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SCIENTIFIC INVESTIGATIONS

The impact of different CPAP delivery approaches on nightly adherence and discontinuation rate in patients with obstructive sleep apnea

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Study Objectives: The impact of direct mail order sales of positive airway pressure (PAP) devices, accentuated by the coronavirus disease 2019 (COVID-19) pandemic, on PAP adherence in patients with obstructive sleep apnea remains unclear. In this study we compared the impact of different modes of continuous positive airway pressure delivery on adherence and daytime symptoms. We hypothesized that adherence would not be affected by remote PAP setup, aided by telehealth technology.

Methods: Three groups were studied: 1) standard group PAP setup (3–4 people); 2) direct home shipment of PAP, followed by telehealth interactions; 3) direct home shipment of PAP, during the COVID-19 pandemic where delivery choice was removed. Demographics, sleepiness, PAP data, and insurance information were also compared.

Results: A total of 666 patients were studied in 3 groups. 1) Standard group PAP setup had 225 patients and adherence with PAP (% of nights used more than 4 hours) was 65.3 ± 2.1%. 2) Direct home shipment of PAP group had 231 patients, and adherence was 54.2 ± 2.4%. 3) Direct mailed PAP units during the COVID-19 pandemic group had 210 patients, and adherence was 55.9 ± 2.5%. Adherence was lower in both groups receiving home shipments compared to those in groups in-center (analysis of variance, Tukey, $P = .002$). Discontinuation of PAP was less in the in-center group setup patients ($\chi 2 = 10.938$ $P \leq .001$).

Conclusions: Patients receiving direct home PAP shipments had lower adherence and were more likely to discontinue PAP compared to standard in-person setup.

Keywords: obstructive sleep apnea, compliance, COVID-19 pandemic

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BRIEF SUMMARY

Current Knowledge/Study Rationale: This study was done to evaluate different continuous positive airway pressure (CPAP) delivery systems and to look at their impact on CPAP adherence, both pre-pandemic and then during the COVID-19 pandemic.

Study Impact: CPAP delivered to patients by trained providers face to face does yield better CPAP adherence than by direct ship methods, but there was not a substantial worsening of adherence during the COVID-19 pandemic.

INTRODUCTION

Accumulating evidence suggests benefits to continuous positive airway pressure (CPAP), with a dose-response relationship of improving outcomes with increasing nightly use.[1,2] Behavioral interventions,[3] intensive positive airway pressure (PAP) support,[4] and education early[5] during PAP use have all been examined and have variable impact on PAP adherence.[6] Direct to consumer, mail order sales of CPAP have also markedly increased recently, further accentuated by the coronavirus disease 2019 (COVID-19) pandemic[7]; however, the impact of these trends on adherence with PAP is unclear.

Previously, we presented preliminary data in abstract form suggesting that group set-ups of patients on PAP, a process that allows for positive interaction between patients and a trained respiratory therapists, has been shown to reduce the discontinuation of CPAP independently.[8] Additionally, preliminary data from our group in abstract form, have suggested that if given the choice of CPAP set up remotely with the therapist using telehealth means vs an in-lab setup, that there is only a minor difference in adherence with PAP use at 90 days.[9] However, since the onset of the COVID-19 pandemic in our setting, CPAP setups have been exclusively shifted from the choice of an in-person, group setting to a remote one with direct shipment of PAP to patients by mail, followed by setups done via telehealth. Currently it remains unclear if CPAP adherence is negatively impacted by any of these changes in CPAP set up method and the educational component linked to them and, more specifically, with the addition of a telehealth option.

In this study we aimed to compare the impact of the 3 different modes of CPAP delivery and set up on adherence and daytime symptoms as measured at 90 days. We hypothesized that,

with the addition of telehealth technology to aid in remote CPAP setup and by standardizing the education component given to patients, 90-day adherence would not be negatively impacted compared to patients started on PAP in group set-ups and a third group emerging post-COVID-19, where no choice of delivery was possible. This study was approved by the Rhode Island Hospital Institutional Review Board.

