ORIGINAL PAPER

A Multivariate Study on the Adherence With Non-invasive Ventilation in People With Obstructive Sleep Apnea

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ABSTRACT

Background: Obstructive Sleep Apnea (OSA) is a sleep disorder that affects a significant number of people worldwide. While Continuous Positive Airway Pressure (CPAP) devices have been proven to be effective in relieving symptoms, ensuring consistent use of those devices throughout the year can be challenging for a lot of patients. **Objective:** The present quantitative observational study in non-invasive ventilation for OSA patients explores adherence and attempts to identify independent predicting factors and year-round adherence differences in a large sample of OSA patients from Greece. **Methods**: Data from 1987 OSA patients using Continuous Positive Airway Pressure (CPAP) devices were collected in 2023. Factors evaluated in the study included the Apnea-Hypopnea Index (AHI), mask type, mask leaks and hours of CPAP device usage. **Results:** The majority were males (77.2%), aged over 60 years (57.9%). CPAP use varied, with 14.0% in their first year, 44.2% for 2-4 years, and 41.7% for <4 years. Adherence was highest in more than 4 years users (54.9%) and nasal/pillow mask users (59.1%). Seasonal adherence varied, with summer having the most non-adherent patients (32.8%). Multinomial logistic regression showed BMI, mask type and seasonal severity influenced adherence. Full-face masks positively impacted adherence (OR=0.585, p=0.001). Non-adherence was associated with higher mask leaking in spring (OR=3.051, p=0.018) and usage of CPAP for < 4 years (OR=3.855, p=0.001). For 50% and 75% adherence, seasonal mask leaking and usage duration influenced adherence. **Conclusion:** CPAP device data can provide valuable insights to OSA therapy compliance. Seasonality plays an important role in adherence to the CPAP device use as is the type of mask with relation to air leaking.

Keywords: Continuous positive airway pressure, Obstructive Sleep Apnea, Seasonal adherence, CPAP Compliance.

1. BACKGROUND

Obstructive Sleep Apnea (OSA) is becoming more prevalent with approximately 1 billion people affected (1). OSA is a sleep disorder in which breathing is repeatedly interrupted during sleep because the upper airway becomes temporarily collapsed or blocked with a complex pathophysiology (2). OSA is characterized by brief periods of cessation of airflow, resulting in fragmented sleep patterns and potential disruptions in the supply of oxygen to the body. Untreated OSA has been linked to various comorbidities such as cardiovascular problems (3, 4), cognitive impairment (5), and nonalcoholic fatty liver disease (6).

Continuous positive airway pressure (CPAP)

So far one of the best therapy options include Continuous Positive Airway Pressure (CPAP) devices that alleviate the symptoms while asleep (7). CPAP is widely regarded as the most effective treatment for OSA (1, 2, 8), as it has been shown to improve sleep-related symptoms and quality of life. It is particularly effective in reducing the Apnea-Hypopnea Index (AHI), which measures the number of apneic and hypopneic events per hour of sleep, especially in patients with severe symptoms of OSA (AHI ≥30 per hour) (3, 4). Furthermore, CPAP has been found to reduce both objective and subjective sleepiness when compared to non-OSA subjects (4, 5).

It has been noted that the use of CPAP may present certain challenges, such as discomfort or feelings of claustrophobia caused by the mask, as well as lifestyle or social factors, or a combination of these (8). Additionally, studies have shown that adherence to CPAP therapy may vary seasonally, further compounding the aforementioned challenges (6). Compliance with the therapy regime of using the device for at least 4 hours each night, though the different seasons, is not easily achieved for a large number of patients (9).

2. OBJECTIVE

The present quantitative observational study in non-invasive ventilation for OSA patients explores coherence and tries to identify independent predicting factors and year-round adherence differences in a large sample of OSA patients from Greece.

3. MATERIAL AND METHODS

Participants

The study population consists of Greek patients diagnosed with OSA and using a Continuous Positive Airway Pressure (CPAP) device. An initial subgroup of 954 patients participated in the pilot study in order to explore seasonal adherence to CPAP therapy (9). The present study utilises the final dataset from an extended sample of 1987 patients with full twelve months monitoring using Continuous Positive Airway Pressure (CPAP) therapy.

