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# The PAM-RL ambulatory device for detection of periodic leg movements: a validation study

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**Abstract**

*Background and purpose*: Restless legs syndrome (RLS) is usually associated with periodic leg movements (PLM) occurring during wakefulness and sleep. The PLM index obtained by the polysomnographic method reflects the degree of motor symptoms and their consequences on sleep structure. Automated analysis of PLM using actigraphy can assess this condition and can therefore be used to assess therapeutic effects in clinical trials. In the current study we assessed the reliability of the PAM-RL, an ambulatory device measuring limb movements and PLM with a high-time resolution.

*Patients and methods*: Forty-three patients consecutively referred to the sleep laboratory for insomnia and/or excessive daytime sleepiness underwent one or two nights of polysomnography (PSG) with simultaneous bilateral recording of limb activity by the PAM-RL device. The PSG recordings were blinded and manually analyzed for PLM, while limb actimetry was scored automatically based on the manufacturer's algorithm.

*Results*: There was a significant correlation between PLM derived from PSG and actimetry ($r=0.87$, $P<0.0001$) with good agreement across a wide range of values. The sensitivity and specificity of the PAM-RL device in detecting patients having a polysomnographic PLM index $>10$ were, respectively, 0.88 and 0.76 with a receiving operating curve having an area under the curve (AUC) of 0.86 for the entire group of patients. All patients with clinically definitive RLS and primary PLM disorder (PLMD) had a PLM index $>10$ on PSG, but among patients with sleep-related breathing disorders (SRBD) 60% reached this cut-off value. Conversely, only 50% of those patients with an actigraphically assessed PLM index $>10$ had clinically definitive RLS or PLMD, and 40% had SRBD.

*Conclusions*: We demonstrate that automatic detection of PLM derived from the PAM-RL device is highly reliable when compared to the 'gold standard' of polysomnography in patients with RLS and PLMD. Therefore, limb actigraphy can be used routinely to assess motor restlessness in patients with RLS and PLMD. The higher discrepancy in patients with SRBD and insomnia may preclude the use of the device in these patients.



*Keywords:* Periodic leg movements; Restless legs syndrome; Polysomnography; Actigraphy; Validation

## 1. Introduction

Periodic leg movements (PLM) are short-lasting movements of the lower limbs occurring periodically every 20–40 s [1] during sleep and wakefulness. PLM are present in 70–90% of patients having restless legs syndrome (RLS) [2], a condition characterized by limb paresthesia and dysesthesia, motor restlessness, worsening at rest and in the evening and relieved by activity [3]. Although a detailed clinical history remains the cornerstone in the diagnosis of RLS, detection of PLM during sleep and wakefulness may be of diagnostic help in clinically unclear cases and may also reflect the severity of the disease [4] and the effects on sleep microstructure [5]. The in-laboratory sleep study is considered the 'gold standard' for PLM diagnosis, but the high cost of polysomnography (PSG), together with long

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waiting lists for sleep studies, have led to the development of a variety of ambulatory sleep study systems. The earliest of these were based on actigraphic devices used for assessment and diagnosis of sleep disorders [6] as well as for RLS and periodic leg movements disorder (PLMD). First attempts to use actigraphic devices in patients with RLS and PLMD [7,8] showed lower sensitivity in the actimeter method compared to PSG, with regard to under-estimation of leg kicks, particularly for short-lasting movements [8], and differences in algorithm scoring [9]. Recent developments in the actimeter hardware and the scoring algorithms [10–12] have improved accuracy in detection of leg kicks, and the technique is increasingly used in the diagnosis of RLS in the general population [13] or in assessing therapeutic effects [14–16]. The PAM-RL device is a novel, low-cost electronic device that detects and counts the number of PLMs for several nights during bedtime and waking periods. In a preliminary study [11], examining a large group of RLS patients, the authors found that the index of PLM detected by the PAM-RL device was strongly correlated ($r^2 = 0.92$) with the PSG index. However, the study was conducted only in RLS patients using just one leg and therefore leading to an over-estimation of specificity and sensitivity of the system. The primary objective of this study was to investigate how specific and sensitive the PAM-RL device is for diagnosing RLS and PLMD in a mixed population referred to a sleep laboratory. A secondary objective was to define whether the device shows a good agreement with the result of the 'gold standard' polysomnography in a subset of patients with different sleep disorders.

