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ORIGINAL ARTICLE

Patient-Reported Usability of Positive Airway Pressure Equipment Is Associated With Adherence in Older Adults

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Study objectives: To examine the usability of positive airway pressure (PAP) devices and its association with PAP adherence among older adults with sleep-disordered breathing.

Methods: We mailed questionnaires to patients aged ≥65 years prescribed PAP therapy during the prior 36 months from two large healthcare systems. Survey participants completed the Usability of Sleep Apnea Equipment-Positive Airway Pressure (USE-PAP) questionnaire, which assessed the usability of their PAP device. Other questionnaire items included demographics and self-rated health. We also abstracted adherence data (mean nightly hours of PAP use available from one site) and interface type from the electronic health record.

Results: Five hundred sixty-four patients completed the survey (response rate = 33%). The mean USE-PAP score (0 = best to 100 = worst) was 20 (*SD* ± 20). Mean duration of PAP use (available in 189 respondents) was 5.2 hours per night (*SD* ± 2.0). In a nested regression model predicting nightly hours of PAP use, a 10-point (0.5 *SD*) increase in USE-PAP score corresponded to a 0.37 hour/night reduction in PAP use. The model including the USE-PAP score explained a significant proportion (R^2 = 15%) of the variation in nightly hours of PAP use above and beyond demographics, self-reported health, and interface type (ΔR^2 = 12%).

Conclusions: Our results demonstrate that PAP usability varies among older patients and is associated with PAP adherence, above and beyond other predictors of adherence. These results support measuring and improving PAP usability to further improve PAP adherence for older patients.

Keywords: sleep apnea, adherence, usability, predictive modeling.

Statement of Significance

We conducted a survey to collect data on patient-reported usability of positive airway pressure (PAP) equipment among older patients, who may be more susceptible to user-device interaction design issues. We found variations in usability issues and showed that usability is significantly associated with PAP adherence. Patient-reported usability is not generally assessed in clinical practice. Because device usability may be a modifiable risk-factor for interventions aimed at improving PAP adherence, we recommend assessing patients' beliefs about and experiences with PAP usability.

INTRODUCTION

Positive airway pressure (PAP) therapy is the most commonly prescribed treatment for sleep-disordered breathing (SDB).[1] Although PAP is an efficacious therapy for reducing the apnea-hypopnea index (AHI), many patients are non-adherent to PAP therapy, with estimates of non-adherence ranging from 28% to 60%.[2,3] Research on PAP non-adherence has focused on psychosocial factors (e.g., outcome expectancies, self-efficacy beliefs, socioeconomic characteristics), disease characteristics (e.g., AHI, sleepiness), technical aspects of devices such as interface type (i.e., nasal pillows versus nasal mask versus full face mask), device modality/titration procedure (e.g., auto-titrating, continuous versus bi-level), and side effects (e.g., claustrophobia, irritation).[3] One category of barriers that has received little attention is the usability of PAP devices.[4–6]

Device usability refers to design factors that impact interactions between individuals and devices.[7] The International Organization for Standardization defines usability as "the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments."[8] Usability may impact the accuracy and completeness with which patients achieve PAP therapy goals such as putting on a PAP mask, the resources expended to achieve these goals, the ease of learning how to use the PAP device, the ease of remembering how to use the device, and the degree to which the user finds the device acceptable and pleasant.[9] Beneficial outcomes of optimizing usability characteristics of medical devices include minimizing risk of error and ensuring device safety (i.e., promoting use of the device in a manner that does not result in harm to the patient or environment).[9] Usability test results are submitted to the Food and Drug Administration (FDA) during the pre-market device approval process.[9]

In addition to impacting device safety, usability has the potential to impact PAP adherence, which in turn may contribute to the overall impact that PAP has on health outcomes.[10,11] Making PAP easier to set up, use, and clean may positively affect adherence to therapy. Large-scale surveys of the usability of PAP devices are lacking, even though interviews with patients about their experiences with these devices suggest variability in PAP usability across patients.[5] Older adults may be more likely to experience usability problems due to the higher prevalence of physical and sensory impairments that occur with advanced age.

