ORIGINAL PAPER

Monitoring Seasonal Compliance of Patients with Obstructive Sleep Apnea Using CPAP Systems via SD Card

Athanasios Karagiannis[1], Maria Tzitiridou[1], Theodora Kafkia[2], Michael Kourakos[3]

[1]Faculty of Midwifery, University of Western Macedonia, Ptolemaida, Greece

[2]Faculty of Nursing, International Hellenic University, Thessaloniki, Greece

[3] Faculty of Nursing, University of Ioannina, Greece

Corresponding author: Athanasios Karagiannis, PhD(c), Faculty of Midwifery, University of Western Macedonia, Address: Keptse, Ptolemaida, 50200, Greece. Phone: +30 6946644003. E-mail::sakis_karag@hotmail.gr. **ORCID ID: 0009-0007-3211-0991**

doi: 10.5455/aim.2023.31.96-101

ACTA INFORM MED. 2023 JUN 31(2): 96-101

Received: MAY 25, 2023

Accepted: JUN 22, 2023

ABSTRACT

Background: Obstructive sleep apnea (OSA) is a common disorder characterized by recurrent upper airway collapse during sleep, leading to neurological and cardiovascular adverse effects. **Objective:** The present study aimed to explore seasonal compliance with Continuous Positive Airway Pressure (CPAP) therapy among OSA patients in Greece. **Methods**: Data from 954 OSA patients using CPAP devices were collected during summer and winter months. Factors evaluated included the Apnea-Hypopnea Index (AHI), mask type, mask leaks, and hours of CPAP device usage. **Results:** The majority of patients were male (78.2%) and aged 60 years or above (58.5%). Most patients had been using CPAP for over 2 years (82.8%), with auto CPAP devices and nasal or pillow masks being most common. Compliance was observed in 57.7% of patients, while 22.1% were non-compliant. A significant number of patients (8.2% and 12%) were compliant only in summer or winter, respectively. Compliance was influenced by duration of CPAP use, BMI up to 25, and the use of nasal/pillow masks. Higher compliance was associated with lower summer severity and both low and severe winter severity. Logistic regression analysis confirmed these findings. **Conclusion:** The findings suggest that utilizing CPAP device data can provide actionable insights on seasonal compliance among OSA patients. Summer compliance is lower, and the use of nasal/pillow masks and auto CPAP devices is recommended for improved compliance.

Keywords: Continuous positive airway pressure, Obstructive Sleep Apnea, Seasonal compliance.

1. BACKGROUND

Obstructive Sleep Apnea (OSA) is a prevalent disorder that can occur with or without symptoms and is associated with significant neurocognitive and cardiovascular adverse effecs (1). OSA is characterised by recurrent partial or complete collapse of the upper airway during sleep. This leads to episodic reduction (hypopnea) or cessation (apnea) of airflow despite respiratory effort (2) . Obstructive sleep apnoea results in intermittent hypoxaemia, sleep fragmentation and wide variations in intrathoracic pressure initiating a cascade of adverse health outcomes (3).

There is evidence to suggest that OSA is a major contributor to poor health outcomes and that therapeutic interventions promote the minimisation of the problems it causes and the improvement of sleep-related quality of life (4). As OSA is likely to become a growing global problem in the coming years (2, 5), effective treatment of OSA could provide an approach to reducing the associated healthcare costs and the negative effects of the condition, such as the cognitive effects of sleepiness (6).

Treatment- Continuous positive airway pressure (CPAP)

CPAP can improve sleep-related symptoms and quality of life and is considered the gold standard treatment for OSA (7-9). CPAP does indeed reduce the Apnea-Hypopnea Index (AHI), an index that combines the number of apneic and hypopneic events per hour of sleep, especially in patients with severe symptoms of OSA (AHI ≥30 per hour) (10, 11). CPAP also reduces both objective and subjective sleepiness com-

pared to non-OSA subjects (11, 12).

Difficulties in using CPAP can be due to the uncomfortable or claustrophobic nature of the mask, lifestyle or social issues, or a combination of these (8). There are evidence that there are seasonal changes in compliance as well as all the above know difficulties (13).

2. OBJECTIVE

The present quantitative observational study aims to explore the seasonal compliance, as there is very limited evidence, in a large sample of OSA patients from Greece, a Mediterranean climate country, especially between the summer (June, July, August) and winter (December, January, February) months.

