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PREDICTIVE FACTORS OF ADHERENCE IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA SYNDROME TO CPAP THERAPY IN ROMANIA

SUMMARY OF THE DOCTORAL THESIS

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Content of the doctoral thesis :

Chapter 1. SYNTHESIS OF MAIN IDEAS

1.1 THE FUNDAMENTAL PROBLEM

1.1.1 Working hypothesis

By analyzing data from the specialized literature, I tried to determine whether there is a correlation between predictive factors, the evolution of OSAS and the adherence of OSAS patients to CPAP therapy in Romania.

1.1.2 Research objectives

The main objective of the study was to investigate how adherence to therapy influences the evolution of OSAS. The secondary objectives of the study were: investigating the existence of other predictors, clinical/demographic/paraclinical parameters for the evolution of OSAS and statistical-descriptive characterization of patients.

Table I.1 Research objectives

General objectives	Secondary objectives
1. Description of the OSAS problem at the level of Teleorman county	Presentation of the current context at the county level Highlighting diagnostic methods Questionnaires for assessing patient symptoms Diagnosing the patient Current treatment modalities Adherence to therapy
2. Description of the patient lots analyzed	Collecting patient demographic data Collecting data related to education level, monthly income, monthly cost of medications/other therapies Identifying risk factors: obesity, male gender, age, alcohol and tobacco consumption IAH at the time of diagnosis Type of mask used CPAP pressure used Whether they live with someone or alone

	Identification of comorbidities Highlighting of common treatments Evaluation of symptoms through questionnaires Self-esteem scale Analysis of other particularities.
3. Comparative analysis of patient adherence to CPAP	Distribution of questionnaires for patients aimed at assessing age, gender, anthropometric indices, Mallampati score, level of education, monthly income, cost of treatment, comorbidities, environment of residence, symptoms, comorbidities, tobacco and alcohol consumption, active or sedentary lifestyle Diet +/- consultation with a nutritionist Treatment compliance: CPAP-number of hours/day, days per week of use, existence of psychological personality type D, factors that determined suboptimal use Comparative analysis of the results.

1.1.3 Research methodology

We conducted a prospective observational study on 86 patients divided into two groups based on adherence to CPAP therapy (minimum 4h/night in at least 70% of the recommended number of days): group 1 consisting of 50 patients considered adherent to therapy and group 2 consisting of 36 patients considered non-adherent to therapy.

The study protocol includes patient assessment by completing a questionnaire regarding anthropometric indices, Mallampati score, education level, family income, living with someone or alone, daytime and nighttime symptoms, existence of personality type D, type of CPAP used and side effects of the mask and device, patient-reported causes for poor adherence and downloading data from the device's memory card.

Patients were evaluated over a 3-month period. The memory cards of the home CPAP devices were first read at one day and one week after the initiation of therapy to determine the level of adherence during the first period of use.

The Epworth Questionnaire is applied to each assessment and identifies the level of daytime sleepiness. It includes a set of 8 questions regarding various daily situations and the establishment of the possibility of falling asleep in these situations. A score above 10 implies excessive daytime sleepiness that may be the cause of a sleep pathology[1].

The Rosenberg Scale includes a number of 10 questions to identify the patient's self-esteem. A score below 30 identifies a level of medium and low self-esteem, while a score above 30 corresponds to a high level of self-esteem[2].

The Denollet scale identifies the psycho-behavioral type D. Denollet was the first to describe this psycho-behavioral type in connection with coronary heart disease in 1996. This type D of personality is characterized by negative affectivity and social inhibition. It consists of two sets of 7 questions, obtaining a score above 10 points for each of the two sets determines the existence of this psycho-behavioral type[3].

Inclusion criteria were: signing of informed consent, age over 18 years, recent diagnosis of SASO, and eligible for CPAP therapy, who had not previously used CPAP and for whom other therapeutic methods were not recommended. Exclusion criteria were: lack of informed consent, age under 18 years, pregnant women, central or mixed apnea, those who had used CPAP in the past, lack of access to a telephone network, inability to complete questionnaires for objective reasons, associated severe comorbidities.

For the statistical processing of the study data, IBM SPSS Statistics for Windows, Version 29.0 was used. (30-day trial version) Armonk, NY: IBM Corp.

In this study, we used several statistical tests to evaluate different aspects of adherence to CPAP therapy. Each test was chosen according to its specific purpose and the nature of the available data, so as to obtain relevant and meaningful results. To provide a basic understanding of the characteristics of the data and to obtain a summary of the main variables, we used descriptive statistics. These are essential for examining the distribution and centrality of the data, providing a starting point for further analysis. They help to identify general patterns, anomalies, or errors in the data set.

