Clinimetric properties of the Activity Monitor for assessing gait parameters in chronic stroke patients

Masterthesis

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“ONDERGETEKENDE

Belinda van Alphen
bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld.”

Samenvatting

Achtergrond: Een deel van de zelfstandig wonende patiënten in de chronische fase na een beroerte wordt met de tijd steeds minder actief. Deze inactiviteit kan leiden tot een verminderde conditie. Daarnaast neemt het risico op comorbiditeiten en een tweede beroerte toe. Op dit moment is er geen 'gouden standaard' voor het meten van loopactiviteit bij deze patiënten. Loopactiviteit wordt vaak gemeten door middel van subjectieve meetinstrumenten. Nadelen van deze instrumenten zijn bijvoorbeeld het risico op 'recall-bias' of sociaal-wenselijke antwoorden. Ook worden er valide stappentellers gebruikt, maar deze zijn beperkt tot het meten van alleen stappen. De gouden standaard voor het meten van loopactiviteit zou het aantal stappen, de afstand en de gelopen tijd over een bepaalde periode moeten kunnen meten. SUSTAIN heeft speciaal hiervoor een Activiteitenmonitor (AM) ontwikkeld.

Doel: Het onderzoeken van de criteriumvaliditeit en de test-herstest-betrouwbaarheid van de AM als meetinstrument voor loopactiviteit bij patiënten in de chronische fase na een beroerte.

Methode: Thuiswonende patiënten in de chronische fase na een beroerte worden met een interval van twee á drie weken getest. Ze voeren een zes minuten wandeltest en een loopband test op verschillende snelheden uit. Loopactiviteit wordt uitgedrukt in verschillende parameters zoals aantal stappen, gelopen afstand en gemiddelde staplengte. De output van de AM wordt vergeleken met video analyse en de daadwerkelijk gelopen afstand. Intraclass Correlatation Coefficients (ICC), grenzen van overeenkomst volgens Bland-Altman, Mean Relative Root Squared Error (validiteit) en de Smallest Detectable Change (betrouwbaarheid) worden berekend om de klinimetrische eigenschappen van de AM te bepalen.

Resultaten: 29 patiënten zijn getest voor het bepalen van de validiteit, 21 patiënten voor de test-hertest-betrouwbaarheid. ICC waarden voor validiteit en betrouwbaarheid varieërden tussen de .826 en .967. Gemiddelde verschillen tussen de methodes en meetmomenten waren rond of lager dan 10%. Individuele verschillen waren groter, tot 38.5%.

Conclusie: Alhoewel de gemiddelde verschillen tussen methodes en meetmomenten op of onder de 10% zaten, waren de verschillen per individu groter. Hierdoor kan de AM geen klinisch verschil detecteren op de loopparameters. Verder onderzoek is nodig om

de algoritmes van de AM te verbeteren en hiermee uitschieters in de metingen te voorkomen. Hierdoor zal de meetfout van de AM afnemen. Dit biedt mogelijkheden voor het gebruik van de AM in zowel de klinische praktijk als bij het onderzoek naar loopactiviteit bij deze populatie.

Abstract

Introduction: A substantial part of the community-dwelling stroke survivors becomes less physically active over time. Post-stroke physical inactivity may cause a loss of physical fitness and increases the risk of comorbidities and a second stroke. There is no 'gold standard' to measure walking activity in this population. Assessment of walking activity generally involves subjective or observer-rated instruments. These instruments have disadvantages such as the risk of recall-bias and social desirability of answers. Valid step counters are also used frequently. Nevertheless, these are restricted to the measurement of number of steps. The 'gold standard' for measuring walking activity should measure the number of steps, covered distance and walking time over a representative period of time in a reliable and valid way. Therefore, SUSTAIN developed an ActivityMonitor (AM) to measure walking activity in chronic stroke patients.

Aim: To investigate the criterion validity and test-retest-reliability of the AM as measure of walking activity in chronic stroke patients.

Methods: Community-dwelling chronic stroke patients will be tested twice, with an interval of two to three weeks. They will perform a six-minute walk test and a treadmill test at different speeds at both testing days. Walking activity will be expressed in different gait parameters (i.e. number of steps, distance, mean step length). Output data of the AM will be compared to video analysis as criterion measurement. Intraclass Correlations Coefficients (ICCs), limits of agreement by Bland-Altman, Mean Relative Root Squared Error (validity) and the Smallest Detectable Change (reliability) will be calculated to determine the clinimetric properties of the AM.

Results: 29 patients were tested to determine the validity, 21 patients of this group were tested twice to determine the test-retest reliability. ICC values for validity and reliability are high, ranging from .826 to .967. Mean error parameters are all around or smaller than 10%. However, individual error parameters based on the 95% limits of agreement are higher, up to 38.5%, and exceed the minimal clinically important differences for gait parameters.

