressure (PAP) therapy: 53% of the patients were on CPAP while other modalities were used in the rest of the sample.
Results: Overall, the built-in software identified residual obstructive AHI (AHI_{PAP}) > 5, 10 or 15 in 18.7, 8.6 or 4.6% of patients, respectively. By using $AHI_{PAP,}$ 28.4% of patients were wrongly classified as "well controlled" despite a residual AHI_{PSG}>5 (6% considering a residual AHI_{VENT} >15); 7% of patients were classified as not controlled while AHI_{PSG} was <5 (1.4% considering a residual AHI_{VENT} >15). Type of ventilation, ventilator parameters, adherence to treatment and level of baseline or follow-up Epworth Sleepiness Scale score were similar between groups. The sensitivity and positive predicted values were very low. Positive likelihood ratio appears adequate only for residual AHI_{PAP} ≥10, but negative likelihood ratio was inconclusive for all the cut-off considered.
Discussion: The results of the present study suggest a more cautious approach in the follow-up of OSA patients, since a protocol based only on AED detection and symptoms assessment may not be accurate especially for AHI_{PAP}<15.

1. Introduction

Obstructive Sleep Apnea (OSA) is a highly prevalent disorder associated with many and potentially severe health consequences [1]. Positive airway pressure (PAP) therapy, mainly continuous positive airway pressure (CPAP), is considered the first-line treatment for patients with moderate to severe OSA [2]. International clinical practices as well as local Health systems suggest or require a regular follow-up to confirm the efficacy of therapy, symptoms resolution and to promote continued adherence to treatment [3]. Since the waiting list for diagnosis and follow-up is increasing in every sleep laboratory over the world, the latest clinical practice suggestions consider the possibility of telemonitoring-guided interventions including remote monitoring of PAP parameters such as PAP use, residual OSA severity, unintentional mask leaks, and PAP setting during treatment initiation and follow-up [2].

Automatic detection of residual apnea-hypopnea index (AED by the CPAP or NIV ventilators) is a current practice in sleep and mechanical ventilation Units, both in the setting of titration procedures or follow-up monitoring [4]. Previous studies reported that AED may overestimate the AHI when the manually scored AHI was low and underestimate the AHI when the manually scored AHI was high [5–9]. However, all these studies recruited very selected patients and were performed in a "laboratory setting" during a technician supervised polysomnography. In this setting, technicians were able to identify and correct all the causes of "poor" quality recordings as well as the causes of unintentional leaks. In a previous validation study, the Authors considered the relatively low

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Abbreviations

OSA	Obstructive Sleep Apnea (OSA)
PAP	Positive airway pressure
CPAP	continuous positive airway
AED	Automatic detection of residual apnea-hypopnea index
AHI	apnea-hypopnea index
AHI_{PAP}	automatic detection of AHI by in-built software
PSG	Polisomnography
HRP	home respiratory polygraphy

rate of inclusion as a potential limitation of their findings ~~is~~ [9].

The reliability of the automatic AHI estimation has not been validated in a wide and composite population of patients with OSA treated with different modalities of PAP therapy. Aim of the present study was to assess the reliability of automatic detection of AHI, i.e AHI_{PAP}, during PAP therapy in a "real-life" condition.

2. Patients and methods

We enrolled 300 consecutive OSA patients (AHI> 15 and > than 50% obstructive events) already on treatment with PAP therapy for at least 3 months that performed a follow-up evaluation at least after 3 months of regular prescription of home nocturnal PAP therapy. All patients received OSA diagnosis after clinical evaluation [10] and home full standard polysomnography (PSG_{home}). After a period of acclimatization to PAP and mask, all patients underwent an in-lab titration according to AASM criteria [11] and home PAP therapy was prescribed. The type of mask was prescribed according to patient's preference. Patients with concomitant severe congestive heart failure, predominant sleep hypoventilation or chronic respiratory failure requiring oxygen therapy were excluded from the study.

The follow-up protocol in our Sleep Center includes home PSG or respiratory polygraphy (HRP) during PAP therapy and a clinical evaluation, i.e. general visit, assessment of symptoms, tolerance and adherence to PAP therapy, and mask problem. The sleep tests were initiated near the participant's usual bedtime and ended at approximately between 06:00 or 07:00 a.m.; a standard montage was used for PSG (n = 144) or HRP (n = 156) accordingly to AASM criteria [12,13]. PAP level and airflow were directly recorded by means of pressure transducer and differential pressure or pneumotachograph. Although different PSG/HRP equipment was used, the recordings were routinely standardized by using the same montage of signals, filters and digitization rates. Sleep studies were manually analyzed using the same software (Remologic 4 – EMBLA System – Kanata – ON – Canada). Residual respiratory events were identified and classified accordingly to AASM criteria [12].

