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How reproducible is home-based 24-hour ambulatory monitoring of motor activity in patients with multiple sclerosis?

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Abstract

Objective: To determine the reproducibility of 24-hour monitoring of motor activity in patients with multiple sclerosis (MS).

Design: Test-retest design; 6 research assistants visited the participants twice within 1 week in the home situation.

Setting: General community.

Participants: A convenience sample of ambulatory patients (N=43; mean age \pm SD, 48.7 \pm 7.0y; 30 women; median Expanded Disability Status Scale scores, 3.5; interquartile range, 2.5) were recruited from the outpatient clinic of a university medical center.

Intervention: Not applicable.

Main outcome measures: Dynamic activity and static activity parameters were recorded by using a portable data logger and classified continuously for 24 hours. Reproducibility was determined by calculating intraclass correlation coefficients (ICCs) for test-retest reliability and by applying the Bland-Altman method for agreement between the 2 measurements. The smallest detectable change (SDC) was calculated based on the standard error of measurement.

Results: Test-retest reliability expressed by the ICC_{agreement} was 0.72 for dynamic activity, 0.74 for transitions, 0.77 for walking, 0.71 for static activity, 0.67 for sitting, 0.62 for standing, and 0.55 for lying. Bland and Altman analysis indicated no systematic differences between the first and second assessment for dynamic and static activity. Measurement error expressed by the SDC was 1.23 for dynamic activity, 0.66 for transitions, 0.99 for walking, 1.52 for static activity, 4.68 for lying, 3.95 for sitting, and 3.34 for standing.

Conclusions: The current study shows that with 24-hour monitoring, a reproducible estimate of physical activity can be obtained in ambulatory patients with MS.

Introduction

In multiple sclerosis optimisation of performing daily activities is a major goal in rehabilitation medicine.¹ In particular, limitations in physical activity and fatigue are acknowledged as key problems in MS, with up to 85% of patients reporting walking difficulties.^{2,3} Specifying these problems has great importance for understanding their impact on ADLs. A central issue in this process is to gather objective information regarding the real quantity and type of daily activities performed in the patient's own home environment. Previously applied methods used to assess the level of physical activity are regular clinical observations (i.e., behavioral mapping,⁴ selfreport questionnaires,^{5,6} patient diaries,⁷ semistructured interviews⁸). However, these instruments measure at discrete points in time and often give a subjective indication of activity level. Self-reported activities are only moderately related to objective registration and do not completely match actual activity because of possible recall bias.⁹

In the past decade or so, advances in technology have fostered the development of objective methods allowing more continuous monitoring of daily physical activity using actigraphy¹⁰ and/or accelerometry.¹¹ The StepWatch,^a for example, using a 3-dimensional accelerometer attached to the ankle, has shown to have acceptable accuracy and reliability in patients with MS in the assessment of ambulatory activity.¹² Pedometers centered on the patients' nondominant hip have acceptable accuracy in determining the number of steps taken during walking at speeds above 3.2 km/h.¹³ However, both systems fail to distinguish among types of activity actually performed and do not discriminate between postures such as sitting and standing and activities such as walking, stair walking, and bicycling.¹⁴ The AM is a system that uses accelerometers attached to the trunk and legs and allows the collection of information about type, amount, and pattern of mobility-related activities.¹¹ On the basis of accelerations and orientation of the individual body segments with respect to gravity, postures (e.g., lying, sitting, standing), and motions (e.g., walking, cycling) can be classified continuously for up to 48 hours.¹¹ The AM is able to discriminate among different activities¹¹ and has been tested for reliability and/or validity in different patient groups such as people with Parkinson's disease,¹⁵⁻¹⁷ leg amputation,¹⁸ chronic heart failure,¹⁹ and failed back surgery.²⁰ However, reproducibility of the AM has not been investigated in patients with MS. Therefore, the aim of the present study was to assess the reproducibility of 24-hour monitoring of mobility-related activities in patients with MS.