Conclusion: Although mean differences between methods and measurement moments were 10% or lower, the individual measurement errors were larger. Therefore, the AM cannot detect a clinical important difference for the gait parameters. Further research is needed to improve the algorithms of the AM to avoid outliers and to decrease the

measurement error. This will offer opportunities for the use of the AM in clinical practice and research of walking activity in this population.

Key Words

Stroke – accelerometry – gait parameters – validity – reliability

Introduction

In many Western nations, stroke is a leading cause of death and serious long-term disability.(1) Based on demographic trends in the Netherlands, it is expected that the number of patients with stroke will increase by 40% between 2010 and 2025.(2) A frequent consequence of stroke is unilateral loss or limitation of muscle function, leading to loss of mobility, movement and functional ability.(3,4) Van de Port et al.(2006) showed that a substantial part of the community-dwelling stroke survivors becomes less physically active over time.(5) Stroke survivors consider a limitation of independent ambulation as one of the most debilitating consequences of stroke(6) and in addition, Lord et al. (2004) showed that 74.6% of stroke survivors rate the ability to walk independently in the community as ‘essential’ or ‘very important’.(7)

When the walking activity of stroke survivors decreases, their walking skills, participation in the community and quality of life will reduce as well.(6) Post-stroke physical inactivity may cause a loss of physical fitness and a decrease of independence of the patient.(8) Furthermore, physical inactivity increases the risk of developing comorbidities and having a second stroke.(8)

Although the above mentioned studies demonstrated that the physical activity of a part of the chronic stroke patients decreases over time, Pearson et al. (2004) concluded that there is no ‘gold standard’ to measure walking activity in this population.(9) Assessment of walking activity generally involves subjective or observer-rated instruments.(9) These instruments have disadvantages such as the risk of recall bias, social desirability of answers, and poor generalisation.(10) Pearson et al.(2004) suggested that the ‘gold standard’ for measuring walking activity should measure total ambulation over a representative period of time. The use of motion sensors has been highly recommended for this purpose.(9)

The StepWatch Activity Monitor (SAM), a step counter, is proven to be valid and reliable for quantifying ambulatory activity in chronic stroke patients.(11,12) Nonetheless, it is limited to only counting the number of steps. To measure walking speed, distance and walking time as well, activity monitors have to be used. Although the reliability and validity of such activity monitors have been studied in diverse populations (13–15), few studies have investigated their use in chronic stroke patients. Saremi et al.(2006) investigated the clinimetric properties of an activity monitor consisting of five biaxial accelerometers.(16) The results of this study show a high reliability and validity for measuring gait parameters (i.e. cadence, gait speed, swing- and stance times) in chronic stroke patients. Nevertheless, only five stroke patients participated in this study. According to the recommendations of de Vet et al.(2011), this sample size is far too small to assess reliability and validity, especially when taking the broad diversity of gait patterns in this specific population into account.(17)

In the chronic stroke population, an asymmetrical gait pattern often exists and the pattern-recognition software of the activity monitors is not particularly suited for these patterns. This probably influences the reliability and validity of these activity monitors for the measurement of gait parameters in this population. Therefore, in the SUSTAIN project (inveStigating and Stimulating long Term walking Activity IN stroke patients) an ActivityMonitor (AM) for the assessment of gait parameters especially in stroke patients was developed.

The importance of an objective, valid and reliable measurement instrument to measure walking activity in chronic stroke patients, is clearly illustrated by the values that stroke survivors attach to community ambulation(7), in addition to the prevalence of stroke(18) and the consequences of a decline in walking activity.(6) If the actual level of walking activity can be measured in a valid and reliable way, the AM can be used in both scientific research and physical therapeutic practice.

Therefore, the aim of this study is to examine the criterion validity and test-retest reliability of the AM as measure of gait parameters in chronic stroke patients.

Methods

Participants

A convenience sample of community-dwelling, chronic stroke patients was recruited from ten private physical therapy practices, the daycare center of 'Zorgspectrum' and the patients' association 'Samen verder' in the Netherlands and the University of Maryland in the United States of America. Stroke was defined according to the World Health Organization definition.(19) Participants were able to walk independently without physical assistance (Functional Ambulation Categories score ≥ 3)(20) and were at least three months post stroke.

Participants were excluded if they had severe cognitive disorders (Mini-Mental State Examination <24)(21), severe communicative disorders (Utrechts Communicatie Onderzoek <4)(22) or acute disorders impairing gait.

Physical therapists from participating institutions estimated whether their patients were eligible for inclusion. Patients who showed interest were contacted by the researchers to participate in the study.

