

Research article

Stroke self-efficacy questionnaire (SSEQ), a reliable measure of disease burden: psychometric validation of the Romanian version

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Citation: Chirap-Mitulschi I.A., Antoniu S.A., Ignat B.E., Alexa D., Pintilie L., Boiculese L. - Stroke self-efficacy questionnaire (SSEQ), a reliable measure of disease burden: psychometric validation of the Romanian version
Balneo and PRM Research Journal 2023, 14(4): 620

Academic Editor(s):
Constantin Munteanu

Reviewer Officer:
Viorela Bembea

Production Officer:
Camil Filimon

Received: 08.11.2023
Accepted: 04.12.2023
Published: 20.12.2023

Reviewers:
Bogdan Caloian
Gabriel Cismaru

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Abstract: Self-efficacy is a relevant outcome measure of functional status in stroke research. It can be measured with various patient-reported outcome (PRO) tools, which can be generic or disease (stroke) related. However, in Romania, there is a limited availability of such measures. The Stroke Self-Efficacy Questionnaire (SSEQ) is a specific PRO scale that measures the impact of stroke on self-management and on performance of daily activities. We conducted a two-stage study: (1) translation and cross-cultural adaptation of the SSEQ-Romanian version (SSEQ-RO) and (2) a prospective cohort clinical study designed for psychometric validation of the SSEQ-RO. For the enrolled stroke patients, Barthel index, quality of life and indexes of disease severity, such as NIHSS, MRC and mRS, were measured at baseline and ten days. For psychometric validation we assessed construct validity, reliability and repeatability. In a sample of fifty stroke patients, SSEQ-RO was found to have an excellent construct validity, excellent reliability (Cronbach's alpha = 0.92), and repeatability (ICC = 0.91). SSEQ-RO was also a good measure of disease burden in mild versus moderate to severe stroke as assessed with NIHSS ($p = 0.002$). In conclusion, for stroke patients, SSEQ-RO is a reliable PRO able to assess the impact of stroke on the ability to perform daily activities and, therefore can reliably be used to monitor functional status dynamics during the disease course.

Keywords: disease burden, functional status, palliative care, psychometric validation, quality of life, Romanian, self-efficacy, stroke;

1. Introduction

Stroke is currently the leading cause of significant long-term impairment in people over the age of 65. Every year, about 800,000 people experience a stroke, with roughly 600,000 of these events being new cases (1, 2). Stroke can significantly impact a person's ability to perform daily activities, as it often resulting in physical, cognitive, and emotional challenges. Stroke recovery is a gradual process, and the rehabilitation program has a critical role in regaining independence in daily activities. Functional status is one of the primary outcome measures used to document the efficacy of rehabilitation and the stroke course and there are several methods used to assess it. One of these measures is represented by self-efficacy, which, in the context of stroke, refers to a person's belief in

their ability to successfully perform specific tasks or actions related to stroke recovery and management (3, 4). Recent studies described self-efficacy as a key factor in the rehabilitation process, this concept being well correlated with various post-stroke outcomes like activities of daily living, mobility and overall quality of life (5, 6). Self-efficacy is also a measure of perceived stroke-related disability and it is therefore used as a marker of effectiveness of rehabilitation approaches in stroke. More recently self-efficacy emerged as a marker of effectiveness of occupational therapies and home self-management which can be performed in such patients (7). Because it influences an individual's capacity to participate in health-promoting activities such as regular exercise, a balanced diet, and medication adherence, self-efficacy is an important predictor of health outcomes (8).

In order to quantify self-efficacy in the specific setting of stroke, Jones and colleagues (9) developed The Stroke Self-Efficacy Questionnaire (SSEQ) as a self-report instrument (patient-reported outcome, PRO). They tested its psychometric properties in 112 stroke survivors who had their acute event between two and twenty-four weeks before being enrolled in the study (9). This instrument was then also successfully validated in Chinese (10), Portuguese (11), Danish (12, 13), Italian (14) and Turkish (15). In Romania, despite the excellent development of stroke-related rehabilitation activities, there is a lack of validated self-efficacy measures. In the following analysis, we translated, cross-cultural adapted, and psychometric validated the Romanian version of the SSEQ-RO in patients with stroke undergoing rehabilitation. We demonstrated that this is a reliable tool which is able to evaluate self-efficacy and which can be used in Romania to assess the effectiveness of rehabilitation activities.

2. Methods

This was a two-stage study aimed to translate and validate the SSEQ-RO in stroke patients. In the first stage, after obtaining permission from SSEQ authors, translation and cross-cultural adaptation according to a standardized procedure were performed and SSEQ-RO final working version was obtained. Cross-cultural adaptation was performed by the first two authors according the recommendations of the guidelines elaborated by the ISPOR Task for Translation and Cultural Adaptation (16). The most clinically acceptable terms were chosen in order to minimally change the meaning of the scale. In order to have semantic and conceptual equivalence it was necessary to adjust some terms for questions 5, 9 and 11. A very good equivalence certified by the author was achieved with the back translation of the working version (Romanian, culturally adapted). The following steps were followed and are schematically presented in the Figure 1:

1. Instrument selection and obtaining the agreement from the original author for translation and validation.
2. Two independent English to Romanian translations by certified translators.
3. Uniformization of the two translation into the first SSEQ-RO working version. At this stage, cross-cultural adaptation was performed by the first two authors.
4. Back translation: given that minimal cultural adaptation required, the back translation (Romanian to English) by a third certified translator was a very smooth process, with no objections from the tool author.
5. Validation process of the SSEQ-RO working version.

