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A new telemonitoring feature for detection of long-term CPAP adherence

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ABSTRACT

Rationale: Suboptimal adherence limits the efficacy of Continuous Positive Airway Pressure (CPAP) in Obstructive Sleep Apnea (OSA).
Objective: To determine whether the Monthly Adherence Standard Deviation (MASD), that quantifies the variability in CPAP use during the baseline month (January 2021, at least the fourth month of treatment) provides predictive information about adherence, 6 and 12 months after baseline that would not be captured by the Monthly Adherence Mean (MAM) value alone.
Methods: This retrospective analysis includes CPAP telemonitoring data from a population of 1612 patients. The overall population was randomly assigned to a construction (80 %) and test cohort (20 %) for internal validation. A threshold on baseline MASD was defined using a Receiver Operating Characteristic (ROC) curve.
Results: A MASD threshold of 1.76 h was identified. Based on this threshold and the standard 4 h/day criterion applied to the MAM, patients were classified into four groups: high MAM/low MASD, high MAM/high MASD, low MAM/low MASD, and low MAM/high MASD. Significant differences were observed among the groups 6 and 12 months after baseline data. Six months after baseline, average MAM for each patient group in the test population were 6.84 ± 1.58, 5.66 ± 1.97, 1.27 ± 2.09, and 3.04 ± 1.90 h/day, respectively ($p < 0.001$); percentages of adherent patients were 91.4 %, 69.9 %, 6.25 %, and 13.9 % ($p < 0.001$). Similar patterns were found 12 months after baseline.
Conclusions: MASD in CPAP adherence can distinguish between patients with different adherence behaviors 6 and 12 months after, capturing patterns not evident from MAM alone.

1. Introduction

Obstructive Sleep Apnea (OSA) is one of the most frequent chronic diseases, affecting nearly one billion people worldwide [1]. Continuous Positive Airway Pressure (CPAP) is the first-line therapy for OSA [2], significantly improving symptoms and quality of life if well adhered to Ref. [3]. Despite the potential benefits of CPAP therapy, adherence to treatment remains paramount. A recent study showed that overall CPAP termination rates after 1, 2, and 3 years were 23.1 %, 37.1 % and 47.7 %, respectively [4]. Factors such as the severity of OSA, psychological considerations, and the management of CPAP-related side effects have all been linked to patient adherence to this treatment [4].

Although several studies have focused on identifying patients at risk of poor adherence to CPAP therapy during the initial months of treatment, little is known about how to effectively telemonitor patients beyond this early phase. In clinical practice, once the first four months have passed, healthcare teams often face the challenge of determining how to continue supporting patients over time. Currently, no standardized metric exists to guide the telemonitoring of patients who

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Abbreviations:

CPAP	Continuous Positive Airway Pressure
OSA	Obstructive Sleep Apnea
MASD	Monthly Adherence Standard Deviation
MAM	Monthly Adherence Mean
ROC	Receiver Operating Characteristic
AHI_{PAP}	Device-reported residual Apnea-Hypopnea Index
TQ	Treatment Quality
NWC	Nights Without CPAP
SMD	Standardized Mean Difference

remain under CPAP treatment after the initial adaptation period, particularly those who were initially predicted to be at high risk of low adherence.

The hypothesis of the study posits that the psycho-behavioral aspect is one of the primary determinants of adherence to CPAP. This study explored this aspect by analyzing how patients use CPAP, by investigating the variability in CPAP usage during a baseline month that is between the fourth and the twelfth month of CPAP treatment. This variability can be quantified by calculating the Monthly Adherence Standard Deviation (MASD), as in [3], of the time series obtained from telemonitoring data:

$$MAM = \frac{\sum_{i=0}^{n} x_i}{n} \quad [1]$$

$$Variance = \frac{\sum_{i=0}^{n} (x_i - MAM)^2}{n} \quad [2]$$

$$MASD = \sqrt{Variance} \quad [3]$$

[1] explains the MAM definition: sum of all the daily values (x_i) of CPAP usage within the given month, divided by the number of days in that month (n).
[2] explains the Variance definition as mean of the squared deviations: squared differences between each daily value (x_i) of CPAP usage within the given month and the MAM, divided by the number of days in that month (n).
[3] explains the MASD definition: square root of the Variance.

This analysis sought to determine if the MASD provides a meaningful indication of adherence and quality of treatment in the long term (e.g., after 6 months and after one year), and whether, when combined with the baseline Monthly Adherence Mean (MAM) value (currently used in clinical practice), it could serve as an added value to stratify patients' adherence outcomes and, subsequently, focus attention of clinicians and technicians.

2. Methodology

2.1. Data recordings and population

The e-QUALISAS study analyzed one-month de-identified telemonitoring CPAP-adherence data from a unique home-care provider (ELIA Medical) database in January, June, and December 2021, including CPAP adherence in hours/day, device-reported residual Apnea-Hypopnea Index (AHI_{PAP}) expressed in events/hour, and 95th percentile non-intentional leaks expressed in l/min. All adults were above the age of 18 years and started CPAP treatment before September 2020 and were treated for at least 4 months before the beginning of the study. All data were collected using the CPAP-software (Airsense 10, Resmed, Australia). CPAP use was considered as the use during the 24 h. Age and gender were also available in the database. All included adults gave their informed consent for data collection and anonymization. The study had been registered on the Health Data Hub platform (N° F20220715144543). Patients included in this analysis have been treated by CPAP device for a period of less than one year.