3. PATIENTS AND METHODS

Participants

The study population consists of Greek patients diagnosed with OSA and using a CPAP device. Diagnosis was set with a wireless Type III portable sleep monitor for untethered sleep studies by their designated physician (due to the limitations of the COVID-19 pandemic during the patient recruitment phase). Weekly data for the summer and winter months 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. In addition to demographic characteristics and individual history, the main factors evaluated were the average number of respiratory events as measured by the AHI (Apnea-Hypopnea Index) per hour of sleep, mask type (nasal, oral), mask losses (leaks) and hours of use to measure therapy compliance following a CPAP compliance of at least 112 hours within a month and 20 days are >= 4 hours within that month (14).

Exclusion criteria

In order for patients to be included in the study he/she should have been diagnosed with OSA for at least 2 years being more than 18 years of age and have to give consent to be included. Exclusion criteria include that the patient having neuromuscular problems, having had surgical procedure up to 1 year prior to recruitment and being on systematic corticosteroid use.

Procedure and ethical considerations

The present quantitative observational study, was conducted in the sleep laboratories of two public hospitals in Thessaloniki Greece, after having obtained permission from University of Western Macedonia and the hospitals Research Ethics Committees. Patient written consent was obtained from all patients and all details were anonymised and treated according to GDPR guidelines (2016/679, „GDPR").

Statistical analysis

The initial sample size was 954, but the final number for analysis was 951, due to SD card loss of data for some patients. Data collection was done using in house Python scripts and was implemented using the Python (v3.10.16) programming language and the following main libraries: ipython v8.0.0, jupyterlab v3.2.8, numpy v1.22.4 and pandas v1.5.2.

Continuous data were expressed as means and standard deviations (SDs), and categorical data were reported as percentages. The study data were compared among two seasons (Summer of 2022 and Winter of 2022-2023). Categorical data were analyzed using the chi-squared test. As the date did not follow the normal distribution differences between means were assessed with the Mann-Whitney U, Kruscal-Wallis and Wilcoxon signed pairwise rank tests where appropriate, between the compliant and non-compliant patients. Multivariate binary regression models were used to determine independent factors of influence on CPAP compliance. For all tests, p values < 0.05 was considered to be significant. Statistical analysis of the results was carried out using SPSS v26 software for statistical analysis.

4. RESULTS

Demographic and clinical characteristics

Patient demographics are presented in Table 1, the majority of patient were male (78.2%), aged 60 years or more (58.5%). Most patients have used CPAP device for more than 2 years (82.8%), with a 17.2% being on their first year with the device. Regarding the type of device, most patients had an auto CPAP type (64.8%) and the majority used it with a nasal or nasal with pillow masks. A large majority (57.7%) were compliant in their use for the CPAP device following the weekly and daily usage hours, while 22.1% did not comply. A lower but still significant number of patients were compliant only during one season, 8.2% in the summer only and 12% in the winter. No major differences were observed initially for the mean summer and winter weekly usage but a statistical difference can be seen in the daily usage with winter use being an extra hour,

Categorical parameters		N	%	χ^2 test (p-value)
Sex	Male	744	78.2%	<0.001
	Female	207	21.8%	
Age groups	<40 years old	29	3.0%	
	40-59 years old	366	38.5%	<0.001
	60 years old & above	556	58.5%	
Years of use group	0-1 years	164	17.2%	
	2-4 years	386	40.6%	<0.001
	> 4 years	401	42.2%	
Device type	CPAP	267	28.1%	
	Auto CPAP	616	64.8%	<0.001
	Bilevel device	68	7.2%	
Mask type	Full Face	327	34.4%	
	Nasal/Pillows	624	65.6%	<0.001
Seasonal compliance*	No	210	22.1%	
	Summer	78	8.2%	
	Yes Both Seasons	549	57.7%	<0.001
	Winter	114	12.0%	
Continuous parameters		Mean	Standard Deviation	
Age		62.24	11.81	-
BMI		29.73	3.55	-
Mean Summer Weekly hour		185.53	110.53	0.758
Mean Winter Weekly hours		186.73	103.89	
Mean Summer daily hours		5.68	3.39	<0.001
Mean Winter daily hours		6.15	3.43	
Mean AHI Summer		2.24	4.28	0.115
Mean AHI Winter		2.26	4.38	
Mean Leaking Summer (l/mins)		0.36	0.32	<0.001
Mean Leaking Winter (l/mins)		0.33	0.30	