The Chi-square test was used to assess whether there was a significant association between two categorical variables. The independent samples t-test was used to compare the means of two independent groups. The Mann-Whitney test is a non-parametric test used to compare two independent groups when the data are not normally distributed. Binary logistic regression was used to analyze the relationship between treatment adherence (binary dependent variable: adherence/non-adherence) and a series of predictors (explanatory variables). A significance coefficient value of $p < 0.05$ was considered relevant for interpreting the statistical significance of the results. P values below this threshold were interpreted as indicating a statistically significant association between the variables analyzed.

The results obtained were analyzed in studies:

Study: ANALYSIS OF CLINICAL-BIOLOGICAL PREDICTIVE FACTORS OF PATIENTS

Study: ANALYSIS OF PREDICTIVE FACTORS: PATIENTS' SYMPTOMATOLOGY

Study: ANALYSIS OF PREDICTIVE FACTORS: OSAS SEVERITY

Study: ANALYSIS OF PREDICTIVE FACTORS: OTHER PATIENT'S DISEASES, TOBACCO AND ALCOHOL DEPENDENCE, LIFESTYLE

Study: ANALYSIS OF PREDICTIVE FACTORS: CPAP DEVICE AND ITS ACCESSORIES

Study: ANALYSIS OF PREDICTIVE FACTORS: REPORTED CAUSES FOR SUBOPTIMAL USE OF CPAP THERAPY

Study: ANALYSIS OF PREDICTIVE FACTORS: FIRST PERIOD WITH CPAP THERAPY

Chapter 2. SYNTHESIS OF THE BASIC CHAPTERS

2.1 SLEEP AND OBESITY

2.1.1 SLEEP

Sleep is a natural, physiological, reversible state, which involves a temporary abolition of consciousness, being, since birth, necessary for normal physical development[4].

Sleep begins with a decrease in the values of vital constants, and the Pa CO2 level increases, approaching the appearance of apnea. NREM sleep begins with the reduction of SRAA activity and REM sleep begins with the activation of cholinergic neurons in the latero-dorsal and pedunculo-pontine core[5]. Sleep has many roles: in neuronal recovery, mental health, physical and psychological well-being, the performance of daily activities and performance in work[6]. Sleep deprivation can negatively influence the patient's affectivity[7]. Short-term sleep deprivation has effects on memory, attention, and less on high-complexity activities[8].

2.1.2 OBESITY

Obesity is defined by the WHO as “an abnormal and excessive accumulation of fat that poses a risk to health”, generally classified based on IMC. According to the WHO, obesity has reached epidemic proportions, with 1.9 billion people considered overweight and 650 million classified as obese[9]. Eating behavior, the choice of overly processed foods, with a lot of sugar and high calories, cheap and poor quality, family environment and surroundings, are some of the causes of the increase in the number of calories ingested[10]. There are many factors proven to be involved in the etiology of obesity: genetic, psychobehavioral, environmental, biological, factors related to the culture of the people to which the individual belongs[11]. To decide whether an obese patient should undergo treatment, several aspects must be taken into account: whether the patient requires treatment, whether he is sufficiently motivated to adhere to treatment, and whether the treatment administered is safe for the patient[12]. Weight loss through diet is associated with positive changes in cardiovascular risk factors; in addition to weight loss, other interventions such as exercise are important for therapy, some of which have results from the beginning, for others this happens after a longer period of time[13].

2.2 OBSTRUCTIVE SLEEP APNEA SYNDROME

Sleep apnea syndrome is a less well-known condition in Romania. The disease is difficult to detect, due to the lack of information among doctors in related specialties,

especially family doctors, and leading to detection in our country in severe stages and when the disease has become visceral[14].

Obstructive Sleep Apnea Syndrome (OSAS) is a respiratory disorder that involves the collapse of the airways during sleep[15]. Apnea episodes are classified as central, obstructive or mixed, the criterion for differentiating between obstructive and central is the presence or absence of respiratory movement during apnea. Mixed apnea has two parts, the first with the absence of respiratory effort and the last with its presence[16]. Sleep fragmentation and sleep deprivation that cause daytime sleepiness have a negative effect on respiratory control, decreasing the ventilatory response to hypoxemia and hypercapnia and the consequences that this has on the cardiovascular system are important and can influence the effects that therapy has in these patients[17]. Individuals with OSAS generally have various upper airway abnormalities, which differ in proportion and pattern from one OSAS patient to another, from abnormalities of bone tissue to an abnormal distribution of fatty tissue at this level, leading to partial airway obstruction in the case of adipose tissue deposition, or relatively absolute obstruction in the case of an abnormality of the craniofacial bone structure, ultimately leading to respiratory collapse[18]. Manifestations occurring during sleep include the following: snoring, episodes of sleep apnea, chest movements or not depending on the type of apnea, night sweats, restless, restless sleep interrupted by awakenings, gastroesophageal reflux, nocturia[14]. The manifestations observed during waking hours are the following: excessive daytime sleepiness, asthenia, fatigue, cognitive, attention and memory disorders, personality disorders, decreased potency, libido, headache, endocrinological disorders[14,19].

