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Patient Engagement Using New Technology CrossMark to Improve Adherence to Positive Airway Pressure Therapy



A Retrospective Analysis

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> BACKGROUND: Sleep apnea has major neurocognitive and cardiovascular and metabolic risks. Treatment of sleep apnea is suboptimal because of variable adherence to existing therapies.

> METHODS: This trial compared positive airway pressure adherence among patients who were provided active patient engagement (APE) technology vs those who received usual care monitoring (UCM). The primary outcome was expressed by using the US Medicare definition of adherence. Adherence data from two cloud-based databases (AirView and myAir) were analyzed for patients with sleep apnea. Data were included if a patient's activation date in the APE tool was within 7 days of the therapy start date in the UCM database during a defined time window. Data were propensity matched in a 1:2 ratio (APE:UCM) based on baseline patient characteristics.

> RESULTS: A total of 128,037 patients were analyzed. Baseline characteristics were typical of a sleep clinic cohort. APE was associated with more patients achieving adherence criteria (87.3%) compared with UCM patients (70.4%; P < .0001 for the difference). Average therapy usage was 5.9 h per night in the APE group vs 4.9 h per night in the matched UCM patients (P < .0001). Patients with sleep apnea "struggling" with therapy adherence had a 17.6% absolute improvement in adherence using APE compared with UCM.

> **CONCLUSIONS:** Robust therapy adherence rates can be achieved by adding modern technology to usual care. Adopting advances in technology in care management may allow clinicians to more effectively and efficiently treat patients who have sleep apnea. Rigorous randomized controlled trials may be required before making strong clinical recommendations.

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KEY WORDS: CPAP; lung; OSA; sleep-disordered breathing; sleep medicine

ABBREVIATIONS: AHI = apnea-hypopnea index; APE = active patient engagement; PAP = positive airway pressure; UCM = usual care monitoring

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OSA is a serious condition with major cardiovascular, metabolic, and neurocognitive sequelae. Treatment with positive airway pressure (PAP) is highly efficacious because it generally eliminates respiratory events in adherent patients. However, the effectiveness of PAP is limited by varying adherence to treatment. Although the data vary, they suggest that PAP adherence may be optimized by using labor-intensive approaches such as detailed support and education. However, reported adherence rates fluctuate widely, ranging from 50% to 80% depending on the study. Many patients also refuse to undergo diagnostic testing or never agree to therapy, emphasizing the need for further education and research into new treatment approaches.

Technological improvements continue to be made, both in the PAP devices themselves and in their implementation using remote monitoring, exception management, and patient engagement. PAP devices have become small and quiet, with built-in humidifiers and comfort features such as inspiratory support, expiratory pressure modulation, and pressure-ramping features. In Improvements in adherence with these technological advances have been modest, leading investigators to pursue new ways to engage patients to use their PAP device. For example, adherence of patients

can be improved by direct feedback and motivation for activity (in the case of Fitbit) or for diet (in the case of iPhone calorie counts). 17,18 In the PAP arena, several technologies have been developed that allow patients to engage in their own care by monitoring adherence (eg, the PAP device displays previous night's usage) and providing direct feedback and coaching messages in real time. This approach can be tailored to provide both positive and negative feedback to the individual based on objective data. Another technology-related approach is to use a cloud-based platform that receives regular data updates from PAP machines. Such an approach allows clinicians to monitor adherence to therapy of PAP patients, including hours of use, residual apneahypopnea index (AHI), and mask leak. 19 However, data are limited regarding the effectiveness of these new technological approaches regarding improving PAP adherence.20

Using this conceptual framework, the goal of the present article was to assess the impact of a real-time feedback patient engagement tool on PAP adherence compared with the usual standard of care (remote monitoring of PAP adherence). We tested the hypothesis that patient engagement would yield important improvements in PAP adherence vs usual care.