A wireless Type III portable sleep monitor was used to aid the diagnosis by their designated physician. Weekly data for all twelve months of the study in 2023, were collected, with patient consent, in-outpatient follow-up visits from the CPAP device's Secure Digital (SD) memory card that the patients brought with them. All relevant demographic information were recorded, in addition to AHI (Apnea-Hypopnea Index) per hour of sleep, mask type (nasal, oral), mask losses (leaks) and hours of use to measure therapy adherence. CPAP patents were considered those that had at least 112 hours of use within a month, with at least 4 hour of use for 20 days per month.

Exclusion criteria

Exclusion criteria were maintained throughout the study namely, at least a 2-year OSA diagnosis, adults of 18 years of age or more, with explicit consent neuromuscular problems, surgical procedures up to 1 year prior to recruitment and being on systematic corticosteroid use were the exclusion criteria.

Procedure and ethical considerations

The present observational study was conducted in two public hospitals' sleep out-patients in Thessaloniki, Greece, after receiving permission from the University of Western Macedonia and the hospitals' Research Ethics Committees. Written consent from all patients was obtained, and all details were anonymized while adhering to GDPR guidelines (2016/679, "GDPR").

Statistical analysis

The study ultimately comprised 1987 subjects, including 951 patients in the final analysis of the seasonal study (9). Data pre-processing was performed with Python (v3.10.16) programming language and ipython v8.0.0, jupyterlab v3.2.8, numpy v1.22.4 and pandas v1.5.2. as main libraries.

Categorical parameters		N	%	χ2 test (p-value)
Gender	Male	1533	77.2%	
	Female	454	22.8%	<0.001
Age groups	<40 years old	68	3.4%	
	40-59 years old	769	38.7%	
	60 years old & above	1150	57.9%	
Years of use group	1 year	279	14.0%	<0.001
	2-4 years	879	44.2%	
	> 4 years	829	41.7%	
Mask type	Full Face	696	35.0%	
	Nasal/Pillows	1291	65.0%	<0.001
Device type	CPAP	564	28.4%	
	Auto CPAP	1306	65.7%	<0.001
	Bilevel device	117	5.9%	
Seasonal Adherence				
Spring	No	584	29.4%	
	Yes	1403	70.6%	
Summer	No	651	32.8%	
	Yes	1336	67.2%	
Autumn	No	560	28.2%	<0.001
	Yes	1427	71.8%	
Winter	No	550	27.7%	
	Yes	1437	72.3%	
Total Adherence %	0%	286	14.4%	
	25%	203	10.2%	
	50%	186	9.4%	
	75%	220	11.1%	<0.001
	100%	1092	55.0%	

Continuous parameters	Mean	±SD	One sample Kolmogorov – Smirnov test (p-value)
Age	61.90	12.05	<0.001
BMI	29.66	3.52	<0.001
Mean AHI Summer	2.22	3.95	<0.001
Mean AHI Winter	2.24	4.02	<0.001
Mean AHI Spring	2.10	3.76	<0.001
Mean AHI Autumn	2.24	4.19	<0.001
Mean Leaking Spring (l/mins)	0.32	0.31	<0.001
Mean Leaking Summer (l/mins)	0.35	0.31	<0.001
Mean Leaking Autumn (l/mins)	0.34	0.31	<0.001
Mean Leaking Winter (l/mins)	0.33	0.30	<0.001

Table 1. Descriptive statistics and CPAP measurement comparisons for all patients