Table 1. Descriptive statistics and pairwise CPAP measurement comparisons for all patients. l/mins= Litres per minutes* Compliance rule: ≥112 hours within a month and 20 days are > 4 hours within that month

		Seasonal compliance								
		No		Summer		Yes Both Seasons		Winter		Cramer's V
			N %		N %		N %		N %	(p –value)
Sex		Male	80.50		76.90		77.80		77.20	0.030 (0.840)
		Female	19.50		23.10		22.20		22.80	
Age groups		<40 years old	2.90		0.00		3.50		3.50	0.049 (0.593)
		40-59 years old	37.60		39.70		37.50		43.90	
		60 years old & above	59.50		60.30		59.00		52.60	
Years of use group		0-1 years	11.40		7.70		16.80		36.80	
		2-4 years	34.80		30.80		45.90		32.50	0.182 (<0.001)
		> 4 years	53.80		61.50		37.30		30.70	
Device type		CPAP	35.70		57.70		21.50		25.40	
		Auto CPAP	60.50		38.50		70.90		61.40	0.178 (<0.001)
		Bilevel device	3.80		3.80		7.70		13.20	
Mask type		Full Face	100.00		16.70		18.90		0.00	0.746 (<0.001)
		Nasal/Pillow mask	0.00		83.30		81.10		100.00	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Kruscal –Wallis p –value
CPAP measure-ments	Mean Summer week (hours)	63.63	54.93	233.82	77.19	253.10	67.39	51.69	39.46	<0.001
	Mean Winter week (hours)	71.71	73.04	37.88	37.76	246.63	62.58	212.02	54.27	<0.001
	Mean AHI Summer	2.46	4.59	3.68	9.63	2.13	3.02	1.36	2.34	<0.001
	Mean AHI Winter	3.00	6.21	1.75	7.92	2.03	2.86	2.34	2.48	<0.001
	Mean Leaking Summer (l/mins)	0.29	0.30	0.40	0.35	0.41	0.31	0.21	0.29	<0.001
	Mean Leaking Winter (l/mins)	0.30	0.32	0.16	0.24	0.37	0.30	0.36	0.27	<0.001

Table 2 Demographics and CPAP measurements by seasonal compliance for all patients. l/mins= Litres per minutes, SD= Standard Deviation

6.15 (±3.43) hours/day in winter from 5.58(±3.339) hours/day in the previous summer. Mean leaking was statistically different between summer and winter by 0.06 l/mins in summer (p<0.001).

Stratifying patients by their compliance allowed for the differences in device mask type and usage to be more prominent. Table 2 has the stratified data and the statistically significant differences. Seasonal compliance seems to be different according to years of use, with patients that use the CPAP device for more than 4 years being less compliant more prominently having only summer compliance or none at all 61.5% and 53.8%, respectively (p<0.001). Also Auto CPAP might be a better promoter of compliance with 70.9% of patient compliant for both seasons using it (p<0.001). But the deciding factor seem to be the type of mask, as the Cramer's V metric a very strong 0.746 (p<0.001) for compliance for patient with nasal/pillow type of mask.

A logistic regression with stratified bootstrapping, was performed to ascertain the effects of age, sex, BMI and mask type, seasonal severity as represented by the AHI index, on the likelihood that participants are fully compliant for both seasons. Table 3 presents all the details. The logistic regression model was statistically significant, χ^2 (12) = 197.844, (p <0.0001) with a good fit model as indicated by the lack of statistical significance of the Hosmer and Lemeshow test with p=0.519. The model explained 25.2% (Nagelkerke R^2) of the variance in CPAP compliance and correctly classified 71.2% of cases. Patients with 2-4 years on CPAP use were 1.70 times more likely to comply for both seasons (p=0.003). Also very importantly BMI was an independent factor of compliance with patients of BMI up to 25 were 4.87 times more likely to comply fully for both seasons (p <0.001). On the same note, patients with nasal/pillow masks were 5.25 times more likely to comply fully for both seasons (p <0.0001). Also OSA severity plays a role for the compliance with summer low severity patient are only 0.52 times likely to comply fully for both seasons (p <0.027) and low and severe winter severity patients are 1.93 (p <0.036) and 2.02 times respectively more likely to comply fully for both seasons (p <0.015). Figure 1 has all the relevant plots of the independent factors.

