

Medical Policy



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Title: Actigraphy

Professional

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Institutional

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DESCRIPTION

Actigraphy refers to the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, which is interpreted by computer algorithms as periods of sleep and wake. Sleep/wake cycles may be altered in sleep disorders including insomnia, circadian rhythm sleep disorders, sleep-related breathing disorders, restless leg syndrome, and periodic limb movement disorder. In addition, actigraphy could potentially be used to assess sleep/wake disturbances associated with numerous other diseases or disorders such as attention-deficit/hyperactivity disorder, chronic fatigue syndrome, asthma, Parkinson's syndrome, post-surgical delirium, stroke, advanced cancer, and intensive care monitoring.

Actigraphic devices are typically placed on the non-dominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of 3 days to 2 weeks, but can be collected continuously over extended time periods with regular downloading of data onto a computer. The activity monitors may also be placed on the ankle for the assessment of restless leg syndrome, or on the trunk to record movement in infants. The algorithms for detection of movement are variable among devices and may include "time above threshold," the "zero crossing method," or "digital integration" method, resulting in different sensitivities. Sensitivity settings (e.g., low, medium, high, automatic) can also be adjusted during data analysis. The digital integration method reflects both acceleration and amplitude of movement; this form of data analysis may be most commonly used today. Data on patient bed times (lights out) and rise times (lights on) are usually entered into the computer record from daily patient sleep logs or by patient-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement, along with movement-related periods of wake. In addition to providing graphic depiction of the activity pattern, device-specific software may analyze and report a variety of sleep parameters including sleep onset, sleep offset, sleep latency, total sleep duration, and wake after sleep onset. Actigraphy has been used for over 2 decades as an outcome measure in sleep disorders research. Numerous actigraphy devices have received U.S. Food and Drug Administration (FDA) approval through the 510(k) process

POLICY

Actigraphy is considered **experimental / investigational** as a technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders.

RATIONALE

This policy was initially based primarily on 2003 practice parameters issued by the American Academy of Sleep Medicine (AASM) (1) with a further literature review through April 2005 to identify any additional published studies. Since all the specific clinical indications for actigraphy were classified as guidelines or options, the AASM practice parameters indicated that all indications for actigraphy would be considered investigational. The parameters suggested that actigraphy could be used to evaluate specific aspects of insomnia. However, review of the literature cited by the American Academy of Sleep Disorders for this indication did not identify any controlled studies of actigraphy versus PSG or other techniques. Indeed, all but 1 of the studies cited were classified as either 4C or 5D, indicating that the study was not blinded or prospective. One study was designated as 2B, indicating a blinded, prospective comparison; however, in this study actigraphy was used as an intermediate outcome measure in an investigation of bright lights as a treatment of delayed sleep phase syndrome. (2) In a review paper that served as the basis for the 2003 practice parameters, (3) the AASM pointed out the challenges in evaluating the diagnostic performance of actigraphy:

- Different actigraphy devices use different algorithms for the evaluation of data. There were no published articles comparing the different algorithms, making comparison between studies difficult.
- Polysomnography (PSG) is considered the gold standard for the evaluation of sleep/wake cycles. However, correlation data may be misleading. For example, a high correlation on total sleep time would mean that individuals who slept longer by PSG criteria also slept longer by actigraphy criteria; however, this would not exclude the possibility that actigraphy data overestimated total sleep time. Different methods of analysis have also been used such as accuracy for identification of true sleep and true wake epochs. The diagnostic performance will also vary according to how much time the patient is asleep. For example, malfunctioning records will falsely identify the patient as asleep. Finally, comparisons between PSG and actigraphy have to be time locked; if the 2 technologies gradually drift apart, different time epochs may be compared with each other.
- Published reports of actigraphy must contain complete reporting of sensitivity, specificity, scoring algorithm, and filters, as well as reliability, validity, ruggedness, and artifact rejection for the device and computer program used.

A 2005 Update for the AASM Practice Parameters (4) continued to list actigraphy as an option, and suggested areas such as restless legs syndrome and characterizing circadian rhythm patterns for further evaluation. No controlled studies had been conducted to compare the results of actigraphy to other methods to determine if actigraphy would provide incremental information that would result in improved health outcomes.

