A Home Monitoring System for Nasal CPAP*

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A compact portable sensing system (PSS) was developed for home monitoring of patients with obstructive sleep apnea treated with nasal continuous positive-airway pressure (CPAP). The system consisted of a solid-state pressure sensor connected with plastic tubing to the side port of the nasal CPAP mask, a power supply, and a strip chart recorder. The device was validated against standard polysomnography in ten patients with obstructive sleep apnea undergoing overnight nasal CPAP trials. A total of 397 apneas and hypopneas were observed in the ten patients. The PSS device detected 386 events (sensitivity, 97.2 percent). In addition, there were 29 false positive events noted by the device (positive predictive value, 93 percent). The device was then tested at home in 23 patients on nasal CPAP. Eight of these patients had persistent apneas requiring adjustment of their CPAP pressure. The PSS device allowed for accurate reevaluation of nasal CPAP settings in the patient's home without necessitating expensive, time-consuming in-hospital laboratory polysomnographic studies.

Nasal continuous positive airway pressure (CPAP) has recently been advocated as a safe and effective mode of therapy for obstructive sleep apnea. Nasal CPAP appears to work primarily as a pneumatic splint which passively opens the upper airway, thus precluding obstructive apneas.

Patient compliance has been shown to be as high as 75 percent, although some patients complain of mask discomfort, nasal dryness, and congestion. We have found a slightly better compliance in our laboratory due to very close outpatient follow-up. Several of our patients, however, have raised questions about the adequacy of the mask pressure because of persistent daytime sleepiness. Others have wondered whether the pressure could be lowered in an effort to decrease mask discomfort. Because of a four- to six-week backlog in our scheduling, it became increasingly difficult to bring these patients back to the sleep laboratory to monitor them on nasal CPAP. Further, questions have been raised about third-party reimbursement for these follow-up studies. It became apparent to us that it would be helpful if a monitoring system was available for determination of nasal CPAP efficacy in the patient's home. With the help of one of our patients, a computer engineer, a portable pressure sensing system (PSS) was developed and tested.

MATERIALS AND METHODS

The system consisted of a solid-state pressure sensor (Micro Switch 1PC01D36) with a range of approximately ±13 cm H₂O and a maximum pressure tolerance of ±5 psi. The device was powered by a Radio Shack 9-V Adapter (270-1552) which could be plugged into a standard 110-V electric outlet. Plastic oxygen tubing connected the pressure sensor to the side port on the nasal CPAP mask (Respironics, Inc). The electric output from the pressure sensor was fed into a Biox 2100 strip chart recorder (Ohmeda), which was set to run at a speed of 3 cm/min.

Validation Procedure

The initial part of the protocol involved validation of the PSS against standard polysomnography. Ten patients with documented obstructive sleep apnea were studied with all-night polysomnography in the sleep laboratory at Rhode Island Hospital. Sleep stages were monitored with an electroencephalographic (EEG) lead, bilateral electro-oculograms, and a submental electromyogram (EMG). Sleep was characterized using the system of Rechtschaffen and Kales. Respiration was monitored using oral and nasal thermistors, surface intercostal EMGs, and pulse oximetry (Biox 3A oximeter, Ohmeda). Signals were recorded on a 17-channel polygraph (Nihon-Kohden).

The patients were fitted with a nasal CPAP mask connected to a blower unit (Sleep Easy, Respironics, Inc). Five of the subjects were tested using the original Respironics system which provided positive airway pressure throughout the respiratory cycle. The remaining five used the modified-Sander's circuit (Respironics, Inc). There is a valve in this circuit that allows airflow to reach the nose and pharynx only during inspiration, although there is positive pressure within the mask throughout the ventilatory cycle. Plastic oxygen tubing connected the mask to the solid-state pressure sensor. The electric output from the sensor in this part of the study was recorded not only on the strip chart recorder, but also on one of the channels of the polygraph to allow for easier comparison between the two methods.

The patients were allowed to go to sleep with the mask at the lowest pressure setting (3 to 5 cm H₂O). As apneas and hypopneas appeared, the pressure was slowly increased to a level at which all respiratory events were obliterated. The pressure was maintained at this level until morning.