5. DISCUSSION

Obstructive sleep apnea (OSA) is a common disorder characterized by recurrent collapse of the upper airway during

Omnibus Tests of Model Coefficients

	Chi-square	Degrees of freedom	p-value
Model	197.844	12	0.000

Model Summary

-2 Log likelihood	Cox & Snell R Square	Nagelkerke R^2
1097.708[a]	0.188	0.252

Hosmer and Lemeshow Test of Good fit

Chi-square	Degrees of freedom	p-value
7.168	8	0.519

Independent factors influencing full compliance for both seasons

	p-value*	ODDs Ratio	95% C.I.for ODDs Ratio	
			[illegible]	[illegible]
BMI groups(1) (BMI up to 25)	0.001	4.780	0.681	1.271
Yeas of use group(2) (2-4 years of use)	0.002	1.699	1.231	2.343
Mask type(1) (Nasal/Pillows)	0.001	5.254	3.861	7.150
Summer severity(1) (No AHI†)	0.018	0.518	0.296	0.909
Summer severity(2) (AHI† 1-3)	0.497	0.832	0.489	1.417
Winter severity(1) (AHI† 1-3)	0.036	1.934	1.078	3.470
Winter severity(2) (AHI† above 4)	0.015	2.016	1.159	3.508
Constant	0.001	0.265		

* = Bootstrap corrected p-value, †= respiratory events per hour of sleep

Table 3. Binomial logistic regression model summary and significant factors with ODDs ratios

sleep. It can lead to significant neurological and cardiovascular adverse effects (1). However, OSA often goes undiagnosed and untreated, particularly in developing countries where awareness and resources are limited (15). The prevalence of OSA increases with age and is higher in men than in women, although the association with obesity and male sex decreases with age (16). Continuous positive airway pressure (CPAP) is considered the gold standard treatment for OSA (7-9). However, difficulties in using CPAP can arise due to mask discomfort, lifestyle factors, and seasonal variations in compliance (8, 13).

This study analyzed patient demographics and compliance with continuous positive airway pressure (CPAP) devices for sleep apnea treatment. The majority of patients were male and aged 60 years or more, in agreement with the international prevalence (17). Most patients had used the CPAP device for more than 2 years. Auto CPAP devices (64.8%) and nasal/nasal with pillow masks were commonly used. Compliance rates were as follows: 57.7% fully compliant, 22.1% non-compliant, 8.2% compliant in summer only, and 12% compliant in winter only. Daily CPAP usage differed statistically, with an extra hour used in winter.

Stratifying patients by compliance revealed significant associations with device mask type and usage. In our study it was found that mask leaking was higher in summer in fully compliant patients by 0.4 litres/min more than winter without affecting compliance though. Allergic symptoms such as asthma, upper respiratory infections, nasal congestion, irritation and sneezing, may exacerbate OSA (18). While, upper respiratory problems linked to the use of a CPAP device such as like dry nose, mouth, throat, or nasal congestion and mask leaking could also affect compliance (19). Oronasal full masks capture more moisture leading to higher condensation especially with a temperature differential while also negatively affecting the effective pressure for CPAP through the breathing tube apparatus (20).

Patients using CPAP for over 4 years showed less compliance, predominantly having summer-only compliance or none at all. Auto CPAP devices were associated with higher compliance rates as previously stated (21). Also notably, mask type (nasal/pillow mask) strongly influenced better compliance as opposed to full/oronasal masks. Our results come to verify the results of Borel et al., that nasal masks offer better compliance in different seasons (19).

Logistic regression analysis indicated that patients with 2-4 years of CPAP use, BMI up to 25, and nasal/pillow masks were more likely to comply fully for both seasons. Age and sex were not found to be independent factors for compliance. Thus, our results are in partial agreement with previous evidence from the first Greek OSA study with 98 subjects (22) and an early Turkish study of 71 patients (23) suggesting an association between OSA severity and CPAP adherence that suggest an association with age, sex, BMI, insomnia severity and self-efficacy.

The much larger sample size of the current study, outweighs the different methodologies, thus we believe our results to be more statistically significant in explaining seasonal compliance. We also found that the association with obesity and

male sex decreases with age possibly as social background and lifestyle factors change with getting older (16, 17, 24).

In our results OSA severity also impacted compliance, with summer low OSA severity patients less likely to comply fully for both seasons, while low and severe OSA winter severity patients were much more likely to comply fully for both seasons. Seasonal variations in OSA severity and upper airway symptoms can impact compliance to CPAP treatment as evident by the recent study from Japan (13). Fujino et al (13) suggested that the Japanese patients had higher AHI in summer and so it seems from our own data as well with mean AHI being higher in summer and both season compliant patients.