Patients and Methods

Study Design and Participants

We performed a retrospective analysis of the AirView (usual care monitoring [UCM]) and myAir (active patient engagement [APE]) databases (ResMed Corp). AirView is a Health Insurance Portability and Accountability Act-compliant, password-protected cloud-based technology. PAP device data are transferred automatically to AirView on a daily basis to help clinicians remotely manage compliance and therapy for patients with sleep-disordered breathing. myAir was developed to provide real-time feedback and coaching to patients based on their data within AirView. Patients sign up themselves, and the patient engagement platform is accessed via logging in on the myAir website. Interactions with the patient include: a myAir score, usage-based praise messages, usage-based exception messages, exception-based leak, exception-based AHI, and "badges." The daily myAir score consists of usage hours, mask seal (to indicate levels of leak), events per hour, and number of times for mask on/off. Personalized coaching and reinforcement messages are sent via e-mail and are designed to increase self-management skills, recognize success, and identify and resolve basic treatment issues. These messages generally provide tips on how to make PAP therapy more comfortable or be messages of encouragement when patients meet a certain milestone (eg, average hours of use $> 4\,$ h). Patients in the APE group do not receive any additional materials. Patients in the UCM group did not use the patient engagement tool.

Data were included in the analysis if the database record met the following prespecified criteria: therapy set-up date between October 1, 2014, and July 31, 2015; activation date in the APE tool was

within 7 days of therapy start date; and use of specified PAP devices (AirSense 10 or AirCurve 10; ResMed Corp). Data include PAP therapy in CPAP, automatic positive airway pressure, and bilevel modes. Patients in both groups represent patients being treated for their OSA from private and academic sleep centers, home medical equipment providers, and primary care offices with locations across the United States and, therefore, a range of follow-up programs. Patients with multiple or inconsistent therapy start dates were excluded from analysis. All data were de-identified prior to analysis. This trial was reviewed by the Chesapeake Institutional Review Board and deemed exempt from institutional review board oversight per Department of Health and Human Services regulations 45 CFR 46.101(b)(4).

Outcomes

The primary outcome was the percentage of patients who satisfied the US Medicare criteria for adherence; that is, use of PAP for ≥ 4 h per night on at least 70% of nights during a consecutive 30-day period during the first 90 days of initial usage. Secondary outcomes included mean nightly PAP usage, median number of days to achieve US Medicare adherence, residual AHI, and mask leak.

Statistical Analyses

To minimize risks of potential bias due to differences between the UCM and APE groups, UCM and APE patients were matched on propensity scores. Propensity scores were calculated with a logistic regression model that predicted whether the patient used APE or not, using baseline patient characteristics. The propensity score modeling accounts for and controls for the following confounders:

age at start of therapy (categorized into quartiles), device model, device type, start date of PAP therapy (categorized into four, 3-month time periods), residual AHI on day 1 (categorized into quartiles), and mask leak on day 1 (categorized into quartiles). Variables that were not measured in the myAir database could not be controlled for and are potential confounders. Residual AHI and mask leak data were derived directly from the PAP device, based on flow and pressure. Residual AHI is equivalent to the term "respiratory event index" and is estimated based on airflow. AirView does not require clinicians to input data such as sex and marital status; these data are therefore not available for most patients.

For this study, all data that met the inclusion criteria were included, and thus the heterogeneity of patients is represented. In the primary analysis, patients in the APE and UCM groups were matched in a 1:2 ratio (APE:UCM) based on their propensity scores, using a window of $\pm 5\%$, producing a pair number identifying matched patients in the groups. The 1:2 ratio was used to increase the statistical power of the analyses. The percentage of missing usage data was small (0.31%), and therefore no model estimation was done, and a conservative approach for handling missing values was taken. Usage was set to 0 h, and residual AHI and leak values were set to missing on a given day in the following instances: (1) a usage day had missing usage; or (2) usage was < 20 min. Missing data were not imputed for any other metrics.

US Medicare adherence rates were compared in the UCM and APE groups by using a mixed effects logistic regression model. Mean nightly PAP usage, residual AHI, and mask leak were statistically compared in the two groups with analogous mixed effects ANOVA models. The median number of days to achieve US Medicare-defined compliance was compared between the APE and UCM groups by using a marginal Cox proportional hazards model. The matched trio number was used as a random effect in the logistic and Cox regression models, using a repeated measures analysis; there were no fixed effect coefficients for the confounders. For the logistic regression model that assesses adherence, the fixed effect coefficient for the group was 1.0607, with an SE of 0.016.

A minimum sample size of 202 patients per group was calculated to achieve 90% power to detect a 14% difference in the percentage of patients achieving adherence (based on unpublished pilot research). The required sample size was calculated in the Tests for Two Proportions Procedure of NCSS Power Analysis Statistical Software (NCSS, LLC). Furthermore, a minimum sample size of 305 per group was calculated to achieve 90% power to detect a difference of 7 days in the median number of days to achieve adherence. The required sample size was calculated in the Logrank Tests (Lakatos) (Median Survival Time) Procedure of the Power Analysis Statistical Software.

