Official title: Maximizing Use of Continuous Positive Airway Pressure in Stroke Rehabilitation Patients With Obstructive Sleep Apnea

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Design: Single-arm, open-label study

Objectives: To assess the effectiveness of a multifaceted and intensive adherence program on 3-month CPAP adherence and measures of stroke outcome (NIH stroke scale and Functional Independence Measure) among stroke patients undergoing inpatient rehabilitation (IPR)

Methods:

Eligible stroke patients (Table I) were enrolled and trialed auto-adjusting CPAP (4–20 cm H2 O; Dream Station, Philips Respironics) over a 3-night run-in period during IPR. Devices were interrogated for nightly usage, average pressure, and a residual apnea-hypopnea index (the respiratory events per hour of sleep). At the end of the run-in period, evidence of OSA was determined based on airflow resistance detected by the machine (see diagnosis of OSA below). Patients with evidence of OSA were eligible for CPAP treatment during IPR and after discharge from IPR. Nurses, respiratory therapists, sleep technologists, and clinical psychologists initiated the SCOUTS intensive CPAP adherence protocol during IPR emphasizing early CPAP tolerance, individual motivation (Table II) and support throughout the treatment period. The primary end point was CPAP adherence over 90 days from CPAP initiation, defined as ≥4 hours of use on ≥70% of days. Secondary efficacy end points were changes in the motor and cognitive components of the Functional Independence Measure (FIM) between admission and 3 to 4 months after discharge from IPR and in the National Institutes of Health Stroke Scale (NIHSS) between enrollment
and 90 days.

Diagnosis of obstructive sleep apnea (OSA)

To avoid delays inherent to administering formal sleep studies and interpreting results during inpatient stroke rehabilitation, we utilized device detected flow resistance. Study participants were started on an auto-adjusting CPAP machine (DreamStation, Philips Respironics) both to rapidly diagnose OSA and to provide earlier treatment.[1, 2] After a 3-night run-in period during inpatient rehabilitation, auto-adjusting CPAP devices were interrogated for the mean pressure over the run-in period and the nightly residual apnea-hypopnea index, based on flow measurements (AHI_{Flow}). The diagnosis of OSA was determined based on data from the CPAP device downloads using one of two criteria: 1) average airflow limitation over the entire run-in period, defined as mean CPAP pressure ≥ 5 cm H_2O over a minimum of 3 hours of use, OR 2) on-treatment $AHI_{Flow} \geq 5$ events/hour on any of the 3 nights. Participants were excluded if the download showed evidence of central sleep apnea with a clear airway index ≥ 10 or of complex sleep apnea with an $AHI_{Flow} \geq 25$.

SCOUTS Intensive CPAP Adherence Program (iCAP)

To improve CPAP use, a SCOUTS iCAP was initiated during IPR and targeted 3 aspects of adherence: CPAP tolerance, motivation and support. To improve CPAP tolerance, rehabilitation nurses, respiratory therapists and sleep technologists led an iterative process of device adjustments, mask interface changes, OSA education and encouragement. To enhance motivation for CPAP use, patients watched a patient testimonial video on CPAP and stroke

recovery and met with a clinical psychologist for motivational interviewing (MI) during IPR to discuss patients' readiness to change, confidence in using CPAP and coping techniques to adjust to CPAP use (see Table II). The 30-minute face-to-face MI sessions occurred within one week of starting auto-adjusting CPAP. The MI session were focused on building motivation to use CPAP and alter the subject's decisional balance about using CPAP as it relates to patient-specific goals. To improve support, the adherence program included nightly visits by respiratory therapists during IPR to improve self-efficacy with CPAP and tailored written feedback prior to discharge from the IPR unit detailing CPAP download data, adjustments made during IPR and goals and barriers for CPAP use. Phone calls were also made weekly for one month after discharge from the IPR unit to encourage CPAP use and troubleshoot any device or mask problems.

Efficacy Measures

The National Institutes of Health Stroke scale (NIHSS; range, 0 to 42; higher scores indicate greater neurologic impairment) scores were obtained in-person on enrollment and at 90 ± 7 days from enrollment. The Functional Independence measure (FIM) scores were obtained as part of routine clinical care. The FIM included a motor and cognitive component (motor range, 13-91; cognitive range, 5 to 35; lower scores indicate greater functional disability). The admission FIM scores were obtained in-person by rehabilitation nurses and therapists upon admission to the IPR unit and follow-up FIM scores were obtained as part of routine clinical care through phone interview by IT Health Track, Inc., between 3 and 4 months from IPR unit discharge (mean 106 days); telephone response rates are approximately 60%.

Statistical Analyses

We compared baseline demographics, stroke severity and rehabilitation characteristics by adherence, using t-tests and Chi-squared tests as appropriate. To evaluate for predictors of adherence (Table III), we performed logistic regression, adjusting for baseline demographic covariates determined *a priori* including age (≥ 65 years), race/ethnicity (White versus non-White or Hispanic), sex, obesity (body mass index ≥30 kg/m^2),baseline NIHSS score ≥ 5 and inpatient rehabilitation length of stay (weeks). As those with aphasia were noted to be adherent to CPAP, we added this stroke characteristic into separate models post-hoc.