2.2. Feature extraction

For each patient, the MASD is computed from the time series of the baseline month (in Fig. 1, four adherence time series at baseline time point from different patients are shown). The MAM (hours/day), 95th percentile leaks (L/min), and AHI_{PAP} (events/hour) at baseline, 6 and 12 months after baseline were calculated as the monthly averages, excluding values corresponding to days with zero adherence. The Nights Without CPAP (NWC) indicates the number of days in each month when CPAP use was zero.

In addition to the numerical features, binary labels at baseline, 6 and 12 months after baseline have been computed, which provide a classification of each patient's adherence, leak rate, and AHI_{PAP} values based on thresholds. The first label (adherence label) distinguishes between adherent and non-adherent patients:

- adherent: MAM $\geq$ 4h/day on $\geq$ 70 % of nights within the months.
- non-adherent: MAM $\geq$ 4h/day on $<$ 70 % of nights within the months.

The second label describes high Treatment Quality (TQ), defined by a combined criterion: MAM $\geq$ 4h/day on $\geq$ 70 % of nights within the months, monthly mean of 95th percentile unintentional air leaks $<$24 l/min and monthly mean value of $AHI_{PAP} < 5$ events/h.

2.3. Population splitting

The total population was divided into a construction set and a test set. Construction set was used for the definition of the threshold and Test set was used for its evaluation on an independent sample not involved in its definition. The division into sub-populations was performed through random sampling carried out separately within each of the two classes (adherent and non-adherent 12 months following baseline), by allocating 80 % of each class to the construction set and the remaining 20 % to the Test set. This approach was chosen to preserve the same class distribution in both sub-populations as in the original population. Subsequently, the standardized mean difference (SMD) between the two subsets was calculated to ensure the absence of any major imbalance in the features age, sex, mask, and years of CPAP use.

2.4. MASD threshold definition

The threshold definition for the MASD at baseline was obtained by constructing the ROC curve on the construction set and maximizing Youden's index [5]. The ROC curve was obtained by evaluating the classification performances (true and false positive rates) of adherent and non-adherent patients at the time point of one year after the baseline by varying the threshold on the MASD at baseline time point. On the curve, the optimal threshold was the one that maximized the vertical distance from the diagonal line (also called the line of no discrimination), which represents random guessing. This means finding the best balance between sensitivity (true positive rate) and specificity (true negative rate).

2.5. Threshold evaluation

Both the construction and test sets were subjected to the MASD threshold and the MAM threshold (4 h/day). The evaluation of the threshold performance consisted in assessing its ability to separate patients into groups that were internally homogeneous and mutually