## 2. Methods and subjects

### 2.1. Subjects

The study group included forty-three consecutive patients (33 men and 10 women, mean age $57.6 \pm 3.7$ years, range 41–74) referred to the Geneva sleep laboratory for insomnia, excessive daytime sleepiness or possible sleep-related breathing disorders (SRBD). Patients were recorded during one or two consecutive nights, allowing analysis of fifty-three polysomnographic recordings. None of the patients referred for possible RLS was under treatment at the time of study and patients previously treated with sedatives, hypnotics, neuroleptics, or anti-depressants ($n$: 10) stopped their medication 2 weeks prior to polysomnography. All patients were informed about the purpose of the study and gave written informed consent.

### 2.2. Methods

The following montage was used for all polysomnographic recordings: electroencephalogram (F3–A2, C3–A2, O2–A1, F4–A1, C4–A1, O2–A1, CZ–A2), right and left electrooculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). Respiratory airflow was monitored with a nasal cannula connected to a pressure transducer (PTAF2, Protech, Minneapolis, MN), thoracic and abdominal respiratory movements with piezoelectric strain gauges, and tracheal sound by microphone. Arterial oxygen saturation ($SaO_2$) was continuously measured with a finger oximeter.

Electromyographic (EMG) activity was monitored using surface electrodes placed on the right and left tibialis anterior muscles. EMG signal was recorded at a time-constant of 0.3 s and a low-pass filter setting of 90 Hz. Electrode impedance was below 5.000 Ω at the beginning of the recording. The quality of the EMG recording was ascertained by asking the patient to flex his knees and feet. At the beginning of nocturnal recording 10 voluntary calibration movements were recorded for each leg. Patients were instructed to slowly dorsiflex and plantarflex each foot to approximately 30° without resistance. For each of these movements the average amplitude was determined and these values were used as amplitude reference values.

### 2.3. Visual scoring

Sleep scoring was performed according to standard criteria [17] using 20 s epoch length and the following sleep parameters were defined: total recording time (TRT), total sleep time (TST), sleep efficiency (SE: total sleep time × 100/total recording time), percentage of each sleep stage and sleep latency. As indices of sleep fragmentation we calculated the number of sleep-stage transitions, the number of awakenings, and the number and the index of arousals, the last scored according to ASDA criteria [18]. Respiratory events were scored as hypopneas, apneas and respiratory-related arousal (RERA) using standard criteria [19].

PLM were scored using Coleman's criteria [1,20], i.e. movements lasting more than 0 .5 s, with an amplitude of at least 25% of the calibration amplitude, with inter-movement intervals of 4–90 s and occurring in series of at least four consecutive movements. The maximal duration of PLM was set at 10 s following the criteria of PLM during wakefulness [4]. This criterion was chosen because actimeter recording does not discriminate sleep from wakefulness, and does not allow distinction between PLM occurring during wakefulness and sleep periods. If the movements occurred on both legs the movement was detected as one combined PLM when the interval between the onset of the movement on one leg and the onset of the movement on the other leg was equal or less than 2 s. PLMs occurring at the end of respiratory events were discarded from the analysis. The polysomnographic data were matched with actigraphic data using polysomnography clock time synchronized with actigraphic time before lights-out.