A) Demographical Factors		Total Adherence %										
		0%		25%		50%		75%		100%		χ^2
		N	N %	N	N %	N	N %	N	N %	N	N %	(Cramer's V, p-value)
Years of use group	1	44	15.4%	34	16.7%	39	21.0%	27	12.3%	135	12.4%	(0.232, <0.001)
	2-4	187	65.4%	133	65.5%	97	52.2%	105	47.7%	357	32.7%	
	> 4	55	19.2%	36	17.7%	50	26.9%	88	40.0%	600	54.9%	
Mask type	Full Face	84	29.4%	61	30.0%	39	21.0%	65	29.5%	447	40.9%	(0.145, <0.001)
	Nasal/Pillows	202	70.6%	142	70.0%	147	79.0%	155	70.5%	645	59.1%	
B) Seasonal Adherence		Total Adherence %										
		0%		25%		50%		75%		100%		Kruskal-Wallis
		N	N %	N	N %	N	N %	N	N %	N	N %	(p-value)*
Spring	No	286	100.0%	134	66.0%	98	52.7%	66	30.0%	0	0.0%	<0.001
	Yes	0	0.0%	69	34.0%	88	47.3%	154	70.0%	1092	100.0%	
Summer	No	286	100.0%	181	89.2%	117	62.9%	67	30.5%	0	0.0%	<0.001
	Yes	0	0.0%	22	10.8%	69	37.1%	153	69.5%	1092	100.0%	
Autumn	No	286	100.0%	182	89.7%	80	43.0%	12	5.5%	0	0.0%	<0.001
	Yes	0	0.0%	21	10.3%	106	57.0%	208	94.5%	1092	100.0%	
Winter	No	286	100.0%	112	55.2%	77	41.4%	75	34.1%	0	0.0%	<0.001
	Yes	0	0.0%	91	44.8%	109	58.6%	145	65.9%	1092	100.0%	
C) CPAP measurements		Total Adherence %										
		0%(a)		25%(b)		50%(c)		75%(d)		100%(e)		Kruskal-Wallis
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	(pair) (p-value) *
Mean AHI Spring		2.06	3.28	2.35	3.8	1.64	2.3	2.47	3.57	2.07	4.09	(c-d) 0.086, (e-d) 0.089
Mean AHI Summer		2.09	3.46	2.41	3.58	1.8	2.53	2.51	3.91	2.23	4.32	0.219
Mean AHI Autumn		1.99	3.46	2.4	3.57	2.01	2.56	2.59	4.1	2.25	4.68	0.136
Mean AHI Winter		2.02	3.43	2.36	3.41	1.92	2.14	2.48	4.39	2.28	4.41	0.155
Mean Leaking Spring		0.37	0.32	0.35	0.30	0.31	0.31	0.33	0.34	0.31	0.31	(a-e) 0.001
Mean Leaking Summer		0.39	0.32	0.38	0.32	0.33	0.31	0.34	0.32	0.33	0.30	(a-e) 0.0024
Mean Leaking Autumn		0.36	0.33	0.36	0.33	0.35	0.31	0.33	0.33	0.33	0.30	0.289
Mean Leaking Winter		0.34	0.33	0.37	0.30	0.35	0.30	0.30	0.32	0.32	0.29	(b-d) 0.009

Table 1. Descriptive statistics and CPAP measurement comparisons for all patients

The data from the study were analysed across four seasons (Spring–Summer–Autumn–Winter), inclusive of two days in March 2023 to ensure a full four-week month. OSA severity as represented by the AHI index, was grouped as no AHI (0-0.99), Mild AHI (1-3.99) and Severe AHI (≥4).

Statistical analysis was conducted using IBM SPSS Statistics for Windows, Version 26.0. (Armonk, NY: IBM Corp) software. Continuous data are presented as means and standard deviations (SDs), and categorical data are reported as percentages. As data did not follow normal distribution, differences between means were assessed using chi-squared test (Cramer's V), Mann-Whitney U, Kruskal-Wallis, and Wilcoxon signed pairwise rank tests, as appropriate, between adherent and non-adherent patients.

Multinomial logistic regression models adjusted for Age, BMI and Gender, were used to determine the independent factors associated with CPAP adherence. For all tests, only p values < 0.05 were considered statistically significant.