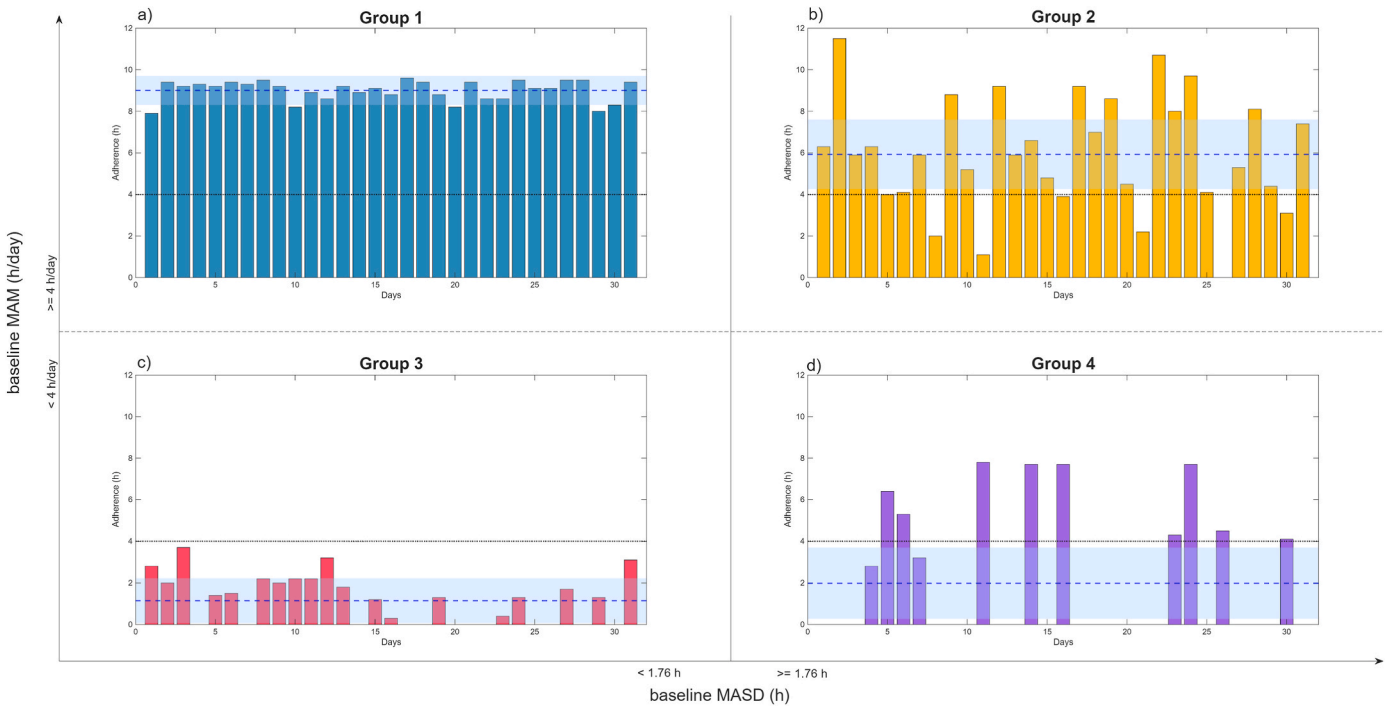

Fig. 1. Baseline adherence time series for group-representative patients defined by baseline MASD and baseline MAM.
Legend: Dashed blue line: baseline MAM of the group-representative patient. Light blue shaded area: baseline MAM ± baseline MASD. Black dotted line: adherence threshold of 4 h/day.
Group 1: MAM ≥ 4 h and MASD <1.76 h at the baseline time point. Group 2: MAM ≥ 4 h and MASD ≥1.76 h at the baseline time point. Group 3: MAM < 4 h and MASD <1.76 h at the baseline time point. Group 4: MAM < 4 h and MASD ≥1.76 h at the baseline time point.

distinct in terms of outcomes observed after 6 and 12 months, including MAM, leak, AHI_{PAP}, NWC, adherence, and QT. This evaluation was performed by computing, for each cluster and for both the construction and test sets, the mean values of MAM, 95th percentile leak, AHI_{CPAP}, and NWC, as well as the percentages of adherent and high-QT patients. For each mean value, the corresponding standard deviation was reported, whereas for percentages, 95 % confidence intervals were calculated using the Wilson method.

3. Statistical analysis

For statistical analysis, the 'scipy.stats' Python library was used.

For continuous variables, the Kruskal-Wallis test was used to compare more than two groups through the 'kruskal' function, while the Mann-Whitney test was applied for pairwise group comparisons using the 'mannwhitneyu' function. For categorical or binary variables, the Chi-squared test was used for both comparisons across more than two groups and pairwise group comparisons through the 'chi2_contingency' function.

As this is a retrospective study, the assumption of random sampling cannot be made. Moreover, age and gender were identified as potential confounding factors, both according to the literature—showing that CPAP usage patterns vary substantially by age and sex [4,6,7]—and from the data itself, as indicated by the correlation analysis between age, gender, and the standard deviation (showing a light but significant difference) computed on the construction set, as well as by the statistical differences observed for these variables across clusters.

To address these limitations, propensity score weighting was employed. This methodology involves the allocation of weights to subjects, thereby ensuring statistical equivalence between groups, as if they were randomized considering pre-defined confounders. The weights for each patient were calculated as the inverse probability (IPTW) of being in their group [8]. The assumption of a normal distribution cannot be made due to the failure of the Shapiro-Wilk test (performed with the 'shapiro' function). The probability was estimated using random forest (using the functions 'RandomForestClassifier' and 'predict.proba' from the library 'sklearn') with 'n_estimators = 100' (the default in recent versions of 'scikit-learn') and random_state = 42 to ensure reproducibility. The following covariates were included: age and gender. Afterward, the weights were stabilized.

Weighted linear regression (using 'statsmodels.api.WLS' function) was applied for continuous outcomes, while weighted logistic regression (using 'statsmodels.api.GLM' function) was used for binary outcomes. These models were used to compute p-values for both pairwise and overall cluster comparisons for each variable, accounting for the assigned weights.

The weights were computed separately for the Construction and Test sets, following the same methodology in both cases.

4. Results

A total of 1612 patients were included in the analysis. The entire population's age ranges from 48 to 74 years, with a mean of 61 years. Males constitute 68.1 % of the total population. Prior to the baseline time point, patients had been receiving CPAP treatment for 0.61 ± 0.24 years (approximately 7 months). The distribution of mask types at the baseline was as follows: 36.1 % used an oro-nasal mask, 18.0 % a nostril mask, and 45.9 % a nasal mask.

The division of the total population into the Construction and Test sets resulted in 1289 patients in the Construction set (382 non-adherent and 907 adherent at 12 months from baseline) and 323 patients in the Test set (96 non-adherent and 227 adherent). The SMDs for the variables age, gender, mask type, and years of CPAP use were all below 0.1, indicating that the two subsets were comparable.

The demographic characteristics of the construction and test subsets are reported in Tables 1 and 2, respectively, in the first column.

The Youden's index maximization yielded a threshold value of 1.76 h on the baseline MASD. This value was employed in conjunction with the

Table 1
Clinical and telemonitoring characterization of the patients in the Construction set population and in the different groups.