On the contrary we do not have similar outcome with the study of Cassol et al (25) which found that although the AHI differed significantly among seasons while being highest in winter, their study was of posysomnography and not based on the use of CPAP, in addition it was conducted in Brazil which has a tropical climate rather than the Mediterranean/ Mild climate of Greece, and also semi-opposing seasons. Thus climate and geographical location should be considered before making direct country comparisons.

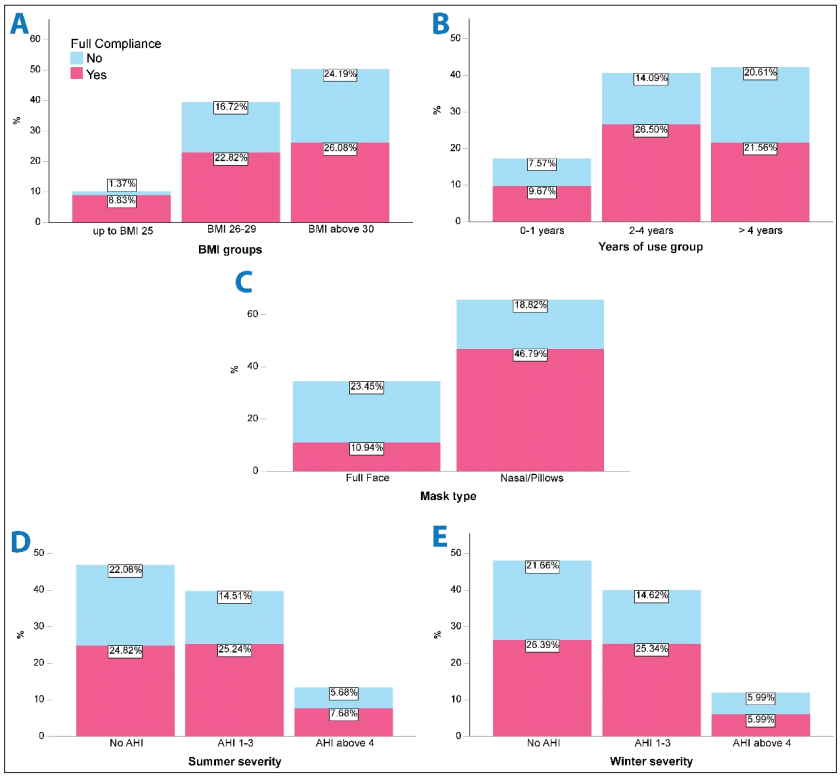

Figure 1. Box plots of Binary linear regression independent factors that affect full patient compliance for the use of a CPAP device in both summer and winter months. A) CPAP Mask type used. D) Summer severity (Mean AHI groups) E) Winter severity (Mean AHI groups)

Limitations of the study

This study has several limitations. It is restrictive as it takes place in north of Greece and might not be directly relatable to different geographical locations especially with different seasonal conditions. Secondly as the study data were collected via SD memory card there was limited information from the patients for their reasons for seasonal compliance. Future studies should include more patients and the yearly CPAP compliance.

6. CONCLUSION

The present study shows that with only data from the CPAP device we can come to actionable conclusion about seasonal compliance of SOA patients about their use of the CPAP device. Summer is a tougher season for CPAP compliance and the use of nasal/pillow mask and an auto CPAP device is preferable and advisable for better compliance.

- **Patient Consent Form:** All participants were informed about 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.
- **Financial support and sponsorship:** None.

REFERENCES

1. Malhotra A, Orr JE, Owens RL. On the cutting edge of obstructive sleep apnoea: where next? The Lancet Respiratory medicine. 2015; 3(5): 397-403.
2. Gottlieb DJ, Punjabi NM. Diagnosis and management of obstructive sleep apnea: a review. Jama. 2020; 323(14):1389-400.
3. Dempsey JA, Veasey SC, Morgan BJ, O'Donnell CP. Pathophysiology of sleep apnea. Physiological reviews. 2010; 90(1): 47-112.
4. Arnardottir ES, Bjornsdottir E, Olafsdottir KA, Benediktsdottir B, Gislason T. Obstructive sleep apnoea in the general population: highly prevalent but minimal symptoms. European respiratory journal. 2016; 47(1): 194-202.
5. Malhotra A, Morrell MJ, Eastwood PR. Update in respiratory sleep disorders: epilogue to a modern review series. Respirology (Carlton, Vic). 2018; 23(1): 16.
6. Briançon-Marjollet A, Weiszenstein M, Henri M, Thomas A, Godin-Ribuot D, Polak J. The impact of sleep disorders on glucose metabolism: endocrine and molecular mechanisms. Diabetology & metabolic syndrome. 2015; 7(1): 1-16.
7. Becker HF, Jerrentrup A, Ploch T, Grote L, Penzel T, Sullivan CE, et al. Effect of nasal continuous positive airway pressure treatment on blood pressure in patients with obstructive sleep apnea. circulation. 2003; 107(1): 68-73.
8. Pavwoski P, Shelgikar AV. Treatment options for obstructive sleep apnea. Neurol Clin Pract. 2017; 7(1): 77-85.

