Requiring oxygen desaturation for tabulation of hypopneas lowers the sensitivity of NPSG testing and leaves many patients untreated. In-lab NPSG testing needs to improve if it is to be preserved

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Introduction:

At the 2012 APSS conference we presented how deficiencies in the scoring criteria, that define hypopneas, result in many patients being left untreated (1). To further enhance our data, we have added more patients to our assessment in this retrospective outcome analysis. Current healthcare trends are attempting to streamline the evaluation of sleep disorders breathing with Out of Center Sleep Testing (OCST) which relies heavily on oxymetry, in conjunction with robust changes in other respiratory signals. Historically, the AASM required a SaO2 desaturation of at least 4% (or 3% using an alternative rule) in order to tabulate hyponeas. More outcome data is needed to justify the tabulation of hypopneas in the absence of elaborate desaturations, demonstrating clinical improvement by treating patients that fall into this category. The objective of this study (and the study presented last year) was to assess patients who suffered from excess daytime sleepiness, in whom the NPSG's only demonstrated significant hypopneas characterized by a decreased flow signal by 30% for a minimum of 10 seconds leading to arousal's, in whom desaturation was less than 4%, to determine if treating such patients provides clinical improvement worthy of supporting this approach.

Method:

Review of patients who presented to our sleep centers in whom the AHI using a minimum of 4% desaturation (Ox- AHI), was less than 5/hr sleep, but in whom the AHI independent of assessing the SaO2 (NonOx-AHI), was greater than 5/hr sleep. Follow-up attempts were made on qualifying patients, tabulating Epworth Sleepiness Scale (ESS), Patient Global Impression (PGI) scores and body weight. These were obtained pre- and post-treatment. Only patients treated for six months or longer qualified for the study.

Results:

We reviewed 270 patient records that meet the criteria of Ox-AHI <5/hr with NonOx-AHI >5/hr in whom treatment was initiated six months or longer at the time of the post-treatment assessment. Of these, 69 patients could not be contacted, 18 never started treatment, 37 were non-compliant with treatment and the remaining 146 patients complied with treatment for six months or longer. Average age was 56 y/o (21 to 83), 45 males, 101 females. Follow-up assessment ranged from 6-to-65 months (ave 22 months). Of note, only 11 of the 146 patients would have been excluded if a 3% threshold were used instead of a 4%, meaning that most of the patients included in the study demonstrated desaturations within 3% fluctuation of the SaO2. Of the 146 patients who complied with treatment 121 patients (83%) demonstrated improved ESS with the mean score changed from 13.5 down to 7.5 and 126 had improved PGI scores (86%). An ANOVA analysis assessing for improvement in ESS, PGI and body weight between pre and post treatment groups was significant, characterized by $p < 0.01$. To determine which variables contributed to the significant ANOVA assessment, T-Tests were done on the ESS, PGI and body weight variables. Both the ESS and PGI scores changes were significant, both with $p < 0.001$. Body weight did not demonstrate a significant change with T-Test of $p > 0.05$ of the 146 treated patients, 21 used oral appliance therapy (OAT), of these 12 used OAT as a monotherapy and 10 used combination therapy with both PAP and OAT.

Conclusion:

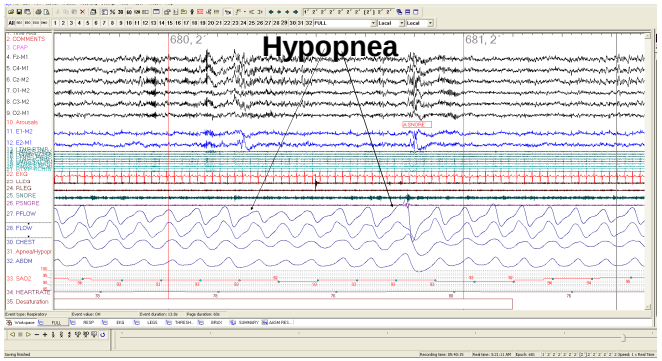
Our results support the principle that treatment is warranted in symptomatic patients who demonstrate fragmented sleep from hypopnic events without desaturation. Our extensive experience of more than twenty-years treating patients with minimal desaturation, who have fragmented sleep from obstructive respirations, is consistent with our statistical findings presented here. Similar results were presented at the APSS, in an oral presentation in June 2012. In the fall of 2012, the AASM released new guidelines for scoring NPSG studies in which desaturation is now no longer required as long as a decrement in flow by 30% for a minimum of 10 seconds leads to an arousal. The new protocol for scoring hypopneas is consistent with the recommendation we presented last year.