### 2.4. Actigraphic data analysis

Activity levels were measured using a PAM-RL activity monitor (SOMNOmedics GmHb, Germany), a device previously used in RLS patients [11]. The PAM-RL is a calibrated (1 g = 9.82 kg/s$^2$) battery-powered accelerometer with central processing and memory to detect movement and store measurements of it. The monitor was placed firmly around the ankles of the right and left feet, installed by the patients themselves before lights-off. The precise location of the device was assured by the technical staff at the start and at the end of the nocturnal study. The PAM-RL, which has a band-pass filter between 0.3 and 20 Hz, can continuously record acceleration with a sampling rate of 40/s. The algorithm first detected and marked as a kick large and rapid changes of the basal curve using a threshold set to 200 mg, with a decay threshold set to 100 mg and a drop-out time to 1 s, the latter indicating the rapidity of acceleration. Thereafter, the algorithm detected PLM episodes on the basis of four features of kicks, that is, minimum duration 0.5 s, maximal duration 10 s, minimum off time to 4 s and minimum number of 4 kicks. After the automatic PLM analysis, the file was exported for combined analysis of left and right movements. An interval of 2 s or less was used to consider a combined movement in analogy with polysomnographic analysis. The analysis was done in the period in bed synchronized with the lights-off and lights-on of polysomnography. Fig. 1 shows an example of actigraphic recording obtained during the nocturnal study.

While polysomnography (PSG) allows PLM measurement in relation to sleep stages, actimeter (ACT) determines only PLM without relation to sleep stages and wakefulness. To compare both methods, the number of PLM per hour of time in bed was calculated for the PSG and ACT recordings. Time spent out of bed was excluded from calculation.

### 2.5. Statistical analysis

The primary outcome of the study was the PSG PLM index, which was considered as the 'gold standard', and the ACT-PLM index, which was the evaluated measure. The agreement between these measures was assessed in three ways. First, correlation analysis using Pearson's correlation test was used to assess the reliability of actigraphic data compared to the PSG PLM index. Second, agreement between motor activity obtained from actigraphy and visual analysis was analyzed according to the Bland and Altman method of concordance [21] to assess potential range-dependent agreement. Sensitivity and specificity were analyzed considering a threshold of PSG PLM index $>10$ as the cut-off point for PLM diagnosis. Based on these threshold definitions, receiver operating characteristic (ROC) curves were derived and area under the curve (AUC) was calculated. In addition, Pearson's correlation analysis was done to assess the variables of nocturnal sleep that may affect the rate of actigraphic detection. Statistical significance was taken as $P \leq 0.05$. Results in the text and in the tables are expressed as mean $\pm$ standard error of the mean.

## 3. Results

Table 1 shows, for the group of patients as a whole, the clinical complaints at the study entry, the pre-PSG diagnosis and the final diagnosis derived by the in-laboratory evaluation. Fifteen patients were referred for insomnia, 14 for excessive daytime sleepiness and 14 for snoring and reported apneas. After PSG, 11 patients referred for insomnia had RLS and they had a mean PLM index of $47.7 \pm 1.8$. Of the 14 patients referred for excessive daytime sleepiness, five received the final diagnosis of sleepiness possibly related to PLMD (mean PLM index during sleep: $29.6 \pm 1.3$). The other 27 patients referred for insomnia and/or sleepiness were diagnosed as having obstructive sleep apnea (*n*: 15, mean apnea–hypopnea index (AHI): $33.1 \pm 1.3$), snoring (*n*: 7, mean AHI: $5.2 \pm 0.7$) and insomnia related to depression and/or irregular sleep–wake cycle (*n*: 5). In these 27 patients the scored PSG PLM index was $19.5 \pm 2.5$.

