SleepMapper

A mobile application and website to engage sleep apnea patients in PAP therapy and improve adherence to treatment

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Abstract

Introduction: Sleep apnea is a serious medical condition with significant health consequences. Treatment with Positive Airway Pressure (PAP) therapy is effective, but adherence to treatment is poor. Lower adherence can result in undertreated patients and, in some cases, may lead to refusal of insurers to pay for therapy. SleepMapper is a mobile application and website that employs theoretically-driven and empirically-tested interventions designed to improve adherence to PAP therapy.

Methods: The investigators analyzed a retrospective group of roughly 15,000 patients from the Philips Respironics' EncoreAnywhere database to determine whether having the SleepMapper application resulted in any differences in PAP adherence rates compared to patients who did not have SleepMapper.

Results: Patients using SleepMapper achieved a 78% adherence rate based upon the CMS guidelines. Patients who did not use SleepMapper demonstrated a 56% rate of adherence. Patients using SleepMapper also used therapy an average of 1.4 hours a night longer than those not using SleepMapper. SleepMapper also helped those patients who struggled early with therapy. Thirty-three percent (33%) of those who struggled and had SleepMapper were able to achieve adherence by 90 days compared to only 11% of those who did not have SleepMapper.

Discussion: Patients who engaged with the SleepMapper mobile application and website showed improved adherence rates compared to standard care (defined in this paper). We believe that improvements in adherence are likely related to better patient outcomes and better patient satisfaction.

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Background

Obstructive Sleep Apnea (OSA) is a serious medical illness[1], affecting at least 4% of the US population[2]. OSA has concomitant medical comorbidities that can threaten life, but treatment has been shown to effectively improve both medical outcomes and quality of life[3,4]. Positive airway pressure (PAP) therapy is the most commonly prescribed treatment for patients with OSA. To be maximally effective, PAP therapy must be used nightly[5,6]. Recent Medicare guidelines have resulted in denial of reimbursement for PAP therapy if patients do not demonstrate adequate adherence to treatment. Adequate adherence is defined as the use of therapy on at least 70% of nights, for at least 4 hours each night, over a consecutive 30-day period in the first 90 days of treatment[7].

Adherence to therapy has been thought to be influenced by a number of factors including the severity of symptoms, treatment response, treatment pressure, socioeconomic status, and race. However, most of these predictors do not hold up across studies[8,9]. To date, the most significant predictor of adherence to treatment has been patient motivation to use treatment and patient confidence that they can use treatment during times of struggle[10,11]. These two constructs are directly related to psychological theories of how people go about changing their health behaviors. Such theories have been used to develop interventions to improve adherence to treatment[12,13].

PAP therapy devices are unique because they offer an objective way to account for therapy utilization and provide insight to efficacy. Adherence, determined by the amount of time a patient breathes at the set therapy pressure, can be objectively recorded by PAP devices and reported daily. PAP devices also identify breathing events based on changes in airflow and help identify excessive mask air leaks that could impact therapy use. Data from the PAP device can be downloaded into various software programs that allow the data to be displayed at varying levels of granularity (e.g., hourly, daily, monthly, etc.). The content and presentation of device data vary by the software manufacturer.

One such software program is EncoreAnywhere (Philips Respironics, Murrysville, PA). Device data (adherence and airflow data) are uploaded into a remotely housed, secure server. To access device data and reports, a password-protected account is created by the account owner, typically a durable medical equipment provider (DME) or medical practice. Each therapy device is registered to that account and is associated with a patient identifier created by the account owner. In addition to device data, the account owner has the option to enter additional therapy, health information, healthcare provider, and payer information associated with the patient. Once a device is registered to the account and associated with a patient, device data are uploaded into the database either manually from a data card (SD Card) or automatically through a wireless modem. Once data are downloaded, the account owner has the option of tracking patients and generating therapy summary reports with user-selected levels of detail. Currently, there are over 5 million active patients in the EncoreAnywhere database. Only data from Philips Respironics' therapy devices can be loaded into the EncoreAnywhere database.