The AASM published updated Practice Parameters on the use of actigraphy in the assessment of sleep and sleep disorders in 2007. (5) Whereas the 2005 practice parameters focused on the comparison of actigraphy with polysomnographically recorded sleep, the 2007 update included 108 additional studies comparing actigraphy to a number of standard clinical assessment tools that included sleep logs, subjective questionnaires, care giver reports, and circadian phase

markers. Actigraphy was recommended as a “standard” only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from “option” to “guideline,” but failed to reach a recommendation of “standard” due primarily to the absence of high-quality trials. Few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. In addition, most of the studies lacked a description of blinding, and there was “an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data.” The AASM Standards of Practice Committee indicated the need for additional research in the following areas:

- Comparison of results from different actigraphy devices and the variety of algorithms used
- Standards for setting start and stop times
- Reliability and validity compared to reference standards
- Clarification of the relative and unique contributions of actigraphy, polysomnography, and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects

In the AASM’s 2007 Practice Parameter on evaluation and treatment of circadian rhythm sleep disorders (CRSDs), the use of actigraphy was considered as either an “option” or “guideline,” depending on the suspected disorder. (6) Specifically, use of actigraphy was recommended as an “option” for diagnosis of irregular sleep-wake disorder and free-running disorder, and as a “guideline” for diagnosis of advanced sleep phase disorder, delayed sleep phase disorder and shift work disorder. The evidence reviewed indicated good agreement between actigraphy and results of other diagnostic tools including polysomnography, sleep logs, and markers of circadian phase. It should be noted, however, that there is a relative lack of evidence for any procedure in the diagnosis or evaluation of treatment of CRSDs. For example, use of sleep logs received a “guideline” recommendation, based primarily on consensus and inclusion in the International Classification of Sleep Disorders 2nd edition (ICSD-2). Insufficient evidence was found to recommend use of circadian phase markers for any CRSDs other than free-running disorder. Polysomnography is not routinely indicated for the diagnosis of CRSDs. (6)

Literature Review

The additional literature reviewed in 2005 focused on randomized studies comparing the results of actigraphy to either polysomnography (PSG), to determine whether actigraphy could be considered an alternative to PSG, or studies comparing actigraphy to other methods, such as sleep diaries or direct observation, to determine whether actigraphy could provide incremental information that would result in an improvement in patient management. The literature search revealed that actigraphy is frequently used as an intermediate outcome in research studies, but there were no randomized studies identified that focused on the use of actigraphy to either diagnose or direct the management of patients with sleep disorders. For example, actigraphy had been used as an intermediate outcome in several trials of melatonin for sleep disturbances in patients with Alzheimer’s disease (7-9) or other drug trials. (10)

Literature review updates through May 2009 did not identify any studies that evaluated if the use of actigraphy would result in improved health outcomes for patients with sleep disorders (clinical utility). A number of studies were identified that assessed sensitivity and specificity in either healthy or clinical populations (clinical validity).

Adults

Paquet et al. compared actigraphic assessment of sleep and wake with PSG under varying conditions of sleep disturbance (night time sleep, day time sleep, day time sleep with caffeine) in 23 healthy subjects. (11) Data were analyzed from a study that evaluated the effects of caffeine on daytime recovery sleep. The experimental protocol involved 2 visits to the sleep laboratory, each including one night of nocturnal sleep, one night of sleep deprivation, and the next day of recovery sleep (once with placebo and once with 200 mg caffeine). The Actiwatch® and PSG equipment were synchronized prior to recording, and assessment of sleep and wake were compared for each one-minute interval to evaluate sensitivity, specificity, and accuracy of actigraphy in comparison with manually staged sleep from PSG recordings. Sensitivity was defined as the proportion of all epochs scored as sleep by PSG that were also scored as sleep by actigraphy. Specificity was the proportion of all epochs scored as wake by PSG that were also scored as wake by actigraphy. Accuracy was the proportion of all epochs correctly identified by actigraphy. Four different sensitivity settings/scoring algorithms were compared. In general, as the threshold to detect movement was raised, sensitivity to detect sleep increased, but the ability to detect wake (specificity) decreased. With the medium threshold algorithm, the sensitivity to detect sleep was 95% - 96%. However specificity, or the ability to detect wake, was 54% for night time sleep, 45% for daytime recovery sleep, and 37% for daytime recovery sleep with caffeine. A main finding of the study was that the more disturbed the sleep, the less the actigraph was able to differentiate between true sleep and quiet wakefulness, with an accuracy of 72% for the most disrupted sleep condition. Through experimental manipulation of the level of sleep disturbance, this study provides substantial information about the limitations of this technology for clinical populations with sleep disruption. Several studies assessed clinical validity in patients with primary or secondary sleep disorders. One study assessed the sensitivity and specificity of actigraphy in comparison with PSG in older adults treated for chronic primary insomnia. (12) Visual scoring of the PSG data was blinded and actigraphic records were scored by proprietary software. The study found that actigraphy agreed with PSG scoring of sleep for 95% of the 30-second epochs (sensitivity), but agreed with PSG scoring of wake only 36% of the time (specificity). The authors concluded that, "the clinical utility of actigraphy is still suboptimal in older adults treated for chronic primary insomnia." Beecroft et al. reported an observational study of sleep monitoring in the intensive care unit, comparing nurse assessment, actigraphy and PSG, in 12 stable, critically ill, mechanically ventilated patients. (13) PSG showed severely disrupted sleep, with decreased total sleep time and sleep efficiency, high frequency of arousals and awakenings (fragmentation), and abnormal sleep architecture (decreased slow wave and rapid eye movement [REM] sleep). Both nurse's and actigraphic assessment of sleep were found to be inaccurate. Actigraphy overestimated the total sleep time, with a median that was 2 – 3 hours greater than PSG. Median sleep efficiency (actual sleep as a percentage of total recording time) was estimated at 61% to 95% by actigraphy, depending on the sensitivity setting, which was substantially higher than the 42% median sleep efficiency shown by PSG with sleep staging.

