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The Wisconsin gait scale – The minimal clinically important difference

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ABSTRACT

Background: Wisconsin Gait Scale (WGS) is an observational tool for the evaluation of gait quality in individuals after stroke with hemiplegia. It is divided into four subscales, which assess a total of fourteen spatiotemporal and kinematic parameters of gait observed during the consecutive gait phases. However, the WGS score change indicative of important and clinically meaningful change has not been determined.
Research question: The study has been designed to define the minimal clinically important difference (MCID) of the WGS.
Methods: Four methods were used to determine the MCID for the WGS in 50 participants who had experienced a stroke: anchor-based study, distribution-based study, linear regression analysis and specification of the receiver operating characteristic (ROC) curve.
Results: In the anchor-based study, the mean change score in the MCID group was 1.9 points (the first MCID estimate). In the distribution-based study, the standard error of measurement for the no-change group was 0.3 (the second MCID estimate). The slope of the regression line was 1.21 which means than 1-point change in the Barthel Index (BI) is associated with 1.21-point change in the WGS. This translates to 2.25 points change in the WGS with 1.85 points change in the BI (the third MCID estimate). The best cut-off point, determined with ROC curve, was the value corresponding to 1 point of change in the WGS (the fourth MCID estimate).
Significance: We established that the MCID of the WGS was 2.25 points, based on the largest of the four MCID estimates. The value 2.25 of the MCID can help clinicians and researchers determine if the change in the scores on the WGS is clinically important.
Clinical trial registration: Data are parts of the following clinical trial: ACTRN12617000436370.

1. Introduction

A minimal clinically important difference (MCID) can be defined as a change in a score reflecting patient-reported assessment of a significant clinical improvement [1]. The first information related to MCID dates from 1989, when it was described as the smallest difference that patients perceive as beneficial [2]. Guyatt et al. [3] defined the MCID as a change in an outcome score corresponding to a change in a clinical status subjectively acknowledged by the patient. Sorensen et al. [4] suggested that the MCID should express a real change in an outcome measure whose value exceeds the test-retest variation (measurement error).

Rodriguez et al. [5] developed the Wisconsin Gait Scale (WGS), an observational tool for the evaluation of gait quality in individuals after stroke. The WGS is valid, accurate, reliable, and easy to use, therefore it is an effective protocol enabling assessment of progress in gait rehabilitation [5–14]. The WGS was first presented as a tool designed for assessing benefits of home gait training programme received by subjects who had experienced stroke and were in a chronic stage of recovery [5]. The authors provide validation for the newly proposed WGS, an instrument of gait measurement potentially enabling comparison of outcomes [5]. Similarity Lu et al. [7] showed that the WGS is a reliable and valid protocol for measuring the hemiplegic gait of individuals after stroke. Yaliman et al. [6] assessed intrarater and interrater reliability of the WGS in individuals after stroke with hemiplegia. It was established that the WGS is highly reliable, and can be recognised as an objective tool designed for documenting results of an observational gait analysis. Wellmon et al. [11] defined the minimal detectable change (MDC) of the WGS. The MDC for the WGS was estimated based on the 95% confidence interval (CI) and amounted to 4.24 [11]. In our previous

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study we showed strong or very strong correlations between the specific items of the WGS and the corresponding objective 3-dimensional (3D) spatiotemporal and kinematic gait parameters [13]. This is evidence confirming that the WGS is a useful diagnostic instrument and in situations when the costly objective methods of gait assessment cannot be applied for various reasons, the scale may be an effective tool enabling gait assessment [13].

However, no studies so far have determined the MCID for the WGS. Due to this the present study has been designed to define the MCID of the WGS using four methods: the patients' perceptions of the change in gait function, determination of the standard error of measurement (SEM), specification of the receiver operating characteristic (ROC) curve and identification of correlations with Barthel Index (BI), the most frequently applied scale and the most popular tool used in assessment of functional performance after stroke [15–18]. The psychometric properties of the 20-point BI in individuals after stroke have been shown to be satisfactory [16,17]. The MCID of the BI in individuals after stroke was estimated to be 1.85 points by Hsieh et al. [18].