Of 53 in-laboratory studies, three studies were rejected: two PSG studies had technical problems on the EMG signal,

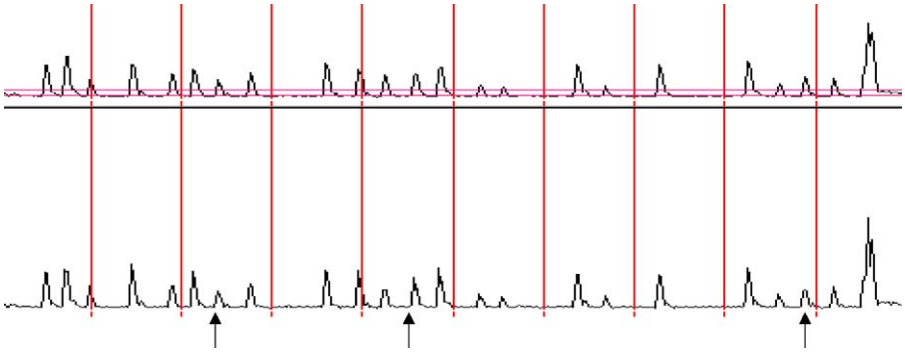

Fig. 1. Actigraphic raw data in a patient with periodic leg movements. The Figure shows the kicks marked by the device in a 5 min period. Arrows indicate the series of movements detected by the actimeter as periodic leg movements.

Table 1
Clinical characteristics, clinical complaints and diagnosis at entry and after polysomnography in the patient group

| Patient | Sex | Age | Clinical complaints | Pre-PSG diagnosis | Post-PSG diagnosis | PSG-I | ACT-I |
|---|---|---|---|---|---|---|---|
| 1 | F | 67 | Insomnia | RLS | RLS | 35.22 | 22.01 |
| 2 | M | 41 | Insomnia | RLS | RLS | 63.30 | 63.76 |
| 3 | M | 55 | Insomnia | Depression | Depression | 6.22 | 7.72 |
| 4 | M | 52 | EDS-snoring | SRBD | OSAS | 2.54 | 3.14 |
| 5 | M | 64 | EDS-snoring | SRBD | OSAS | 59.36 | 68.62 |
| 6 | F | 44 | Insomnia | RLS | RLS | 11.38 | 17.68 |
| 7 | M | 45 | Snoring | SRBD | OSAS | 1.19 | 0.48 |
| 8 | M | 59 | Snoring | SRBD | OSAS | 6.21 | 0.00 |
| 9 | M | 57 | Snoring | SRBD | Snoring | 7.83 | 17.54 |
| 10 | M | 50 | Insomnia | Circadian sleep disorder | Circadian sleep disorder | 8.07 | 3.74 |
| 11 | M | 67 | Insomnia-sleepiness | RLS | RLS | 106.90 | 100.23 |
| 12 | M | 52 | Snoring | SRBD | Snoring | 3.53 | 5.45 |
| 13 | M | 15 | Snoring | SRBD | Snoring | 5.64 | 15.80 |
| 14 | F | 46 | EDS | SRBD | PLMD | 27.81 | 35.29 |
| 15 | M | 46 | Snoring | SRBD | Snoring | 1.39 | 1.81 |
| 16 | M | 51 | EDS | SRBD | PLMD | 20.62 | 10.14 |
| 17 | M | 43 | EDS | Depression | Depression | 5.17 | 9.15 |
| 18 | M | 61 | EDS | SRBD | OSAS | 13.40 | 10.59 |
| 19 | M | 45 | EDS | SRBD | PLMD | 31.55 | 26.19 |
| 20 | F | 57 | Snoring | SRBD | OSAS | 12.39 | 12.62 |
| 21 | M | 44 | EDS | SRBD | PLMD | 24.24 | 21.94 |
| 22 | M | 83 | EDS | SRBD | OSAS | 9.04 | 29.00 |
| 23 | F | 52 | Snoring | SRBD | OSAS | 3.45 | 6.55 |
| 24 | M | 49 | EDS | SRBD | OSAS | 118.56 | 179.91 |
| 25 | M | 54 | EDS | SRBD | OSAS | 16.18 | 39.44 |
| 26 | F | 41 | Insomnia | RLS | RLS | 8.22 | 20.20 |
| 27 | M | 59 | Snoring | SRBD | Snoring | 5.18 | 6.19 |
| 28 | M | 66 | Insomnia | RLS | RLS | 108.67 | 73.81 |
| 29 | M | 74 | Insomnia | RLS | RLS | 61.26 | 94.51 |
| 30 | F | 59 | Snoring | SRBD | Snoring | 1.55 | 4.77 |
| 31 | M | 59 | Insomnia-EDS | SRBD | Depression | 15.39 | 44.16 |
| 32 | M | 74 | Insomnia | RLS | RLS | 40.44 | 28.92 |
| 33 | M | 62 | EDS | SRBD | OSAS | 52.89 | 45.93 |
| 34 | M | 63 | Insomnia | RLS | RLS | 17.53 | 37.26 |
| 35 | M | 67 | EDS-snoring | SRBD | OSAS | 13.20 | 25.79 |
| 36 | M | 68 | Snoring | SRBD | OSAS | 11.31 | 26.42 |
| 37 | F | 56 | Insomnia | RLS | RLS | 53.69 | 91.75 |
| 38 | F | 61 | Snoring | SRBD | Snoring | 5.60 | 5.71 |
| 39 | F | 41 | EDS | SRBD | PLMD | 43.67 | 27.65 |
| 40 | M | 43 | Insomnia | Circadian sleep disorder | Circadian sleep disorder | 62.63 | 118.51 |
| 41 | M | 42 | Snoring | SRBD | OSAS | 15.96 | 29.81 |
| 42 | M | 67 | EDS | SRBD | OSAS | 13.96 | 23.58 |
| 43 | M | 42 | Insomnia | RLS | RLS | 18.28 | 13.40 |