All participants gave written informed consent prior to participation in the study. The research protocol and all informational material was approved by the Medical Ethical Committee (MEC) of the University Medical Center Utrecht and the University of Maryland, Baltimore.

Equipment & experimental protocol

All participants were tested twice with an interval of three to 21 days (T0 and T1). Both test moments included the same treadmill test and the six-minute walk test (6MWT). At baseline, inclusion measurements and collection of personal and anthropometric data were performed prior to the physical tests.

The 6MWT was performed according to the American Thoracic Society Guidelines (23). Walked distance was determined by counting the number of walked laps (20 meters) and adding the final amount of meters, measured by a measuring wheel. Results were used to calculate the speeds for the treadmill test and to assess the overground validity and reliability of the AM.

The treadmill test consisted of three blocks of two minutes at different gait speeds, with transition periods in between. The walking speed measured by the 6MWT was used to define the different speeds for the treadmill test. First, the comfortable walking speed for treadmill (CWT) was calculated as 'Speed 6MWT-10%'. This was considered as Speed 2. Speed 1 and 3 were respectively 15% lower and higher than the CWT. Handrail support was allowed during testing and the treadmills (En Mill treadmill, Enraf Nonius, the Netherlands and Gait Trainer 3™, Biodex, USA) were calibrated prior to the study.

During both tests, acceleration signals were measured by the Activity Monitor (AM). The hardware of the AM consists of a triaxial piezo-capacitive accelerometer. The AM is worn in a strap on the back of the participant, like a waist belt with a small pocket that holds the AM. The accelerations of the body will cause a change in the electric resistance of the piezo-capacitive accelerometer, leading to an output in millivolt (mV). An acceleration of 0,8 m/s^2 leads to an output change of 1 mV. This principle is applied in three different directions (vertical, medio-lateral and antero-posterior) with a sampling frequency of 25 samples per second. The output was saved and stored on an SD card and data was transferred to a computer. Further processing and analysis of the data was performed in Matlab (Matlab 7.10.0, The MathWorks Inc, USA).

The exercise testing on the treadmill was also registered with a video camera (Panasonic, type HC-V70, 50 samples/second, Japan). The video camera was placed behind the treadmill at a distance of 1.2 meters for visual detection of the step activity.

To assess the validity and reliability of the AM, we compared the signals of the AM with counted steps from the video analysis and the real walked distance calculated by multiplying speed and time. This procedure is consistent with procedures from similar validation studies (24–27) and video analysis seems to be the most appropriate standard for the assessment of physical activity.(27)

Data processing and algorithms

From every block of two minutes at different speeds, only the last 90 seconds were analysed, to overcome possible mistakes in speed transitions and to avoid a starting effect. During these blocks of 90 seconds, the researcher counted the amount of steps from the video afterwards and was blinded for the results of the AM. Distance was calculated by multiplying time with walking speed and mean step length was derived from distance and counted steps.

For the same periods, the gait parameters from the AM were analysed using Matlab (Matlab 7.10.1, The MathWorks Inc, USA). We followed the technical recommendations for algorithm development (*unpublished by* Punt et al.(2013)) using Power Spectral Centre of Density to determine the number of steps. To take the individual variety of the speed-acceleration relationship into account (28,29), the algorithm to predict distance at the 6MWT was calculated for each participant separately, according to the method of Schutz et al. (2002).(30) Firstly, the acceleration signal of the treadmill test was recalculated into a Root Mean Square ($RMS_{acceleration}$) value for each of the three testing conditions. Secondly, the relationships between the $RMS_{acceleration}$ and gait speeds were calculated. Finally, with a second degree interpolation based on these relationships, the individual algorithms were calculated. Mean step length was calculated by dividing the amount of steps taken by the distance covered during the same time period.

Statistics

Descriptive statistics were performed for all variables and normality was assessed by visual inspection of histograms and quantile-quantile plots.

To assess the level of agreement between the AM and video analysis, and thus the criterion validity, single measures intraclass correlation $coefficients_{agreement}$ ($ICC_{3,1}$, Two-way mixed model)(31) were calculated for the different gait parameters; number of steps and mean step length obtained from the treadmill test and walked distance at the 6MWT. Furthermore, a Bland-Altman analysis was done to give the 95% limits of agreement (LOAs)(32) and the Mean Relative Root Square Error (MRRSE) was calculated for each parameter. The MRRSE is a measure of the differences between the values of the AM and the observed values, relative to the unit of measurement (see Formula 1). The MRRSE gives an indication of the mean error of the AM per step or number of steps as percentage of the measurement unit.

