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Valid measures of periodic leg movements (PLMs) during a suggested immobilization test using the PAM-RL leg activity monitors require adjusting detection parameters for noise and signal in each recording

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Abstract

Objective and background—Individuals with restless legs syndrome (RLS) (Willis-Ekbom disease [WED]) usually have periodic leg movements (PLMs). The suggested immobilization test (SIT) measures sensory and motor features of WED during wakefulness. Surface electromyogram (EMG) recordings of the anterior tibialis (AT) are used as the standard for counting PLMs.

However, due to several limitations, leg activity meters such as the PAM-RL were advanced as a potential substitute. In our study, we assessed the validity of the measurements of PLM during wakefulness (PLMW) in the SIT for PAM-RL using both default and custom detection threshold parameters compared to AT EMG.

Methods—Data were obtained from 39 participants who were diagnosed with primary WED and who were on stable medication as part of another study using the SIT to repeatedly evaluate WED symptoms over 6–12 months. EMG recordings and PAM-RL, when available, were used to detect PLMW for each SIT. Complete PAM-RL and polysomnography (PSG) EMG data were available for 253 SITs from that study. The default PAM-RL (dPAM-RL) detected leg movements based on manufacturer's noise (resting) and signal (movement) amplitude criteria developed to accurately detect PLM during sleep (PLMS). The custom PAM-RL (cPAM-RL) similarly detected leg movements except the noise and movement detection parameters were adjusted to match the PAM-RL data for each SIT.

Results—The distributions of the differences between either dPAM-RL or cPAM-RL and EMG PLMW were strongly leptokurtic (Kurtosis >2) with many small differences and a few unusually large differences. These distributions are better described by median and quartile ranges than mean and standard deviation. Despite an adequate correlation ($r = 0.66$) between the dPAM-RL and EMG recordings, the dPAM-RL on average significantly underscored the number of PLMW

(median: quartiles = -13: -51.2, 0.0) and on Bland–Altman plots had a significant magnitude bias with greater underscoring for larger average PLMW/h. There also was an adequate correlation ($r = 0.70$) between cPAM-RL and EMG but with minimal underscoring of PLMW (median quartiles = 0.0; -20, 10) and no significant magnitude bias. Two scorers independently scoring 13% of the SITs showed an adequate interscorer reliability of 0.96–0.98.

Conclusions—Our study confirms our expectation that measuring PLMW in a SIT using dPAM-RL is not valid and that adjustments to the detection threshold criteria are required. The PAM-RL, using parameters customized for each SIT provided a valid and reliable measure of PLMW with minimal magnitude bias compared to the AT EMG recordings.

Keywords

Restless Legs Syndrome (RLS); Willis Ekbom disease (WED); Leg activity monitors; Suggested immobilization test (SIT); Periodic leg movements during wakefulness (PLMW); Polysomnography; PAM-RL

1. Introduction

Restless legs syndrome (RLS), also known as Willis-Ekbom disease (WED), has both sensory symptoms and motor signs [1]. The motor signs are rhythmic or semirhythmic movements of the legs called periodic leg movements (PLMs). The PLM feature of RLS/WED usually is measured from nighttime sleep (PLMS). PLMS occur at a high rate in most RLS patients [2] and can provide an objective measure of RLS severity and a sensitive yet nonspecific aid for diagnosing RLS/WED [1]. PLM associated with RLS/WED also can occur during the resting period of wakefulness (PLMW) [3]. Because RLS/WED symptoms are by definition provoked during rest, the suggested immobilization test (SIT) was developed to provide a potential objective assessment of rest-induced symptoms. The SIT establishes a well-defined resting condition maintained for an hour to provoke the RLS/WED symptoms. The PLMW during the SIT are objectively measured using the same criteria for measuring PLMS. The SIT also provides a subjective measure of degree of leg discomfort and urge to move. The SIT has been proposed as a standardized laboratory test for diagnosis and evaluation of severity of RLS/WED [3,4].

