Sleep characterization with smart wearable devices

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PERSPECTIVE

Sleep characterization with smart wearable devices: a call for standardization and consensus recommendations

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Abstract

The general public increasingly adopts smart wearable devices to quantify sleep characteristics and dedicated devices for sleep assessment. The rapid evolution of technology has outpaced the ability to implement validation approaches and demonstrate relevant clinical applicability. There are untapped opportunities to validate and refine consumer devices in partnership with scientists in academic institutions, patients, and the private sector to allow effective integration into clinical management pathways and facilitate trust in adoption once reliability and validity have been demonstrated. We call for the formation of a working group involving stakeholders from academia, clinical care and industry to develop clear professional recommendations to facilitate appropriate and optimized clinical utilization of such technologies.

Key words: sleep; wearables; sleep apnea

Background

While sleep studies were traditionally performed in controlled laboratory settings for diagnosis or management of sleep disorders, home-based assessments are increasingly used in clinical settings for diagnosing sleep apnea (home sleep apnea tests). With the evolution of technology and increased public awareness and interest in sleep, there has been a remarkable growth in the numbers and types of electronic devices, including

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wearables and nearables, marketed directly to consumers for use for monitoring sleep; consumer sleep technologies range from smart mattresses and EEG headbands using dry electrodes [1] or entirely contact-less systems measuring body motions, heart rate and respiration through radiofrequency Doppler technology. Most prominently, over the past five years, the number of wearable fitness trackers and smartwatches shipped worldwide has grown from 89 to 232 million units each year and is expected to reach over 379 million devices in 2025 [2]. While original smart wearable devices focused on fitness tracking, sleep assessment modules were soon integrated into many devices. The currently available sleep assessment ranges from tracking sleep duration to sleep schedules and sleep stages, or even respiratory disturbances. The technology was geared initially toward "wellness" (achieving personalized "sleep goals") of the "quantified-self" community by self-tracking lifestyle applications (Apps). Now, in parallel, the self-tracked lifestyle components, including sleep duration and the detection of suspected sleep disorders, provide metrics that have potential clinical implications. Although longitudinal sleep tracking might yield personalized insights and temporal patterns, it is currently impossible to objectively interpret and compare sleep patterns/architecture provided by the different devices [3]. In addition, most algorithms are not described in detail in the literature; the majority of data reported by these wearables are computed by artificial intelligence algorithms with a "black box" effect [4,5], and lack of comprehensive validation studies are limiting wider acceptance by patients and clinicians.

Sleep Assessment in the Clinic

Sleep is a complex phenomenon that has traditionally been assessed with overnight polysomnography (PSG). It requires an array of sensors, including, most importantly, an electroencephalogram (EEG), to provide a detailed picture of processes characterizing sleep and its disorders. Established approaches to scoring PSG recordings are used according to available guidelines by the American Academy of Sleep Medicine (AASM) [6]. The interpretation of PSG is challenging and requires expert knowledge by specifically trained physicians and allied health specialists, producing a range of metrics capturing different aspects of sleep [7]. The most widely used metrics include the duration, stages and fragmentation of sleep, hypoxemic burden representing the time spent with low oxygen saturation, the apnea-hypopnea index (AHI) (representing the number of hypopneas and apneas per hour of sleep to assess sleep-disordered breathing), periodic limb movements (to assess periodic limb movement disorder), and ECG (for overnight cardiac arrhythmias). Some of these metrics, particularly the AHI and hypoxemic burden have been linked to an increased cardiovascular outcome risk [7–10] aside from a reduced quality of life, including poor daytime performance. However, there is less utility of PSG for understanding variations in sleep duration or timing, or to diagnose insomnia.

Sleep Tracking by Smart Wearable Devices

"Smart" wearable devices are convenient because they collect data unobtrusively, potentially over days or longer, via a limited number of sensors directly integrated into a device worn on the wrist or finger and do not require specific actions by the consumer. Many devices perform actigraphy and photoplethysmography, yielding information on movement and pulse rate from which secondary data can be derived, such as pulse rate variability and respiratory modulation of the pulse amplitude. These data streams are combined to estimate sleep and wake times, and some have been used to perform sleep staging via proprietary algorithms without the use of gold standard EEG. Intuitively, movement detection can be used to detect wakefulness. At the same time, the amount and regularity of pulse rate variations aids the separation of REM from non-REM sleep and light from deep non-REM sleep, where REM sleep is typically associated with more irregular heartbeats and deep sleep by pronounced respiratory sinus arrhythmia [11]. The addition of skin temperature measurement appears to improve sleep onset detection [12]. While these surrogate measures correlate with some EEG-based sleep metrics, there is variability in accuracy for specific parameters (e.g. REM vs light sleep), with misclassification also influenced by person-specific factors (e.g. underlying sleep disorders, movement disorders, and depression). Therefore, the optimal use of metrics from these devices requires a thorough understanding of the meaning and predictive value of these metrics, and in some cases may require population-specific thresholds for defining normative values (e.g. percentage of time in N3 or average sleep duration). In other cases, some metrics may prove to have little value for predicting impairment or risk of disease. In contrast, in other instances, such metrics may prove superior to existing clinical tools. The ability to use data collected over long periods as well as an emphasis on heart rate measures capturing autonomic cardiac control, which is usually not considered in current clinically performed sleep tests, for example, may prove to yield novel predictive data for cardiovascular outcomes [13].