Formula 1

$$MRRSE = \sqrt{\frac{\sum_{i=1}^{n} (X_{obs,i} - X_{model,i})^2}{\overline{X}_{obs}}} * 100$$

$\overline{X}_{obs}$ = *mean of the observed values, criterion measurement, video analysis*

$X_{model,i}$ = *values obtained by the AM*

Single measures intraclass correlation coefficients$_{consistency}$ ($ICC_{3,1}$, Two-way mixed model)(31) and the 95% limits of agreement (LOAs) by Bland-Altman(32) were calculated to analyse the test-retest reliability of the AM. An $ICC_{3,1}$ of ≥ .75 was seen as high as suggested by Burdock et al.(1963)(33)

Additionally, the Minimal Detectable Change (MDC_{95}) was calculated from the Standard Error of Measurement (SEM) as MDC_{95} = [1.96*$SEM_{consistency}$ *√2].(34) and SEM = [sd * $\sqrt{[1-r]}$], where r is the test-retest reliability coefficient $ICC_{agreement\ 3,1}$ and sd is the standard deviation of the scores at T0. The SEM is multiplied by 1.96 to determine the 95% confidence interval and multiplied by the square root of 2 to account for the additional error associated with repeated measurements.(34) The MDC_{95} is the minimal amount of change that must be observed before the change can be considered to exceed the variation and measurement error at the 95% confidence level.

All calculations were performed using SPSS (IBM Software, SPSS Statistics 20, USA) and Matlab (Matlab 7.10.1, The MathWorks Inc, USA).

Results

A total of twenty-nine participants were tested and their data were used to determine the criterion validity of the AM (15 men and 14 women). 21 participants were tested twice, with an interval between 3 and 21 days. The other eight participants did not complete the second testing moment or the collection of data was unsuccessful. Their data was therefore not used for the analysis of the test-retest reliability. Mean age of the 29 participants was 61.8 ± 8.8 and FAC scores ranged from 3 to 5 (mean 4.4 ± .7).

The average distance at the 6MWT was 328.3 meters (range 36 – 580 meters). This led to a calculated comfortable walking speed of 2.9 ± 1.1 km/h (range 0.4 – 5.2 km/h). For the treadmill testing, the different walking speeds varied from 0.3 to 5.6 km/h.

In none of the testing conditions, the number of steps were normally distributed. Mean step length was only normally distributed for the video analysis data and not for the AM data. However, distance at the 6MWT was normally distributed. Consequently, in some conditions, the assumptions for calculating ICCs were violated.

Validity

For both gait parameters at different speeds, $ICC_{agreement\ 3,1}$ varied between 0.841 and 0.955 ($p \leq 0.001$ for all values). Mean Relative Root Squared Errors (MRRSE) ranged between 6.0 and 6.9 % for step count, and between 7.6 to 9.4 % for mean step length. All agreement parameters are presented in Table 1.

Table 1: Criterion validity of gait parameters provided by video analysis and the Activity Monitor - Treadmill walking

Speed	Parameter	Video Analysis	Activity Monitor	MRRSE (%)	ICC
Speed 1 = CWT - 15%		*Mean ±SD*	*Mean ±SD*		
Mean ± SD: 2.4 ± 1.1 km/h	Step Count (steps)	130 ±25	137 ± 29	6.9	.841
Range: 0.3 - 4.4 km/h	Mean step length (m)	0.45 ± 0.15	0.44 ± 0.15	8.3	.950
Speed 2 = CWT					
Mean ± SD: 2.9 ± 1.3 km/h	Step Count (steps)	139 ± 28	146 ± 30	6.3	.848
Range: 0.4 - 5.2 km/h	Mean step length (m)	0.50 ± 0.16	0.47 ± 0.16	9.4	.930
Speed 3 = CWT + 15%					
Mean ± SD: 3.3 ± 1.4 km/h	Step Count (steps)	146 ± 28	148 ± 30	6.0	.852
Range: 0.5 - 5.6 km/h	Mean step length (m)	0.54 ± 0.17	0.52 ± 0.17	7.6	.955

MRRSE = Mean Relative Root Squared Error; percentage mean absolute deviation, ICC = Intraclass Correlation Coefficient, CWT = Comfortable Walking Speed for Treadmill

Bland-Altman plots (see figure 1) show that the mean difference of number of steps was 2.0, 4.4 and 4.4 for the different walking speeds respectively. This is 1.5%, 3.2% and 3.0% of the mean number of steps, obtained by video analysis. For mean step length, the mean differences were -0.01 m (2,2% of the mean), -0.03 m (6%) and -0.02 m (3.7%). See figure 1 for the 95% LOAs.