In this study, we sought to measure PAP usability and to evaluate the associations between PAP usability and PAP adherence among older adult patients prescribed PAP therapy for SDB. We hypothesized there would be a considerable range of PAP usability scores and that usability scores would be associated with adherence to PAP.

METHODS

Conceptual Model

The FDA's model for medical device usability,[9] which is based upon the International Organization for Standardization

9241-10 definition of usability,[12] served as the conceptual model for this study. This model posits that the device-user system includes three major components: device users (e.g., role [patient, caregiver, physician], other characteristics), device use environments (e.g., home, hospital), and device-user interfaces (e.g., components and accessories, controls, displays, feedback, labeling, training). These components affect device use, which, in turn, impacts outcomes. As described in the introduction, the FDA focuses on safe and effective use as the main outcome; however, other important outcomes include adherence.

Study Design and Sample

In 2014, we conducted a PAP usability survey of older adults (≥65 years) who received SDB care in the Los Angeles area. We mailed questionnaires to all individuals prescribed PAP therapy during the prior 36 months from one Department of Veterans Affairs (VA) sleep center ($N = 1,203$) and two sleep clinics affiliated with a university health system in Los Angeles, California ($N = 526$). A $2 bill was included with the questionnaire as an incentive to return the questionnaire, along with a postage-paid return envelope. The total response rate was 33%: 564 surveys were returned by mail.

In addition to the mailed survey, we conducted a structured medical record abstraction of PAP adherence data in participants recruited from the VA site, where PAP adherence data are routinely documented in the electronic health record (EHR) in the course of usual care; abstraction of adherence data were not conducted at the university site, which uses a different EHR system. PAP adherence data (mean hours of use per night) were available for 189 survey respondents. To evaluate the potential for non-response bias, we abstracted adherence data for a randomly selected subset of VA survey non-responders, which was identified by assigning a random number to each of the non-responders, sorting the observations by that random number, and selecting the top 125 observations. We then compared mean nightly hours of PAP use for survey responders with this randomly selected subset of survey non-responders. Usual care at the VA site consists of hands-on training of all new users of PAP devices. All PAP training is performed by a small core group of experienced certified respiratory therapists who have additional training in sleep devices. Patients are provided detailed information about the device parts, proper care of the device, and comfort settings during the training. At all sleep clinic visits, one to three certified respiratory therapists from this group are available to meet with patients who need new supplies for their PAP devices and to troubleshoot device-related issues. In between clinic visits, support from this core group of certified respiratory therapists is available on a walk-in basis.

All study procedures were approved by the institutional review boards at the Veterans Affairs Greater Los Angeles Healthcare System (#2013–091198) and the University of California, Los Angeles (#13-001132). A waiver of documentation of consent for survey respondents and for EHR review was obtained.

Measures

PAP Usability Measure

An adapted version of the Usability of Sleep Apnea Equipment-Positive Airway Pressure (USE-PAP 18-item scale transformed linearly; 0 [best] to 100 [worst]) questionnaire was included in the mailed survey. It assesses patients' experience setting up, using, and cleaning their PAP devices.[6] This questionnaire was developed using in-depth patient interviews (interviews provided qualitative data on the types of usability issues experienced by older adults), technical advisory panel input (survey items were reviewed and edited by a diverse team of clinicians and researchers), cognitive interviews with patients (participants provided information on the clarity, usefulness, and presentation of survey items), feedback from sleep clinicians, and a pilot survey in sleep clinic. We revised items until patients and clinicians understood the meaning of items such as "what it takes to adjust controls." These questionnaire development activities have been described previously.[6] Total score was used for the main analysis. Two usability subscales were developed to provide information about two specific dimensions of usability, efficiency, and satisfaction. The items comprising these subscales were added and transformed linearly (0 [best] to 100 [worst]). Cronbach's alpha were calculated for the scales. The three remaining items, which represent other dimensions of usability (effectiveness, learnability, and memorability), were single items and therefore, were not included in subscales.