Oxygen saturation is of growing importance as an integrative signal for health, as well as being useful for predicting sleep-disordered breathing-related health outcomes. Pulse oximeters are becoming more widely integrated into smartwatches, and some are approved by regulatory bodies as diagnostic devices for measuring oxygen saturation [14]. Advanced algorithms detect episodic desaturations indicative of sleep-disordered breathing [15] and can be used as surrogate parameters to estimate the presence and severity of sleep apnea [16]. However, FDA-approved pulse oximeters being used widely in the clinic have been criticized for overestimating oxygen saturation levels in certain situations (critical care), with differential misclassification in minorities (presumably due to the impact of skin pigmentation on photoplethysmography) [17]. It is important to understand whether these concerns apply to smart wearable devices. In addition, as is true for home sleep apnea tests (HSAT) that do not record EEG, wearable devices may overestimate total sleep time and underestimate sleep onset latency and wake after sleep onset [18], thereby likely underestimating the presence and severity of common sleep disorders, for example, the number of oxygen desaturations per hour of sleep. For these reasons, the current generation of smart wearable devices cannot replace a full PSG but are more similar to a conventional type IV test for obstructive sleep apnea, i.e. an unattended sleep recording of 1–2 channels, typically including pulse oximetry [19]. While the sensitivity of limited channel tests used alone have been found to vary from insufficient to adequate [20, 21], combining them with a pretest clinical score or repeated measurement may improve sensitivity. Indeed, as sleep-disordered breathing testing and diagnosis is increasingly performed by HSAT, a key question

is whether smart wearable devices could substitute for current HSAT, while PSG would be primarily used for evaluating complex disorders and following up on negative tests in cases where there is still a high pretest probability or unexplained sleep-related symptoms. Incorporation of portable EEG signals, such as with a headband (and possibly in the future with in-ear sensors), may further improve the information from oximetry-based devices, addressing some of the concerns pertaining to the current generation of HSAT [22].

A major strength of wearables is to allow multiple-night recordings with a limited cost and in ecologic conditions. Many studies underscore that a single night PSG results in a 20%–50% misclassification regarding sleep apnea diagnosis [23]. Multiple nights' data will reduce misclassification due to nonrepresentative sleep on a single night and allow monitoring of changes in the environment and health to be considered, potentially resulting in improved health outcomes on a large scale. Characterizing night-to-night variability can identify triggers or conditions that modulate severity of OSA. Multiple-night recordings may also help reduce measurement inaccuracies of the wearable device if these errors are random and uncorrelated to the signal, improving the signal-to-noise ratio.

Where to go from Here?

Educating consumers about wearable technology

Typically, software provided by the device manufacturers or third-party apps condense data collected through the night and produce a (simplified) hypnogram, overnight respiration rate recording and overnight oximetry recording using deep learning. Additionally, most smart wearable devices provide a simple aggregate sleep metric for the end-user, conventionally referred to as the "sleep score". Usually expressed in a fixed range, e.g. from 0 to 100, high sleep scores refer to better sleep, while lower scores suggest possible sleep issues. The definitions of what the sleep score incorporates vary between devices and often remain opaque, mainly without any account of correlation to patient-reported outcomes. It may include information on sleep duration, sleep cycle, and respiratory disturbances. Complicating matters further, the sleep score may be modified by personalized sleep goals, e.g. by an individual setting their "ideal" sleep time, further reducing its objectiveness and comparability.

Despite not being officially classified or labelled as a diagnostic tool, it is fair to assume that people longitudinally probing their sleep by wearables may draw some conclusions and change their sleep patterns and lifestyle according to this. The potential implications are profound. If only 10% of people who bought a smart wearable device in 2021 will use it to assess their sleep, perhaps due to concerns about their sleep quality, 23.2 million people will pay attention to their' sleep score' globally.