Construction results		TOT	baseline MAM				p
			≥4 h/day		<4 h/day		
			baseline MASD				
			<1.76 h	≥1.76 h	<1.76 h	≥1.76 h	
N		1289	659	376	128	126	
Clinical features							
Age (years)		61.3 ± 13.2	63.1 ± 12.6	59.9 ± 13.0	57.4 ± 16.3	60.2 ± 11.9	0.4449
Gender (% male)		67.8 %	71.0 %	64.6 %	66.4 %	61.9 %	0.4769
Years of CPAP treatment (years)		0.61 ± 0.24	0.61 ± 0.24	0.58 ± 0.23	0.66 ± 0.24	0.63 ± 0.25	0.1016
Mask	% Oro-nasal	36.7 %	32.3 %	41.5 %	42.2 %	39.7 %	
	% Nostril	18.3 %	19.6 %	16.2 %	18.8 %	17.5 %	
	% Nasal	45.0 %	48.1 %	42.3 %	39.1 %	42.9 %	
Telemonitoring features							
BASELINE	MAM (h)	5.89 ± 2.55	7.31 ± 1.37	6.22 ± 1.45	0.80 ± 1.28	2.62 ± 0.94	<0.001 *
	MASD (h)	1.60 ± 0.95	1.10 ± 0.38	2.51 ± 0.68	0.42 ± 0.61	2.66 ± 0.60	<0.001 *
	Leaks (l/min)	17.7 ± 14.5	17.4 ± 13.8	17.7 ± 14.6	15.1 ± 14.9	20.1 ± 16.8	0.0051 *
	AHI_{PAP} (events/h)	2.06 ± 2.63	1.96 ± 2.46	2.05 ± 2.72	2.53 ± 3.61	2.37 ± 2.61	0.0012 *
	NWC	4.37 ± 8.48	0.12 ± 0.30	2.77 ± 3.05	21.7 ± 12.9	13.7 ± 6.5	<0.001 *
	% adherent	74.8 %	98.5 % [97.2–99.2]	83.5 % [79.4–86.9]	0.00 % [0.00–2.90]	0.79 % [0.10–4.40]	<0.001 *
	% high TQ	50.8 %	67.7 % [64.0–71.1]	55.6 % [50.5–60.5]	0.00 % [0.00–2.90]	0.00 % [0.00–3.00]	<0.001 *
6 MONTHS AFTER BASELINE	MAM (h)	5.52 ± 2.41	6.76 ± 1.53	5.59 ± 1.80	1.60 ± 1.89	2.83 ± 1.78	<0.001 *
	Leaks (l/min)	19.6 ± 15.9	19.4 ± 15.3	19.8 ± 16.3	17.0 ± 14.0	22.1 ± 18.7	0.0169 *
	AHI_{PAP} (events/h)	2.05 ± 2.61	1.91 ± 2.50	2.11 ± 2.71	2.30 ± 2.95	2.44 ± 2.65	<0.001 *
	NWC	4.37 ± 8.11	0.74 ± 2.47	3.85 ± 5.51	17.1 ± 13.0	11.9 ± 9.57	<0.001 *
	% adherent	69.2 %	92.4 % [90.1–94.2]	68.9 % [64.0–73.4]	7.03 % [3.70–12.8]	11.9 % [7.30–18.7]	<0.001 *
	% high QT	43.1 %	57.8 % [54.0–61.5]	43.1 % [38.2–48.1]	4.69 % [2.20–9.80]	5.56 % [2.70–11.0]	<0.001 *
12 MONTHS AFTER BASELINE	MAM (h)	5.72 ± 2.61	6.94 ± 1.68	5.90 ± 2.15	1.73 ± 2.05	2.80 ± 2.00	<0.001 *
	Leaks (l/min)	18.3 ± 15.1	18.4 ± 14.8	17.8 ± 15.6	17.7 ± 13.6	19.8 ± 16.6	0.3168
	AHI_{PAP} (events/h)	1.99 ± 2.56	1.84 ± 2.30	2.10 ± 2.92	2.24 ± 2.98	2.29 ± 2.35	0.0012 *
	NWC	4.79 ± 8.84	1.11 ± 3.90	4.33 ± 6.84	17.2 ± 13.1	12.9 ± 10.7	<0.001 *
	% adherent	70.3 %	92.1 % [89.8–93.9]	71.5 % [66.8–75.9]	10.9 % [6.60–17.5]	13.5 % [8.60–20.5]	<0.001 *
	% high TQ	48.3 %	63.3 % [59.5–66.9]	49.7 % [44.7–54.8]	7.03 % [3.70–12.8]	7.94 % [4.40–14.0]	<0.001 *

Legend: CPAP: Continuous Positive Airway Pressure; MASD: Monthly Adherence Standard Deviation; MAM: Monthly Adherence Mean; AHI_{PAP}: Device-reported residual Apnea-Hypopnea Index; TQ: Treatment Quality; NWC: Nights Without CPAP. Leaks: 95th percentile leaks. Leaks and AHI_{PAP} values are expressed as monthly means. Categorical/binary data are presented as n% [95 % confidence intervals calculated using the Wilson method]; continuous data are presented as mean ± standard deviation. p = p-value of the association across all groups, obtained using weighted linear regression for continuous data and weighted logistic regression for binary data. *p-value <0.05.

threshold of 4 h/day on the baseline MAM, to divide the whole sample population into 4 groups:

- Group 1: MAM ≥ 4 h and MASD <1.76 h at the baseline time point.
- Group 2: MAM ≥ 4 h and MASD ≥1.76 h at the baseline time point.
- Group 3: MAM < 4 h and MASD <1.76 h at the baseline time point.
- Group 4: MAM < 4 h and MASD ≥1.76 h at the baseline time point.

To visually represent the differences in adherence patterns among these groups, the baseline time series of adherence for a representative patient from each group is reported in Fig. 1.

Table 1 delineates the characteristics of the construction set, as well as those of the 4 groups; while Table 2 delineates the characteristics of the whole test set, as well as those of the 4 groups.

As Tables 1 and 2 show, the range of variation of the difference between the construction set and test set outcomes was generally modest: for MAM, between 0.07 and 0.33 h at 6 months and 0.02–0.63 h at 12 months. Differences in proportions were also limited, typically less than 2 % for both adherence and high QT.

