

Night to Night Variability of In-home Sleep Studies – Is One Night Enough?

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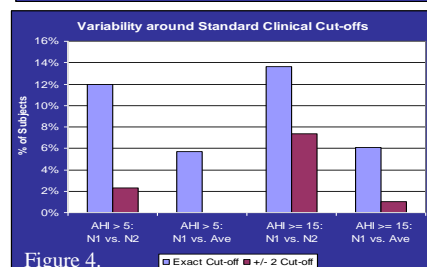
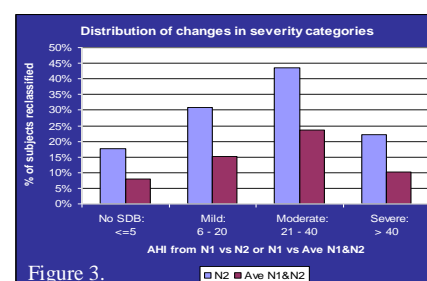
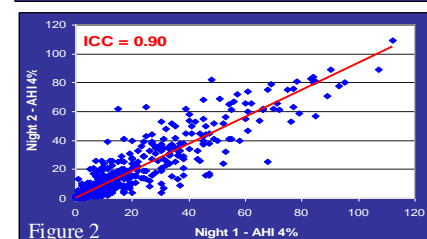
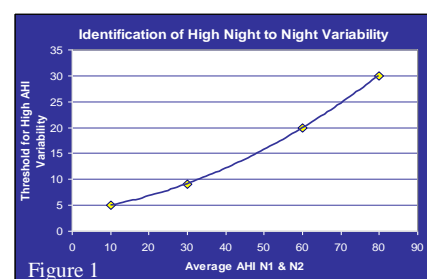
Introduction: This retrospective analysis of an existing database of sleep studies acquired with an ARES Unicorder investigates the night-to-night variability to assess the utility of multi-night studies.

Methods: A total of 476 subjects with >4-hours of recording time on each of two-nights were analyzed. The group included 352 males and 124 females, with a mean age of 50 ± 13 years, with a range of 13 to 89 years. The mean overall valid recording times for Nights 1 and 2 (6.0 ± 0.78 and 5.8 ± 0.90 hours, respectively) were small but significantly different ($p < 0.05$). Difference in valid time supine and non-supine were not significant

Auto-scoring rules identified apneas (10-s cessation in flow) (AI) and hypopneas with 4%-desaturation (AHI-4%). Inter-class correlations were computed between N1 and N2 data. AHI-4% values were stratified into normal (≤ 5), mild (5-20), moderate (21-40) and severe (>40) severity categories for N1, N2 and the average of N1+N2 combined. The subjects were also stratified by those with an AHI-4% > 5 or ≥ 15 on Nights 1 or 2.

An exponential equation (Fig. 1), based on the assumption that the maximum absolute AHI variability at 10, 30 and 60 should be no more than 5, 9 and 20 events/hour, was developed and used to identify potentially important high night-to-night variability. Night to night differences in the AHI resulting in the High Variability classification were then determined for overall, supine and non-supine positions and stratified in AHI ranges based on the average AHI across the two nights. The data set was then stratified into quartiles based on the percentage time supine during N1. The number of High Variability cases and the mean absolute difference in AHI between N1 and N2 for these cases in each quartile were computed.

Results: Strong interclass correlations were observed ($p < 0.001$) between N1 and N2 for the overall recording time ($r = 0.75$), percent time supine ($r = 0.79$), AHI-4% ($r = 0.90$) (Fig. 2) and AHI-1% ($r = 0.89$). The supine AI ($r = 0.55$), AHI-4% ($r = 0.57$) and AHI-1% ($r = 0.52$) was not as strongly correlated ($p < 0.001$). For AHI-4%, the percentage of patients with different severity category for N1 vs. N2 were no SDB=18%, mild=31%, moderate=44% and severe=22%. When comparing N1 to the average of N1 and N2, the distribution of changed severity categories were reduced to: no SDB=8%, mild=15%, moderate=24% and severe=10% (Figure 3). When comparing the significant changes in diagnostic categories between N1 and N2, 1% of patients changed from no SDB to moderate, 4% from mild to severe and 1% from severe to mild. No patient changed more than one diagnostic category when two nights of data were averaged. We examined night variability around two standard clinical cut-offs used by Medicare to determine CPAP reimbursement (Fig. 4). Using the strict clinical cut-off of AHI > 5 , 12% of the subjects were not similarly classified on N1 and N2 and 5.7% were not similarly classified comparing N1 to the average of N1 and N2. When AHI's between 4 and 7 were not treated as misclassifications, only 2.3% of the subjects were classified differently on N1 and N2 and all were correctly classified the AHI from the two nights were averaged. Applying the same kind of analysis to the clinical cut-off AHI ≥ 15 , 13.7% of the subjects were classified differently on N1 and N2 and 6.1% were classified differently when comparing N1 to the average of N1 and



N2. When AHI's between 13 and 17 were not considered misclassifications, 7.4% of the subjects changed classification between N1 and N2 compared to 1.1% when N1 and N2 were averaged.

