Does the Global Rating Scale Correlate with Standard Clinical Outcomes in Chronic Individuals with Stroke?

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Abstract

Several well-accepted stroke assessment scales have been developed for use in clinical settings such as Stroke Impact Scale (SIS), Fugl-Meyer Assessment for the Upper Extremity and Lower Extremity (FMA-UE and FMA-LE), Berg Balance Score (BBS), Modified Ranking Scale (MRS), and the global rating of change scale (GROC). However, clinical outcomes were assessed by patient self-evaluation and physiotherapists, responsiveness and discrimination of high and low disability in the context of functional recovery have not yet been confirmed. The purpose of this study was to 1) compare the Stroke Impact Scale (SIS) and clinical outcomes between the baseline and after the 12-week physical therapy treatment program and 2) to investigate the correlation between the global rating of change (GROC) with the SIS and other clinical outcomes in individuals with chronic stroke. Participants underwent physical therapy at least twice a week. The SIS and clinical outcome measures including Fugl-Meyer Assessment for the Upper Extremity and Lower Extremity (FMA-UE and FMA-LE), Berg Balance Score (BBS), Modified Ranking Scale (MRS), gait speed, and the GROC were measured at the baseline and after the 12-week physical therapy treatment. The data analysis examined the differences between the SIS and all clinical outcomes and between the baseline and after the 12-week physical therapy treatment. Then, the authors explored the correlation between the GROC and SIS in each domain. The authors also explored the correlation between the GROC and changes in the other clinical outcomes after the 12-week physical therapy treatment. The results showed that there was a significant difference in only the SIS score between the baseline and after 12-week of physical therapy treatment in the domains of strength, emotion, ADL, mobility, social participation, and global recovery. Besides, the GROC score showed a median score of +3.25 (3, 4) after the 12-week of physical therapy treatment. Finally, there was a fair correlation between the GROC and the SIS. Therefore, the differences between the baseline and after the 12-week of physical therapy treatment were explored in the SIS, and the GROC scale could be applied to suit the needs of physiotherapists or clinicians when time and difficulties in other methods of assessment exist.

Keywords*: *Global rating of change, the Stroke Impact Scale, Stroke

1. Introduction

Few different functions are impaired by a stroke, the most common cause of disability. Multiple functional impairments following stroke may occur separately or combined, including motor function, perception, cognition, vision, emotion, communication, and mental health (Shah, Vanclay & Cooper, 1990; Sullivan et al., 2013). The long-term impact could be determined by the initial stroke lesion and the extent of subsequent recovery (Lin et al., 2000). Rehabilitation, especially physiotherapy (PT) interventions, plays a major role in post-stroke care, and the prevalence of stroke-related burden is expected to increase over the next decades (Lin et al., 2000; Langhorne, Bernhardt & Kwakkel, 2011). Currently, the PT interventions aim to enhance different domains of the International Classification of Functioning, Disability, and Health: body, activities, participation (at individual and societal levels), and contextual (personal and environmental) (World Health Organization, 2001). These domains are commonly assessed by the WHO Disability Assessment Schedule (WHODAS 2.0) (Üstün et al., 2010), which has been used in the post-stroke rehabilitation to characterize patients based on the ICF evaluation model (Üstün et al., 2010), where individuals with stroke acquire the necessary knowledge and skills needed for the maximum improvement of physical, psychological, and social function (Sullivan et al., 2013). Management of individuals with stroke needs to focus on motor and functional recovery or responsiveness in the context of both impairment and functional outcomes. Responsiveness, identified by a combination of physiotherapist evaluation and

individuals' perception of improvement, corresponds to the actual change (Sullivan et al., 2013; Hayward et al., 2019).