Results

The study cohort comprised 952,819 patients with a total of 137,089,667 nights of recording. A total of 619,331 patients met the prespecified criteria (42,679 in the APE group and 545,690 in the UCM group) (Fig 1). For the primary analysis population, 42,679 patients in the APE group were 1:2 matched on propensity scores to 85,358 patients in the UCM group. The demographic characteristics shown in Table 1 were typical of a sleep clinic, and > 90% of the patients were based in the United States.

More patients in the APE group vs the UCM group achieved US Medicare adherence (87.3% vs 70.4%; difference, 16.9%; P < .0001) (Table 2). Mean nightly PAP usage was 5.9 h in the APE group compared with 4.9 h in the UCM group (P < .0001). There was a 17.1% absolute difference between groups in the proportion of patients using PAP therapy for ≥ 4 h per night (APE group 83.4% vs UCM group 66.3%). The distribution of mean nightly usage for each group is shown in Fig 2. Figure 3 shows good adherence with APE in contrast to poor adherence with UCM patients. The mean and median number of days to reach adherence criteria are shown in Table 2.

The APE group had modestly improved average daily leak compared with the UCM group (16.9 L/min vs 19.4 L/min; P < .0001). In addition, average daily residual AHI was marginally lower in the APE group vs the UCM group (2.7 vs 3.2 per h [P < .0001]; median, 1.7 vs 1.8 per hour; 95th percentile, 8.5% vs 10.4%; range, 0-70.2 vs 0-91.1).

As an exploratory analysis, we evaluated patients defined as "strugglers" who had average PAP usage < 2 h per night in the first 14 days. Using propensity matching, 475 struggler patients in the APE group were matched to 475 struggler patients in the UCM group. Struggler patients in the APE group had better adherence than similar patients in the UCM group (20.6% vs 12.2%; P = .0003) in the first 90 days of therapy.

Discussion

The present analyses showed that the addition of patient engagement tools (APE) was associated with a significant increase in the proportion of patients reaching predefined adherence criteria compared with UCM. In addition, nightly PAP use was better, mask leak reduced, and residual AHI modestly lower in the APE group vs the UCM group.

A variety of approaches have been used to improve PAP adherence, but results as reported in the literature have been inconsistent. Hoy et al^{8,9} provided intensive support using regular nursing visits and detailed education to improve PAP adherence; however, subsequent studies of these labor-intensive strategies have found more variable results.²¹ Similarly, heated humidification was shown in some, but not all, studies to improve adherence to therapy.¹⁵ Different approaches for pressure relief and autotitration have also provided variable results. In addition, nonspecific changes in technology (smaller, quieter, sleeker machines) may have some benefits.²² However, overall, many clinicians

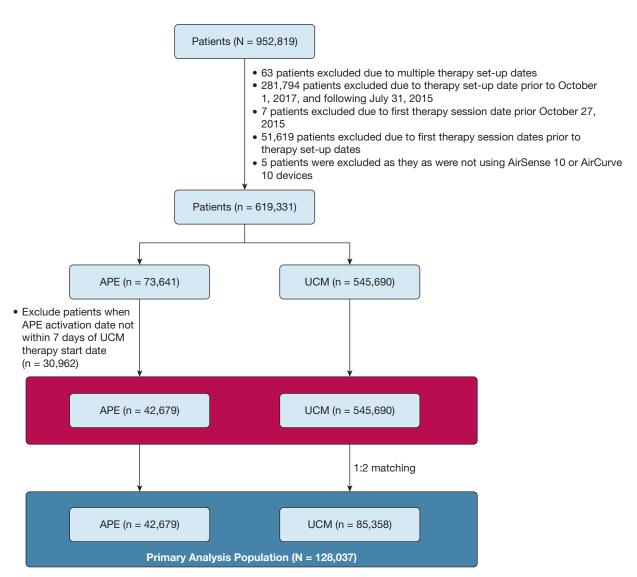


Figure 1 – Flow diagram. APE = active patient engagement; UCM = usual care monitoring.

believe that PAP adherence has been improving over the past 10 to 15 years, perhaps based on increasing appreciation for the major impact of untreated sleep disturbances.¹⁹