The only exceptions were observed in Cluster 3, which showed a larger discrepancy between construction and test: 5 percentage points for high QT at 6 months and 7 percentage points for both adherence and high QT at 12 months. Nevertheless, this cluster consistently displayed the lowest performance across all periods in both datasets, confirming the stability of the overall pattern despite these small absolute differences.

Since the results from both sets are similar, only those from the Test set will be described in detail.

In the test set, Group 1 was the largest (N = 162). Group 3 has the highest percentage of male patients (78.1 %) and is the group with patients who have been using the device for the longest time (0.67 ± 0.25 years). Group 4 is the oldest (62.8 ± 10.4 years).

At 6 and 12 months after baseline respectively, group 1 consistently showed the highest MAM (6.84 ± 1.58 h; 7.15 ± 1.51 h), followed by Group 2 (5.66 ± 1.97 h; 12 months after baseline: 5.92 ± 1.83 h), Group 4 (3.04 ± 1.90 h; 3.29 ± 1.83 h), and finally Group 3 (1.27 ± 2.09 h; 1.10 ± 1.98 h) ($p < 0.001$).

The same trend was reflected in the NWC, at 6 and 12 months after baseline respectively, where Group 1 exhibited the lowest number of NWC (0.81 ± 3.40; 0.86 ± 2.38), followed by Group 2 (3.68 ± 6.08; 3.80 ± 5.66), Group 4 (12.0 ± 8.48; 11.8 ± 9.15), and finally Group 3 (19.8 ± 12.7; 21.9 ± 13.2) ($p < 0.001$).

Similarly, at 6 and 12 months after baseline respectively, the highest percentage of adherent patients was found in Group 1 (Fig. 2a and c) (91.4 % [86.0–94.8]; 93.8 % [89.0–96.6]), followed by Group 2 (69.9 % [59.9–78.3]; 73.1 % [63.3–81.1]), Group 4 (13.9 % [6.08–28.7]; 16.7 % [7.87–31.9]), and finally Group 3 (6.25 % [1.73–20.2]; 3.12 % [0.55–15.7]) (p < 0.001).

Regarding TQ (Fig. 2b and d), at 6 and 12 months after baseline respectively, Group 1 exhibited the highest proportion of patients with high TQ (57.4 % [49.7–64.8]; 64.8 % [57.2–71.8]), followed by Group 2 (45.2 % [35.4–55.3]; 49.5 % [39.5–59.4]), Group 4 (5.56 % [1.54–18.1]; 8.33 % [2.87–21.8]), and Group 3 (0 % [0.00–10.7]; 0 % [0.00–10.7]) (p < 0.001).

Table 2
Clinical and telemonitoring characterization of the patients in the Test set population and in the different groups.

Test results		TOT	baseline MAM				p
			≥4 h/day		<4 h/day		
			baseline MASD				
			<1.76 h	≥1.76 h	<1.76 h	≥1.76 h	
N		323	162	93	32	36	
Clinical features							
Age (years)		61.5 ± 12.4	61.9 ± 12.4	60.2 ± 13.0	61.3 ± 13.7	62.8 ± 10.4	0.4875
Gender (% male)		69.4 %	74.1 %	60.2 %	78.1 %	63.9 %	0.4671
Years of CPAP treatment (years)		0.62 ± 0.23	0.63 ± 0.23	0.60 ± 0.23	0.67 ± 0.25	0.61 ± 0.22	0.7277
Mask	% Oro-nasal	33.8 %	34.6 %	35.5 %	43.8 %	16.7 %	
	% Nostril	16.7 %	16.1 %	12.9 %	15.6 %	30.6 %	
	% Nasal	49.5 %	49.4 %	51.6 %	40.6 %	52.8 %	
Telemonitoring features							
BASELINE	MAM (h)	5.91 ± 2.60	7.38 ± 1.36	6.45 ± 1.25	0.67 ± 1.09	2.52 ± 0.91	<0.001 *
	MASD (h)	1.58 ± 0.87	1.10 ± 0.39	2.35 ± 0.50	0.53 ± 0.63	2.72 ± 0.58	<0.001 *
	Leaks (l/min)	17.4 ± 12.7	16.7 ± 12.6	17.2 ± 11.3	26.4 ± 21.6	17.3 ± 10.6	0.4632
	AHI_{PAP} (events/h)	2.24 ± 3.02	2.20 ± 2.83	2.09 ± 3.43	3.64 ± 3.18	2.22 ± 2.65	0.7998
	NWC	4.53 ± 8.70	0.07 ± 0.28	2.05 ± 2.09	23.3 ± 11.5	14.4 ± 6.26	<0.001 *
	% adherent	74.0 %	96.3 % [92.2–98.3]	89.3 % [81.3–94.1]	0.00 %m [0.00–10.7]	0.00 % [0.00–9.64]	<0.001 *
	% high TQ	50.5 %	64.2 % [56.6–71.2]	63.4 % [53.3–72.5]	0.00 % [0.00–10.7]	0.00 % [0.00–9.64]	<0.001 *
6 MONTHS AFTER BASELINE	MAM (h)	5.53 ± 2.56	6.84 ± 1.58	5.66 ± 1.97	1.27 ± 2.09	3.04 ± 1.90	<0.001 *
	Leaks (l/min)	18.5 ± 12.9	17.4 ± 12.6	18.6 ± 12.7	25.9 ± 18.7	20.4 ± 10.9	0.1989
	AHI_{PAP} (events/h)	2.20 ± 2.55	2.13 ± 2.42	2.00 ± 2.42	3.03 ± 2.70	2.74 ± 3.27	0.4174
	NWC	4.76 ± 8.73	0.81 ± 3.40	3.68 ± 6.08	19.8 ± 12.7	12.0 ± 8.48	<0.001 *
	% adherent	68.1 %	91.4 % [86.0–94.8]	69.9 % [59.9–78.3]	6.25 % [1.73–20.2]	13.9 % [6.08–28.7]	<0.001 *
	% high QT	42.4 %	57.4 % [49.7–64.8]	45.2 % [35.4–55.3]	0.00 % [0.00–10.7]	5.56 % [1.54–18.1]	<0.001 *
12 MONTHS AFTER BASELINE	MAM (h)	5.77 ± 2.58	7.15 ± 1.51	5.92 ± 1.83	1.10 ± 1.98	3.29 ± 1.83	<0.001 *
	Leaks (l/min)	17.2 ± 12.4	16.4 ± 12.1	17.3 ± 13.6	20.4 ± 12.6	19.7 ± 10.1	0.2094
	AHI_{PAP} (events/h)	2.22 ± 2.83	2.10 ± 2.25	2.07 ± 2.76	4.54 ± 6.04	2.31 ± 3.45	0.7127
	NWC	5.01 ± 8.98	0.86 ± 2.38	3.80 ± 5.66	21.9 ± 13.2	11.8 ± 9.15	<0.001 *
	% adherent	70.3 %	93.8 % [89.0–96.6]	73.1 % [63.3–81.1]	3.12 % [0.55–15.7]	16.7 % [7.87–31.9]	<0.001 *
	% high TQ	47.68 %	64.8 % [57.2–71.8]	49.5 % [39.5–59.4]	0.00 % [0.00–10.7]	8.33 % [2.87–21.8]	<0.001 *

