CPAP Outcome Score- Proposal for a New Compliance Measure

Contributors

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Following polysomnography and a positive diagnosis for OSA, the prescription for PAP therapy is the primary therapeutic pathway for the treatment and relief of symptoms. Current standards for compliance with PAP therapy place the emphasis on actual usage. This is often defined using Medicare standards as a percentage of time per 24-hour period used over any consecutive 30-day time span within a three-month window and a minimum of 4 hours per usage. As a primary provider of PAP therapy, National Sleep Therapy's overall goals and mission statements includes the necessary standards for compliance, but additionally we are continually seeking to expand reliable methods that:

1) Assess functional status following the initiation of therapy. We propose using the FOSQ 10.
2) Incorporate validated questionnaires that include ESS and STOP-BANG to augment compliance based on usage and include measures of sleepiness and presence of airflow limitation.
3) Provide treating physicians subjective reported data to aid in the follow-up decision making process.

We hypothesized that if National Sleep Therapy (NST) is able, through the application of a validated process to either:

a) Clinically intervene based on a specific cut-off index to increase the probability of positive functional outcomes in addition to maintaining standardized compliance reporting, OR
b) Alert the treating physician that the patient might require medical intervention when a specific cut-off index is met, THEN
c) Patients should benefit overall, AND
d) The local health care system should benefit from cost-effective application of PAP Therapy.

While the AHI is the primary diagnostic determining factor for a PAP prescription, its decrease following PAP therapy has not been routinely taken into account in determining whether a prescription should continue following standard compliance reporting. Despite the fact that technological advances in PAP devices now routinely report AHI, compliance reporting to the majority of payers does not require its inclusion in case management, either algorithmically driven or through actual person-to person reporting. We believe that inclusion of this CPAP efficacy measure is central to optimal OSA management.

We hypothesized that the addition of the AHI as reported through PAP devices to the current formula accepted by payers would enhance compliance reporting. Intuitively, a higher AH index while on therapy, irrespective of total time used should adversely affect the overall benefits of PAP therapy, while lower AH indices despite possible failure with standard compliance rules can still provide clinical benefits and should be recognized by payers. We hypothesized that if we performed a calculation including the hours used over a specific period by the corresponding AHI as reported by the PAP device, a more robust and meaningful indication of compliance that takes into effect the physiological response to therapy would occur. We tested this hypothesis on a random sampling of patients referred for PAP therapy.

To further validate this calculation we asked patients to simultaneously complete the FOSQ10, an ESS and a STOP-BANG questionnaire. We chose the FOSQ 10 as an indication of functional outcomes, the ESS gave us an indication of residual sleepiness following PAP therapy and STOP-BANG which specifically addresses the risk of sleep apnea provided additional validation for the device generated AHI. Ideally, therefore, a compliance with PAP therapy irrespective of usage time should generate a normal AHI, low ESS, low STOP-BANG scores and high FOSQ scores. However, usage time continues to be addressed if patient's indices indicate that further monitoring is required.

METHODS: We emailed a combined questionnaire that included the FOSQ 10, ESS and STOP-BANG to approximately 3200 patients and received responses from 529 patients. Following receipt of data we excluded patients who had not completed the download process from the prescribed device or who did not fully complete the survey. Based on this first exclusion, 397 patient's data were analyzed using the ESS, FOSQ 10, and STOP-BANG, and compared results to our internal calculation. We stratified the data based on common accepted cut-off points for each of the questionnaires, thus patients who had positive outcomes had an ESS score <9, a FOSQ 10 score >16 and a STOP-BANG score <3. We compared this stratification process to our internal calculation to determine the most appropriate clinical pathway for each of the accepted questionnaires.

RESULTS: Results tabulated below show three distinct clinical outcomes grouped under our theoretical decision tree of either in compliance, requiring monitoring or requiring intervention:

NST INTERNAL SCORE In Compliance >20 Average Values				
Hrs	AHI	ESS	FOSQ10	SB
6.5	2.39	7.1	17.2	2.6

NST INTERNAL SCORE Requires Monitoring 10-20 Average Values				
Hrs	AHI	ESS	FOSQ10	SB
5.6	5.79	9.9	15.7	2.6

NST INTERNAL SCORE Requires Monitoring 10-20 Average Values				
Hrs	AHI	ESS	FOSQ10	SB
3.7	10.7	10.4	14.1	2.8

DISCUSSION: While actual nightly usage is currently the main component of compliance with therapy, clinical benefit does not necessarily follow. Patients may use their PAP device for less than 4 hours/night but report low ESS and STOP-BANG scores and possibly score high on FOSQ 10. Alternatively, ESS scores that point to residual sleepiness along with low FOSQ 10 scores despite nightly usage >4 hours/night might warrant further medical or clinical intervention. As payers demand cost-effective solutions to PAP therapy, PAP usage as the only measure of compliance without supporting data on functional outcomes and some measure of the consequences of untreated sleep apnea may not provide the best definitive answer with respect to whether a patient is benefiting from prescribed therapy. The extent of clinical intervention of a provider, such as National Sleep Therapy, is limited, in most instances to mask interface and PAP prescription adjustments. Optimizing these two clinical pathways while subjective reported data is below normal baseline levels requires "physician-centric" clinical or medical intervention to increase the probability of cost-effective utilization of health care expenditures on the treatment of OSA.

CONCLUSION: National Sleep Therapy is proposing that in addition to providing device usage data as part of standard reporting sequence, it will also internally track patients through an on-going process that combines analysis of ESS, FOSQ 10, STOP-BANG, and AHI. Results from such analysis will allow for classification into three distinct pathways:

A) In Compliance B) Requires Monitoring C)Requires Intervention

Inclusion into one of these pathways occurs following patient reported data and subsequent calculation from self reported ESS, FOSQ 10, STOP-BANG, hours used as reported through the device software and post AHI. The calculation is computed internally and generates the following indices:

- <10: Requires clinical intervention and subsequent communication with treating physician.
- 10-20: Requires monitoring
- >20: ESS, FOSQ 10, STOP-BANG, POST AHI, Device USAGE within normal accepted limits.