

Wireless CPAP Patient Monitoring: Accuracy Study

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ABSTRACT

The objective of this study was to evaluate the accuracy and reproducibility of a novel method for transmitting continuous positive airway pressure treatment (CPAP) compliance and usage data. Using wireless and Internet technology to transmit/receive clinical data, we examined and compared these data to the same data collected using a traditional flow generator-to-PC interface. Previously diagnosed patients were given commercially available flow generators to use in the home setting for a 30-day period. They then returned to transmit these data to a base site as well as to download the same data to a floppy disk for comparative purposes. The study took place at a freestanding sleep disorders center in Atlanta, Georgia, and two HME providers in Buffalo, New York, and Boston, Massachusetts. The patients comprised 21 adults who had been previously diagnosed with obstructive sleep apnea; there were 7 stable CPAP users with at least 1 year on therapy and 14 new users. Data were collected on CPAP units with an integrated computer chip that collects compliance data defined as mask-on duration. Fourteen subjects used a flow generator that collected additional efficacy data such as apnea-hypopnea index. The study confirmed 100% agreement between data sets transmitted wirelessly and the same data set downloaded onsite across all six clinical parameters. This study demonstrates the reliability of this wireless technology for transmitting compliance and efficacy data in both new and established users of CPAP. Potential benefits of this technology include advanced compliance and efficacy along with a potential reduction in health-care costs.

INTRODUCTION

OBSTRUCTIVE SLEEP APNEA is a breathing disorder of sleep that has been shown to occur in approximately 2–4% of the adult middle-aged population in this country. Although the disorder remains both under-recognized and under-treated, a considerable body of evidence indicates that continuous positive airway pressure treatment (CPAP) for obstructive sleep apnea is the treatment of choice. First introduced in 1981,¹ nasal CPAP therapy is effective in reducing or eliminating most sleep-

disordered breathing events by assisting in maintaining the patency of the upper airway during sleep. It does so by delivering pressure to the upper airway that acts essentially as a pneumatic splint.

Typically patients will undergo diagnostic testing either in a sleep laboratory or a home environment. After determination of the presence and severity of obstructive sleep apnea, they undergo a CPAP titration trial. The purpose of the trial is to evaluate the patient's response to nasal CPAP and determine optimal pressure. Optimal pressure can be defined as

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the elimination of most apneas, hypopneas, arousals, and desaturations. Once this is determined, patients are then typically set up for home nasal CPAP therapy.

Considerable efforts have been devoted to evaluating compliance rates in this area. Some studies have shown the initial acceptance rate to be in the 70–80% range, and long-term compliance often declines in hours of nightly use as well as number of nights per week utilized over time.^{2,3}

Several factors have been identified as important in attempting to maximize long-term compliance. Apparently, self-reported hours of use often overestimate actual hours of use,⁴ measured by hour meters integrated with the CPAP unit. Improvements have taken place over the years, including the development of hour meters that measure not just time on of the unit, but actual hours at “mask on” pressure, to ascertain hours of use at the most effective pressure. Further attempts at documenting compliance rates have focused on integral chips within the CPAP units, which collect data on a nightly basis at effective pressures, and store these data over a 1- to 12-month period. Subsequently, the data can be downloaded by the appropriate treatment professional for evaluation, and appropriate steps taken to maximize use.

Various approaches have been developed to expedite the collection and analysis of these data. Current CPAP devices can be interfaced with a computer in the office or home setting to download data. Newer modems can interface with the CPAP unit and the integrated chip to facilitate the reporting of remote data and reduce the need for face-to-face visits. Also, smart cards can be inserted into slots in the CPAP units to imprint the data. These cards are then transported to the appropriate professional in a variety of ways, including the use of mail carriers or other modes, to reduce the need for direct patient travel for regular compliance reporting. However, these methods may be inadequate when the physical presence of the patient is required in the reporting process. Examples include patients losing or failing to mail data cards as well as problems in connecting and operating modems. Compliance reporting has become increasingly important in view of

the therapeutic benefit from CPAP in treating not only sleep-disordered breathing but its sequelae, including hypertension, stroke, and heart disease. Increasingly, third-party payers have also required documentation of use to assure that enrollees are receiving maximum benefit from this intervention.

The present study evaluates a further innovative and evolutionary development in the collection and reporting of compliance data, using wireless and Internet technologies to transmit clinical data. Several parameters of this wireless reporting technology are assessed to determine the accuracy of transmitting data in this modality as compared to the internal chips in CPAP units. In some cases, clinical measures for evaluation included therapeutic data collected by the CPAP units, such as time, median leak, and the apnea-hypopnea index. Although primarily collected to evaluate transmission accuracy, these data are potentially available to evaluate therapeutic efficacy, although this was not undertaken here.