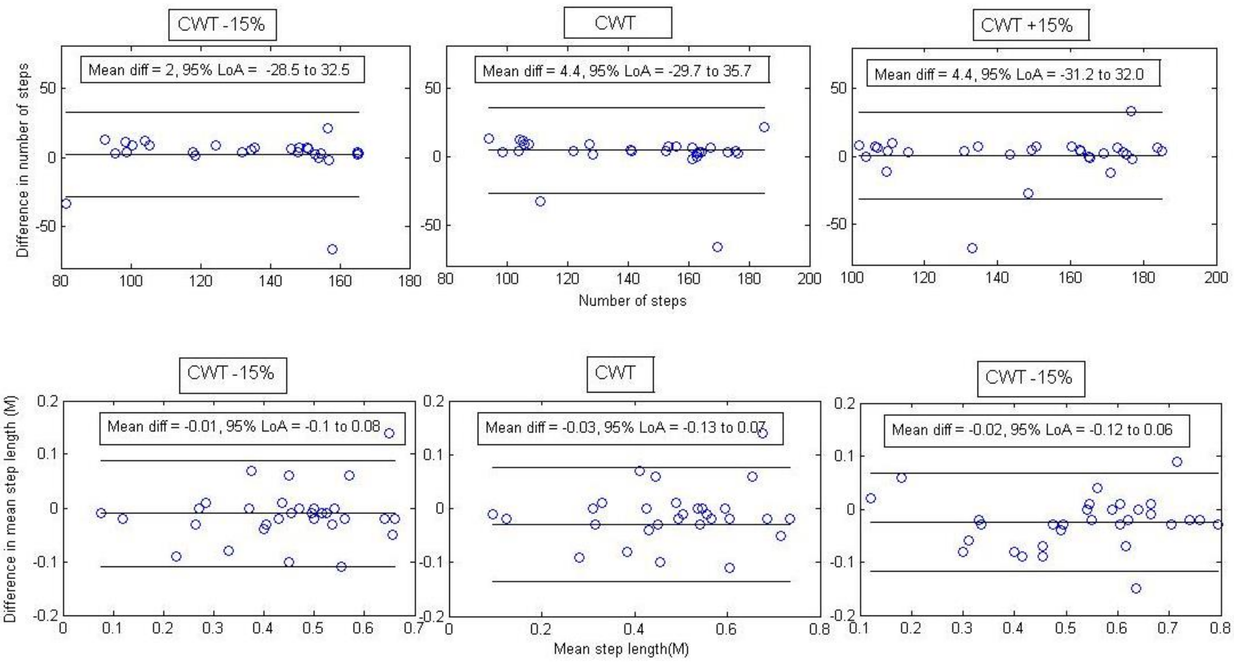

Figure 1: Difference in parameters measured (Activity Monitor – video Analysis), CWT = Comfortable walking speed for treadmill

The ICC$_{agreement\ 3,1}$ score of the AM for measuring distance at overground walking (6MWT) was 0.942 with a MRRSE of 10.5%. (Table 2). Mean difference for the 6MWT according to the Bland-Altman plot is -12.2 meters (3.7% of the mean), with LOAs of –102.2 to 77.7, indicating a potential difference of ± 27.4% in 95% of all cases. (Figure 2).

Table 2: criterion validity of distance measure for overground walking: 6MWT

	Distance at 6MWT (m)	**MRRSE (%)**	**ICC**
Mean ± SD	328.3 ± 136.0	10.5	.942
Range	36.0 -580.0		

6MWT = Six Minute Walk Test, MMRSE= Mean Relative Root Squared Error; percentage mean absolute deviation, ICC = Intraclass Correlation Coefficient

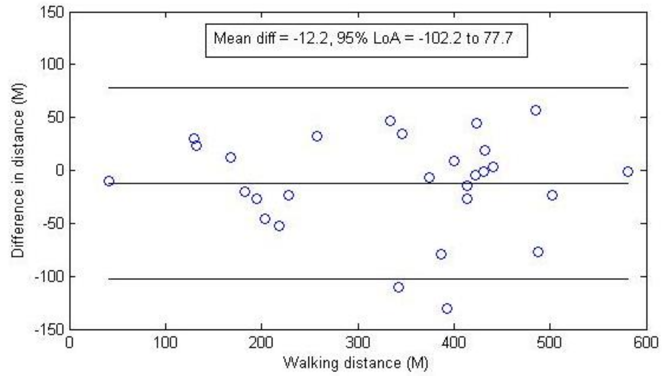

Figure 2: Bland-Altman plot for distance at the 6MWT. Difference in parameter measured (Activity Monitor – Video Analysis)

Reliability

Table 3 shows the test-retest reliability of the AM at the treadmill test. $ICC_{consistency\ 3,1}$ scores range from 0.826 to 0.903 and are all significant at $p \leq 0.001$. The MDC_{95} values for number of steps range from 27.9 to 35.4 steps for the different walking speeds. The MDC_{95} values for the other gait parameters are also given in table 3.