Legend: CPAP: Continuous Positive Airway Pressure; MASD: Monthly Adherence Standard Deviation; MAM: Monthly Adherence Mean; AHI_{PAP}: Device-reported residual Apnea-Hypopnea Index; TQ: Treatment Quality; NWC: Nights Without CPAP. Leaks: 95th percentile leaks. Leaks and $AHIP_{AP}$ values are expressed as monthly means. Categorical/binary data are presented as n% [95 % confidence intervals calculated using the Wilson method]; continuous data are presented as mean ± standard deviation. p = p-value of the association across all groups, obtained using weighted linear regression for continuous data and weighted logistic regression for binary data. *p-value <0.05.

The proportion of patients who changed mask type during the monitored year was 13.9% in the construction set and 12.1% in the test set. In the construction set, the distribution across clusters was as follows: Cluster 1 12.4 %, Cluster 2 13.3 %, Cluster 3 14.1 %, and Cluster 4 23.0 %. In the Test set, the proportions were similar: Cluster 1 9.3 %, Cluster 2 14.0 %, Cluster 3 6.3 %, and Cluster 4 25.0 %.

5. Discussion

The objective of this study was to detect from baseline telemonitoring data, with a simple feature, patients at risk of non-adherence. This was achieved by analyzing the variability of the adherence time series, using the standard deviation. For each patient, the MASD at baseline was calculated, and a threshold was defined on this feature by evaluation of the ROC curve, which was found to be 1.76 h. The patients were divided into four groups according to the MAM (threshold of 4 h/night) and MASD (threshold of 1.76 h). This division revealed statistically significant differences in the utilization of CPAP over the course of the following year (as detailed in the Results section), thereby reinforcing the hypothesis that variability of use may influence the adherence to device use. Eguchi et al. [9] analyzed data from a small population of 219 CPAP-treated patients and found that the standard deviation of daily usage duration in a week possibly correlates to poor CPAP adherence.

The innovative element of this study is the introduction of the MASD as an additional parameter for the characterization of the quality of adherence to CPAP treatment, a subject which has not been explored in other studies to date. The threshold on the standard deviation made possible the distinction of the patients, who would be traditionally divided into two groups by the threshold on the MAM alone (1 and 2 together and 3 and 4 together), into two further groups (separation into groups 1 and 2 but also into 3 and 4), which reported statistically significant differences between them. When patients are grouped using the MAM threshold alone, only two categories emerged: those above and those below 4 h/night. In contrast, the four-group stratification based on both MAM and MASD revealed additional and statistically significant distinctions—particularly between patients with similar MAM values but different MASD (e.g., Group 1 vs. Group 2 and Group 3 vs. Group 4).

A statistically significant difference was observed in the Test set between Groups 1 and 2 (p-values <0.001) in terms of MAM, monthly NWC, and percentage of adherent patients 6 and 12 months after baseline. The strength and innovation of the standard deviation lie in the presence of these differences, which would not have been identified through the application of a single threshold on the mean value of adherence. The traditional approach lacks the capacity to stratify patients who have a monthly adherence value above the threshold yet have achieved it through different trends. In the Test set, Group 2 (baseline MASD: 6.45 ± 1.25 h), in comparison to Group 1 (baseline MASD: 7.38 ± 1.36 h), consisted of patients who demonstrated a substantially more variable adherence trend between days at the baseline, yet still surpass the mean value threshold of 4 h/night. This group reported lower mean values of adherence and percentage of adherent patients and higher monthly NWC, in comparison to Group 1. This information suggests a possible link between higher variability and reduced adherence to