Several well-accepted stroke assessment scales have been developed for use in worldwide clinical settings such as the Stroke Impact Scale (SIS), Fugl-Meyer Assessment for the Upper Extremity and Lower Extremity (FMA-UE and FMA-LE), Berg Balance Score (BBS), Modified Ranking Scale (MRS), Wolf Motor Function Test, Action Research Arm Test, and the ten-meter and six-minute walk tests (Sullivan et al., 2013). All of which have been used as a reference standard or external criterion of changes in individuals with stroke although assessing impairment and disability alone does not provide sufficient information regarding the absolute impact of stroke (Sullivan et al., 2013; Richardson et al., 2016; Hayward et al., 2019). Functional outcome measures are essential in stroke rehabilitation (Duncan et al., 2003b; Sullivan et al., 2013); however, health-related quality of life measures are increasingly used to assess the status of individuals with stroke. The Stroke Impact Scale is recommended and is widely used to identify patient needs within rehabilitation intervention programs (Duncan et al., 2003b; Sullivan et al., 2013).

Furthermore, the Global Rating of Change Score (GROC) is a frequently used outcome measure to allow the self-report direct perceptions of improvement and has been used as an anchor method to determine if clinically important changes have occurred (Kamper, Maher & Mackay, 2009). The GROC has been the alternative outcome for patients with shoulder pain and neck pain in previous studies (Kamper, Maher & Mackay, 2009; Garrison & Cook, 2012; Viriyatharakij, Ratvongsa & Manopanjasiri, 2018). Due to its ease of use and administration, the GROC is designed to quantify patient's improvement or deterioration over time. It is usually used either to determine the effect of an intervention or to document the clinical course of a condition. GROC items are constructed to ask the individual to rate the changes in their current health status, with a recall memory of the previous time-point, and then score the change between that time point and their current status, the magnitude of this difference is then scored as a numerical value or on a visual analog scale. The GROC has been advocated as an outcome measure to improve the applicability of information from clinical trials to clinical practice (Kamper, Maher & Mackay, 2009). However, to date, there is little evidence showing the validity and the use of GROC in individuals with stroke (Fulk et al., 2010; Fulk et al., 2011; Page, Fulk & Boyne, 2012; Fulk, Martin & Page, 2017; Wong et al., 2017). It may come from the questionable ability of individuals with stroke to accurately recall and score a previous health status, which underpins the principal criticism of the GROC scales (Schmitt & Di Fabio, 2005). The GROC could be useful to determine if clinically important changes are reached within clinical trials in individuals with stroke. It is imperative to know if interventions offer a meaningful improvement in individuals with stroke, and whether individuals would choose to receive the same treatment again Besides, clinical outcomes, judged by patient self-evaluation and physiotherapists, for responsiveness and discrimination of high and low disability in the context of functional recovery have not yet been confirmed (Fulk et al., 2010; Fulk et al., 2011). To determine whether a clinically meaningful change has been achieved, the comparison of standard stroke assessments and the GROC may be a useful approach in this population.

2. Objectives

The purposes of this study were

1) To compare the SIS and clinical outcomes consisted of the MRS, BI, FMA-UE, FMA-LE, BBS, and gait speed between the baseline and after the PT treatment.

2) To investigate the correlation between the GROC with the SIS and the clinical outcomes in individuals with chronic stroke.

The authors hypothesized that 1) the SIS will show the improvement in each domain in order to compare with the measurement commonly used in a clinical trial and in the clinic to measure the impact of physical functioning and QOL and 2) the results of GROC will show a good correlation with the SIS and could be used in individuals with stroke to assess the improvement of the PT intervention.