The accepted standard for measuring PLMS and PLMW uses bilateral electromyogram (EMG) recordings of the anterior tibialis (AT) [5]. Cost, accessibility, and high variability over days limits the utility of EMG recordings for PLM. An alternative to the physiologic recording would be the use of motion detectors, e.g., accelerometers placed on the leg. Initial evaluation of this concept found that the standard accelerometers had low sensitivity leading to significantly under reporting of the number of PLMS. [6]. IM Systems, however, developed an accelerometer (PAM-RL, Phillips-Respironics Bend, Oregon) specifically designed to be worn above the ankle to automatically detect leg movements. The PAM-RL automatically detects PLMS based on preset, default parameters defining critical characteristics for onset (movement detection signal), offset (resting noise level), and periodicity of the movements. These detection parameters were set to provide an accurate assessment of PLMS in RLS/WED patients. In a validation study, the PAM-RL counts of PLMS correlated well ($r = 0.87$; $P < 0.001$) with counts from standard scoring of AT EMG on all night sleep recordings from RLS patients. The Bland–Altman plots needed to establish measurement validity over the full range of values showed that the PAM-RL had only a small magnitude bias toward underestimation of the PLMS in the severe cases and overestimation in the mild to moderate cases [7].

Given the overall adequate result for detecting PLMS, it is reasonable to assume that the PAM-RL also will accurately detect PLMW in SIT. However, no such validation evidence

exists for the SIT. In the SIT, unlike night polysomnography (PSG), participants are encouraged to stay awake and not move. This practice encourages participants to inhibit leg movements, possibly resulting in smaller movements. In addition, there may be breakthrough movements at times when the participant is unable to inhibit movements which may be excessively large and of longer duration. So there is the possibility of a larger dynamic range of amplitude and duration for PLMW of the SIT than PLMS of the PSG. Therefore, the parameters for the PAM-RL which were adjusted to detect PLMS may not suffice to detect the putative wider variation of movements for PLMW in SIT.

The main question in our study was if PAM-RL provides a reasonably accurate minimally magnitude-biased estimate of SIT PLMW using the default parameters that work well for PLMS from all night PSGs. If not, can expert scorers establish custom-scoring parameters based on visual inspection of the data that would provide accurate measures of SIT PLMW? Could the methods for producing any such custom parameters produce reliable measurements? Would the custom parameters set across SITs be close enough that an average could be used as new default parameters for all SITs?

2. Methods

2.1. SIT

The standard SIT used for our study included sleep electroencephalogram with electrodes attached to the frontal, central, and occipital area of the head with derivations to contralateral mastoid; electrooculogram for right and left side to record bilateral eye movements; and surface EMG for submental area and bilateral AT. This method provides the measurements for recording PLM as established by the World Association of Sleep Medicine (WASM) [8]. The PLMW were scored from these recordings according to the international standards established by the WASM [8]. In each SIT, the participants were sitting at a 45-degree angle with legs stretched out horizontally for an hour [3]. The test was done twice a day starting at 16:00 and 17:45. Participants wore a PAM-RL on each leg during the SIT. At the start of the SIT, the participant was given a sheet of paper with series of Likert scales for degree of RLS discomfort in the legs. Every 5 min, the participants would sequentially mark the amount of discomfort during the hour-long test on these scales.

2.2. Participants and schedule

Participants were all over 21 diagnosed with primary RLS and treated for RLS on stable drug monotherapy using either a dopamine agonist or an opioid taken at or after 16:00. Participants were excluded if they were not ambulatory or if they were diagnosed with a major sleep disorder other than RLS, a major medical disorder that would disrupt sleep, or a major psychiatric disorder. They were part of a study approved by the Johns Hopkins Institutional Review Board and the respective institutional review boards of each of the other three testing sites. That study used the SIT to evaluate changes in RLS symptoms over 6–12 months for patients continuing on stable treatment. Observations were made at an initial baseline followed by repeated tests 1, 2, 4, 6, 9, and 12 months later. Each visit included a clinical evaluation and two SITs at 16:00 and 17:45. Medications were not taken on test days until after the SIT tests were completed.

2.3. PLMW/h measurement for each SIT

The EMG and PAM-RL activity measures were obtained from each SIT. The PLMW/h for activity measures (PAM-RL) was calculated without knowledge of the PLMW/h from the EMG. All SITs with valid data from both the PAM-RL and EMG recordings were used. The number of PAM-RL activity meters available limited the number of SITs providing data for

our study. The EMG recordings from each SIT were scored for PLMW by a central reader who had an established 90% scoring agreement with an experienced expert in PLMS (RA).