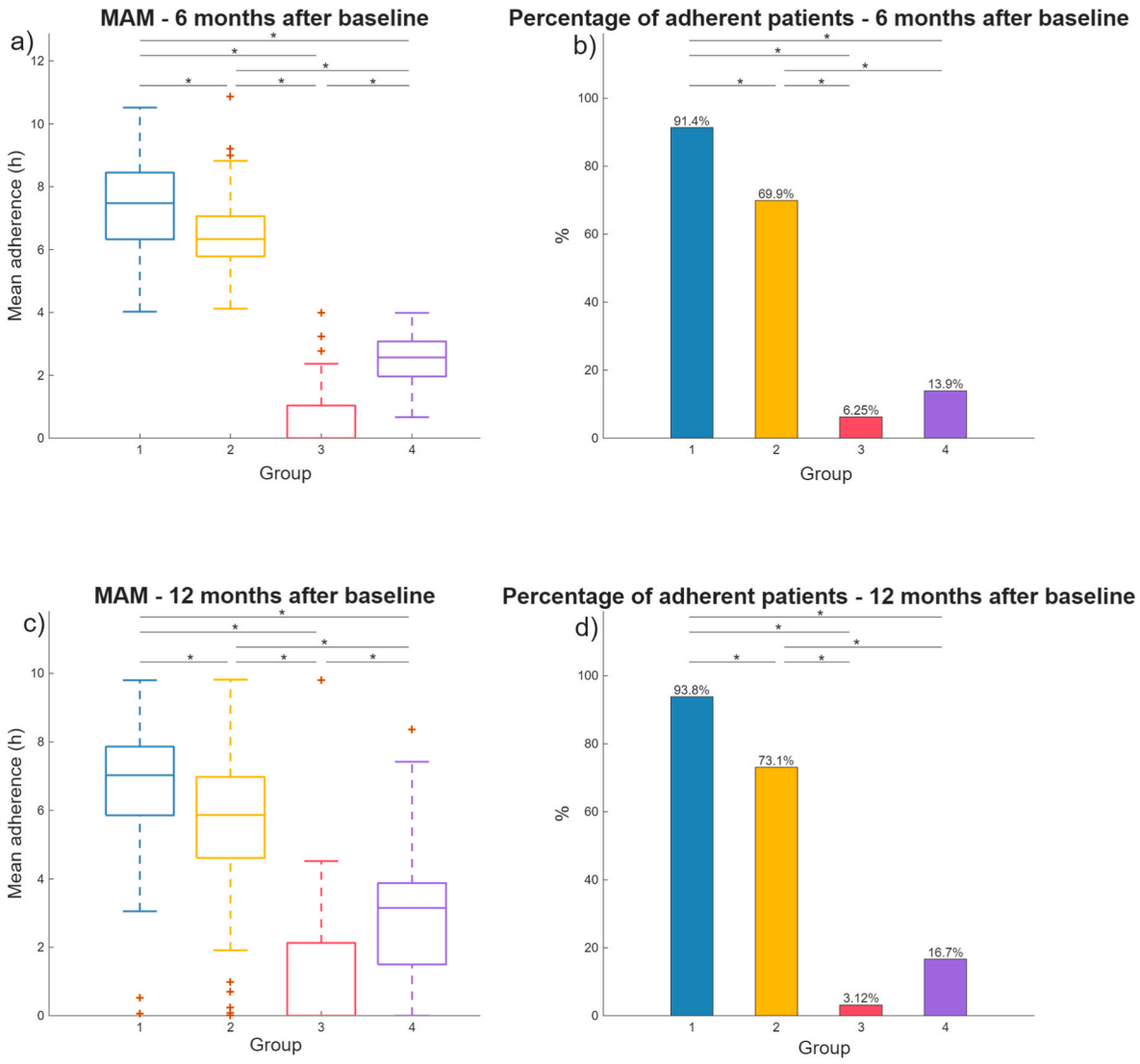

Fig. 2. MAM and percentage of adherent patients 6 and 12 months after baseline.
- Blue: group 1: MAM ≥ 4 h and MASD <1.76 h at the baseline time point. Yellow: group 2: MAM ≥ 4 h and MASD ≥1.76 h at the baseline time point. Red: group 3: MAM < 4 h and MASD ≥1.76 h at the baseline time point. Purple: group 4: MAM < 4 h and MASD ≥1.76 h at the baseline time point. In the boxplots, the central line indicates the median, while the bottom and top edges of the box correspond to the 25th and 75th percentiles, respectively. Whiskers extend to the most extreme data points not considered outliers, which are shown individually using the '+' marker. Statistical differences between groups were assessed using pairwise weighted linear regression for continuous mean adherence values and pairwise weighted logistic regression for the binary adherence label. When significant differences ($p < 0.05$) were found between two groups, they were indicated with a horizontal bar and an asterisk (*).

treatment. The clinical utility of this information is the possible stratification by clinicians of their attention: patients who report low MASD (<1.76 h) and with a MAM above the threshold (≥4 h/night) can be given lower monitoring priority than patients who report a more variable adherence trend (≥1.76 h) and with a mean value above the threshold since the former have a probability of adherence after 12 months of 93.8 % and the latter of 73.1 %.

The marked difference between Group 2 and Group 3 confirmed the power previously emphasized by numerous studies [10–13] of the threshold on the mean value of 4 h/night in predicting adherence over time.