3. Materials and Methods

3.1 Study design and participants

The sample size estimates were calculated from a previous study that used a similar methodology. The sample size was determined using Gpower statistical software (Effect size: f = 0.5, Alpha = 0.05, power = 0.80, sample size = 84, critical t (18) = 12.59, Lambda = 13.75). Therefore, the estimation of sample size in this study was 55 participants. This study was conducted in the Faculty of Physical Therapy at Mahidol University. A 12-week physical therapy treatment program was performed to improve spasticity, range of motion, muscle strength, balance, and function using a combination of passive movement, active-assisted and resisted exercises, electrical stimulation, and balance and functional training. Each participant received a physical therapy treatment for a one-hour session twice a week by an experienced neurological physiotherapist. Physiotherapy interventions were individually tailored based on the participants' body structure, functional impairments, activity and social participation limitations, and the goals of the participants. The inclusion criteria were; presenting with a chronic stroke, aged over 20 years, able to visit the Physical Therapy Centre at the Faculty of Physical Therapy at Mahidol University twice a week, and have sufficient cognitive ability assessed using the Thai version of the Mini-Mental State Examination with a score ≥24/30 (Muangpaisan et al., 2015), able to read and understand the items of the questionnaire, and able to follow verbal instructions. The exclusion criteria were; comorbidities with severe systemic illness (e.g. cancer or autoimmune disease), severe disability caused by previous neurological disorders, and severe pre-existing neurological deficits. All participants were asked to read an information sheet and had at least 24 hours to consider their involvement before signing an informed consent form and participation. This study was approved by the local Ethics Committee on Human Experimentation and adhered to the Declaration of Helsinki (MU-CIRB 2020/120.2005).

3.2 Procedure

For consistency of clinical outcomes, physiotherapist and participant self-assessments were conducted in parallel. The Stroke Impact Scale 3.0 (SIS-3.0), and other clinical outcomes, were recorded at the baseline in the first week and after 12 weeks of physical therapy treatment. The present study used the Thai SIS 3.0 for this assessment, which was translated from the original English SIS and validated by Piyapat et al. (2015). The SIS 3.0 consists of 59 self-report assessment items relating to stroke outcome and was used to assess health-related quality of life. The SIS consists of nine domains; strength, hand function, mobility, physical and instrumental activities of daily living (ADLs and IADLs), memory and thinking, communication, emotion, and social participation where higher scores indicate a better health-related quality of life. For the last domain of the Thai SIS, participants were asked to rate their improvements from 0 to 100.

The Global Rating of Change Score (GROC) is a self-assessment of perceived change, which uses an 11-point Likert scale. A GROC score of zero was considered as unchanged, and GROC scores of +1, +2, +3, +4, and +5 represent minimal, moderate, and large improvements. In contrast, GROC scores of -1, -2, -3, -4, and -5 indicated the degree of perceived deterioration (Kamper, Maher & Mackay, 2009). Previously, the 11 points GROC has been reported to have a threshold of a clinically important change of 2 or greater (Ferreira et al., 2007) and a minimal detectable change of 0.45 (Costa et al., 2008) in individuals with low back pain. The GROC was considered for the nine functional domains of the SIS. Also, the clinical outcomes including the Modified Ranking Scale (MRS), Barthel Index (BI), Fugl-Meyer Assessment (FMA), Berg Balance Scale (BBS), and gait speed calculated from the 10-meter walk test were assessed and compared between the baseline and after the 12-week treatment.

The data analysis examined the differences between SIS and all clinical outcomes between the baseline and after the 12-week physical therapy treatment. Then, the authors explored the correlation between GROC and the SIS in each domain, and, finally, the authors also explored the correlation between GROC and changes in the other clinical outcomes after the 12-week physical therapy treatment.

3.3 Statistical analysis

Descriptive analysis was used for the demographics and participant characteristics. The data distribution was tested using the Shapiro-Wilk test. For almost all of the variables, the data were found to be not normally distributed; therefore, nonparametric analyses were used. The Wilcoxon signed-rank test was used to compare the variables between the baseline and after 12 weeks of physical therapy treatment. To determine the concurrent validity of the GROC with the SIS, the authors explored the correlation between the GROC score and the change in score for each domain of the SIS and the change in score of the other clinical outcomes. Besides, the authors explored the correlation between each domain of the SIS and the other clinical outcomes. All correlations were performed using Spearman's rank correlation coefficient (r_s). All statistical analyses were performed using SPSS (PASW 18.0.0, 2009) and the significance level was set to $P < 0.05$.