ACT-I, periodic leg movement index at the actimetry; EDS, excessive daytime sleepiness; OSAS, obstructive sleep apnea syndrome; PLMD, primary periodic leg movement disorder; PSG-I, periodic leg movement index at polysomnography; PSG, polysomnography; RLS, restless legs syndrome; SRBD, sleep-related breathing disorders.

and one study was rejected due to remotion of left actimeter during the night. The final polysomnography and actimeter study samples included 50 recordings. A wide range of PLM severity was represented in the study group with about equal number of subjects in lower and upper range of PLM index (Table 1). Although, as expected, greater PLM index was present in RLS patients, the mean duration and the mean interval of PLMs were similar between groups (RLS patients: mean PLM duration $4.2 \pm 0.14$, PLM interval: $31.3 \pm 1.3$; PLMD patients: mean PLM duration $3.2 \pm 0.37$, PLM interval: $32.2 \pm 1.6$; insomnia and SRBD patients: mean PLM duration $4.3 \pm 0.17$, PLM interval: $38.4 \pm 1.4$). When we consider all subjects together, no significant difference was noted in the number of detected PLM activity by PSG and ACT. However, the difference between PSG-I and ACT-I in the individual patient varied between $-34.7$ and $+61.4$, indicating both an overestimation and underestimation of the actimetric method. As depicted in Fig. 2,

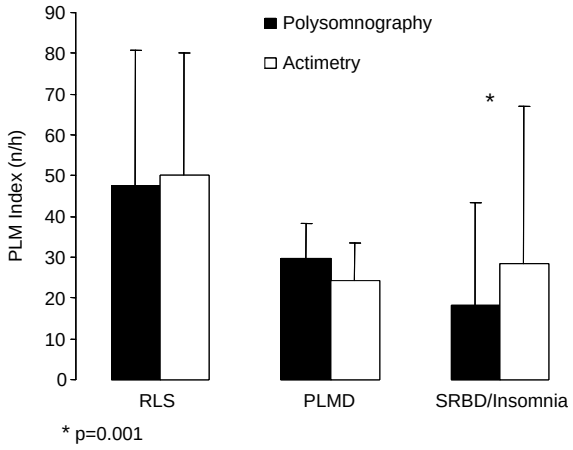


Fig. 2. PSG-PLM index vs ACT-PLM index (mean + SD) in the patient groups classified according to diagnosis. The greater differences were present in patients with sleep-related breathing disorders and insomnia.

no statistical difference of the mean indices obtained by the two methods was found for RLS and PLMD patients. In patients diagnosed as insomnia or SRBD, actimetry significantly overestimated the presence of periodic leg movements ($P=0.001$).