As an offering to patients, a first-of-its-kind tool to engage patients with their therapy experience and provide feedback, information, and device support tools was recently made available. SleepMapper (SM) (Philips Respironics, Murrysville, PA) is a mobile application and website that provides patients with their individual adherence and therapy information, access to information about sleep apnea and therapy equipment, and gives patients other tools and techniques for dealing with their therapy. SleepMapper is different from other mobile sleep applications in two key ways. First, the content of SleepMapper and its algorithms regarding how it communicates with patients are derived from psychological theories of behavior change and supported by empirical research[14]. Second, upon set-up, it can be automatically linked to the individual patient's account in EncoreAnywhere and then report individual unique patient data on adherence and airflow data from EncoreAnywhere. SleepMapper has the potential to positively impact patient acceptance of, and adherence to, PAP therapy.

To date, adherence studies typically involve relatively small numbers of patients and findings may be limited by geographical, socioeconomic, or other sources of bias. We undertook an analysis of over 15,000 records from the EncoreAnywhere database to compare adherence in patients using SleepMapper to a similar group of patients who did not use SleepMapper (referred to as Standard Care or SC in this paper).

Methods

For this retrospective study the EncoreAnywhere database was queried to produce records based on the following criteria. The set-up date in EncoreAnywhere was between November 2012 (when SleepMapper was first introduced) and August 2013. Each patient was monitored the entire time of therapy for this analysis. All participants in this analysis had to have at least 90 days of data that could be downloaded into EncoreAnywhere either automatically, through the wireless modem, or manually from the SD card.

Automatic downloads occurred regularly, assuring that data were not lost. Downloads from SD cards could take place at any time. If the SD card was not downloaded, patient use data did not show up in the EncoreAnywhere database. Reports were generated with adherence data at 30 day intervals so that adherence was summarized at day 30, 60, and 90 of treatment for each patient.

For this analysis, we matched the two groups (SleepMapper and SC) on the percentage of patients with SD cards. We could not analyze only those patients with automatic downloads via the wireless modem as this would represent a sampling bias of only those patients who received the type of care that allowed them to receive and keep modems for 90 days. This would likely artificially increase adherence rates. We analyzed the data in three ways.

Conservative analysis:

First, we analyzed all patients that met our criteria. Missing data on any given day were filled in with the number "0". This assumes no use on days where data were missing. This is a very conservative approach and it may underestimate actual use of PAP.

High user analysis:

Second, we analyzed only those patients who had data filled in for the first 90 days. Non-use days would show up as "0" but these numbers could be trusted as accurate. This method artificially overestimates use because it only includes those who receive the special type of care that includes modems for a full 90 days.

Struggling user analysis:

In addition, data were analyzed for patients with at least one download and less than 2 hours average usage per night in the first two weeks. Patients in this category were defined as struggling with therapy.

Records were from active accounts only to eliminate any accounts established for testing or evaluation purposes. This retrospective data analysis was reviewed and approved by an independent IRB. All patient records are de-identified in the EncoreAnywhere database to comply with HIPAA requirements.

The initial set of records was then separated into SleepMapper users and patients without SleepMapper (SC). The query generated 15,242 records with 7,641 using SleepMapper and 7,601 in the SC group. The following primary variables were then determined for each group: percentage of adherent patients defined using CMS guidelines (≥ 4 hours per night over 70% of the nights across a 30-day consecutive period over the first 90 days of treatment) and average use (hours per night) for the first 30, 60 and 90 days.

Statistical methods:

An analysis of variance (ANOVA) was performed on the endpoints of adherence and AHI to examine the between-subjects factor of intervention (SC vs. SleepMapper) and the within-subjects factor of interval (30, 60, and 90 days). A Chi Square analysis compared the percentage of participants meeting CMS compliance criteria at 90 days. Statistical comparisons were considered significant at $p < 0.05$.

Results

Baseline health characteristics of the patient are not always entered into the EncoreAnywhere database, but some data were available for gender and age. There were 24% women in both groups and 38% men in the SC group compared to 50% men in the SleepMapper (SM) group. Thirty-eight percent (38%) of people in the SC group did not specify their gender compared to 26% of the SM group. The SM group was also slightly younger than the SC group (SM = 50.4±13.3, SC = 55.9±14.9). Age and gender have not been reliably associated with adherence in the scientific literature, but we covaried for these factors in the following analyses.