The two sets of records were independently scored and then compared. An apnea was noted on the polysomnographic tracings if there was a total absence of airflow associated with an oxygen desaturation of at least 4 percent and in most instances associated with an arousal from sleep. A hypopnea was noted if there was a partial decrease in airflow associated with a 4 percent or greater fall in oxygen saturation and an EEG arousal. In a similar manner, the signals from the PSS device on the strip chart recording were also

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A hypopnea was noted if there was a 50 percent or more decrease in the pressure deflection. The sensitivity of the PSS device was determined by dividing the true positives by the total number of respiratory events detected by standard polysomnography. The positive predictive value was determined by dividing the true positives by the number of respiratory events detected by the PSS device. The length of the episodes observed by the two methods were compared by linear regression techniques.

Home Feasibility Study

The device was brought to the home of each of 23 patients after they had been on nasal CPAP for a minimum of ten days. A registered respiratory therapist (S.C.B.) confirmed that they were using the nasal CPAP system correctly and instructed them in how to connect the PSS device to their CPAP mask and how to turn it on. The therapist then adjusted the pressure tracings on to the middle of the strip chart paper as the subject breathed through the CPAP mask with the blower on. The PSS device was left in the patient's home, and recordings were made for two nights. The recordings from these nighttime studies were reviewed by a physician (R.P.M.) who counted the total number of apneas and hypopneas for each night. If multiple apneas or hypopneas were noted and the patient was still experiencing daytime sleepiness, the CPAP mask pressure was increased by 2.5 cm H2O. A home monitoring test was then repeated.

RESULTS

Representative respiratory patterns detected by the PSS device are shown in Figure 1. These patterns were not affected by body position.

All ten patients successfully completed the in-hospital validation studies. The final pressure settings ranged from 7.5 to 15 cm H2O. The apnea and hypopnea detection rate by the PSS device was the same for both nasal CPAP systems, so the results are combined for all ten patients. A total of 397 apneas and hypopneas were detected by standard polysomnography. The PSS device detected 386 of these events (sensitivity, 97.2 percent). There were 29 false positive events recorded by the PSS (positive predictive value, 93.0 percent). The majority of these false positive events actually corresponded to an observed absence of airflow detected by both oral and nasal thermistors. However, review of the polysomnographic record showed that these episodes were not true hypopneas or apneas, because the subjects were awake. These were caused by movement artifacts induced by vigorous body movements during an arousal from sleep. The PSS device could not differentiate apneas from hypopneas compared with standard polysomnography. On 48 occasions the PSS device recorded an event as an apnea, although it appeared to be a hypopnea from the polysomnographic record.

When we compared the lengths of the respiratory events as determined by the two methods, the relationship could be defined by the equation $y = 0.86x + 2.86$ (where $y$ is the length of the respiratory event measured by the PSS device and $x$ is that determined by polysomnography). The standard error of the estimate was 4.46. The difference in length between the two methods plotted against the duration determined by standard polysomnography is shown in Figure 2. The PSS device appeared to be least accurate in estimating apnea and hypopnea duration when the event was over 40 seconds long.

Twenty-three patients successfully used the PSS device at home. Technical problems were minimal and occurred when the recorder ran out of paper or the pen ran out of ink on three occasions. Eleven patients who were clinically improved on nasal CPAP were found to have fewer than five apneic or hypopneic events per hour of sleep by the PSS device. One patient still had persistent daytime sleepiness despite the fact that the PSS device detected fewer than five respiratory events per hour of sleep. Further evaluation of this patient revealed that he had coexistent narcolepsy. Eight patients with persistent daytime sleepiness were found to have persistent apneas and hypopneas with the home monitoring (range, 10 to 80 respiratory events/hour of sleep). The CPAP pressure was increased by 2.5 cm H2O in each of these patients, and the home monitoring study was repeated. In all eight patients the increase in CPAP pressure led to a decrease in apnea severity to fewer than five episodes per hour. This correlated with clinical improvement in seven of the patients. The eighth patient continued...
to have residual symptoms, and on further evaluation was found to have a mildly increased thyroid-stimulating hormone blood level consistent with mild hypothyroidism. His daytime sleepiness responded to thyroid hormone replacement.

Two of the patients who had been on CPAP for several months wondered if their CPAP pressure could be safely lowered from 15 cmH₂O to 12.5 cmH₂O, since they were experiencing mask discomfort. The two patients were fitted with the lower-pressure valves, and after sleeping with lower CPAP pressures for several days, the home monitoring was repeated. In both patients continued CPAP efficacy was confirmed using the PSS device. The patients' daytime sleepiness remained under control, and they continued at this lower pressure setting.