4. Results and Discussion

4.1 Results

Of the 63 potential participants who responded to the advertisements, 55 participants were interested in the study and met the inclusion criteria. Eleven participants were excluded from the present study due to nine participants withdrew from the intervention and two participants could not complete the questionnaires. Therefore, 44 participants were left in the current analysis. These included 26 males and 18 females with a median age of 54 (45.03, 62.75) years and a median time since stroke onset of 3.05 (1.23, 3.75) years. Twenty-four participants had hemiparesis affecting their right side while another 20 had hemiparesis affecting their left side (Table 1).

Table 1 Demographics of the participants (n = 44)

Characteristics	Values
Age (years), median (Q1, Q3)	54 (45.03, 62.75)
BMI (kg/m^2), median (Q1, Q3)	23.29 (20.76, 25.57)
Gender, number (%)	
Male	26 (59.1%)
Female	18 (40.9%)
Side affected, number (%)	
Right	24 (54.5%)
Left	20 (45.5%)
Duration since stroke onset	3.05 (1.23, 3.75)
Type of stroke, number (%)	
Ischemic	23 (52.3%)
Haemorrhagic	21 (47.7%)
Underlying disease, number (%)	
Hypertension	29 (65.9%)
Dyslipidaemia	16 (36.4%)
Diabetes	12 (27.3%)
Heart disease	3 (6.8%)

BMI: Body mass index, Q1: 25th percentile, Q3: 75th percentile

Significant differences were seen between the baseline and after 12 weeks of physical therapy treatment for the SIS score in the domains of strength, emotion, ADL, mobility, social participation, and global recovery. Also, the GROC score showed a median score of +3.25 (3, 4) after 12 weeks of physical therapy treatment, indicating a clinically important change above the threshold of +2 (Table 2).

Table 2 Comparison of the Stroke Impact Scale (SIS) in each domain and clinical outcomes at the baseline and 12 weeks.

Outcomes	Baseline Median (Q1, Q3)	12 weeks of PT Median (Q1, Q3)	*P*-value
SIS domains (100 scores)			
Strength	41.62 (25, 59.38)	50.03 (25, 70)	0.017*
Memory	93.72 (96.41, 100)	94.07 (100, 100)	0.233
Emotion	94.94 (94.44, 100)	98.54 (100, 100)	0.007*
Communication	93.34 (100, 100)	94.56 (93.75, 100)	0.887
ADL/IADL	79.15 (58.13, 97.50)	86.53 (75, 100)	0.012*
Mobility	85.01 (75, 100)	88.47 (56.95, 97.22)	0.009*
Hand function	36.59 (0, 95)	49.09 (0, 98.75)	0.065
Social participation	89.35 (87.5, 100)	96.73 (100, 100)	<0.001*
Global of recovery	40.20 (20, 60)	63.80 (50, 80)	<0.001*
Modified Ranking Scale (0-5 scores)	2.48 (1, 4)	2.45 (1, 3)	0.782
Bathel Index (100 scores)	86.25 (81.25, 100)	87.16 (81.25, 100)	0.344
Fugl-Meyer Assessment – Upper Extremity (66 scores)	27.80 (10, 40)	27.16 (10, 40)	0.476
Fugl-Meyer Assessment – Lower Extremity (34 scores)	19.66 (12, 27.75)	19.66 (12.25, 28)	0.284
Berg Balance Score (56 scores)	42.27 (34.5, 52.75)	42.50 (34.25, 51)	0.684
Gait speed (m/s)	0.60 (0.58, 1.68)	0.64 (0.61, 1.90)	0.313
Global Rating of Change Score (-5 to 5 scores)	-	3.25 (3, 4)	-

* significant ($P < 0.05$) from the Wilcoxon Signed-Rank test
Q1: 25th percentile, Q3: 75th percentile

The Spearman's rank correlation coefficients revealed fair correlations between the GROC score with the changes in 3 of the domains of the SIS (emotion domain, $r_s = 0.38$, $P < 0.05$, mobility domain, $r_s = 0.41$, $P < 0.05$, and global recovery, $r_s = 0.39$, $P < 0.05$, respectively). For the remaining SIS domains, no significant correlations with the GROC were seen ($P > 0.05$) (Table 3). Besides, the GROC showed no correlation with any changes in the MRS, BI, FMA-UE, FMA-LE, BBS, or gait speed ($P > 0.05$) (Table 4).