Conservative analysis:

The SM group was more adherent to PAP therapy than was the SC group (See Table 1). When considering the conservative analysis, 78% in the SM group met the CMS criteria for adherence compared to only 56% of the SC group (X^2=835.53, p<.0001). The SM group also outperformed the SC group in hours of use across all time points, despite this conservative approach (SM = 4.5±2.3, SC = 3.1±2.6, F>100, p<.001). This increase of 1.4 hours a night by day 90 is quite large compared to clinical trials of interventions to improve adherence to PAP therapy[15].

High user analysis:

When examining the high-users who had data for a full 90 days, we find the same advantage for SM users. Seventy-four percent (74%) of those in the high-using SC group met criteria for adherence, while 84% of SM users in this analysis met these criteria (X^2=121.89, p<.001). SM users also showed a 0.6 hours advantage over the SC group in hours of use by day 90 (SM = 5.3±2.1, SC = 4.7±2.4, F>100, p<.001).

Table 1. Standard Care versus SleepMapper on adherence outcomes

	Total patients	Adherent patients	Percentage adherent	Hours across 90 days (Avg ± Std Dev)	Percentage of SD cards
Conservative analysis					
Standard Care	7601	4219	56%	3.1 ± 2.6	46%
SleepMapper	7641	5929	78%	4.5 ± 2.3	47%
High user analysis					
Standard Care	3596	2664	74%	4.7 ± 2.4	27%
SleepMapper	5311	4443	84%	5.3 ± 2.1	34%

Figure 1. Adherence over time with Standard Care

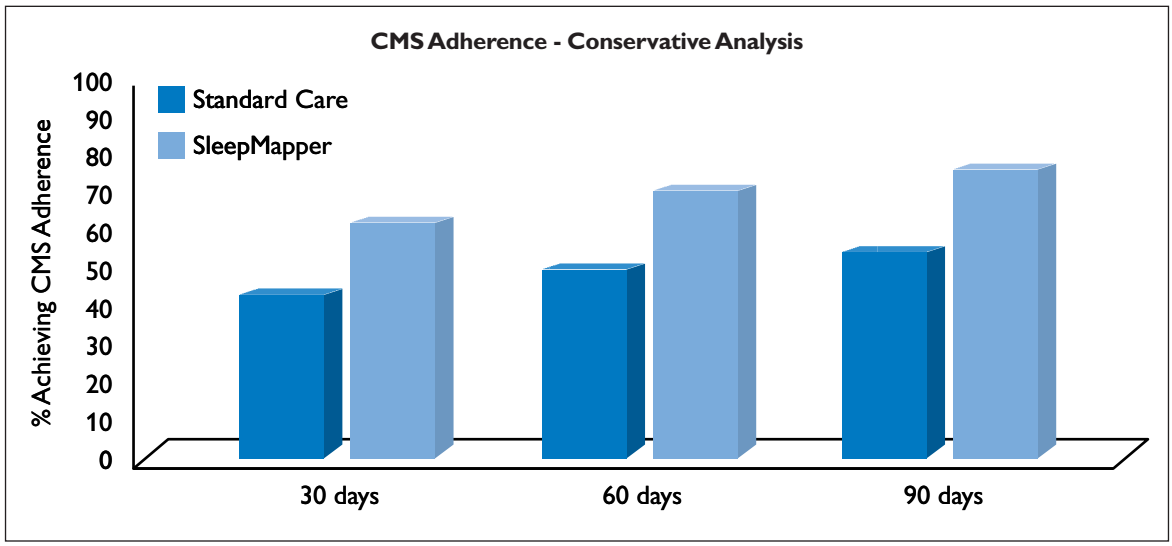

Figure 1 demonstrates the change in percent adherent across time in both groups as well as the time needed to achieve adherence. We see that the group using SleepMapper achieved greater levels of adherence at all time points (30, 60, and 90 days) compared to patients who did not have SleepMapper. Each group increases use as time goes on because adherence percentages are cumulative (e.g., anyone who reached adherence at 30 days will automatically be considered adherent at 60 and 90 days). However, both the percentage and rate of increase in adherence is greater in the SM group compared to the SC group.

