YOUR SLEEPLESS PATIENT: MAKING SENSE OF THE PROCEDURAL AND WEARABLE OPTIONS

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Overview: Sleep Monitoring options for the sleepless patient and those patients hoping to gain greater insight regarding their sleep architecture has increased tremendously in the last 10 years. This talk will focus on the latest technology available and the evidence regarding its efficacy and utility.

Conventional Sleep Monitoring offered in Sleep Centers:

Polysomnography[1]: Polysomnography (PSG) offers observation of sleep-related breathing or movement disorders, yet warrants further investigation when there is negative impact on sleep quality. Polysomnography is **not** indicated in the initial diagnosis and routine evaluation of chronic insomnia but can be used when there is clinical suspicion of sleep apnea or movement disorders. Thus, the specific utility of polysomnography in the diagnosis and treatment of insomnia remains exploratory.

Actigraphy[2]: Actigraphy, a portable device continuously monitoring "sleep-wake activity" over an extended periods of time, provides an estimation of sleep patterns in healthy adults and patients with certain sleep disorders, such as advanced sleep phase syndrome (ASPS), delayed sleep phase syndrome (DSPS), shift work disorder, circadian rhythms disorder, etc. This technology provides a cost-effective method for monitoring sleep patterns in the evaluation and management of the aforementioned sleep disorders. Studies have also suggested that actigraphy is potentially useful for evaluation of patients with jet lag disorder and non-24hr sleep/wake syndrome and to estimate total sleep time for obstructive sleep apnea patients when polysomnography is not available[2].

Sleep profiler: Sleep profiler is a home sleep test offering physicians a newly approved by FDA tool to evaluate sleep architecture. A study[3] obtained EEG recordings from the Sleep Profiler and a full PSG in healthy, good sleep participants in order to determine the validity of the Sleep Profiler in estimating sleep continuity and architecture in healthy adults. The scored PSG record, physician-scored Sleep Profiler record, and the Sleep Profiler record scored by an automatic algorithm were compared and shown to be in agreement. The study concluded that the Sleep Profiler yields reasonable agreement with the sleep architecture recorded by the conventional in-lab PSG in otherwise healthy adults.

Ambulatory/Wearable Devices offered Quantification, Sleep Trackers and associated data, other Apps and Gadgets

Quantified Self: The **Quantified Self** is the idea to use technology to self-track and acquire data on aspects of a person's daily life. Other names for the quantified-self include life-logging, self-tracking, auto-analytics, body hacking, and personal informatics.

Prevalence of Use

- The Consumer Electronics Association (CEA) 2015 shows that 22% of all US Adults use sleep tech. The largest group of sleep tech users at 36% are aged 25-34[4].

Sleep Tracking: Overview of Technology

1. Newest Jawbone "UP4", released in Summer 2015:

- This UP4 tracker uses advanced sensors to automatically track sleep stages—wake, REM, light, and deep. Using this data, Smart Coach gives suggestions to maximize sleep and improve the quality of the user's days.
- Sleep is automatically tracked using Bioimpedance sensors, which read heart rate to track sleep phases with a high degree of accuracy.
- Advanced Sleep Tracking adds an additional dimension to understanding sleep quality by tracking wake, REM, light and deep sleep stages.

Validation Studies on Jawbone:

Study 1:

- Jawbone UP has been shown to have good agreement with PSG particularly in the estimation of TST, SE, and SOL in a large sample of healthy adolescent boys and girls without sleep disorders[5].
- Jawbone UP "Sound sleep" was positively associated with PSG time in N2 and time in REM, and negatively associated with the arousal index[4].
  - Jawbone "Sound sleep" seems to represent stages of PSG sleep associated with fewer movements but surprisingly, what is commonly defined "the deepest PSG sleep stage," i.e., N3, failed to enter in the model.
  - Results showed overall good agreement between methods, with Jawbone UP overestimating PSG TST by, on average, 10.0 min and underestimating wake after sleep onset (WASO) by, on average, 10.6 min.

Study 2:

- In another study, Jawbone UP was shown to have overestimated TST and SOL, while it underestimated WASO[6].
  - Twenty-eight midlife women (age 50.1 ± 3.9y, BMI 24.6 ± 3.6 kgm2) participated. Based on clinical interview, 12 women met DSM-IV criteria for insomnia disorder. Based on clinical PSG assessment, two participants had PLMI>10, and two participants had PLMI>10 + AHI>5.
  - With its poor ability to detect wake (low specificity), Jawbone UP showed less accuracy in the estimation of WASO, particularly on nights of more disrupted PSG sleep.
  - Differences were not observed in the accuracy of Jawbone UP in assessing PSG sleep between women with and without an insomnia diagnosis (similar to previous research with standard actigraphy, which concluded that insomnia did not modify the association between actigraphy and PSG WASO[7]).

Summary of Validation Studies To-Date:

The overall greater discrepancy between Jawbone UP and PSG in the present data from midlife women relative to that previously reported in adolescents is probably related to the overall age-related difference in sleep quality between the two groups.

- Despite limitations, the data suggest that Jawbone UP provides acceptable levels of agreement with PSG measures, when the overall night is considered, and thus may be a feasible alternative for ecologically monitoring sleep-wake rhythms over several days, for example to track changes in sleep timing in large samples of adolescents or shift-workers.

2. Fitbit:

In total, Fitbit offered at least 11 trackers since 2008 and Jawbone offered at least 6 trackers since 2011 (Jawbone currently only sells 4 trackers).

Fitbit Sleep Options

- Fitbit tracker's settings can record sleep in either "sensitive" mode for extremely detailed sleep reporting or "normal" mode for a more basic idea of the user's sleep patterns.
- The normal setting counts significant movements as being awake (such as rolling over) and is appropriate for most users.
- The "sensitive" setting will cause the tracker to record nearly all movements as time spent awake. This setting may be helpful for users with sleep disorders, or those who wear their tracker somewhere other than the wrist while asleep.
- During sleep mode, when the body is completely at rest and unmoving, the Fitbit tracker records that the user is asleep.
- A restless state of sleep indicates that the body has transitioned from a very restful position with little movement to movement, such as turning over in bed. This doesn't necessarily mean that the user was fully awake or cognizant of his/her movements, but it may indicate that s/he was not getting the most restful sleep possible at that time.
- When the tracker indicates that the user is moving so much that restful sleep would not be possible, the sleep graph will indicate that the user was awake.

Summary of Efficacy and Validation Studies on Fitbit:

- The following equation is used to calculate sleep efficiency: *100 * time asleep / (time asleep + time restless + time awoken during sleep).* This equation does not take into account time to fall asleep in the calculation.
- It is possible to get 100% sleep efficiency if the user does not move all night even if s/he takes 20 minutes to fall asleep.
- Head to head study of Fitbit and actigraph[8] differed significantly on recorded TST and SE between each other and polysomnography.
  - Both overestimated sleep efficiency and total sleep time. Sensitivity of both Fitbit and actigraphy for accurately identifying sleep was high; specificity of both Fitbit and actigraph for accurately identifying wake was poor.
- Fitbit overestimated the time participants were asleep by 67 minutes, on average[8].
- The opposite effect in children — the Fitbit One underestimated how long the children were asleep, by 109 minutes[8].

Summary

- Growing number of consumer methods of tracking sleep in the market currently.
- Providers should remain cautious with how that data is used by the patient and by clinicians.

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