With increasing accuracy and uptake of sleep-tracking Apps, the detection of existing and yet undiagnosed sleep disorders will likely increase. Consumers using these "sleep scores" need to be educated about the relevance and importance of sleep disorders, the possible treatment options, and the best way to access appropriate medical advice if further action is required as well as when to consult clinicians regardless of the output of such devices. Additionally, as observed in other consumer-led scenarios of mobile health use, self-monitoring may sometimes be counter-productive [24]. Also, not all potential consumers who may benefit from self-monitoring can use

or access digital technology, contributing to a digital "divide" and digital inequality. Some devices may perform variably across groups, eg, underestimating wake time in individuals with depression or underestimating oxygen saturation in individuals of color, thus potentially aggravating health inequities. Finally, in addition to improvement and standardization of the performance of the Apps, improved information and education are required to support the consumers' and patients' involvement and engagement in data interpretation and the triggering of presentation to a physician to seek medical help and advice. Sleep apps must deliver a positive user experience, engaging and educating consumers if their use is to persist. Chat-bot coaches that guide users through the complexities of sleep data and make a recommendation based on currently available evidence may be one promising approach for improving user benefit [25]. Data-driven decision-support systems will likely play an increasing role in clinical and consumer environments. The line between personalized "wellness" recommendations and providing clinical advice is increasingly blurred but does carry liability issues for both the technology developer and the physician. Sleep apnea diagnosis and management recommendations and guidelines must take this topic seriously, and offer strong, evidence-based consensus statements to guide clinical decision making.

Raising awareness in the clinical community

Physicians and allied health specialists should be prepared to be confronted with "sleep scores" from smart wearable devices collected by patients. While academia and sleep physicians rely on the precise definition, measurement, and cut-off values of sleep metrics obtained with validated PSG or HSAT devices [6], the "sleep score", existing primarily outside the sleep laboratory, has mainly emerged as an output of self-tracking lifestyle Apps for smart wearable devices without any systematic validation and testing. Aside from the misclassification of metrics contributing to the sleep score due to inaccuracies inherent in deep learning strategies, potentially providing misleading results at the individual level, the lack of specificity of information content of the sleep score to guide follow up presents significant challenges. Until the interpretation of aggregate sleep scores is better understood, the clinical value of wearables may better focus on optimal use of conventional sleep metrics, defined clearly and characterized according to their measurement properties. Such metrics may capture features of sleep architecture (total sleep time, time spent in various sleep stages), subcortical arousals via pulse wave amplitude and heart rate changes [26, 27] and sleep-disordered breathing, for example by means of oxygen desaturation index or other measures of hypoxemic burden [9, 28]. As methods for calculating summary indices of multi-dimensional sleep health from research tools are further validated and shown to predict health outcomes [29], there may opportunities to use this research to inform the development of scores using simpler consumer technology.

While wearables have also demonstrated new research capabilities in characterizing changes in sleep health occurring during major societal changes such as the COVID-19 pandemic and associated social restrictions [30, 31], the usefulness of augmenting sleep awareness with devices at the level of the individual is not yet understood. Does self-tracking using these new, sometimes poorly validated, measures improve health
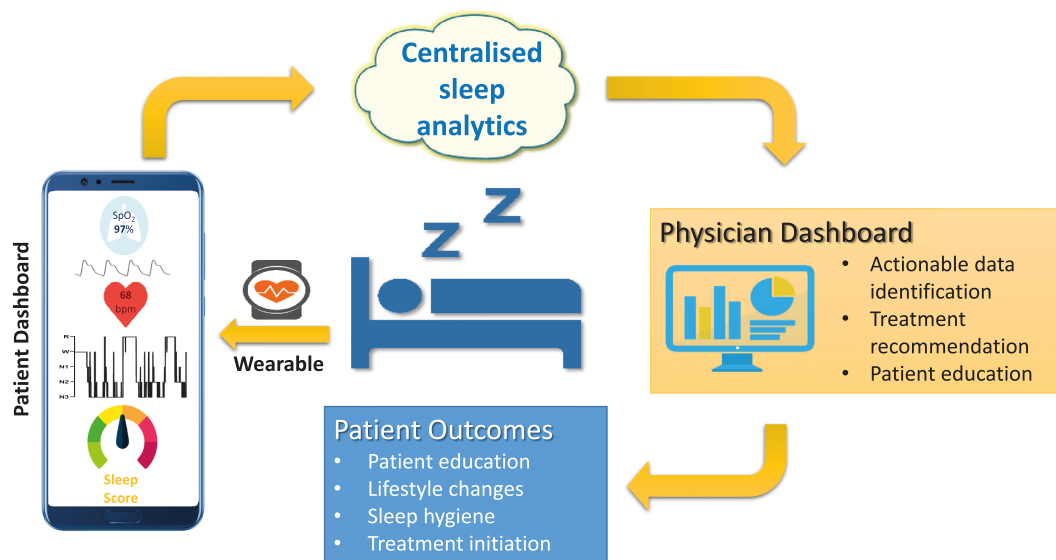
Figure 1. Integration of sleep tracking by wearables into the healthcare framework.

behaviors, or do they lead to anxiety over meeting metrics that may or may not reflect optimal sleep? Do they result in over-utilization of health care by physician consultation to follow up on findings? Do they cause under-diagnosis due to the failure of devices to identify a clinically significant problem or by individuals attempting to improve sleep scores without appropriate clinical support?