Respiratory indices (global AHI, type of events) were compared with those automatically and simultaneously detected by the machine (AHI_{PAP}): the time period of analysis was exactly the same for PSG/HRP and PAP analysis. RERA events were not included since not available in all patients due to different sleep studies and/or not recorded in all PAP tracker.

The study was approved by the Ethical Committee of the Clinical and Scientific Maugeri Institutes IRCCS (n. 2406 CE).

2.1. Statistical analysis

All the variables were checked for normality with the Shapiro-Wilk test. Data are presented as mean ± standard deviation (SD). The primary analysis compared respiratory events index obtained by PSG or AED by means of Wilcoxon matched pairs test. We calculated the difference of AHI measured by the two methods (AHI_{PSG} - AHI_{PAP}); factors that may influence this difference (gender, type of mask or ventilation, adherence to treatment, level of leaks) were accounted for. An ANOVA analysis or Mann-Whitney *U* test was performed to assess differences between groups. The strength of the correlation between variables was assessed by the Spearman Rank test. In addition, Bland-Altman plots of the AHI were generated for visualization of the bias and limits of agreement [14].

The sensitivity, specificity, positive and negative predictive values for given AHI cut-off values were calculated ($\geq$5 vs. < 5, $\geq$10 vs. < 10, $\geq$15 vs. < 15), and Receiver Operating Characteristic (ROC) curves were generated; Area Under the Curve (AUC) and 95% confidence interval (95% CI) were also estimated.

The sample size for frequency in a population was calculated assuming an error rate of 20% (95% CI 15–25) in AHI_{VENT} discriminating AHI_{PSG} measurements by means of OpenEpi version 3 online software tool (https://www.openepi.com/SampleSize/SSPropor.htm).

Statistical analyses were performed by the SPSS computer program (IBM, version 25; Chicago, IL, USA) except for the ROC analysis that was performed by the "roc" function implemented in the R statistical software tool (www.r-project.org) called "pROC". The significance threshold has been set to $p < 0.05$.

3. Results

We analyzed data of 299 patients (105 F): data of a single patient were excluded from the analysis for technical reason (invalid HRP). Patients were treated at home with different modalities of mechanical ventilation: 53% received CPAP, 28.5% BiPAP-auto [15], 8.8% fixed Bi-Level, 7.8% APAP and 1.7% of them Adaptive Servo Ventilation therapy (ASV). Oro-nasal mask was preferred by 53.6% of patients and nasal mask by the remaining. Table 1 reports anthropometrics and diagnostic PSG data.

Overall, 18.7% of patients still had an obstructive AHI_{PSG}>5 at follow-up evaluation. This percentage decreased to 8.6 and 4.6%, considering a cut-off value of 10 or 15. No association was found between persistent OSA (at each cut-off) and gender or persistent excessive daytime sleepiness defined as ESS score at follow-up >9.

The mean AHI detected during PSG (AHI_{PSG}) was higher than AHI_{PAP}, as shown in Table 2; no differences were found between males and females. Of interest, the Obstructive Apnea Index was higher in AED analysis than PSG; opposite trend was observed for Central Apnea index and for hypopnea index. Fig. 1 shows the correlation between the apnea-hypopnea index identified by the device (AHI_{PAP}) and manually scored polysomnography (AHI_{PSG}) and the correlation between the obstructive apnea index (OAI) obtained with the two methods ($r = 0.66$, $p < 0.05$; $r = 0.47$, $p < 0.05$; respectively).

Table 1
Anthropometrics and sleep data at diagnosis.

	Mean	SD
Age (yrs)	53,8	9,4
BMI (kg/m^2)	29,4	5,5
ESS	8.5	4,2
TST (min)	339,5	59,9
SE (%)	81,3	12,7
Sleep Onset (min)	19,3	26,5
REM Latency (min)	120,6	76,8
Awakenings (n)	14,4	12,3
N_1 (%)	12,9	11
N_2 (%)	44,7	13,1
N_3 (%)	23,2	12,7
REM (%)	19,7	7,5
Arousal Index ($ev*hr^{-1}$)	45	26,5
AHI ($ev*hr^{-1}$)	45,3	27,8
T90 (%)	27,9	29,8
ODI ($ev*hr^{-1}$)	39,2	27,5
LMI ($ev*hr^{-1}$)	21,4	26,7
PLMI ($ev*hr^{-1}$)	10,6	18,3

Table 2
Comparison between respiratory indices detected by PSG or PAP machine. *Wilcoxon matched pairs test.

