

CPAP therapy in OSA – A gap analysis between recommendation and usage

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Abstract

Objectives: To examine various factors, primarily socioeconomic, psychological, and physiological, which influence the decision of patients diagnosed with obstructive sleep apnea (OSA) to purchase a continuous positive airway pressure (CPAP) device.

Methods: The first phase involved 343 patients, undergoing polysomnography (PSG), with informed consent from amongst 1,098 subjects, who presented to a comprehensive Sleep Center in Chennai, India.

Among those diagnosed with OSA, a certain number were recommended CPAP therapy, based on the test results and clinical appropriateness. The second phase involved follow-up of these patients prescribed with CPAP. Patients were interviewed on whether they purchased CPAP devices or not, and the most relevant reasons for their decision.

Results: All 343 subjects who underwent the PSG were diagnosed with varying degrees of OSA. Among them, 291 were recommended to use a CPAP device. 41.9% of patients who were prescribed CPAP purchased the device. Out of these, 84.42% responded that it improved their quality of life and relieved OSA symptoms. Those who did not purchase CPAP, stated reasons such as high device cost (36.69%), deferment due to lack of awareness and education (17.75%), lack of awareness on the cost benefits of the device (11.24%), and discomfort during usage (8.88%).

Conclusion: Patients who used CPAP device report improved quality of life. However, amongst those who did not opt for CPAP therapy, socioeconomic factors appear to be the foremost deterrent followed by other factors such as lack of understanding of the importance of therapy and perceived discomfort with the equipment & interface.

Keywords: Continuous positive airway pressure therapy, obstructive sleep apnea, barriers, cost, acceptance, adherence

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Brief Summary

Current Knowledge/Study Rationale

Continuous positive airway pressure (CPAP) remains one of the most common treatments for obstructive sleep apnea (OSA) having proven benefits in clinical improvement and reduction of morbidity. However, the barriers to the acceptability of CPAP therapy are not well established; hence, we have explored the various factors that influence the decision of patients diagnosed with OSA to purchase the CPAP device.

Study Impact

The study shows that reduced device cost, locally manufactured customized masks (interface) to suit facial features and increasing awareness about the importance of therapy to prevent complications would help increase the acceptability of CPAP, thereby improving the quality of life. The study also suggests that OSA is a condition associated with multiple factors like economic, cultural conditions and practices that play a pivotal role in treatment acceptance and compliance.

Introduction

Obstructive sleep apnea (OSA) is a disorder characterized by repeated upper airway obstruction during sleep¹. The symptoms of this syndrome range from excessive nocturnal snoring and apneas² to excessive daytime sleepiness, which could impact professional and learning activities³. OSA is also associated with other comorbidities such as ischemic heart disease⁴, hypertension⁵, metabolic diseases⁶, and other cardiovascular-related events.

Epidemiological studies of the condition in its early attempts have only included men in the sample groups, since clinical reports from the 1970s and 1980s have suggested that the condition predominantly affects men⁷. The other possible biases may have risen due to the perception that the symptoms reported in women are different to those in men⁸, and that the male population is preferred for studying diseases affecting both genders.⁹ Davies and Stradling¹⁰ analyzed 12 major sleep apnea studies of the western countries, and observed that 1% to 5% of men have OSA. Evaluating nine studies,

Lindberg and Gislason reported that the prevalence of undiagnosed OSA cases were between 0.3% to 5%¹¹.

The limitations of infrastructure, resources, and expertise have affected the OSA epidemiology data collection in India. Research by Sharma et al involved the diagnosis and analysis of a total of 2,150 subjects, reporting an OSA prevalence rate of 13.74%¹². Another study, encompassing 2,860 subjects and representing most of the socio-economic strata present in the Indian society, reported a prevalence rate of 9.3% (95% CI=8.2%-10.5%) for OSA¹³. A similar study, on a much larger scale, was undertaken by Vijayan et al on 7,975 subjects. This extensive study sample indicated an OSA prevalence rate of 4.4% (95% CI=3.8%-5.1%) in male and 2.5% (95% CI=2%-3%) in female populations¹⁴.