Fig. 3 shows a scatter graph demonstrating the statistically significant correlation coefficient between the PSG-PLM index and the ACT-PLM index ($r=0.87$, $P<0.0001$). However, estimation of the bias by the mean difference and the standard deviation of the difference in PLM index (Bland and Altman method) (Fig. 4) shows that there was a slight but not significant tendency for the PAM-RL to underestimate motor events in the severe cases and to overscore in the mild range (mean PLM index difference of 6.2, standard deviation of 17.5). Fig. 5 shows the ROC curve reflecting the diagnostic capability of ACT when the threshold of the PSG-PLM index was set at 10 for diagnosis of the PLM syndrome, with an AUC of 0.86. The sensitivity and specificity of the PAM-RL device in

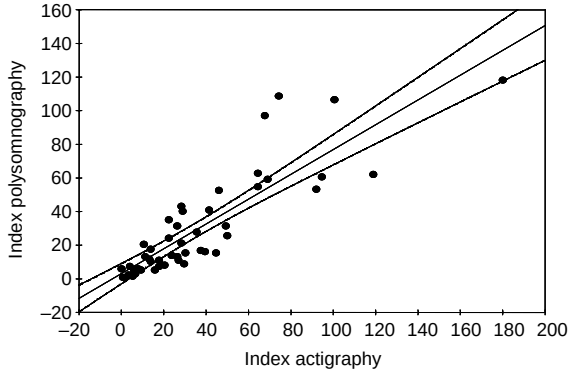


Fig. 3. Scatterplot showing the relationship between the PSG-PLM index and the ACT-PLM index. A very high and significant correlation ($r=0.87$, $P<0.0001$) was found between the ACT-PLM index (ACT-based periodic leg movements) and the PSG-PLM index (periodic leg movement index derived from PSG).

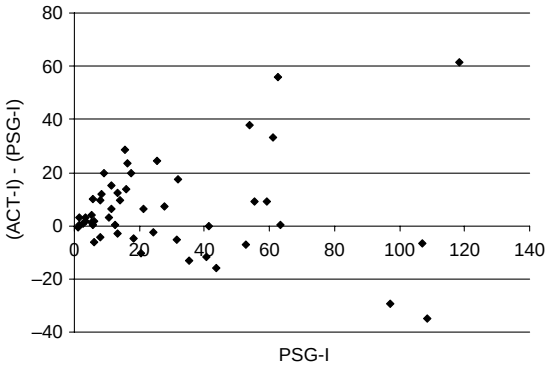


Fig. 4. Bland–Altman plot showing the distribution of the differences between PSG-PLM index and ACT-PLM index ($y$-axis) against the corresponding PSG value ($x$-axis). There was a good agreement between the PSG-based PLM index and the ACT-based PLM index; the mean bias of 6.2 indicated a slight overestimation by the PAM-RL.

detecting patients with at least 10 PLM/h were, respectively, 0.88 and 0.76 (95% CI: 0.72–0.90).

The reproducibility of the ACT measurements was further determined in a subgroup of five patients with RLS syndrome examined for two consecutive nights. There was a close agreement between the two analyses for the PLM index, the PSG index being, respectively, $55.3 \pm 2.6$ and $44.0 \pm 2.6$ in the first and second nights, and the ACT index $59.1 \pm 2.3$ and $48.9 \pm 2.1$. The detection error did not undergo consistent changes, the differences between PSG and ACT being $3.8 \pm 3.0$ and $4.8 \pm 2.8$, respectively.