Methods

Participants

Patients suffering from MS were recruited over a period of 6 months. Patients met the following inclusion criteria: (1) older than 18 years; (2) a definite diagnosis of MS;²¹ (3) an Expanded Disability Status Scale (EDSS)²² score below 6.5, indicating the ability to walk at least 100 meters with or without resting with intermittent or constant unilateral assistance; (4) no co-morbidity that could influence fatigue and/or mobility; and (5) written informed consent in accordance with the ethical standards of the declaration of Helsinki. The medical ethics committee of the VU University Medical Center approved the study.

Activity monitoring

The assessment of the daily activities was performed by means of the Vitaport,^b a portable AM. The system consists of a data recorder and 4 piezoelectric accelerosensors. The system weighs 980g and was carried on a belt around the waist. The accelerosensors measure acceleration events as well as the orientation with respect to the gravitational vector. The following application protocol was used by all research assistants: the accelerometers were attached to the skin using a 3- to 4-cm piece of self-adhesive Rolian Kushionflex^c foam (1.5 mm thick) and standard double-sided tape. The skin was cleaned with alcohol and shaved if needed. On each leg, 1 uniaxial accelerometer was attached on the lateral side of the thigh, halfway between the trochanter major and the lateral epicondyle of the femur. Both leg accelerometers were applied with the sensitive axis in the sagittal plane. Two biaxial accelerometers were attached to the corpus sterni, perpendicular to one another. The biaxial accelerometers were applied with the sensitive axis parallel to the field of gravity or longitudinal axis along the sagittal axis and along the transversal axis. The signals from the accelerometers were continuously stored on the compact flash card of the AM, with a sample frequency of 256Hz and a storage frequency of 32Hz. After the measurement, the data were downloaded to a Microsoft^d Windows 2000 computer (service pack 4) for offline analysis. The signals were analyzed and classified into postures and motions according to the method of Bussmann et al.¹¹ Subsequently, the amount of “static” and “dynamic” activity level (in hours) was calculated. Static activity was divided into the following categories: hours “sitting”, “standing”, and “lying”. Dynamic activity was categorized into a number of sit-to-stand and stand-to-sit transitions including “walking” (hours), “number of walking

periods longer than 5 seconds” (walking >5s), and “number of walking periods longer than 10 seconds” (walking >10s).

Design

Six research assistants were trained to apply the AM (see details in the Activity Monitor section) before the study. The AM was applied and removed in the participants’ own home. Twenty-four-hour monitoring was executed twice, with an interval of exactly 1 week, assuming that activity patterns remain approximately the same between similar weekdays. Research assistants visited the participants on day 1 (application AM) and 2 (pick up AM) and a week later on days 8 (application AM) and 9 (pick up AM). To avoid bias caused by diurnal fluctuations, all participants carried the AM for 24 hours. All participants were instructed to continue their usual daily activities performed in their own environment (i.e., home and community) and use their walking devices or orthoses as they would normally do, but they were asked to refrain from showering and swimming. Participants were told that the system measures body movement, but no elaborate explanation of the purpose of the study and the function of the AM was given until the end of the final measurement session.

Statistical analysis

Reproducibility concerns the degree to which repeated measurements provide similar results.²³ Reproducibility can be assessed in terms of reliability and agreement parameters.

Reliability

Reliability was defined as how well the scores of the participants can be distinguished from each other with an AM application despite existing measurement errors.²³ For all variables, the test-retest reliability was calculated by using a ICC 2-way random-effects model with an absolute agreement definition.²⁴ For the present study, we defined an ICC greater than 0.70 as good reliability and an ICC between 0.40 and 0.70 as moderate reliability. An ICC below 0.40 was defined as poor reliability.