2.4. PAM-RL scoring for PLM

The PAM-RL samples activity at 40 Hz, averaged every four samples to record amplitude of activity at 10 Hz. The PAM-RL filters the activity data to provide an estimate of the envelope of movement activity. These filtered values are used for movement detection. The PAM-RL displays both filtered and unfiltered activity amplitudes over time on a computer screen for time periods as small as 1 min. The filtered data are used for movement detection. The PAM-RL program (PAM-V7, Phillips Respironics) combines data points as needed for the screen display of longer time periods showing either the average or maximum value for each combined set. For our study the display was set to show maximum values. The PAM-RL automatically detects leg movements that meet criteria for PLM. This detection uses amplitude criteria for starting (movement signal for onset) and ending (resting noise level for offset) a movement as shown by lines in Fig. 1. The leg movement amplitude above the onset criteria starts a potential movement which is ended when the movement amplitude becomes and remains less than the offset criteria for at least 0.5 s. The duration of the potential movement must be 0.5–15 s to be considered a candidate movement during a SIT. There needs to be a minimum of four candidate leg kicks, each separated from onset to onset by 5–90 s to be counted as PLMs.

The parameters defining PLM from the PAM-RL match those used for scoring PLM from the AT EMG recordings [8] except for the actual amplitude criteria, which must differ for the two types of measures (movement vs muscular contraction). The PAM-RL manufacturer established default amplitude criteria for accurate detection of PLMS using the PAM-RL, but also allowed adjusting these criteria based on visual inspection of the data. Expert scorers in our study established custom amplitude criteria by visual inspection of data from each leg of each SIT. The scorers in our study (two of the authors, MY and RA) were experienced in scoring PLMW in SITs with an agreement record for EMG PLMW detection exceeding 90%. One author (RA) trained the other (MY) in setting parameters on a different set of data. They set parameters together and then independently until they were within $\pm 15\%$ on 10 consecutive SITs. Both scorers then independently set custom parameters for a randomly selected sample of 33 of the activity and EMG datasets from our study to establish interscorer agreement. One author (MY) set custom parameters for all of the remaining available data.

Custom parameters were set by manually moving the lines displayed on the screen (see Fig. 1). The offset criteria (lower line) was adjusted to rest on the top, barely touching the resting noise level as shown in one-minute displays taken from the first part of the SIT with few leg movements. The onset criteria (upper line) was adjusted from the same data to be slightly above any observed random fluctuations in activity data visually judged not related to a leg movement. These adjustments were further modified based on visual review of 3-min segments over the entire SIT. The PAM-RL computer program provides predetermined equal-interval integer units of amplitude measurements that range from 0 to 4000 covering the acceleration range detected by PAM-RL. The movement detection criteria were specified in these units. The default settings were onset (160) and offset (100). The custom settings were recorded for each SIT test.

The EMG recordings from both right and left legs are evaluated together with each PLMW counted as one movement when it occurs in either leg. Right and left leg movements overlapping each other within 0.5 s are counted as one movement as described for the WASM standard [8]. The PAM-RL measures each leg separately without any method for combining the two legs. The measurement for each SIT used in our study, as most closely

approximating the EMG from both legs, was the maximum of the PAM-RL data from either the right or left leg.

2.5. Statistical analysis

The primary question of the adequacy of using default PAM-RL as a measurement of PLMW during the SIT was evaluated by: (1) determining linear regression of the PAM-RL vs EMG PLMW; (2) displaying a histogram of the distribution of PAM-RL error (PLMW/h from PAM-RL – PSG) and evaluating the error distributions with mean, standard deviation (SD), skew, kurtosis, median, and quartile ranges (Microsoft Excel for MAC v14.3.6 functions); and (3) evaluating magnitude bias using Bland–Altman plots. The last of these is considered the most important, but the others also provide important characteristics of the measurement accuracy. The adequacy of the custom PAM-RL measurement of PLMW was similarly evaluated for all SITs using only the custom parameters set by MY. Inter-scorer reliability for custom parameters was determined by the degree of agreement between the two independent scorers (MY and RA) on 33 SITs. The custom parameters and resulting PLMW/h from the two scorers were examined for degree of correlation, possible magnitude bias, and the average and variance of difference between the scorers. The variance and overlap of the custom parameters were evaluated to assess the feasibility of establishing one set to be used for all SIT data.

3. Results

3.1. Subjects

Data were available from 39 participants (17 men and 22 women; mean age, 61.1 ± 12.3 years; range, 35–80 years). All participants were diagnosed with RLS and on treatment with either dopamine agonists or opioids. Twelve subjects were taking opioids and 27 were taking dopamine agonists. Data were available from 253 SITs from these 39 subjects.