DISCUSSION

This study demonstrates that home monitoring of nasal CPAP patients is feasible and provides an accurate assessment of CPAP efficacy. A solid-state pressure sensor provides a very sensitive index of apnea and hypopnea frequency as well as duration. The use of the device at home allows not only for confirmation of CPAP efficacy in patients who are clinically improved, but also for readjustment of their CPAP pressure if symptoms persist. Further, the use of the home monitoring device alerts the physician to coexistent medical problems, as in the two patients who had narcolepsy and mild hypothyroidism, respectively. The device was easily used by the patients, and the technical problems were mild—a lack of paper and ink supplies.

The device works by sensing changes in pressure within the CPAP mask and thus reflects changes in tidal volume. This differs from oral and nasal thermistors which are detecting changes in airflow. Thermistors cannot really differentiate changes in tidal volume.

For example, rapid, shallow inspiratory maneuvers may give a high flow rate with low volume displacement. Thus, standard thermistors and the PSS device are looking at two different measurements of respiration. The PSS device inaccurately labeled events as apneas when they were registered as hypopneas by standard polysomnography. One possible reason is that the PSS device may be insensitive to very small changes in tidal volume. If one did not try to differentiate apneas from hypopneas, the device was extremely sensitive in detecting total respiratory events.

There are several possible reasons why the mask pressure had to be increased in eight patients after they had been on nasal CPAP at home. One possibility is that an inaccurate assessment was made of the pressure requirements while they were in the sleep laboratory. Another possibility is that the patients developed increased nasal congestion with the use of nasal CPAP and, thus, a higher nasal resistance. At a fixed airflow rate the effective CPAP pressure would thus fall. Since nasal congestion is often noted in sleep apnea patients on nasal CPAP we are now routinely using a topical nasal steroid inhaler or a long-acting antihistamine-decongestant at bedtime in these patients. In addition, the patients may have been consuming alcoholic beverages at home; they were specifically directed to avoid alcohol during the nights they were studied. Alcohol, by decreasing upper airway muscle tone, would increase nasopharyngeal resistance and increase nasal pressure requirements. It is also theoretically possible that the patient could be putting the mask on inappropriately, causing a leak. With a leak there would be a decrease in the effective pressure within the mask, allowing the pharynx to collapse again. The PSS device would appropriately detect the presence of apneas and hypopneas and a shift in the trace from the midline of the strip chart paper. Although increasing the pressure in the mask by one level might overcome the problem, it would
be more advantageous just to fit the mask better.

The true value of the PSS device is that it allows for easy readjustment of nasal CPAP pressure without having to bring the patient back into the laboratory for full polysomnography. At this time, most sleep laboratories are extremely busy as more cases of obstructive sleep apnea are being recognized. Every time a patient returns for readjustment of nasal CPAP this postpones an evaluation of a new patient. Furthermore, there is a potential for a substantial savings in cost. The charge for full polysomnography in our polysomnography laboratory is $700. There is currently no charge for the PSS device; however, a probable charge would be $100 per evaluation, equivalent to the charge for overnight home oximetry monitoring in our region. There was a total of 32 home studies performed in this project, equivalent to a potential savings of $19,200 assuming full third-party reimbursement. This might be an exaggeration of the actual savings, since it may be appropriate to study only those patients who do not have symptomatic improvement on CPAP. However, in those nine such patients in our study, a substantial savings of $8,600 would still occur.

An alternative approach would be to use pulse oximetry in the home to assess CPAP efficacy. The PSS device would probably be more useful in patients with mild obstructive sleep apnea who have frequent apneas and hypopneas but only mildly desaturate, since their baseline saturation is on the very flat portion of the oxyhemoglobin dissociation curve. On the other hand, the PSS device would not be able to detect desaturation without true apneas or hypopneas in those patients with coexistent obstructive sleep apnea and lung disease who are not treated with supplemental nocturnal oxygen. Since these two methods would cost the same and are technically as easy to use, a comparison evaluation of the indications for these two techniques might be indicated in the future.

A portable sensing system has been developed for use in home monitoring of nasal CPAP efficacy. It is easily used by both patient and the home service respiratory therapist. It allows for readjustment of nasal CPAP pressure without requiring return of the patient to an in-hospital sleep laboratory. Thus, it is more time saving and cost effective.

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