	PSG	PAP	P*
	Median [25°–75° interquartile range]		
AHI	6.8 ± 9.2	4.3 ± 6.3	<0.0001
AI	2.8 ± 5.3	2.9 ± 5.6	n.s.
HI	4 ± 6	1.5 ± 2.3	<0.0001
OAI	0.9 ± 3.1	1.9 ± 3.5	<0.0001
CAI	1.7 ± 3.4	1.1 ± 2.9	<0.0001
Obstructive AHI	3.5 ± 6.9	n.a.	
Central AHI	2.9 ± 5.7	n.a.	

AHI_{PAP} misclassified patients: 28.4% of patients were wrongly classified as "well controlled" despite a residual AHI_{PSG} >5 (6% considering a residual AHI_{PAP} >15); conversely, 7% of patients were classified as not controlled despite the presence of AHI_{PSG} <5 (1.4% considering a residual AHI_{PAP} >15). As reported in Table 3, the detection of hypopneas was the main factor responsible for the misclassification. Of interest, we observed a steeper increase in the mean leak during ventilation from the group of patients with no differences between AHI_{PSG} and AHI_{PAP} (Group A) compared to those with underestimation of residual AHI (Group B) or those with an overestimation of residual AHI (Group C). No statistically significant differences were observed between groups in terms of type of follow-up sleep study, type of ventilation, ventilator parameters, adherence to treatment and level of baseline or follow-up Epworth Sleepiness Scale (ESS) score and in terms of changes in ESS score between baseline and follow-up.

The mean difference in AHI between the two methods was 2.42 events*hr^{-1} (CI 1.7–3.1). Differences between methods were not influenced by gender, type of ventilation or masks or type of follow-sleep study (Mann-Whitney test $p > 0.05$).

Bland-Altman plot (Fig. 2) shows the difference between AHI_{PAP} and AHI_{PSG} versus the mean AHI: overall, the underestimation of AHI was lower for lower residual AHI_{VENT} and more pronounced when residual AHI_{VENT} was higher.

Table 4 shows sensitivity, specificity, positive or negative predictive values, as well as the positive and negative likelihood ratio at the different AHI cut-off. The sensitivity and positive predicted values were very low, independently of residual AHI_{PAP} cut-off. Positive likelihood ratio appears adequate only for residual AHI_{PAP} ≥10, but negative likelihood ration was inconclusive for all the cut-off considered. AUC estimates for AHI_{PAP} using different AHI_{PSG} cut-off values are shown in Fig. 3: the AUC improved from 0.80 (95%CI = 0.75–0.85) with a AHI_{PSG} cut-off of 5 to 0.87 (95%CI = 0.82–0.93) with a AHI_{PSG} cut-off of 10 up to 0.92 (95%CI 0.89–0.96) with a AHI_{PSG} cut-off of 15.

Of interest, no differences were found between true positive, true negative, false positive and false negative groups for baseline and follow-up ESS score for each AHI cut-off. We found, only for the AHI cut-off of 5, higher level of leaks in the group of false positive patients: 10.1 ± 12.8; 6.1 ± 7.5; 15.7 ± 12.6; 9.5 ± 9.3 l/min, respectively; p = 0.0001.