4. RESULTS

Demographic and clinical characteristics

Out of the 1987 patients 1533 were male (77.2%), aged 60 years or above (57.9%, (n= 1150) with a sizable percentage being between 40-59 years old (38.7%) with a general mean age of 61.9 (±12.5) years old. Patients on their first year with the CPAP device are the smallest group (14.0%, n=279), while 44.2% (n=879) and 41.7% (n= 829) of the patients have used a CPAP device for 2-4 and less than 4 years, respectively. Most patients used Auto CPAP type (65.7%, n= 1306) and the majority used it with a nasal or nasal with pillow masks (65.0%, n= 1291). A borderline majority (55.0%, n=1092) were fully adherent to their use of the CPAP device following the recommended weekly and daily usage hours, while the remaining patients were almost equally split between varying levels of adherence with a 14.4% (n=286) of them being non-adherent. Seasonal adherence varied, with most of the patients being adherent in any given season, with summer being the season with the most non-adherent patients (32.8%, n= 651). Mean AHI and mask leaking were statistically different between all seasons (p<0.001). Patient demographics are presented in Table 1.

Stratifying patients, by their adherence, allowed for sea-

Total Adherence %(a)		Sig.	Odds Ratio (OR)	95% CI for OR	
				□95% CI	□95% CI
0%	Intercept	0.001			
	Mean Leaking Spring	0.018	3.051	1.252	7.433
	Full Face Mask	0.001	0.585	0.433	0.791
	1 Years of use	0.001	3.855	2.468	6.021
	2-4 Years of use	0.001	5.904	4.234	8.234
25%	Intercept	0.001			
	BMI	0.038	1.046	1.00	1.095
	Mean Leaking Autumn	0.059*	0.281	0.079	1.008
	Mean Leaking Winter	0.028	2.827	1.065	7.501
	Full Face Mask	0.005	0.586	0.416	0.825
	1 Years of use	0.001	4.329	2.595	7.222
	2-4 Years of use	0.001	6.274	4.228	9.311
50%	Intercept	0.003			
	Mean Leaking Spring	0.097*	2.439	0.826	7.205
	Spring severity	0.046	0.703	0.478	1.033
	Full Face Mask	0.001	0.377	0.255	0.556
	1 Years of use	0.001	3.277	2.049	5.242
	2-4 Years of use	0.001	3.322	2.291	4.817
75%	Intercept	0.001			
	Mean Leaking Spring	0.055*	2.557	0.982	6.658
	Full Face Mask	0.001	0.542	0.39	0.751
	2-4 Years of use	0.001	2.06	1.501	2.827

Table 3. Bootstrapped# Multinomial logistic regression significant parameters. Independent statistically significant and borderline factors for each of the Adherence categories.

sonal adherence pattern and CPAP measurements comparisons. Table 2, has the all the relevant stratified data and the statistically significant differences for seasonal adherence seems to be different according to years of use. Highest adherence was evident in the >4 years usage group of patients with 54.9% (n= 600) of them being 100% adherent compared to 32.7% (n= 657) for the 2-4 years users and only 12.4% (n=135) for the new users (p<0.001).

Also, the nasal/pillow type of mask might be a better promoter of adherence with 59.1% of patients (n=645) being 100% adherent compared 40.9% (n=447 (p<0.001).

Semi adherent patients (50-75%) were more adherent in Autumn and Winter, while low adherence (25% adherence) patients were mostly adherent in Winter (p<0.001). These results with their relevant percentages are better depicted in Table 2.

A multinomial logistic regression with stratified bootstrapping adjusted for age and gender, was performed to ascertain the effects of BMI mask type and seasonal severity, on Total Adherence percentage. Table 3 presents all the details with the statistically significant and borderline significant independent factors and their odds ratios. The logistic regression model was statistically significant (χ^2=322.122 p<0.001, Cox-Snell's R=0.150), with a good fit model as indicated by the lack of statistical significance of the Pearson goodness of fit test with p=0.352.