3.2. PAM-RL accuracy

Fig. 2A shows linear regression ($r = 0.66$) between PLMW/h determined by EMG and the PAM-RL using default amplitude parameters (dPAM-RL). The dPAM-RL underscored the number of PLM. The difference between dPAM-RL and EMG was significantly negatively skewed (skew = -1.4) with a mean $\pm$ SD of -31.7 ± 50.9 . The distribution was leptokurtic (kurtosis = 2.1), and thus better described by its median of -13 and quartile range of -51.2 to 0.0 (see Fig. 3). The histogram of dPAM-RL measurement error in Fig. 3A shows the strong tendency toward underestimating the PLMW. In addition, there is greater underestimation error for larger values of PLMW (see Bland-Altman plot in Fig. 4A).

The PLMW/h from the PAM-RL scored using custom amplitude parameters (cPAM-RL) also showed an adequate linear regression with those from the EMG ($r = 0.70$; Fig. 2B). The differences between cPAM-RL and EMG PLMW/h showed no significant skew (skew = -0.2) and on average a slight under estimation of the PLMW with a mean $\pm$ SD of -4.5 ± 51.0 . The distribution was strongly leptokurtic (kurtosis = 2.6), and thus better described by its median of 0.0 and quartile range of -20 to 10 (Fig. 3B). There was no indication for significant magnitude bias over the entire range of values (see Bland–Altman plots in Fig. 4B).

3.3. Characteristics of custom parameters

The custom detection parameters had significantly lower onset and offset values than the default parameters (average $\pm$ SD, 66 ± 21.2 and 49.1 ± 21.7 ; ranges, 26–102 and 10–87, respectively, for custom parameters vs. 160 and 100 for default parameters, respectively).

An example of the effects of these different detection amplitudes for detecting EMG PLMW is shown in Fig. 1.

The noise level identified by the custom offset criteria considerably varied between SITs (10–87 units), possibly indicating effects of different PAM-RLs or battery status. The custom onset criteria were only approximately 35% higher than the offset noise level. The onset offset ranges also considerably overlapped (26–102 vs 10–87). The average of 66 for onset criteria fell within the range of the noise level indicating that, if used as a preset for all SITs, it would for some detect noise as possible PLMW. This lack of separation of criteria indicates that, unlike the sleep condition, a significant number of the SIT movements are too close to a highly variable noise level to allow for establishing one set of amplitude criteria that would apply to all SITs.

3.4. Reliability of custom parameters

The interscorer reliability in setting custom parameters was checked for randomly selected 13% (33) of all 253 datasets. The custom criteria for these datasets scored independently by two of the authors were highly correlated ($r = 0.96$ and 0.98 for onset and offset amplitude, respectively). The mean $\pm$ SD differences between their custom parameters were 4.4 ± 4.1 for onset and 3.1 ± 2.9 for offset criteria, with no indication for magnitude bias. The PLMW/h from the custom parameters set by the two independent scorers were highly correlated ($r = 0.996$) with no indication for magnitude bias (see Fig. 5). The mean $\pm$ SD difference between scorers for PLMW/h was -0.45 ± 4.2 .

4. Discussion

The default PAM-RL detection settings did not provide an accurate measurement of PLMW when compared to EMG-defined PLMW. As shown in our result, there was an unacceptable underestimation (mean of -31.7) using the default PAM-RL, which was greater for larger amount of movements. In contrast, the visually set customized detection criteria provided a reasonably accurate measure of the PLMW/h across the full range of the PLMW/h values as shown by the Bland–Altman plot. Although the dPAM-RL has been well validated for PLMS of RLS patients [7], a more recent study by Gschliesser using a sample of 10 patients with mixed sleep disorders (RLS and sleep-disordered breathing) found the dPAM-RL significantly overestimated the PLMS [9]. The larger study by Sforza et al. [7] similarly showed the dPAM-RL overestimated the PLMS, but the error was much smaller. The direction of both errors is opposite of what we found in this study with the SIT. Some small overestimation may reflect technical issues noted in Fig. 1, but the larger overestimation in the Gschliesser study suggests possible problems with the noise and signal levels in the meters used in that study. In that study they also found that adjusting the onset and offset (resting noise level) parameters for each study produced reasonably valid results. This would be particularly important if they needed to adapt to higher than expected resting noise levels.