Polysomnography monitors two important aspects of sleep: it continuously monitors sleep stages and respiratory activity, highlighting the connection between respiratory events and brain activity at that moment. They are monitored as follows: brain activity through EEG electrodes, muscle activity through Electromyography, cardiac activity through EKG electrodes, Oxyhemoglobin Saturation through Pulseoximetry, oro-nasal flow using thermistors and transducers, abdominal and thoracic movements through Respiratory Inductance Plethysmography, and body position using position sensors[20]. The most widely used outpatient method is nocturnal cardiorespiratory polygraphy which includes at least 4 channels: respiratory flow, respiratory muscle effort, peripheral arterial oxygen saturation, and pulse[21]. Cardiovascular comorbidities are the most common diseases with which OSAS is associated. This association is bidirectional in the sense that the presence of OSAS negatively influences the evolution of these comorbidities, and their

presence in the patient with OSAS has a negative effect on his evolution over time. The presence of OSAS is associated with increased cardiovascular mortality in this group of patients[22, 23]. The management of OSAS includes a series of strategies that involve: general weight loss strategies, physical exercise, lifestyle modification, to which can be added drug treatment, CPAP therapy, oral application devices, surgical treatments in the ENT field (tracheostomy, uvulo-palato-pharyngoplasty, laser uvuloplasty, maxillary advancement operations, etc.)[24].Continuous positive airway pressure (CPAP) therapy is the main therapy for OSAS, with an effect on decreasing the severity of OSAS (decreases AHI and improves hypoxemia)[23]. Very importantly for the patient, the therapy improves daytime sleepiness and prevents cardiovascular complications that OSAS can have[26].To obtain a symptomatic benefit, a high degree of use of the therapy is necessary, good adherence (minimum 3-4h/sleep period) being essential for symptom improvement, so the more the patient uses the therapy, the more this will materialize in the targeted therapeutic effect[27-29].Good adherence to therapy (minimum 4h/night in at least 70% of the recommended number of days) involves several goals to be achieved: first of all, to use it as much as possible, to promptly resolve the side effects of the therapy, namely air leaks at the mask level, to keep the pressure constant[30]. CPAP therapy is used for an indefinite period, generally for the patient's entire life, therefore it is necessary for the patient to be adherent in order for him to feel the benefits of the therapy[31].

2.3 DESCRIPTIVE STATISTICS OF STUDY GROUPS

The study analyzed 86 patients diagnosed with Obstructive Sleep Apnea Syndrome, divided into two categories: patients adhering to CPAP therapy (n = 50) and non-adherent patients (n = 36). The mean age of non-adherent patients was 55.22 years, with a standard deviation of 9.141 years, indicating a moderate dispersion of individual values around the mean. Although adherent patients tend to be, on average, slightly older than non-adherent patients, and the distribution by age group suggests some variation, these differences are not supported by robust statistical significance. In the entire group, the majority of patients were male, representing 70.9%, while female patients constituted 29.1% of the total. Within the non-adherent group, 72.2% of patients were male and 27.8% were female. Among adherents, the gender distribution was similar, with 70.0% male patients and 30.0% female. The similar distribution of men and women in the two groups (adherent and non-adherent), corroborated by the lack of statistical significance, indicates that belonging

to one gender or the other is not a relevant predictive factor for compliance with CPAP treatment. Although the descriptive analysis suggests a slightly different trend depending on the origin (adherents being more frequent in rural areas and non-adherents in urban areas), this difference is not supported by statistical significance. Therefore, the environment of origin does not represent a significant predictive factor for adherence to CPAP therapy in this study. Patients with secondary education seem to be more compliant, while those with higher education are more frequently found among those who do not follow the treatment properly. Although the differences do not reach the formal threshold of significance, the Cramer's V value suggests that this variable deserves further investigation in future studies, on larger samples. The results obtained indicate that living with another person does not significantly influence adherence to CPAP therapy. Although most patients live with someone, this characteristic does not significantly differentiate the adherent and non-adherent groups. Family income is a significant factor associated with adherence to CPAP therapy. Surprisingly, patients with higher incomes are more frequently non-adherent, while those with average incomes tend to be more compliant.

2.4 ANALYSIS OF CLINICAL-BIOLOGICAL PREDICTIVE FACTORS OF PATIENTS

Body Mass Index does not significantly influence adherence to CPAP therapy among patients included in this study. Severe obesity seems to be a common characteristic among all patients with OSA, regardless of whether they follow the prescribed treatment or not. The mean values of Systolic Blood Pressure were very close between the two groups analyzed: 140.56 mmHg among non-adherents and 141.40 mmHg among adherents. These values indicate a moderate and relatively uniform hypertensive profile, with no clinically notable differences between the two categories of patients. Statistical analysis confirmed the absence of a significant link between Systolic Blood Pressure and treatment adherence. Diastolic Blood Pressure does not have a significant impact on adherence to CPAP therapy among patients with OSAS. The differences in blood pressure values between adherents and non-adherents are minimal, and the statistical analysis supports the lack of a relevant link between these variables. The mean Ventricular Rate was higher among non-adherent patients (83.97 bpm) compared to adherent patients (79.62 bpm), the difference between the two means being approximately 4.35 bpm; this difference is not pronounced enough to be considered statistically significant. The mean Vital Capacity was very close in the two groups: 76.00 % of the predicted value in adherents and 76.61% of the predicted value in