Continuous positive airway pressure (CPAP) device is the treatment of choice for patients with symptomatic moderate to severe OSA. It is reported to reduce OSA-related risks of cardiovascular diseases¹⁵, excessive daytime sleepiness,¹⁶ along with an overall improvement in the patients' quality of life¹⁷.

Despite reported benefits of CPAP usage and the availability of a wide range of treatment options, such as bi-level positive airway pressure and auto-adjusting CPAP,¹⁸ the acceptance of treatment and subsequent long-term adherence is questionable. The acceptance of CPAP treatment is influenced by various factors. Some of the prominent factors that play a role are patient's mindset and socio-economic status, equipment variables, physician behavior, healthcare facility, experiences of the family, and government policies^{18,19}. According to a recent study by Simon-Tuval et al, only 40% of patients who were prescribed CPAP had purchased the device¹⁸. As reported in a study by Suri et al, in a resource-limited country such as India, cost is the most significant deterrent to the treatment, with about 80% of patients citing this reason for not considering CPAP therapy. Other important barriers cited, included the need for lifelong usage of the device (40%), inclination to address the problem with alternate therapies (35%), and social stigma (30%).

Objectives

The current study analyzed patients in a Chennai, India-based sleep clinic for various factors that would influence the patient's acceptance of CPAP therapy, subsequent to prescription. The study, in addition, attempts to add

to the Indian epidemiology data on CPAP compliance and adherence.

Methodology

This is an observational study conducted at the Nithra Institute of Sleep Sciences, a sleep institute based in Chennai, India. Between 2008 and 2010, a constant recruitment of 1,098 subjects suspected of having sleep disorders was carried out at the center. As this was an observational study, ethics approval was not taken, however, the study was conducted in accordance to the Declaration of Helsinki, and informed consent was taken from patients before polysomnography tests. Omitting patient non-compliance, refusal for further follow-up consultations and clinical diagnoses of patients such as insomnia and delayed sleep phase syndrome (DSPS) from the total cohort, resulted in 343 subjects undergoing a PSG study for a comprehensive evaluation of their OSA condition. CPAP devices were prescribed for those patients diagnosed with moderate or severe OSA, based on the discretion of the treating physician who took into consideration the patients' apnea-hypopnea index (AHI), partner preferences, and other cultural norms. Two hundred and ninety one patients were recommended to use CPAP devices based on the clinical criteria described above.

A support session and program for patients prescribed with CPAP devices was performed as a routine procedure to enable new adopters to use the device in an appropriate manner. These patients consulted with a respiratory therapist at the center. The results of the PSG study were discussed with the therapist and a titration session scheduled subsequently. Vital clinical data were recorded to determine the required pressure, observe physical changes, and determine patient comfort with the use of the device. The AHI index, generated by the CPAP device (PSG), was recorded and the revised AHI recordings reviewed by the sleep physician. On receiving the results of the titration studies, the sleep physician recommended and motivated the patient to procure a CPAP device. Patients who agreed to comply by the prescription were subsequently educated on CPAP aspects such as benefits and mask selection criteria. Following the procurement of the device, the patients were educated on device operation, usage, and maintenance. Patients were instructed to contact the physician when problems, such as discomfort during usage, nasal dryness, and nasal congestion were experienced. These problems were

addressed by the physician according to accepted protocols and guidelines.

Every patient was followed up diligently by the research team at regular intervals, both telephonically and in person, at the center. Follow-up visits were recommended initially, once in 15 days for the first one month since the patient started to use the device. Subsequently, the recommended visits changed to once a month for the next 6 months followed by once every 6 months.

Data and Statistical Analysis

All data was analyzed using SPSS 15.0, and R environment version 2.11.1 software. Descriptive statistical analyses were carried out for the data variables and the results on continuous measurements presented on mean \pm SD (min-max). Results on categorical measurements were presented in percentage (%) and a 95% confidence interval computed to find significant features. Confidence intervals with lower limit higher than 50% were associated to be statistically significant.

