A Pilot Validation Study for The NOX T3 Portable Monitor as a Screener for OSA

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INTRODUCTION

OSA is a serious medical problem associated with numerous health consequences and increased morbidity and mortality[1].

The use of portable monitors (PMs) aka "home sleep tests" for diagnosing OSA is rapidly expanding in part due to increased prevalence of OSA and better screening/awareness for OSA risk factors, but also because of mandates from insurance carriers to utilize PMs as a first-pass diagnostic strategy for OSA.

Type 3 monitors vary in terms of technical methodology and complexity and as such have varying degrees of associated limitations.

A noted limitation for PM is the rate of device failures and false negatives with rates as high as 18%[2] and 17%[3], respectively.

With the growing trend of PM use, there is a need for highly sensitive and specific devices that are also easy to apply, score, and interpret.

The NOX T3 Type 3 PM is similar to other like monitors in that it records pulse oxymetry, airflow, and respiratory movement. However, the T3 may have advantages over similar devices due to its ability to record actigraphy, real-time audio, and chest/abdominal respiratory inductance plethysmography (RIP).

STUDY AIM: *To provide data on the accuracy of the NOX T3, a Type 3 PM, in detecting OSA compared to simultaneously-recorded PSG data.*

METHODS

32 participants (44% Female, 50% Black) were recruited upon their consultation with a physician at a sleep clinic.

A wide range of sleep apnea presentations were recruited, including suspected OSA severity, sleepiness (ESS_M=10.4±5.4), age (46.8±12.3), and BMI (32.8±6.8).

Each participant simultaneously wore both sets of diagnostic equipment (PSG and NOX T3) during their in-lab sleep study (4 RIP belts and 2 pulse oxymeters; counterbalanced). Nasal pressure was sampled via a dual-lumen nasal cannula to minimize nasal occlusion.

For split-night studies (n=3), NOX T3 data collection was terminated at the onset of PAP therapy.

NOX T3 data was downloaded and scored manually and via the autoscore function.

PSG and NOX T3 records were scored by RPSGTs blinded to study information.

The presence of OSA was defined across two AHI thresholds: at least mild (i.e. ≥ 5 events per hour) and at least moderate (i.e. ≥15 events per hour).

RESULTS

Autoscore-derived NOX T3 AHI was similar to manually-derived T3 AHI -

On average, manual scoring produced an AHI of 18.6 +/- 19.1 whereas autoscoring produced an AHI of 19.6 +/- 18.9; T(31) = 1.8, p = .08.

Auto-scored NOX T3 AHI was similar to PSG AHI (Figure 1)

AHI (auto) and PSG-derived AHI were strongly related r (29) = .93, p<.001, r^2 .86 . The T3-derived oxygen desaturation index (ODI; SPO_2 drop of ≥4%) was also strongly (but to a lesser degree than T3 AHI) correlated with PSG-derived AHI (r (29) = .89, p<.001, r^2= .79).

Figure 1: Scatter Plot of Manual and Auto-Scored NOX T3 AHI

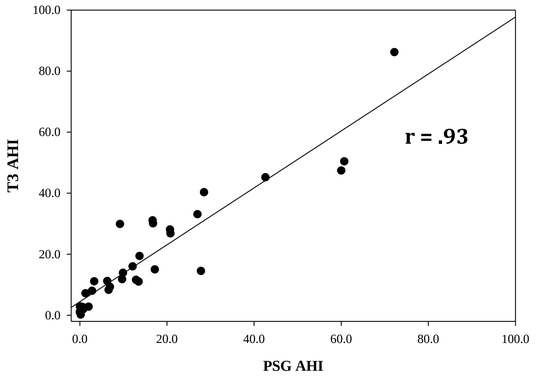


Table 1: AHI Comparison between NOX T3 and PSG AHI

	PSG	HST (Auto)	HST (Manual)	Analyses
AHI	16.3 (19)	19.7 (19)	18.6 (19)	NS
Full Night	12.8 (14)	16.2 (14)	15.0 (13)	NS
Split	51.0 (27)	53.5 (30)	54.3 (34)	NS
AHI Category				
Normal (<5)	10	7		
Mild (≥5)	10	11		
Moderate (≥15)	8	6		
Severe (≥30)	4	8		

The NOX T3 Demonstrated Low Failure Rate

A total of three participants (7.5%) were excluded for poor signal integrity, one for poor nasal pressure signal and two for poor pulse oximetry signal.

The NOX T3 Demonstrated High Diagnostic Accuracy in Detecting OSA (Table 2)

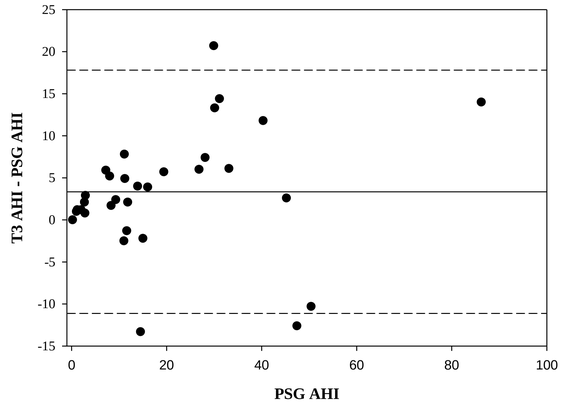
The T3 demonstrated high sensitivity for the presence of mild OSA and acceptable specificity for the exclusion of mild OSA. Overall, for mild OSA, the T3 correctly identified 88% of positive cases and all negative cases. When the presence of OSA was defined more conservatively (AHI ≥ 15), the T3 had a high degree of both sensitivity and specificity.

Specificity was reduced because of 6 false positives with a mean AHI overestimation of 8.2 +/- 6.3 events/hr (range 3.9 to 20.1 events/hr). This difference was attenuated, however, when RERAs were factored in (mean difference of less than 1.2 events/hr).

Table 2: Diagnostic Accuracy of the NOX T3

	T3 AHI Cut-Point	
	AHI ≥ 5.0	**AHI ≥ 15.0**
n	25	14
Sensitivity	100%	92%
Specificity	70%	85%
Positive predictive value	88%	79%
Negative predictive value	100%	94%

Figure 2: Bland Altman Plot



Mean difference between T3-derived AHI (autoscored) and PSG AHI
Limits of agreement (+/- 2 SD)

On average, the T3 overestimated AHI by 3.3 +/- 7.2 events per hour (Figure 2), with 25 overestimates (M = 6.0 +/- 5.1 events/hr) and 6 underestimates (M = 7.0 +/- 5.6 events/hr). One participant had the same AHI via the T3 and PSG.

CONCLUSIONS

The NOX T3 (using autoscored AHI) demonstrated very good measurement agreement compared to PSG, high sensitivity for detecting even mild OSA, and high specificity for excluding moderate to severe OSA. The rate of FN was lower than other similar devices when studied simultaneously in-lab[3] and is encouraging given the concern for FN within the context of increasing PM use in clinical settings[3]. The number of FNs appeared to be due to RERAs being auto-scored as obstructive apneas and may be due to inherent recording and scoring discrepancies between PSG and portable monitors. Data loss in this pilot study was low and should approximate what would occur in the field as technologists were instructed not to adjust sensors. Future studies should investigate the diagnostic accuracy of the NOX T3 in the home environment.

References
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