Agreement

Agreement concerns the measurement error and assesses how close the scores on the AM application are for the 2 measurements.²³ For this purpose, the Bland-Altman method

was used for assessing agreement between the 2 measurements by calculating the mean difference (mean Δ) between the 2 consecutive measurements and the SD of this difference.²⁵ The LoAs were calculated as the mean difference \pm 1.96 times the SD of the differences. The Bland-Altman plot provides a visual interpretation of possible systematic variation in differences over the range of measurement and outliers that are not revealed by regular correlation analyses.

Measurement error

The SDC was calculated as an indication of measurement error, by $1.96 \times \sqrt{2} \times \text{SEM}$ (standard error of measurement). Changes larger than the SDC are considered to be real changes, i.e. changes beyond measurement error.²⁶ The SEM was calculated by $\text{SD} \times \sqrt{(1 - R)}$, with R equal to ICC and SD equal to $\sqrt{(\text{total variance})}$.

Results

Patient characteristics

Forty-three patients with MS (mean age, 48.7y; median EDSS score, 3.5) were recruited from the outpatient clinic of the MS center of excellence at the VU University Medical Center. Fifty potential participants were contacted by telephone, of which 7 declined the invitation because of unavailability or unspecified reasons. No obvious differences were noted between participants and nonparticipants. Table 4.1 shows characteristics of the participants. Figure 4.1 displays the frequencies of EDSS scores of the participants.

Table 4.1 Participants characteristics (N=43)

| Variable | Frequencies | Mean (SD) | Range |
|--------------------------|-------------|--------------|-------|
| Age (years) | NA | 48.7 (7.0) | 38–64 |
| Gender: men; women | 13; 30 | NA | NA |
| Type MS: RR; SP; PP | 26; 10; 7 | NA | NA |
| Disease duration (years) | NA | 14.3 (9.2) | 2–51 |
| Variable | NA | Median (IQR) | Range |
| EDSS | NA | 3.5 (2.5) | 1–6.0 |

SD, standard deviation; EDSS, Expanded Disability Status Scale; RR, relapse remitting; SP, secondary progressive; PP, primary progressive; IQR, inter quartile range; NA, not applicable.

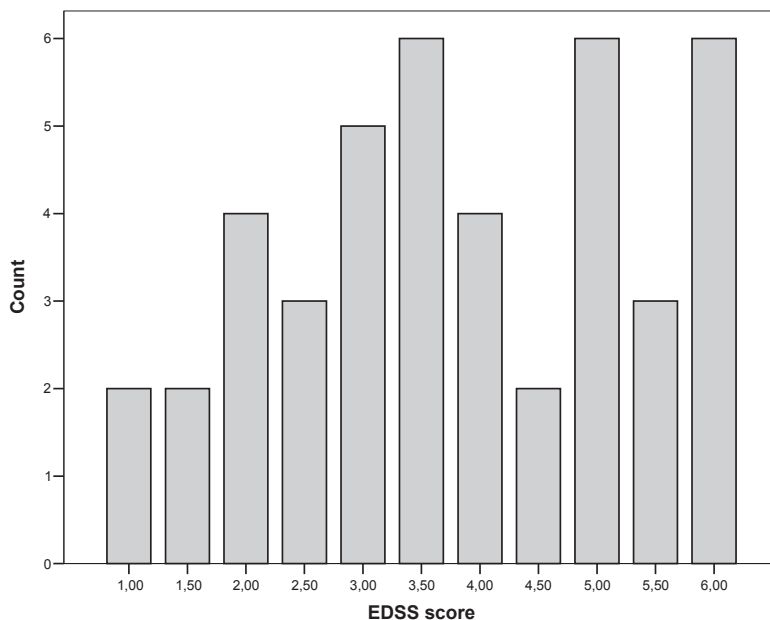


Figure 4.1 Frequencies of Expanded Disability Status Scale (EDSS) scores.