METHODS

To study the impact of these changes in PAP delivery on outcomes, we identified consecutive patients with obstructive sleep apnea (OSA), all diagnosed by home sleep study testing (apnea-hypopnea index [AHI] > 5 events/h, ResMed (San Diego, CA), Apnea link, or Philips Night One (Phillips Respironics, Murrysville, PA)), who had 3 different methods of delivery of their PAP device. From previous studies, we standardized all predelivery education of the patient, including review of their OSA severity, PAP treatment discussions, and mask fit, all aimed at maximizing adherence, as well as educational materials sent home to patients in the box with their PAP device.[9,10]

The durable medical equipment company used in this study was associated with the sleep laboratory performing the testing. The personnel involved in setting up patients on PAP exclusively perform tasks associated with the durable medical equipment and are not involved in the sleep lab side of the process.

The telehealth interactions with patients were either by video (early in the study using Skype or FaceTime, followed later in the study by Zoom platforms) or by telephone and choice driven by the patient preference as well as technical capability as determined by the nonclinical staff member setting up the appointment. The telehealth (and group setup) visits are also supported by an 11-minute YouTube video link (made by 1 of the lead durable medical equipment clinicians, used by our group in prior preliminary studies), which is sent to patients prior to set up. This video serves as an introduction to the automatic PAP device, its major parts (AC adaptor, humidifier chamber, flow generator, tubing, air filter, mask) and the electronic features (ramp, humidification settings, nightly reporting of mask fit, humidifier operation, interaction with the portal). The telehealth interaction then aims to give the patient a hands-on approach to set up. Patients undergo 1) a review of their sleep study, emphasizing severity of OSA and disease awareness, 2) hands on review of the parts of the device, similarly arranged a YouTube link, 3) mask fit and operation of the device, and 4) simple maintenance/cleaning of the device. Mask fit is optimized by aiming to determine nasal vs full face mask preference from the pre-ship call, then walking the patient through upright then supine placement, strap adjustment, leak test with the device on sitting and supine, followed by optimization with mask leak feature on the device. An additional commercially available YouTube video link is also provided to patients for optimizing mask fit.

The follow-up phone visits for patients in all groups were focused on progress with therapy and mostly to answer any questions patients had about therapy or the interfaces. Providers would be notified if patients discontinued therapy or possibly if a new order for supplies was needed. Device downloads were made available to the providers through MyAir application but were not routinely sent to providers.

Orders for PAP therapy in this study came from both Sleep Physicians and directly from primary care physicians (or nurse practitioners).

In the first 2 groups, patients were offered a choice of 1 of 2 different options of auto-titrating PAP delivery: 1) standard in-center auto-titrating PAP setup in groups (3–4 people) with a face-to-face interaction with a respiratory therapist trained in PAP therapy, mask fit, and education or 2) direct home shipment of auto-titrating PAP therapy, followed by telehealth interactions with a respiratory therapist trained in PAP therapy (virtual visit), mask fit, and education as noted above. Both groups were supported with materials and instructions on how to sign up for electronic device downloads (myAir app) and were scheduled for phone interactions post therapy with a CPAP specialist (2 weeks, 1 month, 2 months, 3 months). A third group emerged during the COVID-19 pandemic between March 2020 and January 2021, which was unique where the choice component was removed, and all PAP devices were shipped to patients. Workflow adjustments led to set up, mask fit being done only via telehealth remotely (virtual visits), and follow-up phone calls similarly arranged as above, but with patient choice to come into the center removed. At 90 days, we compared objective PAP adherence rates and self-reported sleepiness scores between groups using analysis of variance (ANOVA). Attempts were made to match the groups by sex, age, body mass index, comorbidities, baseline self-reported sleepiness (Epworth), baseline OSA severity (AHI), mask type, airway pressure level, and insurance type (ANOVA). Adherence was defined as the percentage of nights with CPAP used more than 4 hours. Average hours of use per night were also recorded. Patients who discontinued or never used PAP were also recorded for each group and their demographics, insurance information and sleep study data were compared (ANOVA). Data are presented numerically or as mean ± standard error with alpha $P < .05$.