The high levels of adherence observed in the present study suggest that excellent outcomes can be achieved with PAP therapy by using modern technology. Although excellent adherence has been reported in some clinical trials, more variable results have been observed in clinical practice. Our results suggest that interactive APE technology can achieve robust outcomes in motivated participants. We also observed that the interactive APE technology was helpful for patients struggling with PAP therapy, suggesting potential benefits across a broad range of individual motivations. Of note, by focusing on patient engagement, no extra

burden is placed on busy clinicians, making this approach feasible in modern clinical practice. Nonetheless, we remain supportive of efforts to develop new technologies and therapeutic approaches for wider acceptance of OSA therapy.^{23,24}

This study was not designed to determine mechanisms underlying improved adherence and device usage when patients were managed using APE, but we offer speculation. First, because APE required patients to sign up for the technology, their motivation and education regarding their health may differ systematically from those who did not. Thus, specific patient characteristics may have driven improved adherence to therapy, rather than use of APE itself.²⁵ Second, the health-care providers whose patients underwent APE may be more attentive to their patients in a manner that differs from providers

TABLE 1] Demographic and Baseline Characteristics

| | Group | | |
|---------------------------------|------------------|-----------------------------------|-------------|
| Parameter | APE (n = 42,679) | UCM (n = 85,358) | Effect Size |
| Age at start of PAP therapy | | | |
| No. | 42,443 | 84,891 | |
| Mean \pm SD, y | 51.8 ± 13.0 | $\textbf{52.2} \pm \textbf{13.4}$ | 0.03 |
| Median, y | 52.0 | 52.0 | |
| Minimum, maximum, y | 18.0, 89.0 | 18.0, 89.0 | |
| 95% CI for mean | 51.7-51.9 | 52.1-52.3 | |
| Missing, No. (%) | 236 (0.6) | 467 (0.5) | |
| Start date PAP therapy, No. (%) | | | |
| October-December 2014 | 3,377 (7.9) | 6,716 (7.9) | 0.00 |
| January-March 2015 | 11,826 (27.7) | 23,652 (27.7) | 0.00 |
| April-May 2015 | 12,393 (29.0) | 24,789 (29.0) | -0.00 |
| June-July 2015 | 15,083 (35.3) | 30,201 (35.4) | -0.00 |
| Mode of PAP therapy, No. (%) | | | |
| APAP | 19,367 (45.4) | 38,768 (45.4) | -0.00 |
| CPAP | 18,161 (42.6) | 36,343 (42.6) | -0.00 |
| Bilevel | 4,841 (11.3) | 9,626 (11.3) | 0.00 |
| Missing | 310 (0.7) | 621 (0.7) | -0.00 |

APAP = automatic positive airway pressure; APE = active patient engagement; PAP = positive airway pressure; UCM = usual care monitoring.

whose patients received UCM only.²⁶ As such, certain providers may be more effective in encouraging adherence to PAP therapy or may deliver improved quality of care

than others. Third, the minor improvements in average daily leak and in average daily residual AHI may both have a role in the perception of the patient regarding utility of

TABLE 2] Adherence Rates and Days to Achieve Adherence

| | Group | | |
|---------------------------------------|-----------------------------------|-----------------------------------|----------------------|
| Parameter | APE (n = 42,679) | UCM (n = 85,358) | P Value |
| Adherent, No. (%) | 37,257 (87.3) | 60,097 (70.4) | |
| Nonadherent, No. (%) | 5,422 (12.7) | 25,261 (29.6) | < .0001 ^a |
| 95% CI for percent adherent | 87.0-87.6 | 70.1-70.7 | |
| By days to achieve adherence, No. (%) | | | |
| 0-30 d | 33,960 (79.6) | 51,042 (59.8) | < .0001 ^a |
| 31-60 d | 2,339 (5.5) | 6,301 (7.4) | < .0001 ^a |
| 61-90 d | 958 (2.2) | 2,754 (3.2) | < .0001 ^a |
| No. of days to achieve adherence | | | |
| $Mean \pm SE^{b}$ | $\textbf{33.6} \pm \textbf{0.11}$ | $\textbf{46.1} \pm \textbf{0.10}$ | |
| Median | 23.0 | 26.0 | |
| 95% CI for median | 23.0, 2.0 | 26.0, 26.0 | < .0001° |
| Subgroup adherent, No. (%) | | | |
| Total | 37,257 (87.3) | 60,097 (70.4) | < .0001 ^a |
| CPAP | 15,974 (88.0) | 26,502 (72.9) | < .0001 ^a |
| APAP | 16,811 (86.8) | 26,407 (68.1) | < .0001 ^a |
| Bilevel | 4,236 (87.5) | 6,889 (71.6) | < .0001 ^a |

See Table 1 legend for expansion of abbreviations.