None of the participants used a wheelchair. All monitoring data were normally distributed as determined by visual inspection. The mean monitoring duration was 23.6 hours (SD, 0.61). For all assessments, it took 10 to 15 minutes to apply the AM. The AM data of 2 MS patients (4.4% of total assessments) could not be used for analysis because of a malfunctioning sensor. One participant had an interval of 6 days because the first measurement had to be repeated as a result of system failure. Another participant had an interval of 14 days because of a delayed second measurement as a result of unavailability of the research assistant due to illness. All other subjects had a measurement interval of 7 days according to the measurement protocol. In general, the AM was well tolerated by the subjects even though they could not shower or bathe for 24 hours. No problems were reported.

Reproducibility

On average patients showed 2.1 hours of dynamic activity during the 24-hour registration, of which 1.2 hours was defined as walking activity (Table 4.2).

Table 4.2 Reproducibility of measurement

| | Mean | SD | ICC | Mean _{dif} | SD _{dif} | LoA (low/up) | SDC |
|---------------------------------|-------|------|------|---------------------|-------------------|--------------|------|
| Dynamic activity (hours) | 2.09 | 0.83 | 0.72 | 0.01 | 0.63 | -1.23/1.24 | 1.23 |
| Transitions (N) | 116 | 48 | 0.74 | -8 | 34 | -75/58 | 66 |
| Walking (hours) | 1.20 | 0.73 | 0.77 | -0.01 | 0.50 | -0.99/0.98 | 0.99 |
| Walking periods >5 seconds (N) | 222 | 118 | 0.80 | -5 | 75 | -153/143 | 148 |
| Walking periods >10 seconds (N) | 133 | 75 | 0.76 | -1 | 53 | -104/102 | 103 |
| Static activity (hours) | 21.49 | 1.01 | 0.71 | -0.07 | 0.77 | -1.59/1.44 | 1.52 |
| Sitting (hours) | 7.97 | 2.48 | 0.67 | -0.15 | 2.02 | -4.10/3.81 | 3.95 |
| Standing (hours) | 3.48 | 1.01 | 0.62 | -0.24 | 1.71 | -3.58/3.10 | 3.34 |
| Lying (hours) | 9.70 | 2.51 | 0.55 | 0.42 | 2.39 | -4.27/5.11 | 4.68 |

Mean; pooled mean of the two assessments, SD; pooled standard deviation of the two assessments; ICC, intraclass correlation coefficients; Mean_{dif} mean difference between the two assessments; SD_{dif} Standard deviation of the mean difference; LoA, limits of agreement; low, lower bound; up, upper bound; SDC, smallest detectable change; All ICCs $p < 0.001$. Transitions are sit-to-stand and stand-to-sit.

Reliability

Table 4.2 displays the test-retest reliability for the 24-hour ambulatory monitoring of motor activity. ICCs ranged from 0.55 for the category “lying” to 0.80 for “walking periods longer than 5 seconds.”

Agreement

Figure 4.2 displays Bland-Altman plots for dynamic and static activity of the patients with MS. With exception of the category of “lying”, no systematic differences were observed between the first and second assessments of the various activities. Table 4.2 shows the LoAs.

Measurement error

Table 4.2 shows measurement error expressed by the SDCs for dynamic and static activity and the different categories in patients with MS. Measurement error is 1.23 hours for dynamic activity, 66 for the number of sit-to-stand and stand-to-sit transitions, 0.99 hour for walking, 1.52 hours for static activity, 4.68 hours for lying, 3.95 hours for sitting, and 3.34 hours for standing. Overall SDCs for dynamic activities were better (i.e., smaller) than for static activities.