2. Material and methods

2.1. Participants

Fifty individuals after stroke in a chronic phase of recovery were selected from a database of the Rehabilitation Clinic in the Provincial Hospital No. 2 in Rzeszow, Poland. The qualifying criteria for participants of the study included: single ischaemic stroke incident confirmed by computed tomography or magnetic resonance imaging, age 30–75 years, at least 6 months from stroke, unilateral paresis, independent locomotion (with walking aid -if necessary, walking speed > 0.4 m/s), Brunnström recovery stage 3–4. Exclusion criteria: second or another stroke incident, cognitive function deficits impairing the ability to understand and follow instructions, unstable medical condition and orthopaedic disorders of the lower limbs. The research protocol was approved by the local Bioethics Commission of the Medical Faculty (5/2/2017); the study was registered at the Australian New Zealand Clinical Trials Registry (ACTRN12617000436370). Experimental conditions met the requirements of the Declaration of Helsinki. All subjects gave their informed written consent to participate in the study. Demographic and clinical characteristics of the study participants are shown in Table 1.

2.2. Instruments

The subjects' gait was recorded with two synchronised video cameras twice, at patient's admission to the department of rehabilitation (baseline assessment), and at discharge, 4 weeks later (follow-up assessment). The positioning of the cameras enabled recording of images in both the frontal and the sagittal plane and the equipment was synchronised. The walking distance was 10 m long. One camera was aligned to record the gait in the frontal plane, the other camera registered the image in the sagittal plane and was located halfway along the walking path, 2 m away from the path. The cameras were set to allow visualization of three walking trials, each designed to assess the unaffected and the affected side, i.e. a total of six ambulation trials. The subjects were asked to walk the defined distance at a self-selected (comfortable) speed, with the support of orthopaedic aids used on a regular basis. The recordings were interpreted and the WGS was evaluated by a senior gait analysis physiotherapist.

The WGS allows for a multifactorial gait analysis, takes into account 14 observable gait parameters divided into four sub-scales referring to particular phases of gait, i.e. stance phase, toe off, swing phase, and heel strike. The first five items are included in the stance phase of the affected leg: 1- use of hand-held gait aid, 2- stance time on the impaired side, 3- step length of the unaffected side, 4- weight shift to the affected side with or without gait aid, 5- stance width. The second part of the scale covers the toe-off phase of the affected leg and includes two items: 6-guardedness (pause prior to advancing of the affected leg), 7- hip extension of the affected leg (observation of gluteal crease). The third subscale relates to the swing phase of the affected leg including six items: 8- external rotation during initial swing, 9- circumduction at mid-swing (path of the affected foot), 10- hip hiking at mid-swing, 11- knee flexion from toe off to mid-swing, 12- toe clearance, 13- pelvic rotation at terminal swing. The last part of the scale covers the heel strike of the affected leg and includes only one item: 14- initial foot contact of the affected leg. A summary score, which can range from 13.35 to 42 points, is calculated for the items. Items 2–10 and 12–14 are summed. Items 1 and 11 both contribute to the summary score but each is weighted by 3/5 and 3/4, respectively, before adding the individual items to a total score. Higher scores indicate poorer gait performance and greater gait deviations [5,11].

The BI was developed to assess activities of daily living (ADLs) in individuals with neurological or musculoskeletal disorders. The BI is based on 10 aspects of basic ADLs: feeding, grooming, bathing, dressing, bowel care, bladder care, toilet use, ambulation, transfers, and stair climbing. The total score of the BI is in the range from 0 to 20 [19]. The BI was evaluated by a senior physiotherapist twice: at baseline and at follow-up assessment.

The patients were divided into three groups, based on their own perception of improvement achieved or a lack of improvement in the gait mechanism. The patients' perceptions of the change in gait were assessed. At follow-up, the patients were asked to answer the following question: "Has there been any change in your gait, compared to your condition at admission to the department of rehabilitation?". If the patients reported there had been "no change", they were assigned to the "no-change group". If they admitted that their condition was "better", they were allocated to the "MCID group" (or "positive change group"). If they said that their condition was "worse," they were qualified to the "negative change group".

2.3. Procedures

Four methods were used to determine the MCID for the WGS and ultimately the highest result obtained was selected.

Method 1 - anchor-based study - at baseline (i.e. at patients' admission to the rehabilitation department), the patients' gait was assessed using the WGS. At follow-up (at discharge or 4 weeks after the baseline assessment), a physiotherapist performed another assessment with the WGS and checked the patients' perceptions of the change in gait function since admission.