Results

Among the cohort of 1,098 patients, 439 (39.9%) subjects were suggested further for investigations to evaluate their sleep disorder, while the remaining 659 subjects were not advised to undergo PSG studies since they were clinically diagnosed to have other sleep-related conditions such as insomnia and DSPS. Out of 439 patients, who were deemed to require further investigation, 343 (78.13%) consented and the remaining declined or did not revert for further follow-up Table 1.

PSG, Polysomnography; DSPS, Delayed Sleep Phase Syndrome

Table 1: Number of subjects responding to undergo further clinical investigations

| | Number of patients (n) | % |
|--|------------------------|------|
| Patients not requiring PSG (insomnia, DSPS) | 659 | 60.1 |
| Patients who were advised PSG | 439 | 39.9 |
| Patients who were advised PSG and consented to undergo PSG | 343 | 78.1 |

We noted that all 343 patients who underwent PSG had varying degrees of OSA confirming that the clinician requests for PSG were appropriate. Majority (76.1%) of patients who underwent the test were categorized as having a severe form of OSA Table 2.

Table 2: Severity of OSA based on PSG

| | Number of patients(n=343) | % |
|----------------------|---------------------------|------|
| Mild (AHI 5-15) | 24 | 6.9 |
| Moderate (AHI 15-30) | 58 | 16.9 |
| Severe (>30) | 261 | 76.1 |

OSA, Obstructive Sleep Apnea; PSG, Polysomnography; AHI, Apnea-Hypopnea Index

Based on the findings of the PSG studies and clinical appropriateness as determined by the clinician, 291 patients were recommended to use CPAP devices. A follow-up conducted 6 months subsequent to prescribing the device, observed that only 41.9% (n=122) had purchased the devices while the rest of the 58.1% (n=169) had refrained from doing so due to various factors; elaborated further in the article.

During the follow-up activity, patients who purchased the device (n=122) were questioned on the frequency of usage and impact the therapy had on their lifestyle (Figure 01). Around 84.42% of patients responded that they used the device regularly and it had made a significant impact on their lifestyle by improving symptoms associated with OSA. Another 9.8% of them stated that although it made them feel better, they had been using

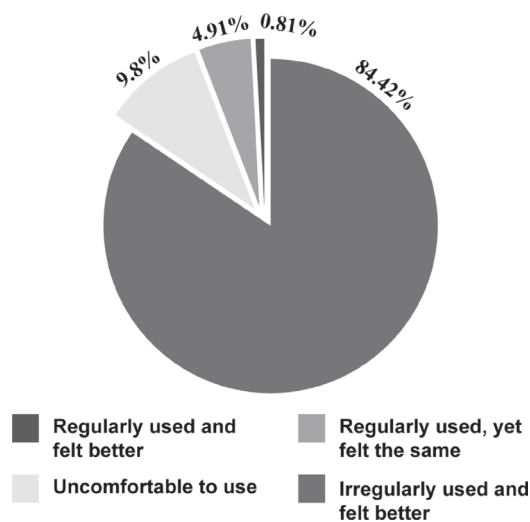


Figure 1: Patients' feedback on the effects of CPAP use

the device irregularly. However, 4.9% felt that the device was uncomfortable to use, and 0.8% found no beneficial effects after its use.

A similar follow-up was conducted on patients who were advised CPAP therapy, but had declined to purchase the device. The primary barrier to purchasing a CPAP device, as determined by our study, was the cost of the device. Among the 169 patients who refrained from buying a device, 36.68% cited that it was unaffordable. Other prominent reasons for declining the purchase of a device included a deferred decision despite having an inclination towards its procurement (17.75%), and unawareness of the cost benefits involved in such an expensive investment (11.24%). The complete list of responses observed from this group of patients is recorded in Table 3.

