News Release

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FOR MORE INFORMATION, CONTACT:
Keely Savoie or Brian Kell
ksavoie@thoracic.org or bkell@thoracic.org
ATS Office 212-315-8620 or 212-315-6442 (until May 14)
Cell phones 917-860-5814 or 516-305-9251
ATS Press Room: 504-670-6926 (May 15 to 20)

Poster session time: 8:15- 10:45 a.m. May 19
Location: CC-Room 267-268 (Second Level), Morial Convention Center

At-Home Sleep Testing Equal to Overnight in a Sleep Lab in Treatment Results

ATS 2010, NEW ORLEANS—Patients with suspected obstructive sleep apnea (OSA) may no longer have to spend an expensive and uncomfortable night at a sleep center to monitor their sleep-disordered breathing. According to new research, those who performed sleep testing in their home with portable monitors showed similar improvements after three months of treatment with continuous positive airway pressure (CPAP) in daytime function as compared to patients who underwent overnight testing in a sleep center.

Furthermore, patient adherence to CPAP over the first three months of treatment was similar in patients with OSA who received home versus in-lab testing.

The research will be presented that the ATS 2010 International Conference in New Orleans.

Obstructive sleep apnea, a breathing disorder during sleep, is common, dangerous, and relatively easy to treat, but expensive to diagnose. “These findings represent a possible turning point for both patients with sleep-disordered breathing and the clinicians who treat them,” said Samuel T. Kuna, M.D., Chief of the pulmonary, critical care and sleep section at the Philadelphia VA Medical Center, who led the research. “One of the biggest

and most insurmountable barriers to treatment is the need for overnight testing in a sleep laboratory. Our research suggests that this may no longer be a mandatory for diagnosis."

It is conservatively estimated that four percent of women and nine percent of men in the United States have moderate to severe OSA and that 80 percent of these individuals are undiagnosed and untreated. Patients with untreated OSA are at increased risk for traffic accidents, hypertension, and cardiovascular disease.

"Currently, most patients with OSA need to perform overnight sleep testing (polysomnogram) in a sleep center," explained Dr. Kuna. "The result has been unacceptably long patient wait times and restricted access to care."

The researchers conducted a two-site study in which they randomized nearly 300 patients to undergo either standard in-laboratory sleep-testing or at-home testing. Of the 223 patients who started CPAP treatment after evaluation, 185 completed three months of follow-up.

They found that those who had undergone at-home testing showed improvements after three months of CPAP treatment similar to those who had undergone in-lab diagnosis.

The CPAP machines used in the study recorded the patient's use of the treatment. Average hours of daily use over the 3 month period were similar in the two groups.

"Proponents of in-laboratory testing argue that patients performing in-lab testing might have better outcomes than those performing home testing. For example, during in-lab testing, the patient spends a greater amount of time with a technologist who is able to educate the patient about OSA and CPAP and help the patient overcome any barriers to diagnosis and treatment that might arise during testing," said Dr. Kuna. "But our results did not find a difference between home versus in-lab testing in terms of clinical outcomes. The two management pathways appear to be equivalent in terms of patients' functional outcomes and ability to use CPAP treatment."

While prospective studies are needed to evaluate the cost effectiveness of home portable monitor testing, medical care costs were examined in the study. "Those results are still being analyzed, but we believe that they will show that home portable monitor testing is less expensive than in-laboratory testing," said Dr. Kuna. Such a result, combined with the equivalent results of portable monitor testing in terms of health-related outcomes suggest that the portable devices may soon make in-lab testing a thing of the past for many OSA patients.

"Our study indicates that home portable monitor testing can be used to diagnose and manage patients with OSA," said Dr. Kuna. "Greater use of portable monitors will improve patient access to care and hopefully reduce medical care cost by replacing an expensive test (in-lab polysomnography) with the less expensive home testing."

This study was done in collaboration with Dr. Charles Atwood at the VA Pittsburgh Healthcare System and the University of Pittsburgh.

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"Non-Inferiority of Functional Outcome in Ambulatory Management of Obstructive Sleep Apnea" (Session D29, Wednesday, May 19, 8:15-10:45a.m., CC-Room 267-268 (Second Level), Morial Convention Center; Abstract 5352)

**Please note that numbers in this release may differ slightly from those in the abstract. Many of these investigations are ongoing; the release represents the most up-to-date data available at press time.*

Non-inferiority of Functional Outcome in Ambulatory Management of Obstructive Sleep Apnea

S.T. Kuna[1], G. Maislin[2], S. Hin[3], K. Hartwig[4], R. Hachadoorian[5], S. Hurley[6], R. Gupta[3], C.W. Atwood[7]
[1]Philadelphia VA Medical Center (111P) - Philadelphia, PA/US, [2]Biomedical Statistical Consulting, University of Pennsylvania - Wynnewood, PA/US, [3]Philadelphia VA Medical Center - Philadelphia, PA/US, [4]VA Pittsburgh Healthcare System - Pittsburgh, PA/US, [5]Biomedical Statistical Consulting - Wynnewood, PA/US, [6]Biomedical Statistical Consulting - Wynnewood, Pa, PA/US, [7]University of Pittsburgh - Pittsburgh, PA/US

Rationale: Home portable monitor testing is increasingly being used to diagnose patients with obstructive sleep apnea (OSA) and initiate them on CPAP. Only a few studies have evaluated the functional outcome of this ambulatory management of OSA.

Methods: We conducted a 2 site, randomized, parallel groups study of the functional improvement on CPAP treatment in veterans with OSA randomized to either standard in-laboratory polysomnographic testing (in-lab group) or home unattended testing (home group), the Veterans Sleep Apnea Treatment Trial (VSATT). Home testing consisted of an overnight recording with a type 3 portable monitor (Embla) followed by at least 3 nights using an autoCPAP apparatus (Philips Respironics). The primary outcome measure was the change in total score on the Functional Outcomes of Sleep Questionnaire (FOSQ) following 3 months of CPAP treatment with an a priori non-inferiority delta of -1 points. Non-inferiority was tested by determining whether the lower bound of a 95% one-sided confidence interval for the group difference in ANCOVA adjusted mean changes exceeded -1.0 points. Preliminary analysis was performed on an evaluable cohort defined as CPAP initiated and having complete baseline and 3-month data. Final analyses will be modified ITT.

Results: Of the 296 randomized patients (95% males), 223 were initiated on CPAP and 185 completed the 3 month follow-up (N=86 in-lab group, N=96 home group). The mean Multivariable Prediction Index at baseline, a measure of OSA severity, was 0.78 in the in-lab group and 0.76 in the home group (p=0.25). There was no difference between the two groups in mean FOSQ total score at baseline (p = 0.55). The mean improvement at 3 months was 1.93 (SD=2.47) in the in-lab group and 1.81 (SD=2.83) in the home group (p value=0.75). The adjusted group difference (at-home minus in-lab) in mean change from baseline to month 3 in FOSQ total score, controlling for baseline FOSQ and investigative site, was -0.04 (SE=0.34) with p=0.90. The lower bound of the 95% non-inferiority CI was -0.60. Since -0.6 > -1.0, the null hypothesis that at-home testing is clinically inferior was rejected ($p<0.05$) based on the evaluable cohort.

Conclusion: This randomized clinical trial demonstrated non-inferiority of functional outcome following 3 months of CPAP treatment in patients with OSA randomized to either standard in-laboratory polysomnographic testing versus unattended home testing with portable monitors.