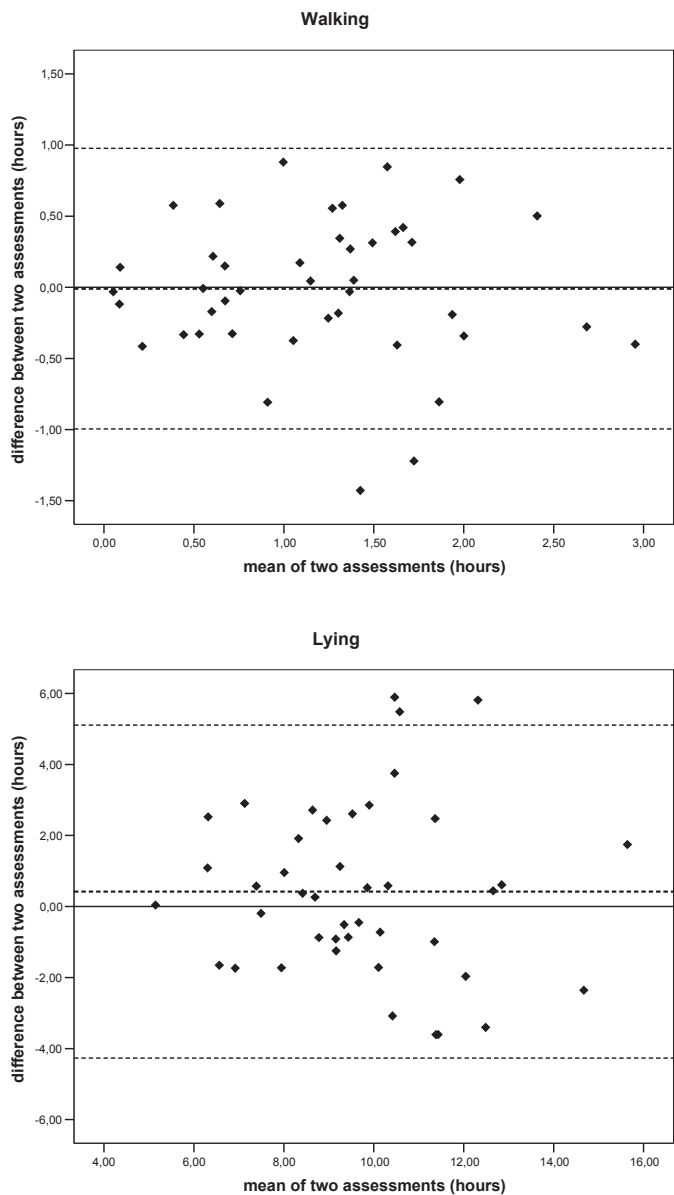


Figure 4.2 Graphic representation according to the Bland and Altman technique for the categories walking and lying.

The ----- bold lines represent the mean difference score, ----- lines represents the limits of agreement, defined as the mean \pm 1.96 the standard deviation of the difference score.

Discussion

The present study examined the reproducibility of 24-hour real-world activity monitoring of mobility-related activity in MS patients in the home and community setting. Until now, the reproducibility of 24-hour monitoring has not been investigated for patients with MS. Overall, the AM showed, with the exception of the category “lying”, moderate to good test-retest reliability. Because the ICC relates the within (test-retest) variation to the between-subject variation, the lower reliability found for the category “lying” may represent, on the one hand, the actual variations in the behavior of the patients between assessments days and, on the other hand, low between-subject variability because of the similar sleeping periods during night-time. The Bland-Altman plot shows relatively large differences between 2 consecutive measurements, indicating that the agreement for the category “lying” is relatively low. In contrast, the Bland-Altman method showed for all other categories satisfactory agreement over the 7-day period between 2 consecutive AM assessments.

For practical reasons, the AM was applied by 6 research assistants. The research assistants were trained according to a standard protocol for applying the AM in a consistent and reliable manner. The test-retest reliability may be affected by differences in the accuracy of the application rather than the other sources of variation, such as variations in subjects and the measurement instrument itself. However, this application of the accelerometer is an essential part of the measurement process and therefore should be included in the reliability analysis.²³

The reliability of the data, which were collected by 6 different research assistants, was moderate to good, indicating that AM on similar weekdays is robust to any variation or bias that may exist among research assistants who apply the AM. In addition, the results appear robust because we included a relatively heterogeneous population containing the different subtypes of MS. Although outside the focus of the present article, future research may clarify the use of AM in these different subpopulations. The present study may serve as a basis for investigating the impact of common symptoms such as fatigue, depression, and cognitive decline on the actual ambulatory motor activity in patients with MS.