non-adherents. The difference between the means of the two groups is minimal (0.61 units), not being sufficient to suggest a real difference between adherents and non-adherents in terms of vital capacity. The distribution by groups shows that the majority of patients, both adherents and non-adherents, had a Mallampati score of grade 2; although, descriptively, a slight tendency is observed for adherents to have a lower (more favorable) score more frequently, the differences between the groups are not marked.

2.5 ANALYSIS OF PREDICTIVE FACTORS: PATIENTS' SYMPTOMATOLOGY

Although the percentage of adherent patients who had apnea observed by the entourage is higher, the differences between the two groups are not sufficiently pronounced; the presence of the symptom of nocturnal apnea reported by the entourage does not significantly influence the adherence of patients to CPAP therapy. A slightly lower frequency of dyspnea is observed among adherent patients, the differences between the two groups are not statistically significant. Snoring seems more frequent among non-adherents, the percentage differences between the two groups are not sufficient to indicate a significant association. Although, in percentage terms, the frequency of nocturia seems higher among non-adherent patients, the differences between the two groups are not consistent enough to be statistically relevant. In the analysis of the relationship between the presence of nightmares and adherence to CPAP therapy among patients with Obstructive Sleep Apnea Syndrome, it was found that this variable has a constant distribution: none of the patients, regardless of their adherence status, reported the presence of this symptom. Among non-adherent patients, 41.7% reported frequent awakenings during the night, compared to only 18.0% of adherents; the presence of frequent awakenings during the night is significantly associated with a lower probability of adherence to CPAP therapy. Among non-adherent patients, 61.1% reported the presence of daytime sleepiness, compared to only 32.0% of adherent patients; the presence of daytime sleepiness may be a possible indicator of non-adherence and should be carefully monitored in clinical practice. Morning headache does not significantly influence adherence behavior to CPAP therapy. Decreased alertness is not a relevant symptom for differentiating between adherent and non-adherent patients to CPAP therapy. The extremely low prevalence of this symptom in the analyzed sample excludes its value as a possible predictor of treatment compliance. The presence of morning fatigue does not significantly influence adherence to CPAP therapy in this sample. Erectile dysfunction or low libido does not significantly influence

adherence to CPAP therapy. Fatigue does not significantly influence patients' adherence to CPAP therapy. Given the low frequency of the symptom and the almost identical distribution in both groups, it cannot be considered a predictive factor of treatment compliance in this sample.

2.6 ANALYSIS OF PREDICTIVE FACTORS: OSAS SEVERITY

The mean AHI in the non-adherent group was 54.17 episodes/hour of sleep (±18.52), compared to a mean of 50.50 episodes/hour (±20.01) among adherent patients. This result suggests a slight tendency for non-adherents to have a slightly higher mean disease severity, but the difference is not considerable. Disease severity, expressed by AHI, did not prove to be a clear predictor of compliance with CPAP treatment in this sample. The Desaturation Index did not differ significantly between adherent and non-adherent patients with CPAP treatment. This finding suggests that the severity of nocturnal hypoxemia, reflected by the frequency of desaturation episodes, is not associated with compliance with therapy in the analyzed sample. Although adherent patients tend to have lower levels of daytime sleepiness compared to non-adherents, the differences are not statistically significant. This result suggests that subjective perception of daytime sleepiness, as measured by the Epworth score, does not decisively influence compliance with CPAP treatment in this sample.

2.7 ANALYSIS OF PREDICTIVE FACTORS: OTHER PATIENT'S DISEASES, TOBACCO AND ALCOHOL DEPENDENCE, LIFESTYLE

Metabolic diseases and Diabetes mellitus do not seem to significantly influence the adherence behavior to CPAP therapy in this sample. Although more frequent among adherent patients, these comorbidities do not prove to be predictive factors of compliance. Although, at a descriptive level, endocrine diseases occur only among adherent patients, their low frequency does not allow the formulation of relevant conclusions. The presence of pulmonary diseases does not significantly influence the adherence to CPAP therapy. These comorbidities occur in a comparable percentage in both groups, without constituting a differentiating factor in terms of compliance to treatment. In the context of this sample, the presence of gastroesophageal reflux disease does not significantly influence the compliance of patients to CPAP therapy. Although the symptoms were present exclusively among adherents, the very low frequency makes it impossible to formulate firm conclusions regarding the predictive value of this condition. Neurological diseases were