We examined for differences in baseline, 3-month and changes between baseline and 3- months in NIHSS, motor FIM and cognitive FIM by CPAP adherence using the t-test with unequal variances (Table IV). We also evaluated for association of CPAP adherence with 3-month NIHSS and cognitive FIM change using linear regression in models adjusting for age ≥ 65 years, sex, race/ethnicity, body mass index ≥ 30, and baseline NIHSS score at study enrollment (Table IV). Finally, we evaluated the proportion of adherent and non-adherent participants who had improvement in the cognitive FIM and NIHSS, which was greater than the mean improvement among the entire sample: ≥ 7 for cognitive FIM improvement and ≥ 4 for NIHSS improvement (Table V).

Table I. Main Selection Criteria

Inclusion Criteria

Informed consent

Acute ischemic stroke or intraparenchymal hemorrhage

Age ≥ 18 years

Admission to inpatient stroke rehabilitation unit at Harborview Medical Center and the University of Washington Medical Center

Exclusion Criteria

Stroke related to bleeding disorder, substance abuse, tumor, vascular malformation, trauma or other secondary cause

Active CPAP use at time of enrollment

Advanced congestive heart failure (New York Heart Association class 3 or 4)

Requiring supplemental oxygen or nasogastric feeding tube

Participation in another research outcome study

Table II. Motivational Interviewing Data Form

Subject's understanding of stroke and sleep apnea:

Subject's readiness to change:

□Pre-contemplation

□Contemplation

□Preparation

□Action

□Maintenance

Any small achievable subgoals:

□ YES □ NO

Subject's reason for using CPAP:

□Stroke prevention

□Stroke recovery

□Sleep improvement

□Other

Subject's reason for not using CPAP:

□Claustrophobia

□Anxiety

□Sleep disturbance

□Mask fit or leak problems

□Device problems

□Other

On a scale of 1-10, how important do you think it is for you to treat sleep apnea and use the

CPAP device?

On a scale of 1-10, how confident are you in your ability to use the CPAP device from now until the next time we meet?

Table III. Baseline factors associated with 3-month CPAP adherence, odds ratio (95% confidence interval)*

*All models included age, sex, obesity and weeks on inpatient rehabilitation. Model 1 additionally included race and baseline NIHSS ≥ 5; model 2 for race and aphasia; model 3 for race, aphasia and baseline NIHSS ≥ 5.

	Model 1	**Model 2**	**Model 3**
White race	10.9 (1.7, 701)	3.7 (0.7, 19.8)	8.2 (1.1, 62.3)
Aphasia	-----	12.9 (1.3, 129)	8.0 (0.7, 87.7)
NIHSS≥5	14.9 (1.9, 115.7)	----	10.6 (1.2, 92.6)

Table IV. Improvement in cognitive FIM and NIHSS associated with CPAP adherence

	Adherent, mean (SD)			Non-adherent, mean (SD)			*P*-value*	
	Baseline	3-months	Change	Baseline	3-months	Change	Unadjusted	Adjusted
Motor FIM†	48.5 (11.2)	79.7 (12.1)	31.2 (15.7)	47.3 (17.6)	77.5 (10.8)	30.2 (13.2)	0.83	0.65
Cognitive FIM†	24.1 (6.9)	32.4 (3.7)	8.2 (6.5)	28.5 (3.9)	33.1 (2.4)	4.6 (3.0)	0.03	0.02
NIHSS ‡	6.5 (4.3)	2.7 (3.1)	-3.8 (2.6)	4.1 (2.2)	2.6 (2.6)	-1.6 (2.2)	0.003	0.03

CPAP indicates continuous positive airway pressure; SD, standard deviation; NIHSS, National Institutes of Health Stroke Scale; Cognitive FIM, cognitive component of Functional Independence measure

* Difference between mean changes in outcome between adherent and non-adherent patients: unadjusted using t-test with unequal variances and adjusted for age, sex, body mass index, race and baseline NIHSS using linear regression

† n=22 adherent group and n=12 non-adherent

‡ n=30 adherent group and n=19 non-adherent

Table V. Improvement in cognitive FIM and NIHSS associated with CPAP adherence

Patient characteristics	Adherent	Non-adherent	*P*-value
Cognitive FIM improvement ≥ 7, n (%)*	10 (45)	3 (25)	0.24
NIHSS improvement ≥ 4, n (%)†	16 (53)	3 (16)	0.01

* n=22 adherent group and n=12 non-adherent

† n=30 adherent group and n=19 non-adherent

REFERENCES

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2. Bravata DM, Concato J, Fried T, Ranjbar N, Sadarangani T, McClain V, et al. Continuous positive airway pressure: Evaluation of a novel therapy for patients with acute ischemic stroke. *Sleep*. 2011;34:1271-1277