Pearson's correlation analysis showed that the differences in the detection scoring were not correlated with the amount of each sleep stage, the AHI and the number of awakenings and shifts between sleep stages. A relationship

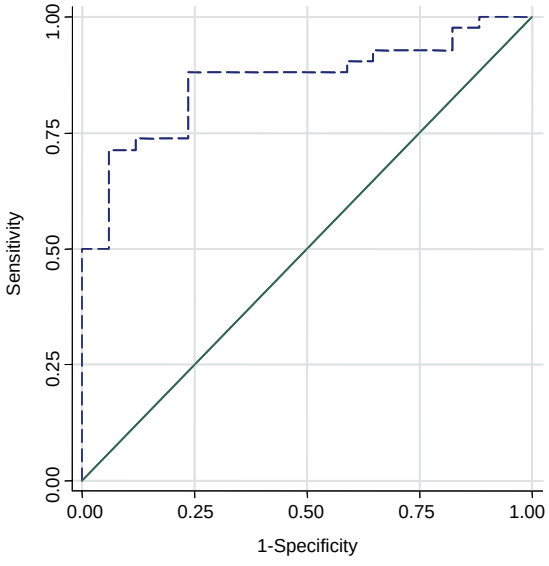


Fig. 5. Receiver operating characteristics (ROC) curve for identifying pathological PLM index (threshold 10 PLM per hour) based on ACT vs polygraphic criteria. The area under the curve (AUC) was 0.86 ($P=0.0001$) yielding potentially high sensitivity and specificity in diagnosing PLM frequency by ACT.

was found with WASO ($r=0.32$, $P=0.02$), sleep efficiency ($r=-0.33$, $P=0.02$), and PLM duration ($r=0.29$, $P=0.04$) suggesting that ACT overestimated periodic motor activity during wakefulness and longer PLMs.

## 4. Discussion

This study shows that the PAM-RL is a simple, reliable and accurate device for detection of PLM in a heterogeneous population of patients referred to our sleep laboratory. The measured ACT-PLM index correlated well with the in-laboratory PSG-PLM index ($r=0.89$, $P<0.0001$). Moreover, the in-laboratory results were reproducible, with a correlation coefficient of 0.90 between two actigraphy studies. These data suggest that the use of a simple, self-administered and well-tolerated device may allow a correct and objective estimation of PLM activity and may be used to evaluate efficacy of therapy for motor symptoms in patients with RLS and PLMD.

We know that the clinical data obtained from history and physical examination should allow clinicians to determine with reasonable certainty whether insomnia is related to RLS, to evaluate the severity of the disease and to assess the efficacy of therapy. However, in unclear cases or in patients showing a high variability in frequency and intensity of the sensory and motor symptoms, the evaluation of PLM during wakefulness and sleep may be a useful test to confirm or reject diagnosis and to evaluate the severity of the disease. Evaluating the reproducibility of PSG PLM scoring from different sleep laboratories, Bliwise et al. [22] and Downez et al. [23] reported an inter-scorer agreement of 0.95 and 0.90 for the number of PLMs. Another study considering difference in the PLM detection in in-laboratory compared to home recording [24] showed an inter-method correlation of 0.64. Thus, an automated method of detecting PLM seems warranted to exclude subjective bias in a clinical and research setting. The first study using ACT for diagnosis of RLS [7] yields an inter-scorer agreement of about 0.92 in the automatic detection of PLM, but scorer adjustment was necessary to confirm pathological motor activity. Our study shows that the monitoring of PLMs by PAM-RL has several advantages, i.e. it is automatic, which makes it reproducible, and time saving, with no manual correction needed for the analysis. With these advantages we found good sensitivity and reproducibility similar to that previously described [8,11]. In addition, since PLMs may not occur simultaneously in both legs, we decided to use two-leg actimeters allowing a more specific assessment of the motor disorder severity. We noted that the use of the device in both legs yields a greater specific estimation of PLM without higher rejection rate, only one actimeter recording having been lost during the study. A second interesting finding was that in five patients, over two consecutives nights, we found a good night-to-night reproducibility in the PSG and ACT-PLM index, suggesting that the device might be a useful tool for cases showing a high night-to-night variability [25]. Moreover, since subjective estimates of sensory symptoms do not correlate highly with motor events [4] and therapeutic improvement is difficult to evaluate solely on the basis of questionnaires or sleep logs [6], the use of PAM-RL may yield objective estimates of clinical improvement in the follow-up of treated RLS patients [8,13–15]. Finally, other potential advantages of this system are its simplicity, with minimal required intervention in patient preparation and lack of any discomfort, as reported by our patients.