Significant differences emerged, in the Test set, between Group 3 (baseline MASD: 0.67 ± 1.09 h) and Group 4 (baseline MASD: 2.52 ± 0.91 h) that would not be captured by the threshold on the mean value of adherence alone. In particular, statistically significant differences (*p*-values <0.001) were found for the MAM and for monthly NWC 6 and 12 months after baseline. In contrast to the trend observed between Groups 1 and 2, the group with lower mean monthly adherence values and higher monthly NWC between Groups 3 and 4 was Group 3. This suggests, in this case, a possible link between higher variability and higher adherence to treatment. Patients classified in Group 4 exhibited higher MAM at 6 and 12 months compared with those in Group 3. This finding may suggest that Group 4 patients, although using their CPAP device on fewer nights, tended to use it for longer durations when they did, possibly allowing them to perceive the clinical benefits of therapy more clearly. Social factors may also contribute to variability in CPAP use, such as childcare responsibilities, family caregiving duties, or irregular work schedules. These factors can influence usage patterns without necessarily reflecting problems with treatment tolerability or efficacy. Conversely, patients in Group 3 appeared to use their CPAP more consistently but with lower mean adherence, likely insufficient to achieve a meaningful therapeutic effect, which might have limited their motivation to maintain treatment over time. The higher variability observed in group 4 is consistent with the higher proportion of patients who changed masks, suggesting greater discomfort or difficulties tolerating positive airway pressure therapy. This observation highlights the

importance of not only monitoring average adherence but also considering variability in night use and interface stability, as these factors may reveal different adherence trajectories and underlying barriers to long-term treatment success.

Patients with low MASD (<1.76 h) and MAM below the threshold (<4 h/night) are, among all, those most in need of attention.

Intervention in patients at high risk of non-adherence is crucial [14]. These patients could benefit from intensified follow-ups, therapeutic education, and coaching on the importance of regular sleep patterns and CPAP adherence. Since the clinical workload for clinicians and technicians responsible for fine-tuning device settings and adapting them to patients' needs is high, it can be focused on a smaller subgroup of the macro-categories defined by a single mean value threshold. The standard deviation retains the simplicity of calculation, intuitiveness and easy extraction (automatically by the device) from the telemonitoring data.

Adherence standard deviation may reflect a psychological or behavioral trait associated with mean adherence. Type D personality, characterized by negative affectivity and social inhibition, is prevalent in a significant portion of OSA patients and is associated with lower adherence rates and a higher likelihood of treatment discontinuation [15]. Regular and consistent CPAP use may indicate patients with better sleep routines and more structured habits. These traits not only facilitate better CPAP adherence but also extend adherence to other treatments and medications. It is well established from both cardiovascular [16] and non-cardiovascular [17] clinical trials that adherence per se, including adherence to placebo, is associated with markedly improved health outcomes, an effect that is often substantially larger than that of active therapy. On the other hand, irregular CPAP use may reflect poor sleep routine, frequent awakenings, or irregular sleep schedules, which increase opportunities to discontinue the device. Frequent disruptions during sleep may make it harder for patients to adapt to CPAP therapy, further reinforcing irregular patterns of use [18].

6. Limitations and future perspectives

One limitation of this study is the lack of data regarding patients' initial clinical characteristics, including baseline AHI, severity, sleepiness, psychological considerations and BMI. Secondly, CPAP settings (e.g., pressure), all of which could have diverse impacts on CPAP adherence, are missing. A further limitation of this study is that the baseline month (first month of data collection) doesn't coincide with the first month of CPAP use. Future research is needed to determine whether the same threshold identified here also apply to the first weeks or months of treatment.

The CPAP initiation date is known, but is unclear whether patients had previously been treated with CPAP and discontinued it before starting again.

Another limitation is that in order to prevent interpretation based on missing data, patients with missing data over at least one period over the three were removed from the database during the preprocessing. Potential causes of missing data include technical transmission failures—resulting in the absence of usage information—or complete discontinuation of device use by the patient.

7. Conclusion

This study demonstrates an association between a new variable—monthly adherence standard deviation—and both adherence and quality treatment in a CPAP-treated population with a treatment duration of more than four months but less than a year. It is also a prognostic indicator of stability and high treatment quality at 1 year. CPAP telemonitoring could integrate this new variable to focus on patients at high risk of poor-quality treatment, enabling detection and intervention. Although the present study design does not allow conclusions about the early phase of adherence, the findings suggest that, among patients who have already passed the initial adaptation period, this metric could be useful for guiding the frequency of long-term follow-up. Specifically, within the high mean adherence group, greater variability in adherence emerged as a predictor of poorer outcomes, whereas in the low mean adherence group, lower variability was associated with the worst results.

CRediT authorship contribution statement

Benedetta Giachetti: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Clément Blanloeil:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization. **Elena Mugellini:** Writing – review & editing, Supervision. **Marco Ghislieri:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Dany Jaffuel:** Writing – review & editing. **Frédéric Gagnadoux:** Writing – review & editing. **Arnaud Prigent:** Writing – review & editing, Writing – original draft, Validation, Supervision, Methodology, Conceptualization.

Data sharing statement

The data underlying this article (deidentified participant data, data analysis plan) will be shared (after publication) on reasonable request to the corresponding author, with a signed data access agreement.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used ChatGPT-4o in order to improve the readability and language of the manuscript. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

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FG reports personal fees from RESMED, INSPIRE MEDICAL, SEFAM, BIOPROJET, CIDELEC for lectures, presentations, speakers bureaus, manuscript writing or educational events, outside the submitted work. FG reports personal support for attending meetings and/or travel, outside the submitted work.

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