Table 3 The correlation between the Global Rating of Change Scale (GROC) and each domain of the Stroke Impact Scale (SIS)

	SIS domains	Spearman correlation (r_s)	*P*-value
GROC	Strength	0.22	0.151
	Memory	0.02	0.951
	Emotion	0.38	0.048*
	Communication	0.007	0.664
	ADL/IADL	0.24	0.120
	Mobility	0.41	0.032*
	Hand function	-0.27	0.078
	Social participation	0.18	0.251
	Global of recovery	0.39	0.038*

* significant ($P < 0.05$) from Spearman's correlation coefficient
ADL: Activity daily living, IADL: Instrument activity daily living

Table 4 The correlation between the Global Rating of Change Scale (GROC) and other clinical outcomes

	Clinical outcomes	Spearman correlation (r_s)	*P*-value
GROC	Modified Ranking Scale	-0.19	0.218
	Bathel Index	0.25	0.143
	Fugl-Meyer Assessment – Upper Extremity	-0.27	0.076
	Fugl-Meyer Assessment – Lower Extremity	-0.03	0.883
	Berg Balance Score	0.22	0.587
	Gait speed	-0.19	0.604

* significant ($P < 0.05$) from the Spearman's correlation coefficient

4.2 Discussion

This study aimed to compare the SIS and other clinical outcomes including the MRS, BI, FMA-UE, FMA-LE, BBS, and gait speed between the baseline and after 12 weeks of physical therapy treatment. Secondly, to investigate the correlation between the GROC with the SIS and clinical outcomes in individuals with chronic stroke. The SIS 3.0 was designed to capture a range of domains related to health and quality of life in individuals after a stroke. Concurrent differences between the baseline and after 12 weeks of physical therapy treatment were explored in SIS and clinical outcomes with the same or similar domains. However, significant differences were only seen in all the SIS questionnaire domains except for communication. Consistent with previous literature, the SIS and other clinical measurements (MRS, BI, FMA-UE, FMA-LE, BBS, and gait speed) taken may not be associated with functional improvements (Duncan et al., 2003a; Carod-Artal et al., 2008; Choi et al., 2017). The SIS is often cited as overcoming floor and ceiling effects which are present in other measures including the Functional Independence Measure (FIM), BI, and MRS (Carod-Artal & Egido, 2009). In this study, there was no evidence of floor effects. However, ceiling effects were noted for several SIS domains, which may be due to confounding factors influencing health-related quality of life, such as gender, psychological and social participation, that appear to affect this data. Previous studies have found that women who survive stroke have less favorable outcomes than their male counterparts and are more likely to have physical impairments and limitations in their ADL (Carod-Artal & Egido, 2009; Olsson & Sunnerhagen, 2007). Besides, in terms of psychological factors, especially depression commonly occurs after a stroke, with an estimated prevalence as high as 30% in the first year after the stroke event (Carod-Artal & Egido, 2009). Post-stroke depression affects functional recovery, cognitive function, and healthcare use in individuals with stroke (Carod-Artal & Egido, 2009). Social participation also affects those individuals with stroke considered fully recovered. Individuals with stroke who are perceived as functionally independent at 3 months after the stroke event still experience social isolation and social participation difficulties (Carod-Artal & Egido, 2009; Scott et al., 2012).