Adherence Measure

Mean Nightly Hours of PAP Use Documented in the EHR. for all VA patients who responded to our survey, we performed structured data abstraction from VA EHR sleep center notes, which typically include PAP adherence information since PAP adherence is one of the main topics discussed during most sleep center encounters, and staff are expected to record this information. The sleep center note closest to the date the survey was mailed was selected for abstraction. If no PAP adherence data were available in the selected note, the next sleep center note was reviewed for PAP adherence data, and so forth until the start date of the approved abstraction period (May 1, 2011) was reached. Sleep center notes occurring after the date the survey was received by our research center were also abstracted for PAP adherence data (available in only a limited number of participants) and for 13 participants who did not have any PAP adherence data prior to sending the survey but who had "post-survey" adherence data, these post-survey data were used. Machine-measured data on hours of PAP use/night obtained directly from querying the PAP device or from the PAP device's memory card were used for this study.

Other Measures

Gender and age were obtained from the medical records during survey mailing preparation. The survey included items on race, ethnicity, and educational level, as well as a single item of self-rated general health from the 12-Item Short Form (SF-12).[13,14] Poor self-rated health is associated with worse medication adherence,[15] and this item is predictive of hospitalization and mortality.[16] Previously validated items on beliefs about PAP effectiveness and importance in sleep apnea management were included in the survey (2 items) to measure how effective individuals believe regular use of PAP is for managing sleep apnea and how important they believe regular use of PAP is for controlling sleep apnea.[17]

Interface and PAP Device Type. The brand and model of the interface were abstracted from medical records and were reliably available for participants from the VA site. We categorized the interface by interface type: nasal pillows, nasal mask, and full face mask. Interface types have been found to be associated with adherence and satisfaction.[18] The brand and model of the PAP device were also abstracted for participants from the VA site.

Data Analysis

We used standard descriptive statistics (e.g., mean, standard deviations) to describe continuous variables and frequencies to describe categorical variables. We estimated the internal consistency of the USE-PAP scale, using Cronbach's alpha.[19] We used Student's *t*-test, Pearson's chi-squared test, and Fisher's Exact tests to compare demographic and usability measures between participants from the VA and university sites.

For the VA subset of participants with adherence data, we regressed USE-PAP score on mean nightly hours of PAP use. To assess for nonlinearity, we plotted residuals versus fitted values and ran models that included quadratic and cubic terms. Then, we ran a nested multivariable regression model predicting mean nightly hours of PAP use to measure the change in R^2 associated with USE-PAP score, above and beyond demographic variables, self-rated health, and PAP interface type. Covariates were put into three blocks in the nested regression model, and each block was successively added. Block 1 included sociodemographic (i.e., age, race, education) and self-rated health. Block 2 included types of PAP interface. Block 3 included the USE-PAP score. Device model was not entered into the regression model, because all patients were prescribed devices from the same manufacturer and there was little variation in the device model at the VA site. Gender was not included in the model, because the VA sample was predominantly male.

In post hoc analyses, we examined the relationship between the usability subscales (efficiency and satisfaction) and hours/night of PAP use, by substituting the USE-PAP total score in Block 3 with the two subscales and the three other USE-PAP items. In addition, we calculated the number of days that elapsed between the date the adherence data were documented and the date the survey was mailed. Because we observed a large range in the number of elapsed days, we examined whether the relationship between USE-PAP total score and hours/night of PAP use was the same for participants with adherence data that were closer to the survey mail date as those with adherence data farther from the survey mail date, by running a nested multivariable regression model that included an interaction between USE-PAP total score and number of elapsed days.

For these statistical tests, $p < .05$ was considered statistically significant. All statistical analyses were conducted with Stata/SE 13.1 (College Station, TX: StataCorp LP).

RESULTS

Descriptive Results

A total of 564 individuals participated in the survey (response rate = 33%). Table 1 shows the characteristics of the study participants. The overall mean age of participants was 71 years (*SD* 5.9; university site = 74 [*SD* 7.0], VA site = 71 [*SD* 5.7], $t(563) = 5.53$, $p < .001$). Overall, the sample was predominantly male (85%) and non-Hispanic white (60%). The university site had more women than the VA site (44% versus 1%, $p < .001$), but the two sites were similar in percentage of non-Hispanic white participants (63% versus 61%, $\chi^2 = 0.138$, $p = 0.711$).