RESULTS

Three groups emerged for comparison. First, between January 2016 and October 2016, 225 consecutive patients with OSA were set up on PAP in groups of up to 4 patients together. **Table 1** reveals their demographics and PAP data. Six patients returned their device (2.6%) within 90 days. Adherence with PAP, defined as the percentage of nights used more than 4 hours, was 65.3 ± 2.1% (**Figure 1**). From this group, 127 patients achieved what Centers for Medicare and Medicaid Services (CMS) defines as adherence, which is adherence with PAP at least 4 h/night for at least 70% of nights. Second, between January and November 2019, 231 patients with OSA were started on therapy by getting a home shipment of PAP delivered to their house/apartment. These patients were given the option to pick up their device in person

Table 1—Demographics and PAP data across groups.

	Group Setup (n = 225)	Home Ship Setup (n = 231)	COVID Ship Setup (n = 210)	*P*
Demographics				
Age (years)	50.9 ± 1.3	46.1 ± 2.1	51.8 ± 2.5	.29
Sex (M:F) (n)	156:69	150:81	114:96	.32
BMI (kg/m^2)	39.9 ± 1.0	39.2 ± 1.1	38.0 ± 1.1	.82
AHI pre-PAP (events/h)	34.3 ± 3.5	31.4 ± 2.9	29.2 ± 3.9	.80
ESS pre-PAP	9.1 ± 0.6	11.1 ± 1.2	10.1 ± 0.7	.08
HTN (%)	38.0 ± 2.3	42.0 ± 1.2	40.1 ± 2.3	.65
DM (%)	23.5 ± 2.7	28.9 ± 1.6	29.2 ± 1.9	.76
Commercial: Medicaid insurance (n)	185:34	181:24	167:23	.20
PAP data				
AHI post-PAP (events/h)	3.1 ± 0.1	2.9 ± 0.3	2.1 ± 0.7	.76**
ESS post-PAP	8.0 ± 0.5	9.2 ± 0.6	8.1 ± 0.6	.12 ¥
Median PAP level (cm H_2O)	11 (9–13)	11 (9–13)	11 (9–12)	.06
Median adherence: % nights > 4 h	77 (43–93)	60 (13–90)	63 (20–93)	.005¶
Median PAP use (hours)	5.4 (4–7)	5.2 (4–6.8)	5.2 (4–6.9)	.53
Mask type, nasal: full (n)	140:79	138:67	144:46	.055
Discontinuation of PAP (%)	2.6	11.2	9.5	< .001*

Data are presented as mean ± standard error or median with 25–75% confidence interval in parentheses. **P < .05 post-PAP therapy AHI, compared with pre-PAP AHI. ¥P < .05 post-PAP therapy ESS compared with pre-PAP ESS; both posttreatment comparisons based on the number of patients remaining in the group after removing those who returned the device: group setup (n = 219), home ship setup (n = 205), COVID ship setup (n = 190). ¶Adherence between group setup compared to both home ship setup and COVID ship setup groups. *Group setup discontinuation percent compared to both the home ship setup and COVID ship setup. AHI = apnea-hypopnea index, BMI = body mass index, Commercial = Medicaid: ratio of commercial insurance to Medicaid insurance, COVID = coronavirus disease 2019, DM = diabetes mellitus, ESS = Epworth Sleepiness Scale, F = female, HTN = hypertension, M = male, PAP = positive airway pressure.