In brief, the purpose of this study was to examine the accuracy and reproducibility of subject data wirelessly transmitted to a remote site and to compare the data to traditionally collected data either from the ResMed S6 CPAP (K#961783) or the ResMed AutoSet T (K#980721) via download.

MATERIALS AND METHODS

Study design

This study was conducted at three locations. The first was a CPAP clinic affiliated with a free-standing sleep disorders center in Atlanta, Georgia. The second was in Buffalo, New York, and the third location was in Boston, Massachusetts. The patients in the second and third locations were affiliated with an HME provider who was managing their post-CPAP set up therapy under the direction of the referring physician.

After appropriate patient recruitment, along with the assignment of identification numbers as well as patient set-up, patients used their flow generators in the home setting for a minimum of a 30-day period. At the end of the 30

days, the patients returned to the initial location of set-up to download the data from the flow generator, as well as to transmit this same data wirelessly to the base site.

Wireless data transmission was accomplished by first attaching a transmission device, described below, to the flow generator. Then, by accessing a secure Web site, a request for data was sent from a secure sever, located in Peachtree City, Georgia, through land lines to the carrier's local transmission antenna, located within several miles of the device and location set up, where it is transmitted wirelessly to the device. Once the device received the request, the data were retrieved from the memory of the flow generator, transmitted wirelessly to a receiving antenna, located within several miles of the device. Then, through land lines back to the secure server, the data became available on the aforementioned Web site.

Subjects

Subjects consisted of 21 patients recruited at random from these three locations. The patients were all adults who had been previously diagnosed with obstructive sleep apnea. In Atlanta, all subjects were users of nasal CPAP for at least a year, and all were stable on nightly CPAP use. In Buffalo and Boston, the patients were new users who agreed to participate in the study to evaluate the technology.

All subjects signed an informed consent and were subsequently enrolled in the study at their local site. Patient confidentiality was protected by the administration of an identification number linked to the data, which can be identified only by number.

CPAP technology

All subjects were set up using commercially available CPAP devices with an integrated computer chip that collects compliance data. This method for the collection of compliance data is a proven and accepted approach that has been in widespread use for several years. The present study used these data, rather than a created data set, because the wireless data transmission device was developed to access existing data sets stored in the internal flow generator's computer chip.

Fourteen of the patients utilized a CPAP device that collects both compliance and efficacy data. At the Atlanta site, all patients used a Resmed S6 Elite Flow Generator that collects compliance and usage-related data. In Boston and Buffalo, the patients used a Resmed Auto-Set T Flow Generator, which collects usage/compliance data as well as therapeutic data that measure efficacy. The S6 Elite provides continuous positive airway pressure at a pre-set level determined by titration. The Auto-Set T provides either fixed pressure in CPAP mode or delivers variable pressure levels that are determined using an algorithm that adjusts pressure according to inspiratory flow. As a result, users will experience variations in pressure on a night-to-night basis, as well as throughout the night depending on changes in sleep staging and position. For purposes of this study, the Auto-Set T devices were used in fixed pressure CPAP mode only.

Both devices deliver pressure to the upper airway through a patient interface. In all cases, the patients were previously fitted with a nasal mask during initial set up and were sent home with the mask. A variety of mask types and sizes were used. Each flow generator was uniquely assigned to an individual patient throughout the trial. The patients were identified by number only.

At the start of the trial, each unit had the internal clock and date set to the current date and time, and existing data in the flow generator chips were set at zero.

Wireless and Internet-based technologies

For data downloading at the end of the trial, an investigational wireless-to-Internet data collection/transmission system, being developed by ResMed, and named the "Spectrum System," was employed in this trial. The Spectrum System consists of the flow generator, a wireless communication device, code-named "Cyrchat," and a secure Web server located in a remote location. The secure Web server receives patient-related clinical data (compliance and efficacy parameters) from the Cyrchat wireless transmitter and it stores the information for clinician viewing, analysis, and reporting through a secure Web browser.

TABLE 1. SUMMARY OF AVAILABLE DATA: COMMON DAYS

Patient ID	Autoscan efficacy	Wireless efficacy	Autoscan compliance	Wireless compliance	Common days ^a	Artifact days ^b	Count
01-001	0	30	28	28	28	2	30
01-002	0	29	28	25	27	2	30
01-003	0	30	27	27	27	3	30
01-004	0	0	25	0	0	0	25
01-005	0	36	27	27	27	9	36
01-006	0	30	28	28	28	2	30
01-007	0	36	27	23	27	9	36
02-001	31	28	31	26	28	0	31
02-002	50	27	47	17	27	3	50
02-003	31	29	29	28	28	3	31
02-004	30	29	29	29	29	1	30
02-005	29	24	29	24	24	0	29
02-006	30	22	30	22	22	0	30
02-007	18	17	18	14	17	0	18
03-001	30	28	30	24	28	0	30
03-002	36	25	36	24	25	0	36
03-003	30	25	30	25	25	0	30
03-004	31	25	31	24	25	0	31
03-005	30	30	30	24	30	0	30
03-006	30	29	30	22	29	0	30
03-007	10	9	10	9	9	0	10
Totals	416	538	600	470	510	28	633

^aCommon days (days in which there is a value in both the wireless and Autoscan data sets) minus (artifact days).