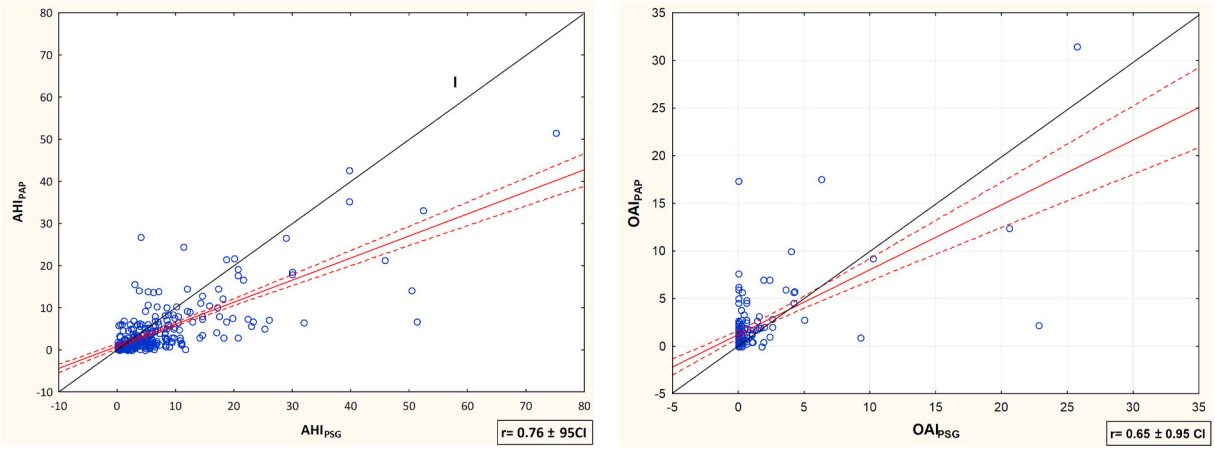
4. Discussion

The main finding of the present study is that, in OSA patients regularly treated at home with PAP devices, the automatic detection of residual AHI by the in-built software is not reliable in a "real-life" context. A high percentage of false negative patients occurred, which cannot be predicted by the type of PAP therapy, type of masks, level of leaks or by persistence of symptoms like excessive daytime sleepiness. As a consequence, follow-up protocols based only on AED detection and symptoms evaluation seems not adequate [2,16].

The AED provided by the in-built software, now included in the great majority of PAP device available in the market, may help clinicians to assess the efficacy of treatment, to modify the ventilator setting, to explain residual symptoms eventually reported by the patient or to make a decision about the need for an additional titration procedure. A limited

Table 3
Differences in ventilation indices during sleep in the 3 different groups of patients using a cut-off 5 ev*hr-1 of residual AHI. Group A = no differences between AHI_{PSG} and AHI_{PAP} (post-hoc p = n.s.). Group B: underestimation of residual AHI (post-hoc p= <0.0001). Group C overestimation of residual AHI (post-hoc p < 0.0001).

	Group A	Group B	Group C	Anova
	(n = 193)	(n = 85)	(n = 21)	
Adherence (hr/night)	7.2 ± 1	7,3 ± 0.74	7 ± 1.3	n.s.
AHI_{PSG} ($ev*hr^{-1}$)	5 ± 8.9	11,3 ± 9.3	3,8 ± 2.8	<0.0001
AHI_{PAP}($ev*hr^{-1}$)	4,1 ± 7.1	3,8 ± 3.3	10,2 ± 6.4	<0.0001
Δ ($ev*hr^{-1}$)	−0,98 ± 3	−7,5 ± 7.4	6,3 ± 5.4	<0.0001
AI_{PAP} ($ev*hr^{-1}$)	2,7 ± 6.6	2,4 ± 2.2	7,4 ± 4.5	0.053
HI_{PSG} ($ev*hr^{-1}$)	2.4 ± 4.7	8.1 ± 7.3	1.9 ± 1.4	<0.001
HI_{VENT} ($ev*hr^{-1}$)	1.3 ± 2.5	1.4 ± 1.4	3.2 ± 3.1	<0.001
Leaks (L/min)	7,3 ± 3	9,1 ± 9.5	13,9 ± 13	0.009
Baseline ESS	8.4 ± 4.8	8.7 ± 4.8	9.5 ± 4.2	n.s.
Follow-up ESS	4.8 ± 3.7	4.4 ± 3	4.7 ± 4.3	n.s.
Δ ESS	−3.6 ± 5.3	−4.3 ± 5	−4.8 ± 4.7	n.s.



1A 1B

Fig. 1. (A) scatterplot between AHI_{PSG} and AHI_{PAP}. (B) scatterplot between OAI_{PSG} and OAI_{PAP}.. The lines are the linear regression analysis (±95 CI) and line of identity is denoted by I.