Table 1—Participant Characteristics (n = 564).

Characteristic	Mean (*SD*) or frequency (%)
Age, in years	71.4 (5.9)
Male	477 (85%)
Non-Hispanic white	339 (60%)
Education	
≤8th grade	3 (1%)
Some high school, but did not graduate	9 (2%)
High school graduate or GED	52 (10%)
Some college or 2-year degree	215 (39%)
Trade or technical school	33 (6%)
4-year college graduate	110 (20%)
More than 4-year college degree	127 (23%)
Self-rated health	
Excellent	27 (5%)
Very good	131 (25%)
Good	194 (37%)
Fair	133 (26%)
Poor	36 (7%)

The mean USE-PAP score was 21 (*SD* = 20; range = 0–100) and was not significantly different between the two sites ($p = .29$). The median was 15 (interquartile range 4, 31). Cronbach's alpha for the USE-PAP was 0.94. The USE-PAP efficiency subscale mean was 20 (*SD* = 20; range 0–100) and median was 14 (interquartile range 0, 89), and the USE-PAP satisfaction subscale mean was 21 (*SD* = 22) and median was 12.5 (interquartile range 0, 100). Cronbach's alpha was 0.88 for the USE-PAP efficiency subscale and 0.87 for the USE-PAP satisfaction subscale. Table 2 shows summary statistics of the USE-PAP items. The items with the most favorable usability ratings were related to connecting the tubing (72% strongly agreed that they can easily connect the tubing and 68% were satisfied with what it takes to connect the tubing). The items with the least favorable usability ratings were related to the device controls (11% strongly disagreed that they know how to adjust the device controls) and to the mask/headgear (9% strongly disagreed that they can easily adjust their mask/headgear so it seals).

For the subset of participants with adherence data measured in hours per night (n = 189), the mean nightly hours of PAP use was 5.2 (*SD* = 2.0). The mean nightly hours of PAP

Table 2—Usability of Positive Airway Pressure Device.

USE-PAP item	Strongly agree, *N* (%)	Agree, *N* (%)	Neither agree nor disagree, *N* (%)	Disagree, *N* (%)	Strongly disagree, *N* (%)	Sample size, *N*
Quickly get equipment ready for use	341 (63.6)	115 (21.5)	33 (6.2)	27 (5.0)	20 (3.7)	536
Quickly learned how to get equipment ready for use	290 (53.7)	159 (29.4)	38 (7.0)	35 (6.5)	18 (3.3)	540
Could easily remember how to get equipment ready for use	318 (59.8)	117 (22.0)	52 (9.8)	24 (4.5)	21 (3.9)	532
Know how to adjust controls	194 (36.1)	134 (25.0)	83 (15.5)	68 (12.7)	58 (10.8)	537
Can easily operate controls	250 (47.0)	128 (24.1)	69 (13.0)	45 (8.5)	40 (7.5)	532
Can easily adjust mask/headgear so it seals	243 (45.1)	150 (27.8)	41 (7.6)	58 (10.8)	47 (8.7)	539
Can easily connect tubing	388 (72.1)	101 (18.8)	17 (3.2)	24 (4.5)	8 (1.5)	538
Can easily operate humidifier	296 (59.1)	103 (20.6)	62 (12.4)	24 (4.8)	16 (3.2)	501
Can easily replace filter	328 (61.4)	94 (17.6)	67 (12.5)	27 (5.1)	18 (3.4)	534
Easy to know when working properly	245 (45.4)	144 (26.7)	72 (13.3)	44 (8.1)	35 (6.5)	540
Satisfied with what it takes to adjust controls	197 (37.0)	143 (26.8)	100 (18.8)	52 (9.8)	41 (7.7)	533
Satisfied with what it takes to put on mask/headgear	269 (50.2)	129 (24.1)	53 (9.9)	48 (9.0)	37 (6.9)	536
Satisfied with what it takes to connect tubing	367 (68.0)	100 (18.5)	42 (7.8)	13 (2.4)	18 (3.3)	540
Satisfied with what it takes to prepare humidifier	279 (55.5)	107 (21.3)	61 (12.1)	32 (6.4)	24 (4.8)	503
Satisfied with what it takes to replace filter	306 (56.9)	107 (19.9)	61 (11.3)	35 (6.5)	29 (5.4)	538
Easy to clean equipment	275 (51.5)	126 (23.6)	59 (11.0)	47 (8.8)	27 (5.1)	534
Easy to transport	273 (50.7)	108 (20.1)	64 (11.9)	54 (10.0)	39 (7.2)	538
Would recommend to a friend	308 (57.1)	89 (16.5)	84 (15.6)	19 (3.5)	39 (7.2)	539