Totally, non-adherent patients, that did not manage to fulfil the required usage hours in any of the seasons, were affected by higher mask leaking in spring (March – May) (OR=3.051 95% CIs 1.252-7.433. p=0.018), or have used the CPAP device only a single year or up to 4 years (1 year OR=3.855 95% CIs 2.468-6.021. 2-4 years OR=5.904 95% CIs 4.234-8.234 p=0.001). Use of full-face mask had a large positive effect towards adherence (OR=0.585 95% CIs 0.433-0.791. p=0.001). Higher adherence patients still have the full mask positive effect almost with identical OR as seen it Table 3.

The 25% adherence group differs, with seasonal mask leaking for autumn and winter this time being negatively influencing adherence and higher BMI also is a mild negative influence. Having used the CPAP device only a single year or up to 4 years also has negative influence with higher ODs. Table 3 has the ODs and significances.

For 50% adherence, meaning 2 out of 4 seasons the patient followed the usage guidelines. Negatively influencing factors were almost the same but with lower ODs. The springtime OSA severity has a positive effect in adherence. Mask leaking in spring is borderline significant with a high OD, but lower than previously.

Finally for 75% adherent patients, mask leaking in spring is borderline significant with a high OD similar to 50% and being a 2–4 years user also has a negative effect in adherence. Table 3 has the ODs and significances.

Figure 1 has all the relevant plots of the mean mask leaking (l/mins), Seasonal OSA Severity using Mean AHI and years of use by Total Adherence groups to illustrate the effects they have in adherence.

5. DISCUSSION

The demographic and clinical characteristics of 1987 patients with Obstructive Sleep Apnea provide a comprehensive overview and reveal interesting patterns and associations within CPAP adherence. The predominantly male cohort (77.2%), with a significant proportion aged 60 years or older (57.9%), represents a demographic bias towards older men (10-12). This demographic trend is consistent with recent research highlighting the increasing prevalence of OSA in the ageing population (12, 13).

The highest adherence rates are observed in patients with more than four years of CPAP use (54.9%), highlighting the positive impact of prolonged engagement with the device and mask apparatus. It is documented that long term- adherence is higher if the patient has initially complied throughout their first year (14) thus familiarisation with the apparatus helps.

The prevalence of automatic CPAP devices (65.7%) and the common use of nasal or nasal pillow masks (65.0%) are in line with current trends in CPAP technology and interface preferences (15-17). The significance of these demographic and usage characteristics could be of use in tailored interventions and patient-centred care regimes.