Table 3: Reasons for not purchasing CPAP

| | Number of patients (n=169) | % |
|---|----------------------------|-------|
| Cost | 62 | 36.69 |
| Expressed interest for purchase, but needed time | 30 | 17.75 |
| Oblivious of cost benefits | 19 | 11.24 |
| Feel uncomfortable/inconvenient for use | 15 | 8.88 |
| Unable to track patients | 12 | 7.10 |
| Decide on weight reduction measures as 1 st option | 11 | 6.51 |
| Want to buy from a different place (US) | 8 | 4.73 |
| Not willing to give information | 7 | 4.14 |
| Scared to use | 5 | 2.96 |

CPAP, Continuous Positive Airway Pressure; US, United States

Discussion

Our study observed that the patient groups who accepted the treatment, purchased the device, and used it regularly experienced a significant positive outcome in managing their OSA and its associated problems. We also found that among our patient population, close to 60% never initiated the therapy due to various reasons mentioned previously. We observed that some of the main reasons for not purchasing a CPAP device were sensitivity to

cost, peer and family influence as to the place of purchase, and alternate medical therapies viz losing weight and reversing the condition. The following discussion considers the observations of our study and the prevalent literature.

Improvements in OSA-related symptoms

Observations compiled through self reporting by the patients in our study revealed that 84.42% of those who purchased the device and used it regularly experienced positive outcomes from the treatment. They had lesser daytime sleepiness and other improvements in associated symptoms such as alertness, focus, and a general enhancement in quality of life.

A randomized control study²⁰ reported that CPAP usage significantly reduces daytime sleepiness when compared to the placebo group (mean sleep latency=7.2 [SE=0.7] vs. 6.1 [0.7] min; P=0.03), reflecting a similar outcome as seen in our study. A review article published in 2006²¹ reports the impact of CPAP under various parameters. With respect to the reduction in apnea, the study reported that CPAP has a greater impact when compared to other treatment measures such as placebo, conservative management, and positional therapy.

With regard to improvements in daytime sleepiness, a randomized control study comparing CPAP with an optimized placebo²² reported that CPAP has a much superior effect in relieving daytime sleepiness as measured by Epworth Sleepiness Scale readings (-9.5 versus -2.3; P<0.001). Additionally, the study reports improvements with other OSA-related symptoms such as vigilance and general productivity.

Barriers to purchasing the CPAP device

Cost: It has been determined in our study that the top deterrent for patients not purchasing the device has been the costs involved. While Suri et al found 85% of patients citing cost as the reason for the non-acceptance of CPAP therapy; our study demonstrated a much lesser rate of non-acceptance at 36.69%²⁶. This may be explained by the change in attitude towards cost over the years. Another study reported that 29% of their patient population cited cost of the device as the reason for not accepting CPAP therapy, thereby reflecting similar results¹⁸.

Developing countries such as India, having a large population living under extreme financial pressures, cast a shadow on the ability to afford expensive devices such as CPAP. The fact that third party insurance coverage is minimal and most patients pay out of pocket is a major factor influencing this

A longitudinal interventional study conducted in Israel²³ has demonstrated that the financial factor is a major barrier to accepting CPAP treatment in a healthcare system that requires the mandatory 25% to 50% of CPAP cost payment from the patient. The study²³ explored whether financial incentives had a better acceptance and provide a more positive stimulus among patients to purchase the device. The study reported that among patients who were classified under an average or higher income group, CPAP acceptance was primarily influenced by the severity of the condition and their partner's preferences rather than the financial factor. It was reported that the patient group that received financial aid demonstrated a 43% higher acceptance to treatment when compared to the group that received no incentive.

This further reiterates our finding that cost is a significant factor that determines the acceptance of CPAP treatment among various patient groups. Unlike some developed countries such as US where CPAP devices are covered under insurance schemes,^{24, 25} India has this provision only for a select group of patients such as for some central government employees²⁶.

Deferment of decision to purchase: The next most prominent reason for not purchasing the device, according to our results, was deferral of the decision. We report here that nearly 18% of our study population deferred their decision to buy the device, which is close to about 20%, as reported by another Indian study.²⁶ This deferred decision-making may be the result of an apprehension that subsequent to bearing the complete cost of the device, it may result in wasteful expenditure if it does not eventually suit the patient.