In the present study, subjects were kept as naive as possible about the aim of the study and the purpose of the AM, and they were explicitly instructed to maintain their usual activity pattern. Nonetheless, a somewhat reduced level of performance as a result of wearing a wired system for 24 hours may have occurred (“reactivity”). For example, subjects may be

less likely to undertake sporting activities, jogging, and bicycling when wearing the AM. However, it is reasonable to assume that these reactivity effects are similar for both the test and retest assessment.

For lying and sit-to-stand transitions, relatively large SDCs were found. This suggests that the actual performance of these activities varies considerably between 2 consecutive measurements, as confirmed by Figure 4.1. Bland-Altman analysis of the other variables indicated no large systematic differences with regard to the LoAs for both dynamic and static activities, justifying the calculation of the SDC on the basis of the limits of agreement, which is based on SEM consistency.

To our knowledge, no previous data on measurement error of AM have been published in patients with MS, making it difficult to interpret and compare the calculated SDCs. However, our results on reliability of AM are in line with previous studies using other monitoring systems in MS such as the StepWatch, a 3-dimensional accelerometer (ICC, 0.86),¹² and a pedometer and accelerometer (ICC, 0.80–0.90, with monitoring periods of 3 to 7 days).²⁷ These findings further confirm that with a relatively short monitoring period of 24 hours, a sufficiently reliable estimation of dynamic and static activity can be obtained, with a high degree of detail about the type of activities (e.g., walking, walking >5s, walking >10s, number of sit-to-stand transitions).

Study limitations

The present study has some limitations. First, only ambulatory MS patients were included (i.e., EDDS score below 6.5). This limits the generalization of the present findings to ambulatory MS patients. Second, the application of the AM was restricted to the legs and the trunk, whereas a more elaborate AM setup with sensors on the arms would also allow one to measure wheelchair propulsion activity. Further studies are needed to include nonambulatory MS patients who are bound to a wheelchair. Third, the distribution-based method we have used to gain insight into the percentage change between the 2 assessments, which should be exceeded in order to exclude measurement error, is not necessarily informative as to the extent these data are clinically meaningful. To determine clinically meaningful information regarding the relationship between the observed change and its clinical importance, a patient's or clinician's perspective is needed. A distribution-based method informs about observed change in the sample, and anchor-based methods estimate minimal important change directly.²³

Finally, the dynamic activity of AM showed a relatively high SDC of 1.23 hours. Future studies investigating treatment effects could decrease the within-subject variability, and thus the measurement error, by using longer registration periods or more frequent assessments over predefined time intervals. In addition, further research is needed to compare and interpret the SDCs for the separate variables of walking and the sit-to-stand transitions.

Conclusions

The present study shows that 24-hour ambulatory monitoring of motor activity is a feasible and reproducible method to measure physical activity in ambulatory patients with MS. The highest test-retest reliability was found for walking-related activities, whereas the lowest value was found for “lying”. The results confirm the practical utility of AM because our study design included 6 different research assistants who applied the AM and measurements took place in patients’ own home setting. These findings support the robustness and feasibility of the AM for use in clinical studies. However, future studies should confirm the validity of the AM for proper classification into the different activity categories, implementing new advances in hardware and software.

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Suppliers

- a. Step Watch, Oklahoma City Corporate Office: 840 Research Prkwy, Ste 200, Oklahoma City, OK 73104.
- b. TEMEC Instruments, Spekhofstraat 2, 6466 LZ Kerkrade, telephone 003145 5428888 Kerkrade, The Netherlands.
- c. Smith & Nephew, Postbus 525, 2130 AM Hoofddorp, The Netherlands.
- d. Microsoft B.V. Evert van de Beekstraat 354, 1118 CZ Schiphol, The Netherlands.