Method 2 - distribution-based study – the patients selected for this study presented stable gait function, and were qualified to the no-change group; this means their WGS scores at baseline and at follow-up did not change, and SEM was calculated for the change in such patients. To ensure that the patients' gait was stable during the study period, it was assumed that any patients who developed other medical conditions

Table 1
Demographic and clinical characteristics of study participants.

Characteristic	Study participants (n = 50)
Age [years], mean (SD)	60.9 (11.2)
Sex [females/males]	18/32
Side of lesions [right/left]	15/35
Time from stroke month, mean [range]	42.0 [8–120]
Gait speed (m/s), mean (SD)	0.65 (0.20)
WGS baseline score, mean (SD)	21.58 (5.55)
WGS follow-up score, mean (SD)	20.08 (4.59)

SD – standard deviation, WGS - Wisconsin Gait Scale.

potentially impairing gait, including those who experienced recurrent stroke, would be disregarded.

Method 3 - linear regression analysis – a change in the WGS, i.e. the tool assessed, was compared to a clinically important change in the BI, i.e. the change by 1.85 points in the BI, this specific value being reported in the literature as the MCID for the BI [18].

Method 4 - ROC curve - this study took into account two groups of patients: the “no-change group” and the “positive change group”, and the analyses were designed to determine the cut-off point for the change in the WGS which most successfully separated these two groups with the ROC curve.

2.4. Data analysis

All statistics were calculated using Statistica 13.1 software (StatSoft). Descriptive statistics were calculated (mean, standard deviation). Significance level was set to $p < 0.05$; mean difference and a CI at 95% were used for the statistical comparisons.

Method 1 - anchor-based study – which was a follow-up study to estimate the MCID of the WGS, as an anchor using patients’ opinion of whether or not an improvement occurred. The mean change in the score on the WGS, in the MCID group (“positive change group”), served as the first estimate for the MCID of the WGS.

Method 2 - distribution-based study - was designed for determining the SEM of the WGS change in patients with stable gait function. The SEM was calculated as the square root of the variance of WGS change in this subgroup [20,21]. In this study, one SEM served as the second estimate for the MCID of the WGS.

Method 3 - linear regression - was used to assess the relationship between the change in the WGS (dependent variable) and the change in the BI (independent variable) [22] - the third estimate for the MCID of the WGS.

Method 4 – ROC curve - was designed for determining the optimal cut-off point for the change in the WGS. We analysed the effect of a certain numerical variable (change in the WGS) in the chances for the occurrence of an event (improvement in gait, qualifying the patient to be assigned into the “positive change group”). We looked for the cut-off point, i.e. the value of the change in the WGS which would most successfully “separate” the cases in which the event occurred from the cases in which it did not occur. Sensitivity and specificity were calculated for each cut-off point. It is assumed that a method is highly sensitive if it accurately indicates the cases in which the event can be expected and it is highly specific if it accurately indicates the cases in which a lack of the event can be predicted. Based on this the ROC curve was created. We chose the point on the curve which was closest to the upper left-hand corner. This point corresponded to the change in WGS scores with the best trade-off between sensitivity and specificity, in identifying the MCID [22,23] - the fourth estimate for the MCID of the WGS.

2.5. Sample size

The minimum size of the sample was calculated taking into account the number of individuals after stroke hospitalized annually in the rehabilitation ward, i.e. approximately 200 patients, of which those in the chronic phase of recovery constitute about 40%. It was assumed that 80% of the patients would have a minimum gait speed greater than 0.4 m/s, and that in our group, 80% of the patients would achieve an improvement of more than 0.06 m/s (MCID; Small meaningful change for gait speed in patients after stroke; Perera et al., Stroke 2006). A fraction size of 0.8 was used, with a maximum error of 5%, a sample size of 45 patients was obtained.

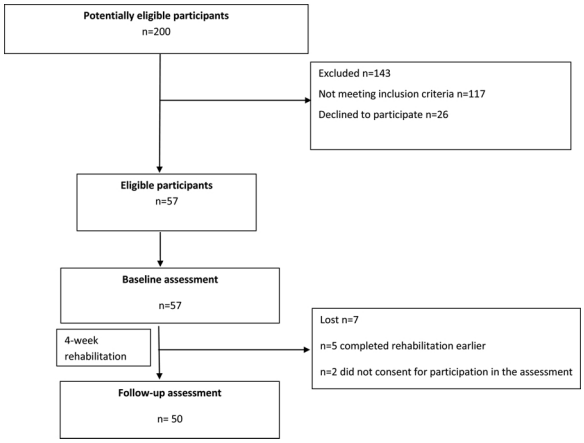

Fig. 1. Flow of subjects through the study.