reported extremely rarely, being present in only 2 patients (2.3% of the total); neurological diseases do not influence adherence to CPAP therapy in this sample. In the entire group, cardiological diseases were frequently reported, with a prevalence of 90.7%; although cardiological diseases are very common among patients with OSA, they do not seem to significantly influence adherence to CPAP treatment. They are relatively evenly distributed in both adherent and non-adherent groups. ENT diseases do not significantly influence patients' compliance to CPAP therapy in this sample. The low frequency of this comorbidity and the balanced distribution between the two groups do not support a differentiating role in terms of treatment adherence. Across the entire sample, 7.0% of patients reported psychiatric comorbidities. These conditions were significantly more common among non-adherent patients (13.9%) compared to adherent patients (2.0%). The data obtained support the existence of a statistically significant relationship between psychiatric diseases and adherence to CPAP therapy, with patients with such comorbidities being more likely to not follow the recommended treatment. Within the sample, 38.4% of patients presented type D personality. Of these, 44.4% are found in the non-adherent group and 34.0% in the adherent group. Although type D personality are more common among non-adherent patients, this difference is not statistically significant. Thus, within this sample, type D personality does not seem to be a determining factor in compliance with CPAP therapy. Self-esteem assessed by the Rosenberg scale does not differ significantly between adherent and non-adherent patients to CPAP therapy. Therefore, this psychological aspect does not seem to influence adherence behavior in the analyzed sample.

Alcohol consumption does not influence adherence to CPAP therapy among patients included in this study. The similar proportions of consumers and non-consumers in both groups, along with the lack of statistical significance, support the idea that this variable has no predictive value regarding treatment compliance. Among non-adherent patients, one third (33.3%) are smokers, while 66.7% are non-smokers. In contrast, only 8.0% of adherent patients declared that they smoke, and 92.0% are non-tobacco users. In conclusion, tobacco consumption is significantly associated with lower adherence to CPAP therapy. Smoking patients are more likely to be non-adherent, compared to non-smokers. These results suggest that smoking may represent an important behavioral risk factor for treatment non-compliance. Although a higher proportion of patients with an active lifestyle is observed among those adhering to CPAP therapy, the difference is not large enough to be statistically significant. Analysis of the relationship between adherence to CPAP

therapy and consultation with a nutritionist shows that a higher percentage of adherent patients (18%) consulted a nutritionist, compared to only 8.3% of non-adherents. Following a diet does not seem to significantly influence adherence to CPAP treatment among participants in this study.

2.8 ANALYSIS OF PREDICTIVE FACTORS: CPAP DEVICE AND ITS ACCESSORIES

In the analyzed sample, 66.3% of patients used an Auto-CPAP device, and 33.7% used another type of device (fixed pressure CPAP). Among non-adherent patients, 69.4% used Auto-CPAP, and 30.6% did not. Among adherent patients, 64.0% used Auto-CPAP, and 36.0% did not. The type of device used does not seem to be a determining factor in patient compliance with CPAP treatment, within this sample. A higher proportion of nasal mask users is observed among adherent patients compared to non-adherent patients (20.0% vs. 8.3%). Although no statistically significant association was identified, descriptive data indicate that the use of a nasal CPAP mask is more frequent among adherent patients. This observation could support the hypothesis that the type of mask influences comfort and, implicitly, compliance. The nasal mask, although less commonly used, is more common among adherent patients, while the oro-nasal mask is more common in the non-adherent group. High CPAP pressure may be associated with lower adherence, while the use of lower pressures appears to be more common among adherent patients. Humidifier use does not influence adherence to CPAP therapy. The very close proportions between humidifier users and non-users in both groups, as well as the absence of statistical significance, suggest that this factor is not a relevant element in explaining patient compliance with treatment. Although dry mouth is a common adverse effect reported by patients treated with CPAP, there are no significant differences between adherents and non-adherents in this regard. Rhinitis was reported as an adverse effect of CPAP therapy in a very low percentage in both groups analyzed. Although conjunctivitis is not common, it could represent a more specific adverse effect among consistent CPAP users, requiring additional clinical monitoring. Skin lesions as an adverse effect of CPAP therapy were reported in a low proportion in both groups analyzed. Anxiety as a side effect of CPAP therapy was reported to a significantly higher extent among non-adherent patients compared to adherents; statistical analysis revealed a significant difference between the two groups, these results suggest that anxiety related to CPAP may be a potential factor of non-adherence to treatment. Chest pain and aerophagia were reported as side effects of CPAP

therapy in one case, belonging to a patient in the non-adherent group (2.8%). Noise produced by the CPAP device was reported as a side effect by a small number of patients in both groups: 8.3% of the non-adherents and 10% of the adherents. Discomfort felt by the patient's bed partner as a result of using the CPAP device was rarely reported, both in the non-adherent (5.6%) and adherent groups (4.0%). Headache reported as a side effect of CPAP therapy was mentioned by a small percentage of patients, being more frequent among the non-adherents (8.3%) compared to the adherents (2.0%). However, the majority of patients in both groups did not complain of this symptom.