Seasonal adherence patterns provide an interesting dy-

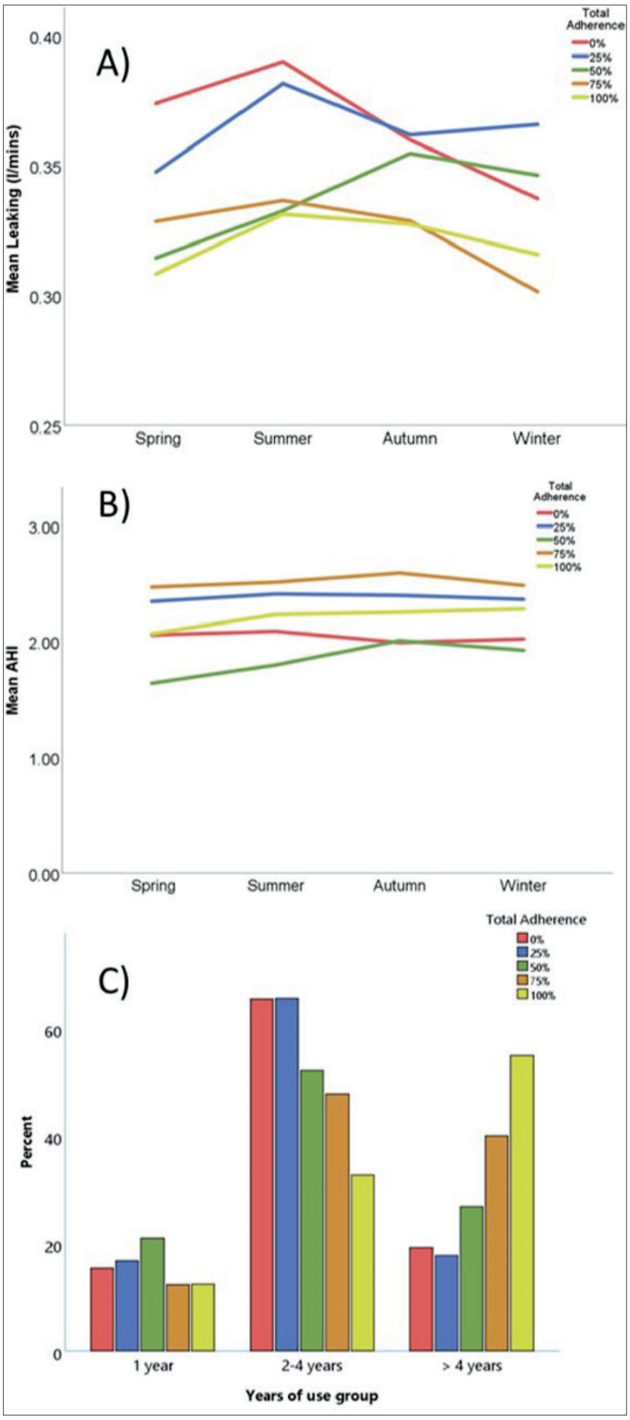

Figure 1. A) Mean mask leaking (l/mins) in all 4 seasons for all patients grouped for adherence. The axis starts at 0.25. B) Mean AHI in all 4 seasons for all patient grouped for adherence. C) Total adherence per years of use.

namic, with the highest non-adherent rates (32.8%) occurring in summer. The observed variation is consistent with existing literature highlighting the influence of environmental factors on CPAP adherence, and calls for a closer examination of potential barriers during warmer seasons (6, 9). The statistically different mean mask leakage variability, between all seasons ($p<0.001$) highlights the need for a season-specific approach to addressing OSA severity and mask-related issues. Mask leaking is a well-known issue for adherence (18, 19) but not previously connected to seasonal effects. Solutions aimed at controlling mask humidity (20) as well as temperature could be of use despite some controversy (21).

The multinomial logistic regression models highlight these factors that seasonally affect Total Adherence. The models were all corrected for age, gender and BMI. Totally non-adherent patients, that did not manage to fulfil the required usage hours in any of the seasons, were affected by higher mask leaking in spring (March – May). Also, the positive effect of full-face masks on adherence highlights the central role of mask selection in shaping patient coherence to therapy. The potential impact of seasonal variations on mask performance and patient adherence is highlighted by the association between non-adherent and higher mask leakage in spring. Finaly it is noteworthy that the 25% adherence group has a unique dynamic, with seasonal mask leakage in the autumn and winter having a negative impact on coherence to therapy.

Thus, this study highlights the importance of customized interventions during those particular seasons, especially, since the fact that mask leaking is seasonally affected and adherence was not affected by the demographics as such, but by the apparatus and its performance throughout the seasons.

This study has some limitations. It is a more localised, albeit large, study in a Mediterranean climate country thus, its conclusions cannot be considered directly comparable to different climate locations as evident in the literature for other studies (14). Also, due to the nature of the monitoring, there was limited information from the patients for their personal reasons for non-adherence.

6. CONCLUSION

CPAP device data can provide valuable insights to OSA therapy adherence. Seasonality plays an important role in adherence to the CPAP device use as is the type of mask with relation to air leaking. Despite its geographical and climate limitations, this study highlights the need for seasonal interventions and shows how seasonality affects patient CPAP adherence.

- **Patient Consent Form:** All participants were informed about the subject of the study.
- **Author's Contribution:** A.K. had substantial contributions to conception and design, to acquisition of data, analysis and interpretation of data, article preparation for drafting or revising it critically and gave final approval of the version to be published; MT,TK, had a part in analysis and interpretation of data, had a part in article preparing for drafting or revising it critically for important intellectual content and gave final approval of the version; MK had substantial contributions to conception and design, had a part in article preparing for drafting or revising it critically for important intellectual content and gave final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- **Conflicts of interest:** There are no conflicts of interest.
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