Children

Werner and colleagues assessed agreement between actigraphy and parent diary or questionnaire for sleep patterns in 50 children, aged 4-7 years, recruited from kindergarten schools in Switzerland. Sixty-eight families agreed to participate out of 660 families invited (10%). (14) Each child was home-monitored with an actigraph for 6 to 8 consecutive nights, and parents were requested to complete a detailed sleep diary (15-minute intervals) during the monitoring days to indicate bedtime, estimated sleep start, wake periods during the night and estimated sleep end. Parent's assessment of habitual wake time, get up time, bedtime, time of

lights off, sleep latency, and nap duration were obtained through questionnaire. Satisfactory agreement, defined a priori as differences smaller than 30 minutes, was achieved between actigraphy and diary for sleep start, sleep end, and assumed sleep. Actual sleep time and nocturnal wake time differed by an average of 72 minutes and 55 minutes, respectively. Satisfactory agreement was not reached between actigraphy and questionnaire for any of the parameters. The authors concluded that the diary is a cost-effective and valid source of information about children's sleep-schedule time, while actigraphy may provide additional information about nocturnal wake time or may be used if parents are unable to report in detail. Compliance and accuracy in the diaries is likely to be affected by the motivation of the parents, who in this study were self-selected.

Another study examined the validity of actigraphy for determining sleep and wake in children with sleep disordered breathing with data analyzed over 4 separate activity threshold settings (low, medium, high, auto). (15) The low and auto activity thresholds were found to adequately determine sleep (relative to PSG), but significantly underestimated wake, with sensitivity of 97% and specificity of 39%. The medium and high activity thresholds significantly underestimated sleep time (sensitivity of 94% and 90%), but were not found to be significantly different from the total PSG estimates of wake time (specificity of 59% and 69%). Overall agreement rates between actigraphy and PSG (for both sleep and wake) were 85% to 89%.

A validation study of actigraphy for determining sleep and wake was conducted in 10 preterm infants using videotaped behavioral observations. (16) The study was conducted for a 24-hour period each week while the infants were in the nursery, resulting in a total of 38 studies. Wakefulness was scored as quiet wake with eyes open and "bright", active wake with eyes open and gross body movements, or crying. Sleep included quiet sleep with regular breathing and eyes closed, active sleep with irregular breathing and rapid eye movements, and indeterminate sleep where characteristics of both active and quiet sleep were observed. Behavioral sleep-wake scoring was carried out blinded to the knowledge of the actigraphy data. The actigraph, which was synchronized to the video recording, was placed in a custom-designed sleeve bandage and positioned on the infant's leg midway between the knee and ankle. The agreement rate between actigraphic determination of sleep and wake, and behavioral scoring ranged from 66% for the high sensitivity setting at the youngest gestational age (30 – 33 weeks) to 89% at the low sensitivity setting for infants of 37 – 40 weeks gestational age. For the youngest infants, sensitivity and specificity at the low threshold were 88% and 34%, respectively. For infants of 37-40 weeks of gestational age, the sensitivity and specificity were 97% and 32%, respectively. Similar results (97% sensitivity and 24% specificity) were obtained with an epoch-by-epoch comparison of actigraphy and videosomnography in 22 autistic, 11 developmentally delayed, and 25 normally developing preschool children. (17)

Summary

The clinical validity of actigraphy depends, to a large extent, on the modality with which it is being compared.