Struggling users analysis:

We examined patients who had at least one download and less than two hours average usage per night in the first two weeks (SM = 11.5%, SC = 32%). Thirty-three percent (33%) of the SleepMapper users who met these criteria went on to achieve compliance with the CMS guidelines, while only 11% of the SC users who met these criteria did.

Discussion

PAP adherence has been a consistent problem in assuring that patients and their caregivers reap the full benefits of treatment. Studies have shown that even minimal use of PAP therapy confers benefits[16], but that maximal outcomes are associated with greater long-term use of therapy[5,6]. Advances in device technology have been notable over the past two decades, but these may have begun to plateau in the past few years. Therefore, we need to focus more on the right methods and tools with which the patient can interact to improve their adherence to treatment. These efforts are the purview of the field of Health Psychology and health behavior change experts.

SleepMapper is designed from prominent theories of health behavior change and empirically tested behavioral PAP adherence interventions.[13,14] The SleepMapper tool is the culmination of several years of study focused on why patients choose to use PAP therapy and what factors influence patient engagement and motivation. Constructs from Social Cognitive Theory are employed to develop an intervention that guides patients carefully and with regard to their own capabilities. Feedback and goal-setting are used in ways consistent with Motivational Enhancement Techniques (MET) developed by one of the authors (MSA).

The SleepMapper application uses a personal approach, engaging patients in their own therapy and providing information that is relevant to the patient and his/her family to encourage active engagement in therapy. Educational modules are employed when necessary, but the program operates on the proven point that education alone does not change behavior. Finally, specific METs are employed to enable SleepMapper to provide relevant information to the right users at the right time in order to enhance motivation to change. This retrospective study was designed to test the efficacy of SleepMapper on PAP therapy in the real world.

The results from our retrospective analysis suggested that using SleepMapper confers benefit on adherence to treatment. We demonstrated a marked improvement in time on PAP therapy, as well as on the number of patients who met CMS criteria for adherence to treatment in both the conservative analyses and the analyses of high-users. There were benefits in adherence to early strugglers as well.

Our analyses demonstrated that over 60% of SleepMapper users reached CMS adherence criteria even as early as 30 days into therapy. Comparatively, only 56% of Standard Care patients reach this level after 90 days. CMS criteria for adherence are important, as payers are now implementing similar guidelines across the US and many believe that similar approaches will be taken across the world. Such guidelines require patients to utilize therapy to a set criterion, with proof of adherence, in order to receive reimbursement for their therapy. Our analysis suggests that motivational tools and techniques such as those included in the SleepMapper application and website create a unique opportunity to better engage patients and enable them to help themselves throughout the course of therapy.

SleepMapper may also be particularly helpful to those patients who are struggling. We found that individuals who struggle greatly with PAP therapy within the first two weeks adhere to PAP therapy much better when using SleepMapper. **Thirty-three (33%) in the SleepMapper group who struggled early in therapy went on to achieve CMS adherence criteria compared to only 11% in Standard Care.** This suggests that the mobile application is particularly helpful early in therapy when a patient struggles.

Without adequate adherence, patients struggling early in the course of treatment may be required by their insurance provider to return their therapy device because reimbursement will likely be denied. This may leave patients with minimal options to treat their apnea. There have been no long-term studies of the outcomes of these patients, but it is likely that many of them go untreated for many years after failing therapy.

There are many unique aspects to the SleepMapper mobile application. Perhaps the most notable is the employment of several, empirically-tested methods based on theories of behavior change. There are many health behavior applications on the market today but not many studies reporting the outcomes of using these applications. This is largely because changing behavior is more complex than simply providing feedback and educating and letting patients set their own goals. Feedback about poor use can lead to feelings of failure and abandonment of therapy. Setting the wrong goals can result in similar outcomes. Also, simple education has been demonstrated to work only for motivated patients.

The key to successful and lasting behavior change lies in taking an informed approach to patient engagement and activation. SleepMapper was created using behavior change models, incorporating tools and techniques developed through decades of research into a single mobile application.

We believe that the success of mobile applications for health issues will rely mostly on the approach they take to engage and work with patients to help them solve their own problems and to motivate themselves during time of struggle. In this "real world" example, SleepMapper seems to provide this support and motivation for patients with sleep apnea and it does so within relatively short periods of time.

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