Table 3: test-retest reliability of gait parameters obtained by the Activity Monitor (AM)

Speed	Parameter	T0 (*Mean ± SD)*	T1 (*Mean ± SD)*	ICC	MDC_{95}
Speed 1 = CWT - 15%	Step Count (steps)	134.0 ± 28.1	132.9 ± 25.1	.872	27.9
	Mean step length (m)	0.44 ± 0.15	0.43 ± 0.14	.903	0.13
Speed 2 = CWT	Step Count (steps)	145.0 ± 30.0	138.8 ± 25.6	.850	32.2
	Mean step length (m)	0.48 ± 0.15	0.50 ± 0.17	.890	0.14
Speed 3 = CWT + 15%	Step Count (steps)	146.8 ± 30.6	141.4 ± 30.6	.826	35.4
	Mean step length (m)	0.52 ± 0.16	0.57 ± 0.19	.826	0.18

CWT = Comfortable Walking speed for Treadmill, ICC = Intraclass Correlation Coefficient, MDC = Minimal Detectable Change

The Bland-Altman plots in figure 3 show mean differences between both testing moments to be around zero. Mean differences for number of steps are -1.09 (0.8 % of the mean), -6.19 (4.3%) and -5.14 (3.5%) and -0.01 (2.3%), 0.02 (4.2%) and 0.04 (7.7%) for mean step length. For limits of agreement, see figure 3.

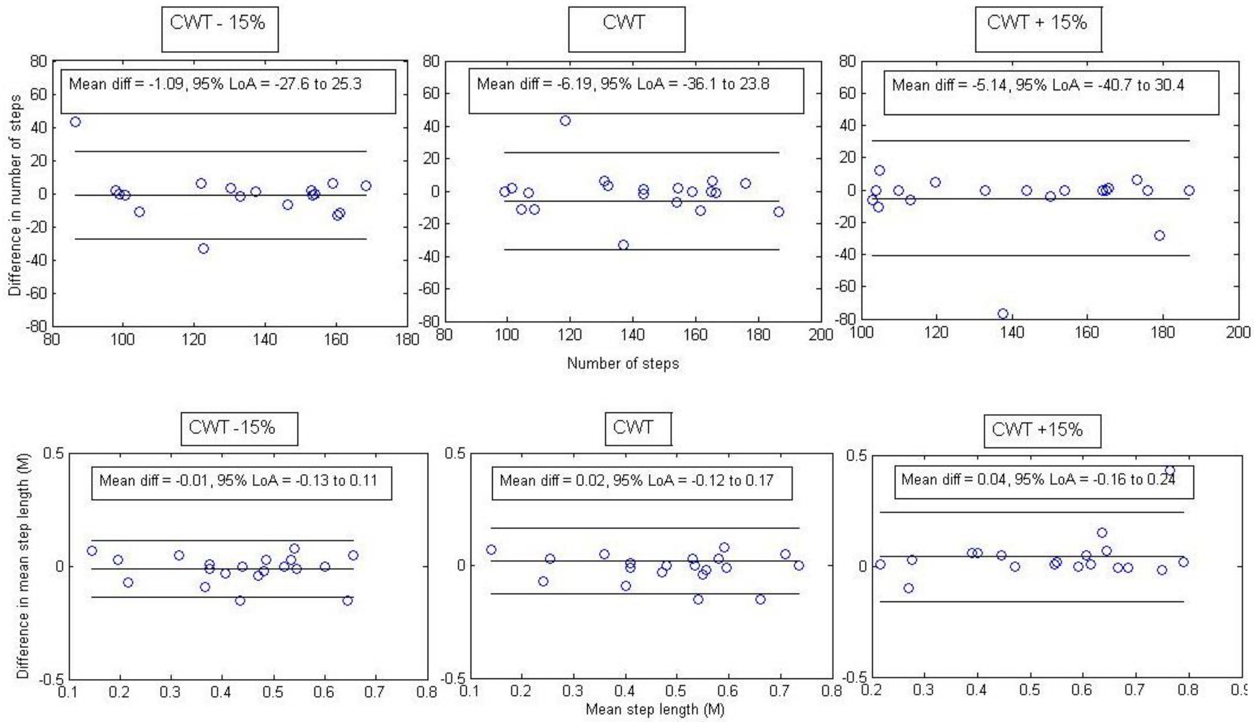

Figure 3: Bland-Altman plots for number of steps and mean step length for the three different walking speeds at the treadmill test. Difference in parameters measured by the AM (T0-T1). CWT = Comfortable Walking Speed for Treadmill

For distance at the 6MWT, an $ICC_{consistency\ 3,1}$ of 0.967 was found for the test-retest reliability of the AM, compared to 0.979 for video analysis. The MDC_{95} score for the AM was 62.44 m, compared to 46.29 m for the video analysis (see table 4).