 $^{^{\}mathrm{a}}\mathrm{Mixed}$ effects logistic regression used to calculate P value.

^bThe mean time and its SE were underestimated because the largest observation was censored and the estimation was restricted to 90 days.

^cMarginal Cox proportional hazards model used to calculate P value.

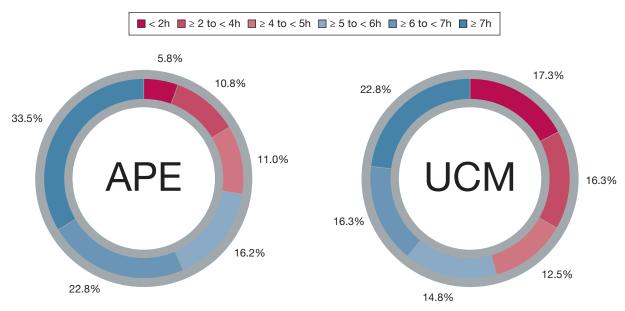


Figure 2 - Distribution of mean nightly positive airway pressure usage. See Figure 1 legend for expansion of abbreviations.

therapy.^{27,28} Even minor improvements in perceived benefit and/or tolerance of PAP therapy may lead to important improvements in outcomes. Fourth, the provision of feedback to patients with a poor night of adherence may motivate improved usage on the subsequent night. This type of real-time feedback is likely to keep patients actively engaged/motivated and thus may have important benefits. Therefore, although definitive conclusions cannot be drawn, we believe that there are several biologically plausible mechanisms that might explain the observed effects.

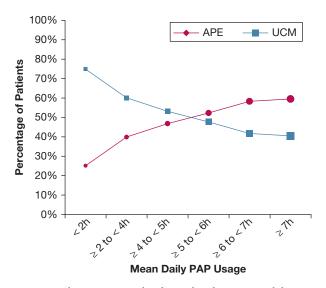


Figure 3 – Changes in group distribution based on mean nightly PAP usage. The y-axis shows the percentage of patients, and the x-axis displays mean daily PAP usage in hours. The size of each dot is weighted by the number of patients it represents. PAP = positive airway pressure. See Figure 1 legend for expansion of other abbreviations.

The present study had a number of strengths, including a large sample size, use of clinically relevant outcomes, and the real-world nature of the sample assessed. However, we acknowledge a number of limitations. This study was not a randomized trial and thus, in theory, unrecognized confounding variables may be responsible for at least some of the findings. We attempted to mitigate bias by performing propensity matching but cannot guarantee that some residual confounding does not persist. In addition, selection bias may occur because participants in the APE group had to choose to join the program actively, or were encouraged by their health-care provider, and therefore their health-related motivation and education may differ from those who chose not to use APE.²⁵ However, adherence in the control group (UCM) was excellent (70.4%), suggesting that all participants were likely well motivated to have their OSA treated.

In addition, we could not quantify how much the APE technology was used and thus cannot account for this variability in our analyses. We acknowledge that the conclusions are limited to the population studied and are supportive of future randomized trials to assess patient engagement approaches in PAP therapy management. Finally, it could be argued that our prespecified outcomes (eg, PAP adherence) are primarily surrogate measures, meaning that the true impact of improved PAP adherence remains to be determined. A 1-h change per night in PAP adherence is a clinically meaningful improvement based on multiple different outcome measures in the literature. 6,29,30

Nevertheless, additional studies are needed to assess the

impact of patient engagement tools on health utilization, cost-effectiveness, and hard clinical outcomes.³¹

Conclusions

Addition of a patient engagement tool was associated with improved adherence to PAP therapy in patients

with OSA. This finding suggests that use of new technology can facilitate OSA patient engagement leading to important improvements in adherence to PAP therapy. Further efforts to improve PAP adherence using new technology are encouraged to improve outcomes in clinical trials and in clinical practice.

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