(and be assigned to the group setup) or to be mailed the device. They were included in this group if they agreed to have the device mailed to their home and have the therapy started remotely. The patient then underwent set up using a similar review of their sleep apnea severity and the same educational components used by those set up in groups, but this information was delivered via a telehealth visit, either phone or video visit. Demographics and PAP data of group 2 are listed in **Table 1**. Of 26 patients, 11.2% either never used the PAP machine or returned it before 90 days. Adherence at 90 days was 54.2 ± 2.4% (**Figure 1**). From this group, 103 patients achieved CMS-defined adherence. Third, 210 consecutive patients were mailed PAP units during the COVD pandemic (ie, mailed device with no option for in-center pick up) and set up was done remotely as noted above using telehealth visits. Demographics and PAP data of this group are described in **Table 1**. Twenty patients (9.5%) either never used or returned their device within 90 days. Adherence in this group was 55.9 ± 2.5% (**Figure 1**). The number of patients achieving CMS-defined adherence was 97 in this group. PAP adherence was lower in both groups receiving home shipments compared to those patients set up on PAP devices in-person (ANOVA, Tukey P = .002) (**Figure 1**). The number of patients achieving CMS-defined adherence (> 70% of use per night) was also less in the groups where PAP was mailed to patients ($\chi 2$ = 9.2065, P = .01). There was no further worsening of adherence during the COVID-19 pandemic for the COVID ship setup group compared to the home setup group who chose to have their PAP devices shipped (ANOVA, Tukey, P = .86).

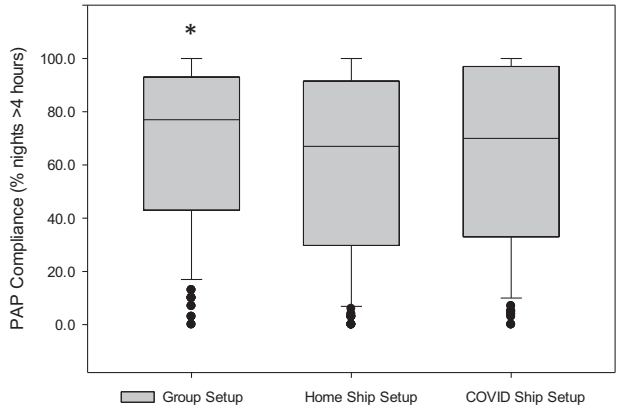
Discontinuation of PAP was less in the in-person group setup patients (2.6%) compared to those set up by having machine shipped (11.2%) and shipped during COVID-19 (9.5%; $\chi 2$ = 10.938, $P \leq .001$) (**Figure 2**). Those who discontinued PAP had similar age, sex, pretreatment AHI, body mass index, comorbidities, and Epworth score (ANOVA, P = .67). Last, in patients who did not discontinue use of their device, group mean AHI, and Epworth scores improved at 90 days; however, there was not a difference between groups.

As noted, the telehealth interactions were a mix of both phone and video contact with patients. We do not have enough granular data across groups to know which methodology was used in every instance. The technology did improve over the time of the study such that early on we were using a mix of Skype or FaceTime with patients which then evolved to more use of Zoom during the COVID-19 pandemic.

DISCUSSION

Two findings in this study were of note. First, that adherence with PAP was less in both groups receiving direct home

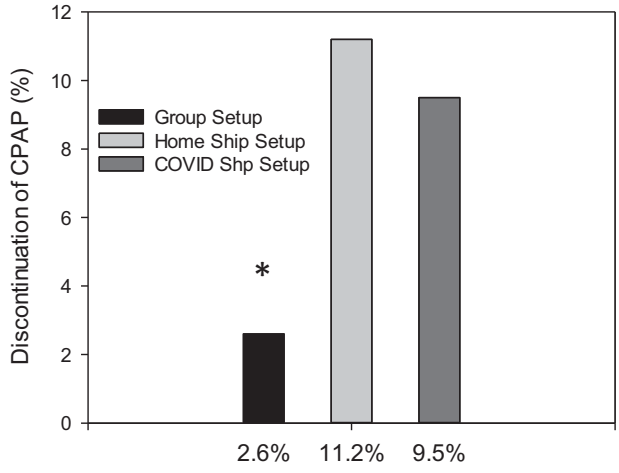
Figure 1—Median PAP adherence/adherence across groups.