The GROC is frequently used in clinical trials as an outcome measure to rate self-perceived improvement independently. It has also been used as an anchor method to determine minimal clinically important change scores (Ferreira et al., 2007). However, no previous study has been carried out which considers the correlation of the GROC with the changes in clinical outcomes in stroke patients. This study investigated the correlation between the GROC with the change scores in the SIS and other clinical outcomes in individuals with chronic stroke. The GROC showed a fair degree of correlation with the change scores of SIS and with the other clinical outcomes after 12 weeks of physical therapy treatment, with significant correlations between GROC and three domains of the SIS; emotion ($r = 0.38$, $P = 0.048$), mobility ($r = 0.41$, $P = 0.032$), and global recovery ($r = 0.39$, $P = 0.038$). Possible explanations for only achieving a fair correlation are that the GROC may measure a construct outside of the domain of functions that will depend on the exact nature of the GROC question (Kamper, Maher & Mackay, 2009; Bobos et al., 2019). Because the SIS is a multidimensional questionnaire, one could argue that that construct is specific to each patient, and this finding may have limited impact (Carod-Artal et al., 2008; Garnjanagoonchorn & Dajpratham, 2015; Richardson et al., 2016). However, the GROC scores showed a group clinical improvement between the baseline and after the physical therapy treatment, which were in agreement with the group changes in strength, emotion, ADL, mobility, social participation, and global recovery domains of the SIS, suggesting that the

chances for identification of a self-perceived improvement reduce over 12 weeks of the PT treatment program in individuals with chronic stroke and other studies examined GROC related positive outcomes over a shorter term (Kamper, Maher & Mackay, 2009; Garrison & Cook, 2012). As the majority of studies have only used the GROC for short-term analysis, it is unlikely that this phenomenon has been observed during these studies (Fulk et al., 2010; Fulk et al., 2011; Garrison & Cook, 2012; Page, Fulk & Boyne, 2012; Garnjanagoonchorn & Dajpratham, 2015). Furthermore, the GROC showed no correlation with any changes in the MRS, BI, FMA-UE, FMA-LE, BBS, and gait speed. There are some criticisms of the GROC scale, which is frequently based on Ross's theory of implicit change relating to how people construct their memories (Ross, 1989). Ross suggested that people formulated a view regarding the presence or absence of change within a certain construct and their change score is based on this view. This rating method may lead to either understatement or exaggeration of the score when compared to the actual change determined by serial measurements (Ross, 1989). Besides, participants may have difficulty recalling their initial status when reporting the change of ability on the GROC scale and maybe more inclined to report on their current status level instead. However, in our population who are individuals with chronic stroke, it appeared that they were able to accurately report the change in emotional, mobility, and global recovery on the GROC as there was some degree of correlation. Other queries have been raised by researchers regarding the reliability of the estimation of previous health status by patients (Herrmann, 1995; Kamper, Maher & Mackay, 2009). A previous study described the problem of "recall bias" in particular when events between the anchor points influence the recall of the original status (Kamper, Maher & Mackay, 2009). Moreover, Schwartz and Sprangers described a "response-shift" where the response of a patient is influenced by changing the perception of their contexts (Schwartz & Sprangers, 1999).

Further work should consider the ability of patients to accurately recall and score a previous health state, which is one of the principal criticism of the GROC scales. The criticism is that the scores are unduly influenced by a patient's current status rather than the intended measurement of transition. It could also be limited in individuals with impaired memory, or the duration of treatment is not sufficient to be able to recognize a change. Further work is also needed to determine the best-tailored question in individuals with stroke, and the confounding factors influencing the ceiling effects of the SIS domains should also be considered in more detail in future studies.

5. Conclusion

Comparisons between the baseline and after-treatment showed significant grouped improvements in some domains of the SIS, which was accompanied by a clinically important change in the grouped GROC scores. There was a fair correlation between the GROC and the SIS; therefore, the GROC scale could be applied to suit the needs of physiotherapists or clinicians when time and difficulties in other methods of assessment exist.

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