3. Results

3.1. Flow of participants

A total of 57 patients participating in a rehabilitation program of the Rehabilitation Clinic in the Provincial Hospital, who met the inclusion criteria, were selected out of 200 patients with a medical history of stroke. A total of 57 patients completed the baseline assessment, but 7 patients were lost to follow-up due to the following reasons: 5 patients - completed rehabilitation at the centre earlier than after 4 weeks, 2 patients did not agree for the assessment after 4 weeks. The remaining 50 patients completed both assessments, and their data were analysed in the study. The flow of the subjects through the study is shown in Fig. 1.

3.2. Method 1 - anchor-based study

The patients’ mean WGS baseline score was 21.58 points. The 50 patients were divided only into 2 groups (MCID /positive change group and no-change group) based on their perceptions of the change in gait, because no patient reported that their gait deteriorated during the study period. 11 patients were classified in the no-change group, and 39 subjects were classified in the MCID (positive change) group. The mean WGS scores of the MCID group were 23.16 at the baseline assessment and 21.26 at the follow-up assessment. The mean change in WGS score of the MCID group was 1.9 points, 95% CI [1.56–2.24], which constituted the first estimate of the MCID of the WGS (Table 2).

3.3. Method 2 - distribution-based study

The mean WGS scores of the no-change group were 15.98 at baseline, and 15.89 at follow-up. The SEM for the no-change group was 0.3, 95% CI [0.21-0.53], making the second estimate of the MCID of the WGS (Table 2).

Table 2
Four methods establish the MCID for the WGS with 95% confidence interval.

Methods	MCID estimate (95% CI)
1. Anchor-Based Study	1.9 [1.56-2.24]
2. Distribution-Based Study	0.3 [0.21-0.53]
3. Linear Regression Analysis	2.25 [1.75-2.79]
4. ROC curve	optimal cut-off point 1

MCID - minimal clinically important difference, CI - confidence interval, SEM - standard error of measurement, ROC - Receiver Operating Characteristic.

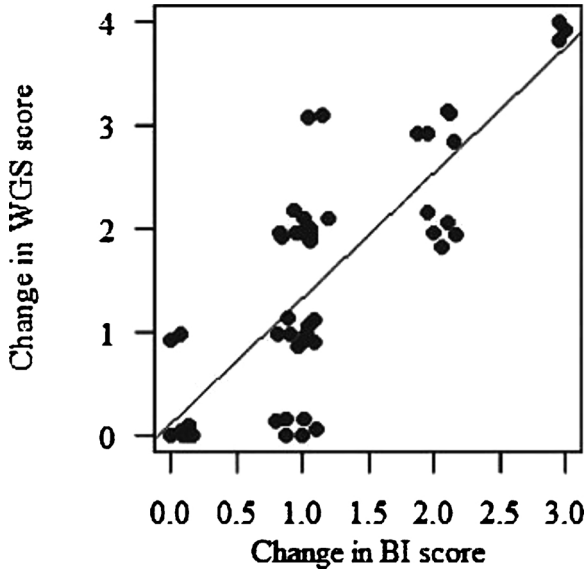

Fig. 2. Scatterplot of the WGS vs the BI.

3.4. Method 3 - linear regression analysis

The change in the WGS correlated with the change in the BI ($R2 = 0.63$, $p < 0.001$) – Fig. 2. The slope of the regression line was 1.21 which means than 1-point change in the BI is associated with 1.21-point change in the WGS 95% CI [0.95–1.49]. This translates to 2.25 points change in the WGS 95% CI [1.75–2.79] with 1.85 points change in the BI, representing the third estimate of the MCID of the WGS (Table 2).

3.5. Method 4 – ROC curve

It was found that the best cut-off point, determined with ROC curve, and separating two groups of patients, i.e. no-change versus positive change group, was the value representing 1 point of change in the WGS (Fig. 3) - the fourth estimate of the MCID for the WGS.

The highest of the four MCID estimates was 2.25, which consequently is suggested as the MCID for the WGS in stroke patients.