9. Chaudhary SC, Gupta P, Sawlani KK, Gupta KK, Singh A, Usman K, et al. Obstructive Sleep Apnea in Hypertension. Cureus. 2023; 15(4).
10. Basner RC. Continuous positive airway pressure for obstructive sleep apnea. New England Journal of Medicine. 2007; 356(17): 1751-1758.
11. Chang JL, Goldberg AN, Alt JA, Mohammed A, Ashbrook L, Auckley D, et al., editors. International consensus statement on obstructive sleep apnea. International forum of allergy & rhinology; 2022: Wiley Online Library.
12. Brimioulle M, Chaidas K. Nasal function and CPAP use in patients with obstructive sleep apnoea: a systematic review. Sleep and Breathing. 2022; 26(3): 1321-1332.
13. Fujino Y, Oka Y, Wakamura T. Seasonal effects on the continuous positive airway pressure adherence of patients with obstructive sleep apnea. Sleep Medicine. 2021; 80: 126-133.
14. Kribbs NB, Pack AI, Kline LR, Smith PL, Schwartz AR, Schubert NM, et al. Objective measurement of patterns of nasal CPAP use by patients with obstructive sleep apnea. Am Rev Respir Dis. 1993; 147(4): 887-895.
15. Benjafield AV, Ayas NT, Eastwood PR, Heinzer R, Ip MSM, Morrell MJ, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. The Lancet Respiratory medicine. 2019; 7(8): 687-698.
16. Peppard PE, Young T, Barnet JH, Palta M, Hagen EW, Hla KM. Increased prevalence of sleep-disordered breathing in adults. American journal of epidemiology. 2013; 177(9): 1006-1014.
17. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. American journal of respiratory and critical care medicine. 2002; 165(9): 1217-1239.
18. Craig TJ, Sherkat A, Safaee S. Congestion and sleep impairment in allergic rhinitis. Current allergy and asthma reports. 2010; 10: 113-121.
19. Borel JC, Tamisier R, Dias-Domingos S, Sapene M, Martin F, Stach B, et al. Type of mask may impact on continuous positive airway pressure adherence in apneic patients. PloS one. 2013; 8(5): e64382.
20. Bacon JP, Farney RJ, Jensen RL, Walker JM, Cloward TV. Nasal continuous positive airway pressure devices do not maintain the set pressure dynamically when tested under simulated clinical conditions. Chest. 2000; 118(5): 1441-1449.
21. Xu T, Li T, Wei D, Feng Y, Xian L, Wu H, et al. Effect of automatic versus fixed continuous positive airway pressure for the treatment of obstructive sleep apnea: an up-to-date meta-analysis. Sleep and Breathing. 2012; 16: 1017-1026.
22. Amfilochiou A, Tsara V, Kolilekas L, Gizopoulou E, Maniou C, Bouros D, et al. Determinants of continuous positive airway pressure compliance in a group of Greek patients with obstructive sleep apnea. European journal of internal medicine. 2009; 20(6): 645-650.
23. Yetkin O, Kunter E, Gunen H. CPAP compliance in patients with obstructive sleep apnea syndrome. Sleep and Breathing. 2008;12: 365-367.
24. Young T, Shahar E, Nieto FJ, Redline S, Newman AB, Gottlieb DJ, et al. Predictors of sleep-disordered breathing in community-dwelling adults: the Sleep Heart Health Study. Archives of internal medicine. 2002; 162(8): 893-900.
25. Cassol CM, Martinez D, da Silva FABS, Fischer MK, Lenz MdCS, Bós ÂJG. Is sleep apnea a winter disease?: meteorologic and sleep laboratory evidence collected over 1 decade. Chest. 2012; 142(6): 1499-1507.