The data are presented in a Bland-Altman plot (Fig. 5) which highlights the region considered to be Low and High Variability based on the equation derived from Figure 1. In this plot, the bias is essentially zero and the variability around the mean is approximately nine events/ hour. Applying the high variability threshold algorithm (Fig. 1) to the distributions of variance across the 476 studies, 27% of the studies (129/476) presented high overall night to night variability, 47% (225/476) of the studies presented high supine variability, and 23% (110/476) of the studies presented high non-supine variability. There were significant differences in the valid time supine for N1 and N2 ($p < 0.01$). for the 173 subjects identified as having supine high variability While there were no significant night-to-night differences in the time supine for the low variability studies, there were significant differences between the low variability and high variability or outlier subjects in the amount of time spent supine on Night 2 ($p < 0.05$). Thus it appears that subjects with high variability spent less time supine on night 2.

The ratio of high variability studies to the total number of studies in each AHI range overall, supine and non-supine is presented in Figure 6. When computing these distributions, 75 records were dropped because the total time supine was not > 15 minutes and 28 records were dropped because the total time non-supine was not > 15 minutes. For example, in the AHI range 21 to 30, 52% of the subjects had an overall AHI considered to be highly variable, while 72% and 40% of the subjects had highly variable supine and non-supine AHI's respectively. The highest ratio of high variability cases was observed in the AHI range from 11 to 30 (i.e., approximately 50% of subjects). The proportion of subjects with high supine AHI variability was greatest in the 21 to 40 range.

The percentage of cases with high variability in each of the quartiles (derived from stratification of time supine on N1) is presented in Figure 7. Thirty-two percent of the 119 cases in the quartile with the greatest percentage of time supine (61-100%) were classified with high variability as compared to 24% of the cases in the quartile with the least percentage of time supine (0-16%). The pattern of the mean absolute difference in AHI between N1 and N2 across the four quartiles of time spent supine confirms that the variability is greatest when the percentage of time supine is the lowest. There appears to be no difference in the amount of night to night variability in supine AHI after patients spend approximately 35% of their time supine.

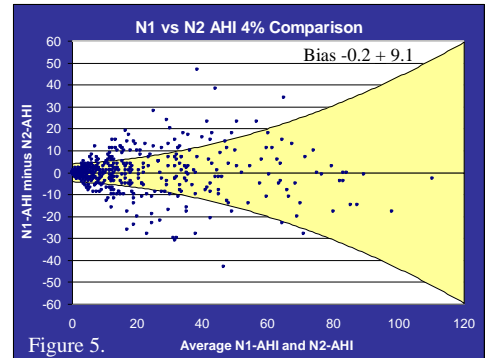


Figure 5.

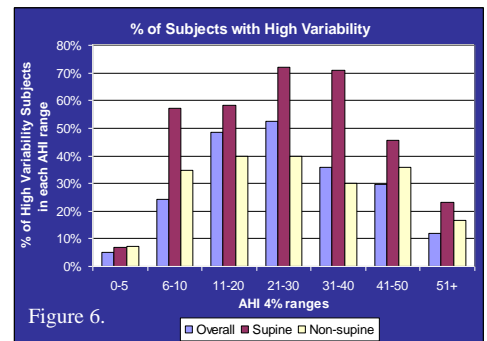


Figure 6.

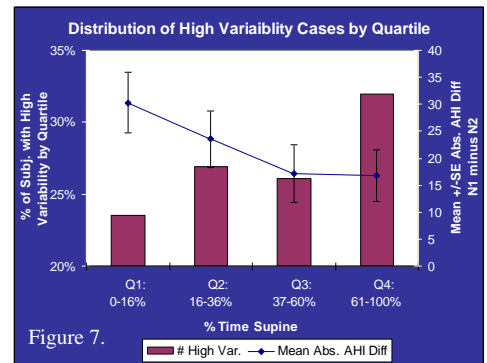


Figure 7.

Conclusions: There is sufficient night to night variability to cause changes in diagnostic and severity categories, especially in the moderate OSA range. This variability can be reduced by the averaging of two nights of data. Variability in the overall AHI is greatest in the AHI ranges 11 – 30 and much lower in the minimal and severe AHI ranges. The percentage of subjects with high variability in the supine AHI is substantially greater than the percentage of subjects with high variability in the overall AHI. The percentage of patients with high variability increases in conjunction with the percentage of time supine, however, the difference night to night in supine AHI is fairly constant after the time in the supine position exceeds 35%. Models that predict AHI severity or studies to assess treatment outcomes, as well as investigations comparing diagnostic techniques, might benefit from multi-night studies.