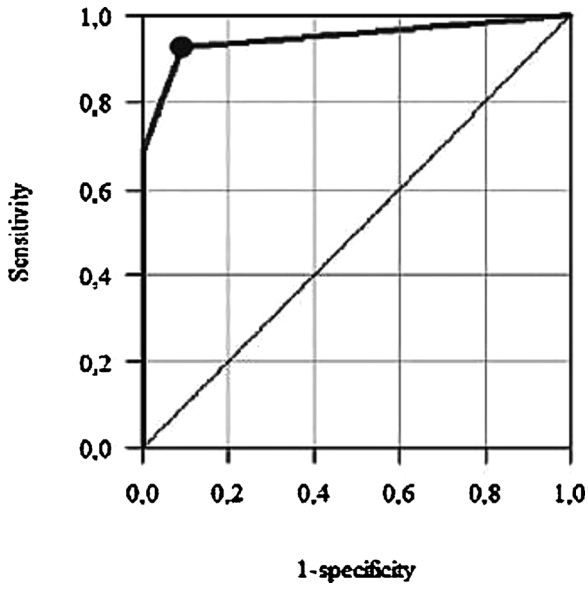

Fig. 3. ROC curve – optimal cut-off point (black point in the graph).

4. Discussion

To the best of our knowledge, the MCID for the WGS has not yet been calculated, therefore this is the first study to examine and report the MCID for this scale. Our findings will help researchers determine if the change in the scores within a group of patients with stroke has reached the MCID in outcome or follow-up assessments. If a group of patients with stroke achieves an average of 2.25-point improvement on the WGS, it is likely the change in the subjects' gait function is reproducible and clinically important. Conversely, if the mean improvement in the group is lower than 2.25 points, the clinical importance of the change is questionable.

The strength of this study lies in the fact that we used four methods to determine the MCID of the WGS, and ultimately the highest result obtained was selected. By combining the four methods it is possible to ensure that the MCID takes into account the patients' subjective perceptions of changes in gait function, it is greater than the measurement error in the WGS, it accounts for the significant correlation with the BI and the best trade-off between sensitivity and specificity. Importantly, the assessments based on all the methods were performed in the same, uniform group of patients at the same recovery stage (chronic phase) and with similar disability levels (Brunnström recovery stage 3–4). It should be emphasised that in the estimates based on the second method (determination of the SEM), the MCID of the WGS is lower than the estimate based on the first method (patients' perceptions of gait changes) – 0.3 and 1.9, respectively. It is assumed that if the measurement error of an instrument is higher than the related patients' ratings, the instrument can be considered unreliable in detecting patients' perceptions, and consequently the MCID is questionable [24]. Therefore, it can be argued that our estimate of the MCID for the WGS is appropriate.

Based on literature review it can be concluded that the present study is the first attempt to apply four methods in determining the MCID. Hsieh et al. [18] used both anchor-based and distribution-based methods to establish the MCID of the BI in patients with stroke. However, patients recruited for the anchor-based and distribution-based study differed in terms of the recovery stage and disability level - ADL function. In the anchor-based study, the authors included subjects receiving inpatient care who had severe or moderate ADL disabilities post-stroke. On the other hand, the distribution-based study only took into account individuals (mostly outpatients) who had experienced stroke six or more months earlier, and at the time of the study generally presented mild to moderate ADL disabilities. Hence, there were some unavoidable differences between these two groups [18]. Beninato et al. [25] identified the MCID for the Functional Independence Measure Instrument in patients with stroke from ROC curves. On the other hand, linear regression was used to define the MCID of the Edinburgh Visual Gait Score using correlations with the Gross Motor Function Classification System and the Functional Assessment Questionnaire by Robinson et al. [1].

The limitation to the present study is the modest size of the sample used in distribution-based study determining the SEM of the WGS change in patients with stable gait function. Further studies with larger sample sizes and at early stages post-stroke are needed.

5. Conclusions

This study provides a result based on four methods applied to establish the MCID for the WGS in patients with stroke at a chronic phase of recovery. We established that the MCID of the WGS was 2.25 points, based on the largest of the four MCID estimates. The value 2.25 of the MCID can help clinicians and researchers determine if the change in the scores on the WGS is clinically important.

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Conflict of interest statement

None of the authors have any financial or personal relationships or affiliations that inappropriately influence decisions, work or the content of the manuscript.

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