Note: USE-PAP = Usability of Sleep Apnea Equipment-Positive Airway Pressure.

use for a randomly selected subset of survey non-responders ($N = 34$) was 5.1 (2.1) hours per night. No significant difference in PAP adherence was found between the survey respondents and randomly selected survey non-respondents ($t(221) = .27$, $p = .790$.).

Bivariate and Multivariable Results Predicting Adherence

In a bivariate analysis among the subsample with EHR adherence data, worse USE-PAP score was associated with lower mean nightly hours of PAP use (beta coefficient = −.033, $p < .001$), and additional analyses confirmed the linearity of the relationship (residuals versus fitted values plot showed no relationship, and quadratic and cubic terms were not significant).

In model 1 ($F(4,153) = 1.10$, $p = .360$, none of the demographic or self-rated health variables were significantly associated with hours/night of PAP use. In model 2 ($F(2, 151) = 0.20$, $p = .822$), no specific interface type was a significant predictor of hour/night of PAP use. As shown in Table 3, in a nested multivariable regression model predicting mean nightly hours of PAP use (see model 3 [full model]), worse USE-PAP score was significantly associated with fewer nightly hours of PAP use (a 10-point increase in USE-PAP total score corresponded to a 0.41 hour/night [24.6 minutes] reduction in PAP use; a 1-standard deviation increase in USE-PAP total score corresponded to a 0.37 hour/night [22.2 minutes] reduction in PAP use). USE-PAP total score increased the model's R^2 by 12% (from 3 to 15%; $F(1,150) = 21.43$, $p < 001$). In this full model, age was significantly associated with hours of PAP use/night.

In a nested multivariable regression model that replaced USE-PAP total score in Block 3 with subscales for efficiency and satisfaction and individual items for learnability, memorability, and effectiveness, the satisfaction subscale was significantly associated with hours/night of PAP use (beta = −482, $p = .005$), while the efficiency subscale ($p = .703$), learnability item ($p = .405$), memorability item ($p = .941$), and effectiveness item ($p = .057$) were not statistically significant (data not shown in a table).

The number of days that elapsed between the survey mail date and the date adherence data were documented ranged from 2 days to 1,089 days (mean 381 days [*SD* 271]). In a nested regression model that included a variable representing the number of days elapsed between these dates and an interaction term between USE-PAP total score and days elapsed (in Block 3), neither the number of days elapsed ($p = .922$) nor the interaction term ($p = .738$) were significant (data not shown in a table).

DISCUSSION

In this study, we observed wide variability in usability ratings among older adults prescribed PAP and found that usability ratings were associated with non-adherence, with each 10-point increase in the USE-PAP score corresponding to

Table 3—Nested Multivariable Regression Modeling Adherence (Hours of Therapy Use Per Night) to Positive Airway Pressure Therapy, Full Model (*n* = 158).