Box plot showing PAP adherence/adherence as a percentage of nights across the different PAP delivery methods, presented as median (line) and interquartile range, 25th–75th percentile (gray box) with maximum, minimum (error bars). *P = .002 for group setup compared to both home ship setup and COVID ship setup groups. COVID = coronavirus disease 2019, PAP = positive airway pressure.

shipments of PAP compared to the group with standard setup in a center. These differences were not explained differences in sex, age, body mass index, OSA severity (baseline AHI), self-reported sleepiness (baseline Epworth Sleepiness Scale score), medical insurance, or mask type (although nasal masks, rather than full face masks were more commonly used) (**Figure 1**). Compared to the home ship setup group, there was no worsening in adherence during the COVID-19 pandemic when choice of PAP delivery was removed. It is possible that as people became more accustomed to telehealth/video conferencing later in the pandemic that the in-person education and motivation feel of a face-to-face set-up for PAP is not as necessary to achieve optimal adherence. Prior studies have shown that intensive education or motivational enhancement helps with CPAP adherence and may be more effective in person.[3,4,11,12] However, more recent studies have not shown significant drop off in adherence during the COVID-19 pandemic[7,13,14] and thus adaptations to the delivery of CPAP or the initial setup may not be as important if the patient feels as engaged and as ready to try PAP as they would during an in-person setup.

Figure 2—Percentage of patients discontinuing CPAP in the different groups.



Bar graph showing percent (%) of patients discontinuing CPAP in each group, across the different PAP delivery methods. *P < .001 for the group setup compared to both home ship setup and COVID setup groups. Actual percent in each group listed below the bars. COVID = coronavirus disease 2019, CPAP = continuous positive airway pressure, PAP = positive airway pressure.

Second, we observed that more PAP discontinuation was seen in home ship groups compared to in person group setup. Further analysis of the discontinuation group revealed similar demographics, sleepiness, and OSA severity to those who continued PAP. The reason for this finding remains unclear, but it is possible that an unidentified socioeconomic factor may explain some of the differences we saw on adherence between groups, despite similarities in demographics or insurance information. Socioeconomic factors have been identified as a predictor in prior studies[15–17] and reinforce the need for potentially more intensive education, interaction by telemedicine, or quick follow up by extenders to intervene early to keep at risk patients with OSA on PAP.[18]

Limitations to this study include that the data set, although continuous in each group, was taken from 3 separate study sets. It is possible, therefore, that some technologic capability was different early in the home ship portion of the study that did not exist in later in the COVID-19 pandemic. Mask technology may have also been slightly different between groups due to the group setups being done in 2016 compared to 2019–2020. It also remains unclear if there was a different number of masks used if you were in the home ship compared to group setup data, despite having similar ratios of nasal to full face masks between groups. Additionally, we followed patients to 3 months, and it is possible that some of these differences may have changed if longer follow up was completed. Last, home sleep studies rather than in-lab studies were used exclusively in this study. It is possible that the amount of interaction during an in-lab study may further erode any differences between groups.

In summary, this study revealed that adherence with PAP was less and more patients discontinued PAP therapy in those patients with OSA receiving direct home shipments of the device compared to standard in-person setup on PAP therapy. However, there was not further worsening of PAP therapy adherence during the COVID-19 pandemic, which necessitated only a home shipment option. Thus, as we move to set up more patients remotely on PAP therapy for OSA, care must be taken not to lose the personalized attention provided by an in-person interaction that will translate into better adherence from the start.

ABBREVIATIONS

AHI, apnea-hypopnea index
ANOVA, analysis of variance
COVID-19, coronavirus disease 2019
CPAP, continuous positive airway pressure

OSA, obstructive sleep apnea
PAP, positive airway pressure

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DISCLOSURE STATEMENT

All authors have seen and approved this manuscript. Work for this study was performed at Epoch Sleep Centers and Dr. Stanchina's office address noted above. Michael Stanchina has received speaking honoraria from Jazz Pharmaceuticals, Astra Zeneca, and Boehringer Ingelheim. Seth Koenig reports income from educational fees from Fugi SonoSite and Cook Medical for lectures given. Atul Malhotra is funded by the National Institutes of Health. He reports income for medical education from Equillium, Jazz, Corvus, and Livanova; ResMed gave a philanthropic donation to the University of California San Diego, in support of a sleep center. The other authors report no conflicts of interest.