2.9 ANALYSIS OF PREDICTIVE FACTORS: REPORTED CAUSES FOR SUBOPTIMAL USE OF CPAP THERAPY

Statistical analysis revealed a significant difference between adherent and non-adherent patients in terms of the perception of side effects of the mask and device as a reason for not using CPAP therapy. Thus, 47.2% of non-adherent patients mentioned side effects as a reason for not using the device, while only 6% of adherent patients indicated the same reason. The results of the statistical analysis on the impact of bed partner discomfort as a possible reason for not using the CPAP device indicate that this problem is rarely mentioned by both non-adherent (8.3%) and adherent patients (2%). The results of the analysis on the influence of misperception on the severity of Obstructive Sleep Apnea Syndrome as a factor for non-adherence to CPAP therapy indicate a statistically significant difference between the two groups. Statistical analysis revealed a significant association between adherence status and distrust in CPAP therapy as a reason for not using the treatment: in the non-adherent group, 27.8% indicated distrust in the effectiveness of CPAP therapy as a reason for refusing to use it, while none of the adherent patients mentioned this reason. Only one participant in the non-adherent group (2.8%) reported a poor relationship with the doctor as a factor for not using CPAP, while no adherent patients mentioned this aspect. All participants in the sample (n = 86) stated that they did not choose another treatment method as a reason for not using CPAP therapy.

2.10 ANALYSIS OF PREDICTIVE FACTORS: FIRST PERIOD WITH CPAP THERAPY

Analysis of data on the experience of the first night of CPAP use indicates a significant difference between the adherent and non-adherent patient groups. Descriptively, 38.9% of non-adherents had good adherence from the first night, while 90.0% of adherents

reported a positive experience during the first use. Thus, the majority of those who subsequently continued treatment had a favorable initial adaptation, in contrast to those who abandoned the use of the device. These results suggest that the first experience with CPAP therapy is an important predictor of subsequent adherence to treatment. Comfortable and effective use from the first night is associated with an increased likelihood of maintaining therapy in the long term. Analysis of the experience of the first week of CPAP use highlights very clear differences between adherent and non-adherent patients. Among non-adherents, only 41.7% reported good adherence in the first week, compared to a significantly higher percentage — 98.0% — of adherent patients. Thus, the vast majority of those who continued long-term treatment had a positive experience from the first days. The results emphasize that the first week of CPAP use is essential in determining adherence behavior, being a critical period for patient adaptation and therapy success.

2.11 CONCLUSIONS AND PERSONAL CONTRIBUTIONS

2.11.2 CONCLUSIONS

Obstructive sleep apnea syndrome is a common and underdiagnosed pathology in Romania. Adherence of patients with chronic conditions, including those with OSAS, to prescribed therapy is low. CPAP therapy is the main therapeutic method but the main problem is adherence to therapy. In order for patients to be considered adherent to therapy, they must use it at least 70% of the recommended number of days and at least 4h/day.

Identifying and addressing predictive factors for adherence is important for disease management. The present study shows that multiple factors may be involved in the adherence of patients with OSAS to CPAP therapy. Reimbursement of the device rental by the National Health Insurance House can be essential for the adherence of patients with OSAS to CPAP therapy, this has been possible since 2023. Prior to this date, the lack of reimbursement represented an impediment to the acquisition of the CPAP device. The research objectives were: the primary objective was to investigate how adherence to therapy influences the evolution of OSAS. The secondary objectives of the study were: investigating the existence of other predictors, clinical/demographic/paraclinical parameters for the evolution of OSAS and statistical-descriptive characterization of patients.

There were a higher number of men than women in the study, which is consistent with previous studies.

The identified and reported causes for inappropriate use of therapy were: mask/device side effects, bed partner discomfort, misperception of the severity of the disease, lack of confidence that CPAP therapy is beneficial for treating OSA, poor doctor-patient relationship, low involvement of family and entourage in therapy, patient education, choice of an alternative treatment. In non-adherent patients, all causes that can lead to therapy discontinuation were more frequent.

The mean AHI was high, suggesting that the study included many patients with severe OSA; the results of these studies may not be similar if the study included many patients with mild OSA.

Personality type D (prone to social inhibition, negative self-image, low self-esteem, anxiety, pessimism, depression) was much more common in non-adherent patients.

Involving family and friends in therapy may be essential. Patients who live with someone versus those who live alone seem to be more adherent to CPAP therapy.

The first contact and the first period of therapy use can be predictive of future adherence.

The strengths of the study include the fact that there are a sufficient number of patients compared to previous studies, there are new cases of SASO, the relatively long follow-up period (1 year), and the study design.