^bArtifact days, days in which mask on duration = 0, occurring after the last treatment day.

Data collection methods

Patients were asked to return with their CPAP unit to their respective set-up locations. Data were wirelessly transmitted using the Spectrum System to the secure Web server. These data were then downloaded onto a storage disk using a predetermined Microsoft Excel format for later comparison with the same base set that was manually downloaded from the flow generators using the same format. All disks were marked with patient codes to assure anonymity. In the tables that follow, the terms "wireless" and "autoscan" refer to the wireless and base data sets, respectively.

Outcome variables

The primary variable of interest was the accuracy of the data transmitted wirelessly compared to the baseline data downloaded from the source-flow generators for one compliance parameter and five efficacy parameters. For the purposes of this study, compliance was defined as an evaluation of patient usage based on mask-on times, mask-off times, and cumulative

TABLE 2. AGREEMENT ANALYSIS FOR MASK ON DURATION

Patient ID	Common days	Duration I ^a	Duration D ^b	Percent agreement
01-001	28	28	0	100
01-002	27	27	0	100
01-003	27	27	0	100
01-005	27	27	0	100
01-006	28	28	0	100
01-007	27	27	0	100
02-001	28	28	0	100
02-002	27	27	0	100
02-003	28	28	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	510	510	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

TABLE 3. AGREEMENT ANALYSIS FOR MEDIAN LEAK

Patient ID	Common days	Median Leak I ^a	Median Leak D ^b	Percent agreement
02-001	28	28	0	100
02-002	27	27	0	100
02-003	29	29	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	347	347	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

mask-on duration. No standard was set for compliance using minimum hours of use. Rather, actual hours of use were utilized. In part, this was because the subjects were mixed, including new and established users who varied in their use. Efficacy measures included indices of mask leak, along with the apnea-hypopnea index, among others. Efficacy data are available only from the ResMed's Auto-Set T flow generator, which was not used for 7 of the subjects. A complete list of all compliance and efficacy parameters is found in the Results section.

Data analysis

Initial analysis of the data set indicates that there were some days in the wireless efficacy data set that did not correspond to the base data sets. It was determined that on these days the mask values were all set to zero, and this discrepancy occurred after the last treatment dates in the base data set. These data were excluded from the analysis. The final comparisons were based on "common days," which simultaneously appeared in the input and output data sets. Agreement analyses were calculated based on percentages as to the degree to which the wireless data in each individual data set agreed with the manually downloaded data.

RESULTS

The study confirmed 100% agreement between both data sources for all clinical parameters. This agreement was maintained across the six clinical parameters:

1. Mask-on duration
2. Median leak
3. Leak 95th percentile
4. Maximum leak
5. Apnea index
6. Apnea-hypopnea index.

Overall, the study recorded a total of 633 unique patient days. Of these, 510 days were defined as common days (80.6%) and 28 were artifact days. A total number of common days for each patient was computed. These data are contained in Table 1. No data were obtained on patient 01-004, who did not return to the set-up site.

Table 2 presents data for each individual patient for mask on duration. Percentage agreement for common days is 100%. Table 3 presents data for median leak in a similar fashion. Again, agreement is 100%. Tables 4–7 display data for the leak 95th percentile, maximum

TABLE 4. AGREEMENT ANALYSIS FOR LEAK 95% PERCENTILE

Patient ID	Common days	Leak 95 I ^a	Leak 95 D ^b	Percent agreement
02-001	28	28	0	100
02-002	27	27	0	100
02-003	29	29	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	347	347	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

TABLE 5. AGREEMENT ANALYSIS FOR MAXIMUM LEAK

Patient ID	Common days	Max Leak I ^a	Max Leak D ^b	Percent agreement
02-001	28	28	0	100
02-002	27	27	0	100
02-003	28	28	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	346	346	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

leak, apnea index, and apnea-hypopnea index, respectively. As previously noted, agreement was 100% in all these cases after correcting for common days.

