

## PORTABLE VS. FACILITY-BASED SLEEP TESTING – PART II

by Steven Grenard RRT, RPSGT



This installment is part two of the continuing debate and now scientific effort to determine if home, portable sleep studies can match attended, facility-based sleep studies in terms of reliability, validity, accuracy, expedience, comparative costs and outcomes for patients.

With the ink hardly dry on the exchange of views between the American Sleep Apnea Association (ASAA) a patient advocate and the professional sleep society, the American Academy of Sleep Medicine (AASM), the latter has already issued an RFP to determine if portable home sleep testing is as valid as attended studies conducted in a facility based sleep lab. As readers will recall from the last issue of *Focus* and this column, there are several broad areas that need to be addressed in this debate.

To briefly recap: Both organizations seem to agree that a centrally coordinated multi-center study needs to be conducted to compare the sensitivi-

ty of home versus facility based sleep testing. Both organizations seem to agree that post testing follow-up management and treatment of patients diagnosed with OSAHS needs to be improved. The AASM says that awareness on a global level of the need for restful sleep of sufficient duration needs to be increased. The AASM is concerned about the high number of patients who fail in the consistent use of PAP modalities. It is estimated that this may be as much as 50% of all the patients testing positive for OSAHS and who, in the lab, respond to PAP therapy.

In order to scientifically study the above, the AASM through the American Sleep Medicine Foundation has issued an RFP dated October 18, 2006 with a deadline for submissions by January 31, 2007. That this is apt to be one of the most closely watched and monitored funded studies in the history of sleep medicine would be an understatement. And while any individual component of the study may return a positive or close correlation with in-lab testing and titration, the issue of short and long term outcomes need to be compared as well. The study is proposed to take two years to complete.

In the background the RFP points out that if there is sufficient positive diagnostic information to confirm a diagnosis of OSAHS home patients will still have to undergo a second test for PAP titration. This given eliminates the use of the split night protocol which, for some patients at least, speeds the process from diagnosing to titration and wait for treatment. In the absence of a possibility for splitting the night into diagnostic and therapeutic portions, portable at home testing eliminates economies both in time frame and perhaps even to the global financial impact. It may look like there are economies on some cases on a case by case basis but when an entire group is added together such economies may vaporize. Every portable OSAHS positive patient will de facto need at least two studies whereas now, using the in-lab split night protocol, only a fraction may require a second study for titration.

The design of the study proposal involves two phases. One is the selection of similar patients who meet inclusion criteria and are not subject to exclusion because of co-morbidities or related problems.

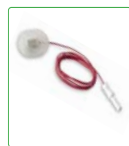
At this point the study group is randomly assigned to one of two arms or tracks, Arm 1 and Arm 2. Arm 1 are patients randomly assigned to have attended, facility based PSGs and split night protocols in the lab if the split night criteria is met. The criteria for split night mirrors that used in most labs as a matter of practice:

1. AHI of greater than 15/hr during the first two hours of sleep

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2. At least 3 hours during which PAP can be titrated before lights on

3. Standard definitions for apneas and hypopneas to be counted

Arm 2 patients are assigned to portable, home monitoring for diagnosis followed by 5-7 nights at home to determine a PAP pressure level using auto-titrating PAP units (APAP). APAP should provide an adequate pap pressure level number on titration night one but additional titration nights are included to determine if the APAP returns different pressures on different nights. From experience patients who come in for attended studies as re-titrations (without any significant changes such as ENT surgery, work shift, or weight loss) end up on the same pressure originally titrated or, at most, plus or minus 1-2 cmH2O. It will be important to see if APAP is as consistent and if not then to determine why. Any patient in the study who fails APAP or if APAP is unacceptable (e.g. incomplete) for any reason after two trials will also be given an in-lab titration.

Pre-testing then covers the inclusion/exclusion phase. Patients are selected at random from a general population based on two criteria: neck circumference of 17 inches or more and an Epworth Score of greater than 12, which indicative of EDS.

Patients who meet these two criteria, however, may then be excluded for any one of 10 reasons: current symptomatic psychiatric disease, de-compensated cardiac or pulmonary disease, unable to undergo home testing, concern about unsafe driving, substance abuse, severe COPD or use of nocturnal supplemental oxygen, chronic narcotic use, history of cataplexy, moderate to severe RLS, a pre-existing diagnosis of sleep apnea.

With the pool of subjects selected, the next phase is to qualify them through testing, either portable home testing or in-lab attended testing. Subjects with AHIs greater than 15 on either home or in-lab attended studies would then be selected for PAP titration. However, the proposal has to account for the fact that while in-lab attended PSGs with EEG channels can diagnose the presence of sleep, unattended portable home studies which do not normally provide EEG channels cannot. The way around this then is two separate definitions for the AHI determination. For the in-lab patients the AHI of 15 occurs over 2 hours of sleep since sleep can be diagnosed (staged) in the lab. In the home patients an AHI of 15 is permitted if it occurs over two hours of "monitoring" since it is impossible to know if an unattended home patient is sleeping or not. That this completely changes the definition of "sleep apnea" to something it isn't is a matter for separate debate or perhaps not. This is because subjects who test negative for, er, let's call it nocturnal apnea at home will then be sent for an attended PSG to see if they are still negative or actually have sleep apnea. Patients who test positive for nocturnal apnea will be sent directly to the APAP phase.

Negative nocturnal apnea patients at home who test positive in the lab will then also be sent for APAP. While this plan covers the possibility of false negatives with home testing it doesn't cover the possibility of false positives. During wake some patients sigh/yawn, followed by breath holds, resulting in simulated apneas conceivably may cause a false positive test.

The subjects not assigned to the portable home study track are assigned to the in-lab attended study track. All lab based patients are prospectively considered split night or attempted split night. If the usual reasons for not being able to split the night into a diagnostic and therapeutic phase do not occur, such patients received PAP titration in lab the same night. If a split night is not possible because events occur too late, or there is too much wake time, then

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the initial night is scored as a whole night study and an in-lab test subject diagnosed as positive for sleep apnea comes back for a second night to have a full night PAP titration.

In neither track is there any consideration given to the fact that some patients may do better on bi-level than CPAP. The proposal mentions "CPAP" only so it is assumed CPAP only will be studied. Presumably bi-level can be reserved for home subjects who fail CPAP and then these could come into the lab for a bi-level titration in accordance with protocol. In the real world there is no reason, however, why intervention with bi-level cannot be used in a split night scenario done in an attended, in-lab study.

### Outcomes

The outcome data collected and being measured includes acceptance levels for CPAP (=number of patients who accept treatment and take a unit home), objective adherence (compliance) to CPAP at one and three months (4 hours or more as% days, at prescribed pressure) and time interval between diagnostic study and initiation of CPAP at home. Secondary outcome data to be collected includes any changes in subjective EDS, changes in sleep specific quality of life measures, changes in general quality of life measures, the number of patients requiring crossing over to conventional pathways, costs of each evaluation and management pathway, % of patients with acceptable titration (resulting in AHI <10) and % of subjects needing diagnostic and CPAP titration PSGs outside the plan in each of the two treatment arms or tracks.

The results of this project will be eagerly anticipated by a wide variety of players and payers in sleep medicine. So unless something earthshaking happens before, we need to wait until 2009 to see what happens next. Have a Happy New Year everyone.