- Comparisons with sleep diaries show reasonable correlations for measures of bedtime, sleep onset, and waketime. The relative and unique contributions of actigraphy and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects remains to be demonstrated.
- Comparisons with the more resource-intensive PSG or behavioral scoring indicate that, with the appropriate sensitivity threshold, actigraphy has sufficient sensitivity to detect sleep, but

has poor specificity in distinguishing between quiet wake and sleep. The literature also indicates that the accuracy of actigraphy to differentiate between sleep and wake decreases as the level of sleep disturbance increases.

Overall, progress has been made since the 2007 AASM research recommendations in assessing the reliability and validity of different algorithms in comparison with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and waketime in some patient populations, the clinical utility of actigraphy over the less expensive sleep diary has not been demonstrated. Moreover, accumulating evidence indicates that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. Evidence to date does not indicate that this technology is as beneficial as the established alternatives. Therefore, actigraphy is considered investigational.

Technology Assessments, Guidelines and Position Statements

American Academy of Sleep Medicine Practice Parameters

The recommendations of the American Academy of Sleep Medicine are categorized as standards, guidelines, or options. Standards describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. Guidelines reflect a moderate degree of clinical certainty, while options imply either inconclusive or conflicting evidence or conflicting expert opinion. As noted here, there is only one recommendation considered a standard, and this addresses the technical performance of actigraphic devices (first bullet below). There is also only 1 recommended guideline (second bullet below), and this addresses the small subset of patients with insomnia and restless legs syndrome with specific indications. All of the other recommendations are considered options.

Recommendations of the American Academy of Sleep Medicine (AASM) from 2003: (1)

- Actigraphy is reliable and valid for detecting sleep in normal, healthy adult populations. (Standard)
- Actigraphy is not indicated for the routine diagnosis, assessment of severity or management of any of the sleep disorders. However, it may be useful in the assessment of specific aspects of insomnia (assessment of sleep variability, measurement of treatment effects, detection of sleep phase alterations), and restless legs syndrome/periodic limb movement (assessment of treatment effects). (Guideline)
- Actigraphy may be a useful adjunct to a detailed history, examination, and subjective sleep diary for the diagnosis and treatment of insomnia, circadian-rhythm disorders, and excessive sleepiness under certain conditions. (Option)
- The use of actigraphy may be useful in assessing daytime sleepiness in situations where a more standard technique, such as a multiple sleep latency test, is not practical. (Option)
- Actigraphy is an effective means of demonstrating multiday human rest-activity pattern in clinical situations in which a sleep log, observations, or other methods cannot provide similar information. (Option)
- Actigraphy may be useful in characterizing and monitoring circadian rhythm patterns or disturbances in elderly and nursing home patients, newborns, infants, children, and adolescents; hypertensive individuals; depressed or schizophrenic patients; and individuals in inaccessible situations (i.e., space flight). (Option)
- Actigraphy appears useful as an outcome measure in interventional trials in patients with sleep disorders, outcome studies of healthy adults, patients with certain medical and psychiatric conditions, and children and the elderly. (Option)

- Actigraphy may be useful in determining the rest-activity pattern during portable sleep apnea testing. However, the use of actigraphy alone in the detection of obstructive sleep apnea is not currently established. (Option)
- Actigraphic studies should be conducted for a minimum of 3 consecutive 24-hour periods, but this length of time is highly dependent on the specific use in a given individual. (Option)

A 2005 Update for the ASSM practice parameters (4) continued to list actigraphy as an option and also suggested areas, such as restless legs syndrome and characterizing circadian rhythm patterns, for further evaluation. Updated practice parameters in 2007 on the use of actigraphy in the assessment of sleep and sleep disorders (including a separate practice parameter on circadian rhythm sleep disorders) recommended actigraphy as a "standard" only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. (5, 6) Other indications changed from "option" to "guideline," but failed to reach a recommendation of "standard" due primarily to the absence of high-quality trials.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

95803 Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

REVISIONS

10/19/2009	Policy added to bcbsks.com web site.
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