Unfortunately, current listed guidelines by Medicare are not consistent with our clinical knowledge or the AASM guidelines and still require a minimum desaturation for the tabulation of hypopneas. Adhering to these guidelines is discriminatory and leaves many symptomatic patients untreated. It is imperative that our leadership, within the field of sleep medicine, and those experienced in treating these types of patients, continue promoting the enhancement of standards within the medical field and work to replace obsolete guidelines with those that will support treating symptomatic patients who have obstructive respirations without meeting a desaturation threshold. Furthermore, with the trend towards OCST it becomes more important to recognize that there is a significant group of patients that may go undiagnosed with these less sophisticated devices. Part of the problem that has led third party payers to embrace OCST stems from comparative studies evaluating OCST results to those of in-center NPSG testing. If both methods of testing require a 3% or greater desaturation in order to tabulate hyponeas, then the analysis will not characterize a true distinction between these two methods.

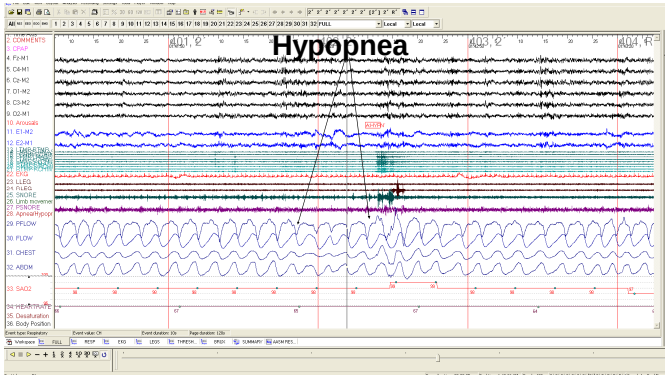
There is no doubt that a need exists for OCST, but these devices cannot replace the role of the In Center Sleep Testing (ICST) NPSG (type 1) testing. It would serve our field of sleep medicine well if we increased the quality of In Center NPSG Testing. One way to achieve this would be to implement tabulation of respiratory events in the absence of desaturation. Another quality measure is to implement more sensitive techniques such as esophageal pressure monitoring (Pes) that would enhance our ability to objectively identify the Upper Airway Resistance Syndrome (see figure to the right demonstrating a RERA unequivocally identified by the Pes signal). This would create a delineated gap in what can be provided from (in-lab) ICST and that from OCST.

Further studies should be performed on treating the more subtle forms of obstructive respirations in order to determine justification in allocating resources to this population for such treatment.

Hypopnea noted by a decrease in air flow for more than 10 seconds ending with an arousal with the SaO2 maintained between 92% to 94%

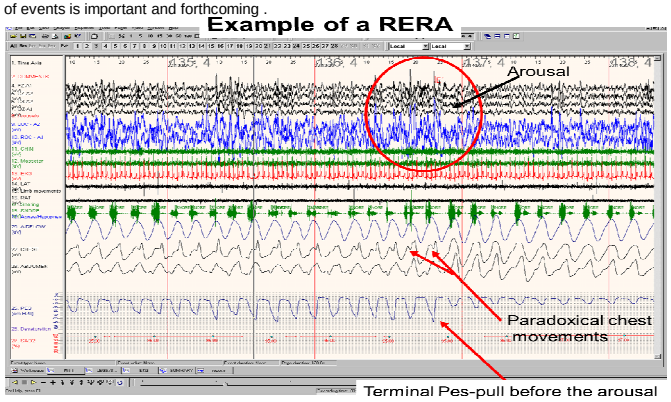


Hypopnea noted by a decrease in air flow for more than 10 sec ending with an arousal with the SaO2 maintained between 98% to 99%



2 minute display screen

This is an example of an Respiratory Effort Related Arousal (RERA) that does NOT meet the criteria of the 30% decrease in flow, but nonetheless, it is clear that this represents a respiratory event. The Pes signal has a crescendo increase leading to an arousal. Mild paradoxical thoracic movements can also be observed. This type of event was NOT par of the current study presented here. Nonetheless, further research characterizing the significance (importance) of tabulating these types of events is important and forthcoming .



1) Simmons J. , Barlow, S, Sleep, Vol 35S A135, 2012