As weaknesses of the study we can identify: the fact that the study is monocentric, the use of nocturnal cardiorespiratory polygraphy and not polysomnography (the latter represents the diagnostic standard but the accessibility of patients to this type of investigation is low). Another weakness may be the fact that most patients have the diagnosis of severe OSAS, the results of this study may not be applicable to patients with mild and moderate OSAS. Prospects for future studies are: increasing the number of patients, making the study multicentric, analyzing other predictive factors (psychological, paraclinical), using Polysomnography as a diagnostic method, increasing the follow-up period, using other statistical processing methods. The present study brings to attention the issue of OSAS, the underdiagnosis of this pathology, adherence to therapy and the importance of identifying predictive factors for adherence, the role of symptomatology and psychological factors in adherence to CPAP therapy. The multitude of factors involved suggests the complexity of this pathology, the role of each factor individually but also in association, in patients who in most cases have other comorbidities that require specific therapy. Although from the year 2023 there was the possibility of paying the rent of the CPAP machine for patients insured through the National Health System(prior to this year, the lack of settlement was an

impediment to the continuation of the therapy) the present study demonstrates that other factors besides those of an economic nature can be involved in the adherence to the therapy.

2.6.2 PERSONAL CONTRIBUTIONS

The present study brings to attention the issue of OSAS and patient adherence to CPAP therapy. We conducted this study to determine some of the causes of non-adherence to therapy and how they evolve in relation to other predictive factors. The results of the study were published in medical journals indexed in the Pubmed database and in a journal with ISI impact factor. We also made oral presentations about the results of the study at the national congresses of Pulmonology and Internal Medicine. Throughout the study, patients received information about diagnosis and therapy, and where there were problems with adherence or side effects to therapy, we insisted on patient support and their resolution.

1. This study makes several important contributions regarding predictive factors for adherence of OSAS patients to CPAP therapy in Romania(chapter 2).
2. A first original aspect would be the study design, with two groups of patients depending on adherence to CPAP therapy: </> 4h/night in 70% of the recommended number of days(chapter 4, paragraph 4.1) .
3. Adherent patients had a higher mean age than non-adherent patients, suggesting that older age may be associated with better adherence to therapy (chapter 5, paragraph 5.1).
4. In both groups of patients, the male gender was predominant, the presence of SASO in males is much more frequent than in females (chapter 5, paragraph 5.2).
5. Non-adherent patients were more frequently from urban areas and adherent patients from rural areas. A high percentage of patients included in the study from rural areas can also be explained by the specifics of Teleorman County, a predominantly agricultural county (chapter 5, paragraph 5.3).
6. There were more patients with secondary education among adherent patients and more with higher education among non-adherent patients (chapter 5, paragraph 5.4).
7. Higher monthly incomes were recorded among non-adherent patients, so a higher income is not associated with better adherence to CPAP therapy (chapter 5, paragraph 5.6).
8. Ventricular Allure was higher in non-adherent patients (chapter 6, paragraph 6.4).
9. The percentage of non-adherent patients with a Mallampati score of 3 was double that of adherent patients with this score (chapter 6, paragraph 6.6).

10. The percentage of patients who reported apnea as a nocturnal symptom reported by their entourage was higher in the case of adherent patients (chapter 7, paragraph 7.1).

11. Nocturnal dyspnea was reported more frequently by non-adherent patients than by adherent patients (chapter 7, paragraph 7.2).

12. Non-adherents reported snoring more frequently as a nocturnal symptom (chapter 7, paragraph 7.3).

13. The percentage of non-adherent patients who reported frequent nocturnal awakenings as a symptom was double that of adherent patients (chapter 7, paragraph 7.6).

14. In the case of non-adherent patients, the percentage of those who reported excessive daytime sleepiness was double that of adherent patients (chapter 7, paragraph 7.7).

15.Morning fatigue, as well as daytime symptoms, was reported to a higher percentage by non-adherent patients (chapter 7, paragraph 7.10).

16.Adherent patients were most represented in the moderate OSA category while non-adherent patients were in the severe OSA group; higher disease severity may be associated with lower adherence (chapter 8, paragraph 8.1).

17.The level of daytime hypersomnolence (Epworth score) was higher in non-adherent patients compared to adherent patients, so that less pronounced daytime symptoms may be predictive of adherence (chapter 8, paragraph 8.3).

18. There were more patients with Diabetes Mellitus in the adherent group than in the non-adherent group (chapter 9, paragraph 9.1).

19. There were more patients with pulmonary comorbidities in the non-adherent group, their presence could be a factor for low adherence to therapy (chapter 9, paragraph 9.3).

20. Cardiological comorbidities were the most common type of diagnosis associated with OSAS in both groups of patients (chapter 9, paragraph 9.6).

21. Non-adherent patients had more psychiatric comorbidities than adherent patients (chapter 9, paragraph 9.8).

22. There were more patients with psychological type D in the non-adherent group, this personality type could be associated with low adherence to therapy (chapter 9, paragraph 9.9).