Lack of awareness and education: Another predominant reason for deferring purchase of the device, as elicited from our study, was the lack of awareness on the beneficial effects of using CPAP.

A randomized control study compared two groups of patients: one that received usual support and another that received an extended level of nursing support along with CPAP education at home, involving their partners, and CPAP compliance and outcomes were compared

among the two groups. It was observed that the group that received extended support had greater compliance to the treatment over a 6-month period when compared to the parallel group²⁷. Another study²⁸ used video-based education on the benefits of CPAP during the patients' first clinical visit and reported that those who viewed the educational video were more likely to accept the treatment and follow-up on the clinical visits regularly.

The same reason of lack of awareness and education about the therapy can also be attributed to 3% of our study population who expressed a deep concern and anxiety to use the device. Appropriate and an extended patient education and support program needs to be an integral part of the treatment plan for patients diagnosed with OSA in order to overcome such challenges.

Our study also made a unique observation: those patients who evinced interest in adopting the treatment module with CPAP were not in favor of purchasing the device in India, instead expressed a particular desire to procure it from the US. We were unable to document the reason for this viewpoint, but we feel it is linked to a consumer pattern that developed countries, such as US and UK, offer better quality of medical devices than developing countries such as India despite the fact that CPAP equipments available in India are all imported from US or UK.

Discomfort: The point of discomfort while using CPAP devices have been discussed extensively in literature, and our study found no contrast to the observations made in the previously reported publications.

Although various types of masks are now available to negate the discomfort experienced by the patients²⁹, we have still observed that this still remains one of the primary reasons for non-compliance for CPAP therapy. Some of the commonly reported incidences have been local skin irritation, leakage, nasal congestion, and nasal and throat dryness. A previous study, measuring the factors for compliance and non-compliance of CPAP therapy, reported that 91% and 65% of the non-compliant group complained of adverse effects and mask discomfort, respectively³⁰. Another study reflected the similar findings in 53% of their sample, who disrupted of treatment due to mask discomfort. The study further reports that the adverse effects of mask discomfort ranged from broken skin or open sores to less severe events such as redness on the skin and persistent pain³¹.

Reporting mask strap-related concerns expressed in

25% of the patient cohort, another Indian study²⁶ discusses that since most of the devices are manufactured in western countries, the cranio-facial design do not necessarily conform to the Indian ethnic race, leading to discomfort and injury, and non-compliance. Promoting customized nasal masks molded with elastic prosthetic material may aid in relieving the discomfort from usage³⁰.

Conclusion

The observations and findings of our study add to the previously known determinants of CPAP acceptance found in the medical literature on the subject. As reported in numerous previously published studies, our study has reiterated that CPAP therapy can definitively improve in relieving the symptoms of OSA. Despite this, we found that there exist numerous barriers to CPAP acceptance, influenced by certain local, cultural, geographical, and economic factors. Certain recommendations that we would suggest through this article include the following:

- Reduction in cost of the device may result in better acceptance of the treatment. The medical fraternity should promote research to innovate and develop low cost and easily accessible devices so that it can benefit a large populous country such as India.
- Sleep physicians need to improve the awareness level and adopt innovative models to educate patients who have been prescribed therapy with CPAP. With a large section of the Indian population still remaining illiterate, such measures will help augment the existing models to improve the proportion of patients opting for CPAP therapy. Extended clinical follow-up and psychological support is necessary to improve compliance and adherence to treatment.
- Locally manufactured and customized masks and devices will not only help relieve discomfort and improve experience and treatment outcomes, but will also help in making the device affordable.

OSA is a condition surrounded by multiple factors such as economic, cultural conditions, and practices that play a pivotal role in treatment acceptance and compliance. The condition needs a multi-specialty approach during treatment, primarily driven by financial assistance, patient education, and psychological support.

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