

The SleepStrip®

A Disposable Sleep Apnea Screening Device

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- Patient operated, self contained single use SAS screening test.
- Combined oral and nasal thermal flow detection.
- Real time analysis of flow signals and apnea count.
- Study results permanently displayed on sensor immediately after study.

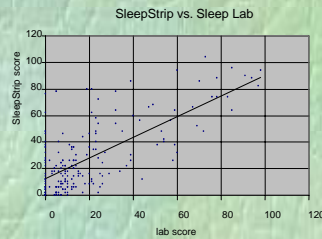


Method

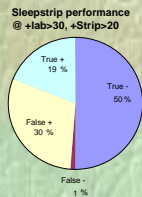
- 196 Subjects were selected from patients referred to the Technion sleep lab for suspected SAS.
- Screeners were tested either during the lab study, or at home on the same week.
- Screener results were correlated with sleep lab RDI score.

Results

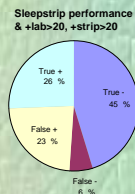
- Scatter diagram of 196 patients who successfully completed both studies, reveals a linear correlation coefficient of 0.71.
- Setting a cutoff point of RDI=20 as a treatment decision, sensitivity is 82%, and specificity is 66%.



Setting the SleepStrip “positive” threshold to different values can increase sensitivity for screening purposes. For severe sleep apnea patients, with RDI>30, setting the SleepStrip threshold to 20 gives a much improved sensitivity and reduced specificity.



True -	98
False -	2
False +	59
True +	37
TOTAL	196
Sensitivity	0.95
Specificity	0.62
Correlation	0.71



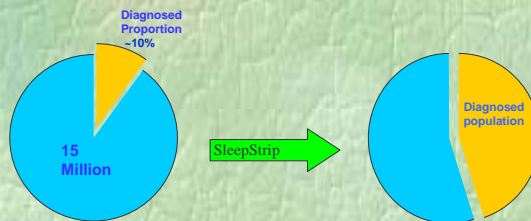
True -	89
False -	11
False +	46
True +	50
TOTAL	196
Sensitivity	0.82
Specificity	0.66
Correlation	0.71

Conclusions

- The results show a close agreement between the RDI obtained in the sleep lab, and the screener score.
- Screener performance are better than other screening methods, such as questionnaires, sleep expert evaluation, and are comparable with all night oxymetry .
- Screener may be useful for screening large populations, setting priorities in sleep-lab patients queue, long term follow-up on treatment outcome, and epidemiological research.

Diagnosed Proportion of Americans with Sleep Apnea year 2000

Source:
Sleep, 1997;
New England Journal of Medicine, 1993;
American Sleep Disorders Association



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