Table 4: test-retest reliability of distance measure at 6MWT obtained by the AM and Video analysis

	T0 (*Mean ± SD)*	T1 (*Mean ± SD)*	ICC	MDC_{95}
AM	347.5 ± 124.0	351.7 ± 131.1	.967	62.44
Video	324.6 ± 118.1	336.3 ± 118.6	.979	46.29

6MWT = Six Minute Walk Test, AM = Activity Monitor, ICC = Intraclass Correlation Coefficient,

MDC_{95} = Minimal Detectable Change

For distance walked at the 6MWT, the Bland-Altman plot (figure 4) shows a mean difference between both testing moments of 4.2 meters (1.3% of the mean), with 95% Limits of Agreement of -59.9 to 68.5 meters, indicating a potential difference of ± 19.8 % in 95% of all cases.

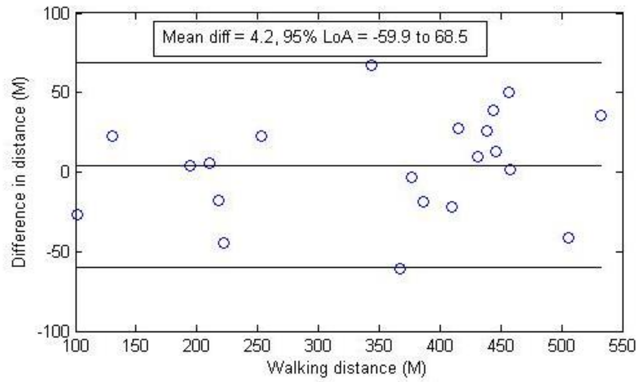

Figure 4: Bland-Altman plot for distance at 6MWT. Difference in parameters measured by the AM (T0-T1)

Discussion

The aim of this study was to examine the criterion validity and test-retest reliability of the Activity Monitor (AM) as measure of gait parameters in chronic stroke patients. To the best of our knowledge, this study is the first to assess these clinimetric properties of an activity monitor that uses accelerometry to measure gait parameters in a population of chronic stroke patients. In fact, we validated the AM at three different speeds within one participant. This innovative way of validating an activity monitor is very important, since the walking speed of one person varies widely during the day. This way of validation, at a range of walking speeds within one person, increases the ecological validity of the AM strongly.

Harris-Love et al.(2001) have shown that gait parameters of chronic stroke patients differ for treadmill walking and overground walking.(35) When walking on a treadmill, the gait patterns of chronic stroke patients are more symmetrical and stable compared to overground walking. Eventually, the AM should be used in free-living conditions. Therefore, to give an indication of the validity and reliability of the AM for overground walking, the distance at the 6MWT predicted by the AM was analysed as well.

For both gait parameters at the treadmill test; number of steps and mean step length, high agreement between the AM and the criterion measure of video analysis was found; ICC's ranged from 0.841 to 0.955. This was also the case for the walked distance at the

6MWT, with an ICC of .942. However, although the mean error parameters such as MMRSE and the mean differences obtained by the Bland-Altman plots were all around or smaller than 10%, in individual cases, the differences between both methods were frequently larger. These individual differences ranged from ± 21.6 to ± 23.5% for number of steps, ±16.7 to ± 20% for mean step length, and ± 27.4% for distance at the 6MWT. These percentages are all based on the 95% LOAs.

Despite the large individual differences, no clear trend can be seen between the error parameters and the three walking speed conditions. This indicates that the validity of the AM is not affected by gait speed.

Calculation of ICC values for test-retest reliability showed that the AM is reliable to measure gait parameters in chronic stroke patients. ICC's$_{consistency\ 3,1}$ ranged from 0.826 to 0.967. For the error parameters of the test-retest reliability the same contrast between mean and individual errors appeared as with the validity error parameters. Mean differences based on the Bland-Altman plots ranged between 0.8 and 7.7%. Individual differences were larger, with ±19.7 to ± 24.4% for number of steps, ± 27.3 to 38.5% for mean step length and 19.8% for walked distance at the 6MWT.

As can be seen in the Bland-Altman plots, in some cases, the AM gives extreme values, with a large error. This is due to a misinterpretation of the acceleration signals by the software of the AM. Currently, we are not able to overcome these misinterpretations, and we therefore decided to include these extreme values in the analysis, despite the fact that these outliers affect the LOAs and individual error parameters strongly.