Despite good reliability between ACT and PSG, the agreement obtained in our sample demonstrates that the device cannot be used alone to diagnose RLS/PLMD syndromes. It should be noted that leg movement is not exclusively associated with RLS and PLMD syndromes, but may also arise in association with a variety of other sleep disorders. In order to maximize the specificity of the PAM-RL device, the automatic algorithm was designed to be based not only on the presence of kicks, but it also takes into account their periodic nature, length, the motor threshold and the combination with the other leg. Despite this correction, we found (Fig. 2) that greater differences in the PLM detection were present in patients with SRBD and insomnia, and a cut-off value of 10 PLM per hour measured by actigraphy was reached by 60% of patients with SRBD. This is easily explained by the fact that while PLMs occurring at the end of respiratory events are discarded from the polysomnographic analysis, leg movements associated with arousal due to respiratory disturbances are included in the actimeter analysis. Therefore, since the PAM-RL is unable to differentiate periodic apnea-related movements or generalized motor restlessness related to sleep maintenance or sleep onset disorders from real PLMs, the device must be used in patients in whom the clinical history suggests the presence of an RLS syndrome.

There are several limitations in this study that may affect our results. First, the purpose of the study was to evaluate the reliability of an ambulatory device. However, in order to compare it to the ‘gold standard’ method, the study took place in the sleep laboratory to assess the accuracy of the system. Obviously this device will have to be studied in the home environment to assess its usefulness in an unattended setting. Second, since we compared automatic PLM detection with EMG signal, it is not unlikely that we have introduced some methodological bias related to the fact that the EMG-based criteria, as nowadays defined (American Sleep Disorders Association (ASDA) criteria), are not sensitive enough to assess motor activity in RLS patients. It is possible that we have overestimated short EMG bursts detected by PSG that do not induce any movements and, therefore, do not disturb sleep [26]. Moreover, since during wakefulness PLMs may last longer [4,26] than the proposed five-second duration [1,20], we have applied the criteria used to assess PLM during the suggested immobilization test which allow a better estimation of motor restlessness in RLS patients [4]. Despite the use of these criteria that could

be considered atypical, we suggest that application of these new criteria may be necessary to improve the assessment of motor activity in these patients. Finally, to assess sensitivity and specificity of PAM-RL we have used an arbitrary index of 10 PLMs/h to define abnormality. We knew that the area under the ROC curve was considered a measure of the overall efficacy of the score for all possible values of the ACT-PLM index, an AUC value of 0.5 indicating an insignificant score for separating RLS patients, and a value close to 1 indicating a very efficient score. Taking a PLM index of 10/h we were able to better identify RLS patients with an AUC of 0.86, suggesting that lower threshold would not be sensitive enough to identify patients with RLS and PLMD. This result replicates the data obtained during the suggested immobilization test in that a score of 10 PLMs/h differentiates RLS patients from controls [27].

In conclusion, our results suggest that the PAM-RL device is a simple, reliable and accurate device for detecting PLM in wakefulness and sleep, allowing accurate estimation of the motor symptoms of RLS and PLMD. The discrepancy in patients with other sleep disorders, such as insomnia or SRBD, may preclude the use of the device in these patients in whom the actigraphy does not differentiate PLM from generalized motor activity associated with sleep discontinuity and sleep fragmentation.

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