	Model 1 sociodemographics	Model 2 + interface	Model 3 +usability
	Beta coefficients (*p*-value)	Beta coefficients (*p*-value)	Beta coefficients (*p*-value)
Block 1 (sociodemographics)			
Age	.133	.132	.171
	(.100)	(.830)	(.027)*
Non-Hispanic white	.016	.012	.022
	(.848)	(.830)	(.779)
Education	.027	.024	.107
	(.747)	(.774)	(.184)
Self-rated health	−.076	−.076	−.004
	(.347)	(.353)	(.958)
Block 2 (PAP interface type)			
Nasal pillows		.000	−.005
		(.997)	(.954)
Nasal mask		.050	−.004
		(.563)	(.965)
Full face mask (reference)		—	—
Block 3 (usability)			
USE-PAP total score			−.370
			(<.001)**
Observations (*N*)	158	158	158
R^2	.028	.030	0.15
F	1.10	0.79	3.83**
(df)	(4,158)	(6,151)	(7,150)

Note: *$p < .05$; **$p < .01$; USE-PAP = Usability of Sleep Apnea Equipment-Positive Airway Pressure. Standardized regression coefficients are presented above.

a 0.41 hour (24.6 minutes) reduction in PAP use per night. Usability ratings help explain the variation in nightly hours of PAP use above and beyond demographic, self-rated health, and interface type. These results, which suggest that a subset of older patients prescribed PAP therapy have challenges using PAP devices, corroborate findings of variation in usability from our previous work testing a prior version of the survey among a smaller sample of adults[6] and support the need for assessing and improving PAP usability among older patients.

Our findings suggest that some older adults frequently struggle with PAP usability issues, despite pre-FDA market approval usability testing, which typically includes a sample of 15 representative users for summative testing, and FDA-required mitigation plans for usability issues affecting device safety.[9] The post-FDA approval usability issues uncovered in our survey might not impact device safety, but may compromise the impact of PAP on health outcomes by reducing adherence to therapy. For PAP therapy, the relationship between usability and adherence is even more important because adherence rates are so low. Other factors associated with adherence to PAP therapy (e.g., psychosocial) have been studied in many studies,[3] but the usability of the device has received less attention.

Systematically surveying patients and other end-users about PAP usability after the devices have been approved by the FDA and creating a registry of PAP usability data could be beneficial to many individuals, including patients/caregivers, prescribers, purchasers, and manufacturers of PAP equipment, especially if these data could be made available to manufacturers and if prescribers/purchasers of the equipment have the data at the point of prescribing/purchase. The FDA has growing interest in usability surveillance studies, requiring surveillance of some devices (e.g., devices posing greater than minimum risk that are life-sustaining).[20] Usability may be particularly important when prescribing and fitting devices for individuals at higher risk for usability issues, such as individuals with physical limitations, sensory impairments,[5] or cognitive impairment, all of which are common in older adults. For example, information about the types of interfaces most easily used by individuals with severe

arthritis or hemiplegia could help other individuals with these comorbidities who are looking for a new interface.

Our study has a number of strengths and several limitations. A strength of our design was the sampling frame, which was comprised all patients who had been prescribed PAP therapy in two large healthcare systems during a three-year period, not just patients who attend clinic appointments. Another strength was the availability of machine-measured PAP adherence data and interface type in a subset of respondents from the VA site, where comprehensive, granular durable medical equipment data are readily available in the EHR. This approach enabled us to collect information from patients who may have had been lost to clinic follow-up. One limitation was the low survey response rate, a finding that is increasingly common in mailed surveys.[21] However, we found no differences between survey responders and non-responders in PAP adherence, and using a mailed survey facilitated participation of older patients and those with lower socioeconomic status.[22,23] We only had adherence data from the VA site, which may limit the generalizability of our findings to women and non-veterans. The number of days that elapsed between the date adherence data were documented and the survey mail date was large for the majority of participants. Although we did not find that the association between usability and adherence was different for those with more versus fewer days elapsed, future studies should consider using adherence data for the period immediately preceding survey completion (which may be more feasible with the increased availability of PAP modem data and online surveys that provide more accurate estimates of date of survey completion). Another limitation is that we did not have an opportunity to assess health literacy level, to perform cognitive testing, or to measure level of sleepiness objectively. These patient characteristics could confound the relationship between usability and PAP adherence.

In conclusion, we that found that usability ratings help explain variation in PAP adherence. Future large studies are needed to describe PAP usability and its relationship to adherence and health outcomes in samples with more women and racially/culturally diverse patients. In addition, PAP usability may be important to address in future interventions aimed at improving PAP adherence.

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DISCLOSURE STATEMENT

None declared.