Integrating sleep data from wearables into clinical workflow

Effective strategies must be found to make sleep data from wearables useful to clinical care and to empower patients to be involved in data collection, which can finally be integrated into clinical management pathways (Figure 1). The widespread use of heart rate and rhythm monitoring by several mobile Apps within the cardiology setting may provide an example of how sleep tracking metrics continuously collected by smart wearable devices may soon enter the clinical field [32, 33]. Similarly to sleep assessment, most heart rate and rhythm assessment Apps were initially developed for consumer-initiated self-tracking of health and lifestyle but subsequently rapidly found their way into the clinical setting [32]. Recently, Cardiology societies have been provided up-to-date practical guidance on the use of digital devices for arrhythmias, from early detection through the management and clinical implementation. Potential barriers and side effects concerning patient engagement or digital literacy as well as several challenges, including the definition of useful clinical scenarios and integration of actionable data in treatment pathways learned in the Cardiology field, should be considered for sleep management as well. Specific challenges in the sleep use case may be the involvement of multiple specialties. There is a potential that the implementation of digital technology and cloud-based analysis and data sharing may improve healthcare fragmentation [34].

The accuracy of wearable-derived sleep metrics and the best way to integrate these findings into clinical decision making and treatment pathways remain unclear. Although specific guidance

is not available, a general statement from the AASM indicates that consumer sleep technologies are not substitutes for medical evaluations, given the unknown accuracy of these devices. However, they may be used as an adjunct to an appropriate clinical evaluation [35].

The sleep community recognizes the importance of achieving data transparency [36]—European Data Format, developed by a few biomedical engineers as the result of the 1987 international Sleep Congress in Copenhagen, has become the de-facto industry standard and is now widely adopted by PSG and EEG equipment. Yet, implementation details may differ, and minimum data requirements, for example, were not specified. To facilitate the transition of wearable-derived sleep data from the lifestyle-tracking consumer-led setting to the clinical physician-led setting and to allow the integration of these new sleep metrics into the decision-making process by physicians and other health professionals, future consensus documents should focus on establishing minimum requirements for transparency, documentation, and independent validation of these tools [36]. Manufacturers of smart wearable devices that provide sleep assessment should understand of the critical needs to adopt approaches for improving data transparency when developing testable, actionable and clinically valuable metrics- which will be essential for the clinical implementation of wearable-derived sleep tracking and release its true potential to society. The business case of these wearables developed in wellness is completely different from medical device pathways targeting reimbursement [37]. Novel means are needed to engage manufacturers of smart wearable devices to incentivize transparency and validation, eg by providing "certification" endorsed by professional societies for those products that meet minimum requirements established by consensus guidelines. The fluidity of algorithm development and continuous system updates, in particular those using deep learning remains a challenge. To address these issues, professional societies may curate large open-access benchmark training databases and offer in-house performance assessments using blinded test datasets [36].

Several other aspects currently prevent the broad integration of consumer wearables into clinical workflows, such as the inflexible IT infrastructures, privacy issues, concerns regarding data protection and ongoing discussion about data ownership. Additionally, the large amounts of data for healthcare personnel, unsolicited recordings and recordings sent out of hours can increase workload and open up areas of legal uncertainty. Also, wearables and related software for maintaining or encouraging a healthy lifestyle unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition are not considered medical devices. While FDA does not currently regulate these devices, new bodies may be needed other than professional societies to ensure public needs are met.

Conclusions

Technological advancements of wearables detecting sleep characteristics and dedicated devices for sleep assessment are rapidly progressing along with fast adoption by the general public. However, these advances and uptake have outpaced the ability to implement approaches to validate these data and provide relevant clinical applicability. There are untapped opportunities for a partnership of scientists in academic institutions, patients, and the private sector to validate and refine consumer devices to allow effective integration of these data into clinical management pathways and facilitate trust in adoption once reliability and validity have been demonstrated. Professional societies may set guidelines for the standardization of reported data, a unified validation framework for device and software components, and offer minimal "certification" for products that meet these standards. We call for the formation of a working group comprising stakeholders from academia, clinical care and industry to develop clear professional recommendations to facilitate appropriate and optimized clinical utilization of such technologies. Key points that need to be established include:

- A minimum set of clearly defined sleep metrics to be reported by the device,
- Minimum performance evaluation requirements against PSG and accuracy reporting of sleep metrics [38],
- Ensuring a rigorous approval procedure of sleep diagnostic capabilities by regulatory agencies, eg oxygen desaturations for diagnosing obstructive sleep apnea,
- A transparent interface for data download and IT infrastructure integration.

Conflict of interest statement. None declared.

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