Agreement for each patient and overall was defined as the total number of common days in which the values provided by the base unit and wireless data sets were equal, divided by the total number of common days (after removing artifact days). In all the tables, variables ending in "MS WIRELESS" indicate that there is a numeric value for Autoscan but not for wireless. An analogous variable was defined for missing Autoscan data. All missing Wireless dataset values were explained as either artifact days or non-common-days.

Individual data were available for compliance and efficacy for new patients using the Auto Set T device. Although a number of problems were identified, such as high mask leaks, poor use, and a high number of mask-off events, it is beyond the scope of this paper to discuss these issues in any detail.

DISCUSSION

These data indicate an impressively high success rate in data transfer for patients on

nasal CPAP therapy using the spectrum wireless technology. When mature, this approach can have a potentially significant impact on the management and treatment of obstructive sleep apnea.

Considerable effort has been devoted to CPAP compliance in a number of different areas. In one review paper,⁵ problems with the use of nasal CPAP therapy were grouped into six primary categories:

1. Skin reddening or pain over the nasal bridge
2. Leaks into the eyes
3. Mouth leaks
4. Claustrophobia
5. Intolerance to pressure
6. Treatment inconvenience.

Several strategies have been proposed to alleviate if not eliminate these problems, including the use of different masks or other types of patient interfaces, mask cushioning, the use of a chin strap, heated humidification, full-face mask, gradual acclimation or desensitization strategies, ramping features, autotitrating or bilevel devices, as well as patient education, support, and follow up. All approaches require accurate and timely data.

TABLE 6. AGREEMENT ANALYSIS FOR APNEA INDEX

Patient ID	Common days	Apnea Index I ^a	Apnea Index D ^b	Percent agreement
02-001	28	28	0	100
02-002	27	27	0	100
02-003	28	28	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	346	346	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

TABLE 7. AGREEMENT ANALYSIS FOR APNEA HYPOPNEA INDEX

Patient ID	Common days	AHI I ^a	AHI D ^b	Percent agreement
02-001	28	28	0	100
02-002	27	27	0	100
02-003	28	28	0	100
02-004	29	29	0	100
02-005	24	24	0	100
02-006	22	22	0	100
02-007	17	17	0	100
03-001	28	28	0	100
03-002	25	25	0	100
03-003	25	25	0	100
03-004	25	25	0	100
03-005	30	30	0	100
03-006	29	29	0	100
03-007	9	9	0	100
Overall				100
Totals	346	346	0	

^aI, Days in which the numeric values for wireless and Autoscan were identical.

^bD, Days in which the numeric values for wireless and Autoscan were different.

Early approaches to obtaining this information relied on patient self-report done either in person or over the telephone. More recent efforts involve the use of sophisticated technology to collect and transmit these data.

In some cases where compliance with CPAP is required for continued certification for job performance, the collection of information regarding therapeutic benefit could be considerably enhanced. For instance, in patients who are involved in a transportation industry, such as pilots or truckers, CPAP data could be collected on a predetermined schedule to ascertain and assure that the person is obtaining maximum benefit.

This method for collection and transmission of data has potential promise in a number of other clinical areas of medicine, such as cardiology and endocrinology. Holter monitoring could be enhanced by the transmission of data wirelessly. Also, patients with implanted pacemakers may benefit from this wireless technology. Similarly, diabetic patients who require periodic monitoring of blood sugar levels (glucometry) could benefit by transmitting these data to their physicians. Other potential uses include ambulatory blood pressure monitoring and pulse oximetry.

Finally, as new technologies are introduced in the field of medicine, new areas for potential enhancement of treatment and cost savings present themselves. There is a large body of data to indicate that health-care utilization is significantly higher among patients with untreated obstructive sleep apnea than those who are on appropriate treatment. This includes hospitalization and physician visits. Overall medical costs prior to diagnosis were significantly higher among patients with untreated obstructive sleep apnea as compared to those who were treated appropriately. One study indicated that sleep-monitoring procedures for sleep disordered breathing resulted in cost savings of \$9,200 to \$13,100 dollars per quality-adjusted-life year gained.⁶

This study has some limitations. The data are based on a small number of patients, and thus the study should be replicated on a larger sample. Additionally, although wireless services are broadly available in patient homes based on population densities throughout North America, this technology is dependent upon signal strength. As a result, signal strength may not be sufficient in certain areas, particularly remote locations.

Once safety, accuracy, and efficacy of this technology is demonstrated, it may be commercially available for routine home use. The technology does not require the use of the patient's home telephone lines or an outside power source. The patient wears the CPAP unit as prescribed and is not required to do anything further to collect and/or transport the data.

CONCLUSION

In conclusion, spectrum technology is a reliable source for transmitting compliance and efficacy data in a wireless method for both new and established users of nasal CPAP. This technology would enhance patient compliance and efficacy while potentially contributing to cost containment.

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