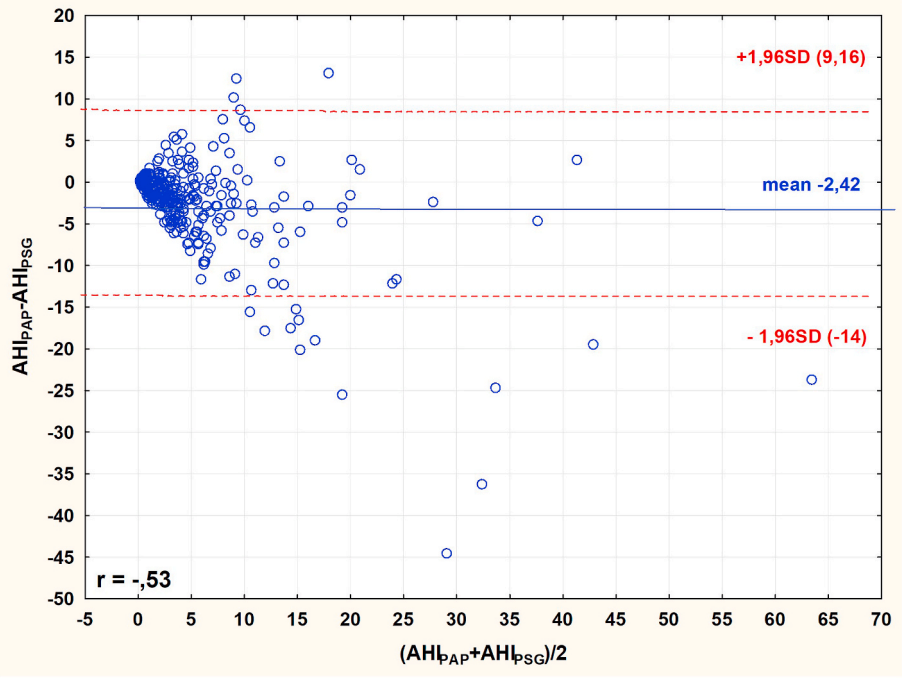


Fig. 2. Bland-Altman plots of apnea-hypopnea index (AHI) with the difference between the respective AHI_{PAP} and AHI_{PSG} measures plotted against the average of the values.

Table 4
Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive (LR+) or negative (LR-) likelihood ratio for each cut-off of residual AHI_{PSG} considered.

	Sensitivity	Specificity	PPV	NPV	LR+	LR-
AHI 5	48.1	90	78.5	69.5	4.81	0.58
AHI 10	44.2	96.3	71.8	89.1	11.9	0.58
AHI 15	41.9	98.5	76.5	93.6	27.9	0.59

number of studies have compared the respiratory events automatically detected by algorithms with those manually scored during PSG or HRP [5–9,16]. All these studies were performed in a "laboratory setting" with small sample size or including selected patients. They compared data obtained by a single manufacturer PAP device, usually CPAP or auto-CPAP, sometimes no longer available in the market; surprisingly, none of them reported the type of mask used. In a real life condition, the patients receive devices for home PAP treatment that are produced by different manufactures. The residual events (apnea/hypopnea) and leak data are not as easy to interpret and the definitions of these parameters differ among the manufacturers. Previous studies as well as a previous statement generally agree that AED tends to overestimate the residual AHI when the AHI is < 10 and tends to underestimate the residual AHI when AHI >20 [7–9,16]. The Authors concluded that treatment of OSA is likely to be effective if AHI <10 events/h, and is likely to be inadequate if AHI >20 events/h. However, in the present study we demonstrated a general underestimation of residual AHI (Figs. 1 and 2): performance of the test is not effective, as summarized in Table 4 and Fig. 3, independently of the AHI cut-off. A negative likelihood ratio is inconclusive at each level of AHI cut-off while a positive likelihood ratio is adequate only for AHI ≥10. Similarly, the negative predictive values are significantly lower than those previously reported in the literature [5,7,9]. On the other hand, differently for previous studies [5–7,9,17] we did not observe a good correlation between device detected and manually scored breathing events for apnea (Fig. 1b). These findings have several explanations. Firstly, as mentioned above, we performed a real life study with home recordings giving us the opportunity to