It is very difficult to decide whether the calculated error parameters of the AM are acceptable for clinical practice. For specific measurements, measurement errors should be smaller than the Minimal Clinically Important Difference (MCID) to detect a valuable effect for individuals. The MDC_{95} score of the AM for walked distance at the 6MWT was 62.44 meters. This is larger than the MCID of 54.1 meters.(36) However, for the treadmill tests, no MCIDs are defined. Nevertheless, there is a general clinically important difference for walking parameters of 10 to 15 % described in the literature.(25,37) Although the mean error parameters are within this range of differences, the individual error parameters, based on the 95% LOAs or the MDC_{95} scores, exceed the 10 to 15%

clinically important difference limit. Based on this information, we can conclude that the validity and reliability of the AM should be improved to detect valuable changes in the gait parameters of individuals with chronic stroke.

Therefore, further research is needed to improve the stroke specific algorithms of the AM to avoid outliers and to reduce the individual margins of measurement error. Furthermore, the clinimetric properties and the feasibility of the AM for overground walking in free-living conditions have to be investigated more extensively.

Our results are hardly comparable with other studies, because as far as we know, no other study has investigated the clinimetric properties of an activity monitor to measure gait parameters in the chronic stroke population. Previous studies with a similar design and aim as we had, included other patients or healthy subjects(13–15,38). These studies used ICCs and LOAs by Bland-Altman to determine the level of agreement between the instrument of interest and the criterion measurement. In this study, we added a new measure for validity; the Mean Relative Root Squared Error (MRRSE). Other than the name $ICC_{agreement}$ suggests, the ratio of variances is calculated, rather than the absolute agreement score. (39) Furthermore, it is known that ICC values are strongly influenced by the magnitude of the variance within the study sample. When taking a closer look at the ICC formula, it is clear that a large variance in patient scores, as in this study, will eventually lead to a higher ICC.(39) Studies with different variances in their study populations, can therefore not be compared very well. To get a better insight in the true agreement between the output of the AM and video analysis, and to eliminate the effect of the high variance in our study population, we decided to calculate the MRRSE for each gait parameter. The MRRSE shows directly how much the output from the AM averagely can differ from the actual value, expressed in the unit of measurement of the parameter. Therefore, this score cannot be influenced by testing time or length, because it is expressed as a percentage of the measurement unit. This score is very easy to use in daily practice, easy to interpret properly and not dependent of variance between patients . Therefore, we suggest to use the MRRSE in future research in this area, for a better comparison of study results.

For ICC calculations, de Vet at al.(2011) advised to include 50 participants to reach a convenient level of power.(17) When taking this recommendation into account, our study is underpowered. If we compare our sample size with similar studies in non-stroke populations, the sample size is comparable or even larger.(13–15)

The AM has several advantages over other methods for assessing walking activity; it can measure different gait parameters such as number of steps, distance, speed, walking time and the number of walking periods, whereas a stepcounter can only registrate the number of steps. The AM can measure for a longer period of time and can provide the researcher or clinician with real-life information, with no risk of recall bias or socially desirable answers as is the case with diaries or questionnaires. Finally, the AM is relatively inexpensive and easy to use in comparison with large optical or force plate systems as Gaitrite® (CIR Systems Inc., Sparta, USA) or Vicon motion analysis system (Vicon Motion Systems, Inc., Lake Forest, USA) that cannot measure walking activity in the free-living situation and therefore have a poor ecological validity.

The possibility to measure walking activity of chronic stroke patients in a valid and reliable way, offers a variety of perspectives for research and treatment in this population. In future research, the walking-activity profile and possibly predicting factors of walking activity can be better assessed. In daily practice, physical therapists can analyse the walking activity of their patient and tailor the intervention based on that information. Additionally, therapy compliance can be monitored. Important factors in therapy adherence are feedback and encouragement (40), which both can be given by the AM. Summarizing, these new applications of a measurement instrument to measure walking activity, will possibly lead to an increased level of walking activity in this population and therefore an increased quality of life as well.(6)

Conclusion

Based on ICC values, this study demonstrated good criterion validity and test-retest-reliability of the Activity Monitor (AM) for measuring gait parameters in chronic stroke patients. However, individual margins of error were high in comparison with MCID values for gait parameters. This indicates that the AM cannot detect a valuable effect at gait parameters for individuals with chronic stroke. Further research is needed to improve the algorithms of the AM to avoid outliers and to reduce the measurement errors. The validity of other gait parameters for overground walking and the usability and feasibility of the AM in the chronic stroke population have to be thoroughly investigated as well. This will offer opportunities for the use of a valid and reliable measurement instrument to assess gait parameters in the chronic stroke population, in both clinical practice and academic research.

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