As expected the default PAM-RL amplitude parameters validated for PLMS during a night's sleep were set too high to detect PLMW movements on the SIT. This is consistent with the view that the SIT conditions (awake resting sitting, instructed not to move) produce a wider range of movement amplitude than in sleep. In the SIT leg movements include those as large as or even larger than during sleep, but also many leg movements of lower amplitude than those observed in sleep. Reducing movement onset thresholds to detect these smaller movements should not alter detection of the larger movements, except it may increase duration measures of the larger movements. Future evaluations may find it useful to adjust the duration criteria depending on the magnitude of the movement. Fig. 1 gives clear examples of EMG PLMW detected by custom but not default PAM-RL parameters.

These results establish the validity of the cPAM-RL as an unbiased estimate of EMG PLMW on a SIT. It is important, however, to be aware of what is being measured. Actual leg movement measured by activity meters differs from AT EMG activation measured by physiologic recordings and under certain conditions differs considerably. On one hand, AT EMG may be activated with only toe or small foot movements without significant leg movements. This produces more PLM events from EMG than cPAM-RL measurements. On the other hand, leg movements may occur with larger activation of muscle groups other than AT. These would be detected with activity meters but not with AT EMG. Fig. 1 includes an example of such a leg movement on the PAM-RL with little AT EMG activity. That leg movement would not be counted from the EMG measure but it meets criteria for a PLMW based on an actual leg activity. This action produces more PLM events from cPAM-RL than EMG measurements. These two differences between the measurements may account for the few cases with extreme differences seen in Fig. 2b. These differences produce a marked positive kurtosis and large SD for the difference between cPAM-RL and EMG PLMW. Thus the cPAM-RL – EMG PLMW/h has a reasonable interquartile range of only 30, which is much smaller than the expected interquartile range of about 69 for a normal distribution with a SD of 51. Which measurement, the activity meter or the EMG, should be used given these few extreme differences related to inherent differences in the measurements deserves some consideration? The SIT attempts to measure the ability to remain awake and relaxed without moving the legs. Given this goal, the leg activity measure may be slightly preferable to AT EMG for measuring PLMW on a SIT test.

As noted above, the PLMW onset detection parameters are too close to a highly variable noise level to allow establishing one set of parameters for all SITs. This variable might be corrected by working to reduce variability in the noise level from the PAM-RLs or by developing an automatic method for detecting noise level and then setting the detection criteria relative to the noise. Both of these approaches should be considered for future development of PAM-RL scoring of PLMW on a SIT.

Our study indicates that PAM-RL is valid for measuring PLMW on a SIT test when using custom-set amplitude criteria but not the default criteria provided by the manufacturer. These custom amplitude criteria can be reliably set following the procedures described for our study.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Fig. 1. Minute example showing periodic limb movements during wakefulness detection from electromyogram and, custom and default PAM-RL.

Fig. 2.

From the top: electromyogram (EMG) recording, custom PAM-RL, default PAM-RL RL (cPAM-RL) vs polysomnography (EMG) periodic limb movements during wakefulness with best fit regression with 95% confidence interval range. Max PAM-RL indicates maximum of Right or left leg was used for the PAM-RL values.

Fig. 3.

Histograms showing the measurement errors for the PAM-RL compared to the periodic limb movements during wakefulness (PLMW) per hour defined by the electromyogram. (A) Default parameters for PAM-RL show marked skew and a significant error bias toward underestimating PLMW. Mean + standard deviation (SD) -31.7 ± 50.9 , skew = -1.4 , kurtosis = 2.1 , median: quartiles = -13 : -51.2 , 0.0). (B) Custom parameters for PAM-RL show a more balanced distribution of errors with no significant skew and only a minimal error bias toward underestimating PLMW. Mean $\pm$ SD = -4.5 ± 51.1 , skew = -0.2 , kurtosis = 2.6 , median quartiles = 0.0 (-20 , 10). Both distributions are leptokurtic with strong central tendencies and more extreme values than expected for a normal distribution. The median and quartile ranges therefore describe the distributions somewhat better than the mean and SD.

Fig. 4. Bland–Altman plot showing the distribution of differences between both (A) default and (B) custom PAM-RL periodic limb movements (PLMs) and electromyogram (EMG)-PLM (y-axis) against the average PLMs of PAM-RL and EMG (x-axis). There is clearly a big underestimation (mean, -31.7) by the default PAM-RL. The negative bias is mostly gone when PAM-RL onset and offset lines were customized. The mean bias of -4.5 indicated a slight underestimation by the cPAM-RL.

Fig. 5. Linear regression for suggested immobilization test periodic limb movements during wakefulness per hour from parameters independently set by RA and MY ($r = 0.996$).