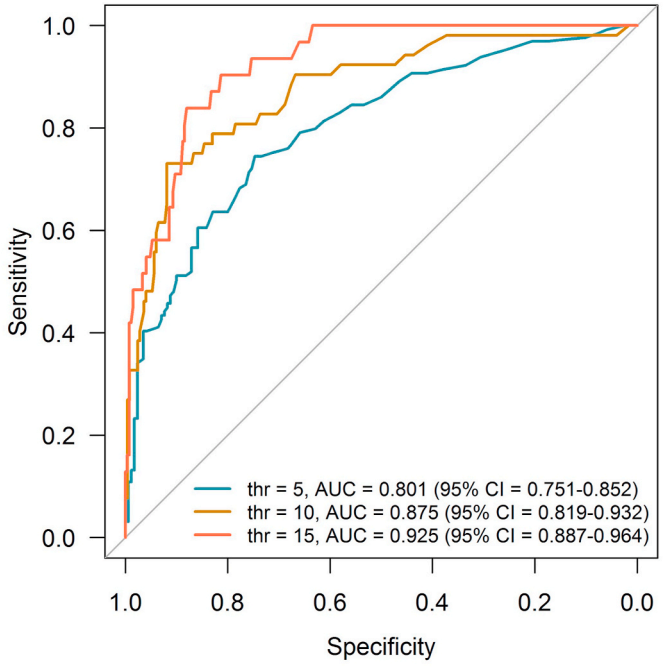


Fig. 3. The ROC curve obtained at each AHI threshold. AUC = Area Under the Curve; 95% CI = 95% Confidence Interval. Thr 5 = AHI_{PSGT} cut-off 5. Thr 10 = AHI_{PSG} cut-off 10. Thr 15 = AHI_{PSG} cut-off 15.

describe a more realistic picture. Indeed, we observed that false positive subjects are those with the highest degree of leaks, though within the "normal" range of the single devices. The second is the well-known critical issue related to the hypopnea scoring: according to AASM criteria, the manual analysis requires either an oxygen desaturation or an arousal to be scored, while automatic scoring is only based on a reduction in airflow [2,17,18]. The sub-optimal agreement between measurement for apnea is an unexpected result since the apnea

classification by manual scoring does not require the presence of arterial oxygen desaturation. The agreement between AED and manual scoring was postulated to be better for apneas than hypopneas but this seems not to be the case. In the present study we used a direct measurement of flow instead of the flow signal derived by the ventilator as done in the above mentioned studies, since using the same flow signal might favourably influence the correlation between residual respiratory event indices determined by the PAP machine and by PSG [6].

Previous studies reported a high percentage of patients, already on PAP treatment, who showed persistent respiratory events despite absence of symptoms or major side effects (large mask leak, congestion, reduced tolerance). We found a lower rate (18.7%) of persistent OSA (obstructive AHI >5) [19–21] that was not associated with residual ESS or residual symptoms. Altogether, these data suggest to reconsider previous AASM or ATS recommendations [2,16]. According to AASM, a new PAP titration procedure is not indicated for patients apparently doing well on PAP treatment [2]. ATS suggested that a follow-up sleep recording under positive airway pressure therapy is not required in patients with a clinical improvement and a device AHI <10 or 20 events/h [16].

4.1. Limitations and strength of the study

The first limitation is that all patients received a home unsupervised sleep study that inevitably leads to some technical limitations (reduced quality of some signals). However, only one patient was excluded from analysis because of poor quality of the sleep study. The second limitation is related to the use of PSG or HRP of different manufacturers: this may lead to different analysis of hypopnea with a possible underscoring of events associated only with arousal. We took particular care to use the same montage of signals, filters and digitization rates as well as to use the same software of analysis. The third limitation is related to the use of PAP machine of different manufacturers: this may lead to different analysis of AED according to the different algorithms included in the built-in software. However, this is a real-life study specifically designed to assess the reliability of residual AHI calculated by any PAP device, and the choice of the manufacturer is often not made by the prescriber physician.

One strength of the study is the enrollment of a large number of unselected OSA patients already on home PAP treatment with different kind on ventilation modalities and/or different kind of masks. We avoided most of the limitations reported in the previous studies: small sample size, predominance of males, predominance of obese patients, low or very low overall residual AHI. A low residual AHI may improve the negative predictive value or the negative likelihood ratio: in the present study both these values were not adequate, particularly at the residual AHI cut-off of 5 or 10. The second strength of the study is the comparison of AHI values that were obtained simultaneously by two different methods, PSG/HRP vs AED. In this way we excluded all the factors that usually may influence the AHI: sleep state composition (i.e. REM amount), body position, use of medications, etc.

5. Conclusions

In conclusion, to the best of our knowledge this is the first study on the reliability of AED estimation of AHI in a large population of OSA patients on PAP treatment. The results of the present study suggest a more cautious approach in the follow-up evaluation of OSA patients: a protocol based only on AED detection and symptoms assessment should be reconsidered.

Credit author statement

Study design: FF.
Data Collection: NDA, RT, SA, AP, MPM, CP.
Data analysis and interpretation: FF, AM.
Literature search and generation of figures: FF, AM.
Manuscript preparation: FF, AM, MRB.
Manuscript drafting: FF, AM, MRB.
All authors approved the final version of the manuscript.

Appendix A. Supplementary data

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