23. The percentage of smokers was higher in the group of non-adherent patients (chapter 9, paragraph 9.12).

24. Non-adherent patients were more sedentary than those who were adherent to therapy (chapter 9, paragraph 9.13).

25. Adherent patients consulted a nutritionist more frequently compared to non-adherent patients (chapter 9, paragraph 9.14).

26. Adherent patients followed a diet in a higher percentage than non-adherent patients (chapter 9, paragraph 9.15).

27. Nasal mask use was more common among adherent patients, so the use of this type of mask could be associated with better adherence to therapy (chapter 10, paragraph 10.3).

28. Non-adherent patients had a higher mean Pressure set on the CPAP device than adherent patients (chapter 10, paragraph 10.5).

29. Conjunctivitis as a side effect of therapy was reported only by adherent patients (chapter 10, paragraph 10.9).

30. A significantly higher percentage of non-adherent patients reported anxiety about the device as a side effect of therapy (chapter 10, paragraph 10.11).

31. Headache was more frequently reported by non-adherent patients (chapter 10, paragraph 10.15).

32. The identified and reported causes for inappropriate use of therapy were: mask/device side effects, bed partner discomfort, misperception of the severity of the disease, lack of confidence that CPAP therapy is beneficial for treating OSA, poor doctor-patient relationship, low involvement of family and entourage in therapy, patient education, other reasons(chapter 11, paragraph 11.1-11.8).

33. The first period of therapy influenced future adherence, most patients in the adherent group had good compliance during this period. In non-adherent patients, compliance during the first period was low (chapter 12, paragraphs 12.1-12.2).

34. Patient awareness of the importance of the diagnosis of OSAS for health and the benefits of therapy is essential for therapy(chapter 11, paragraph 11.1-11.8).

35. The active involvement of those around, the entourage, the family, the life partner in the management of this type of therapy is important for the patient's evolution(chapter 11, paragraph 11.1-11.8).

36. A good doctor-patient relationship, prompt treatment of side effects of therapy, and motivational support for the patient to follow therapy can be an important factor for compliance(chapter 11, paragraph 11.1-11.8).

37. More active patients, those who consult a nutritionist or follow a diet may adhere better to CPAP therapy (chapter 9, paragraph 9.13-9.15)..

38. Most of the patients in the study were classified as severe, the results of this study may be different in patients with mild OSAS(chapter 8, paragraph 8.1).

39. A more careful approach to patients with this diagnosis is necessary, as is monitoring and the implementation of educational programs for this type of patients(chapter 4, paragraph 4.1) .

40.It is necessary to increase the number of Somnology laboratories and the number of doctors with expertise in Somnology(chapter 14, paragraph 14.1).

41. It is necessary to make scientific presentations about OSAS and CPAP therapy at as many national congresses and conferences as possible to raise awareness of this pathology and related medical specialties, especially family physicians(chapter 14, paragraph 14.1) .

42. Developing a health strategy to reduce obesity, the main factor involved in the occurrence of SASO and other pathologies, must be a primary objective of public health policies(chapter 14, paragraph 14.1).

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List of published scientific papers

1.**Romică Burcea**, Florin Dumitru Mihălțan, The importance of a diet in patients with OSAS(Obstructive Sleep Apnea Syndrome) and CPAP(Continuous Positive Airway Pressure) therapy-a case report*, Maedica-A journal of Clinical Medicine*, year: 2025, volume:20, number:2, pages 432-436, journal indexing: Pubmed, EBSCO, category B, DOI: 10.26574/maedica.2025.20.2.432 (chapter 6, pag. 16-27).

2**. Romică Burcea**, Ancuța-Alina Constantin, Florin Dumitru Mihălțan, ADHERENCE TO CONTINUOUS POSITIVE AIRWAY PRESSURE THERAPY: HOW MUCH DOES THE START MATTER?**,** *FARMACIA-OFFICIAL JOURNAL OF THE ROMANIAN SOCIETY FOR PHARMACEUTICAL SCIENCES*, year: 2026, volume:74, number:1, pages 101-106, journal indexing: Science Citation Index Expanded, SciVerse Scopus,Chemical Abstracts Service, EMBASE, SCImago Journal&Country Rank,IPA, British Library, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC, category ISI, Impact Factor: 1.2, https://farmaciajournal.com/issue-articles/adherence-to-continuous-positive-airway-pressure-therapy-how-much-does-the-start-matter (chapter 12, pages 170-173).

3. **Romică Burcea**, F D Mihălțan, The role of side effects in adherence of patients with Obstructive Sleep Apnea Syndrome to Continuous Positive Airway Pressure therapy*, Maedica-A journal of Clinical Medicine*, year: 2026, volume: 21, number: 1, pages: 21-26, journal indexing: Pubmed, EBSCO, category B+, https://doi.org/10.26574/maedica.2026.21.1.21 (chapter 10, pages 133-159).