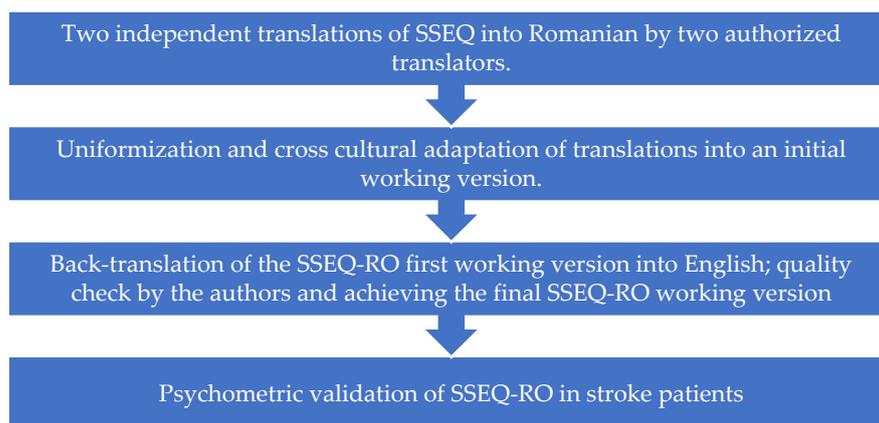


Figure 1. Description of validation process of the SSEQ-RO questionnaire.

In the second stage, a prospective cohort clinical study was performed with SSEQ-RO in stroke patients. This study was conducted and hereby reported according to the STROBE Guidelines (17).

2.1 Study participants

Patients with stroke undergoing rehabilitation, hospitalized between June 2023 and August 2023 in the Neurology Department of the Clinical Rehabilitation Hospital of Iasi, Romania, were enrolled after signing the informed consent and after being checked for eligibility criteria. The inclusion criteria were: age over 18 years, confirmed diagnosis of stroke by image or medical report and adequate cognitive status. Excluded were patients who refused to sign the informed consent, were too ill to complete the questionnaires, and those with severe aphasia or dysarthria. The study received Ethical Approval from the Hospital Ethics Committee.

2.2 Variables and parameters

Age, gender, presence of comorbidities (hypertension, diabetes and atrial fibrillation), type of stroke, stroke duration, nutritional status, quality of life, scores of stroke severity, functional status and inflammation status were recorded.

Quality of life was measured with the Visual Analogue Scale of the EuroQOL-5D-5L (EuroQol-VAS). The EuroQol-5D-5L (EQ-5D-5L) questionnaire is a widely used generic tool for assessing health-related quality of life. The EQ-5D-5L questionnaire consists of two parts: a descriptive System and a Visual Analog Scale (VAS), where individuals rate their overall health on a scale from 0 (worst imaginable health) to 100 (best possible health). EuroQol-VAS provides a single summary score for an individual's health. The following characteristics recommend EQ-5D-5L as a valuable tool for measuring health outcomes: (1) easy to administer, (2) it is brief and straightforward for patients to complete, and (3) provides a standardized way to compare the health-related quality of life across different conditions and populations (18). For stroke survivors, including those with palliative care needs, EuroQoL-5D was found to be a reliable tool for assessing quality of life (19, 20).

Stroke severity scores were represented by:

- The NIH Stroke Scale (NIHSS) is a widely used neurological assessment tool designed to evaluate the severity of stroke-related neurological deficits in patients. It is administered by a trained healthcare professional, such as a physician or nurse, (21). The NIHSS score, which runs from 0 to 42, is calculated as the sum of 15 separately assessed components. There are several categories for stroke severity: no stroke symptoms, 0; minor stroke, 1–4; moderate stroke, 5–15; moderate to severe stroke, 16–20; and severe stroke, 21–42.
- The Modified Rankin Scale (mRS), or the Modified Rankin Disability Scale, is a clinical measure used to assess functional disability or reliance in people who have had a stroke or other neurological illness. It offers a systematic method to evaluate a person's handicap level and how it impacts their everyday life. The Modified Rankin

Scale consists of seven levels, each representing a different degree of disability or functional impairment. The mRS standardizes how a patient's functional status is communicated, making it easier for healthcare providers to track changes over time and compare outcomes across different studies and patient populations (22).

- The MRC (Medical Research Council) muscle power scale, also known as the MRC scale or MRC grading system, is a system used by healthcare professionals to assess and quantify the strength or power of specific muscle groups in patients. It is commonly used in clinical practice, particularly in neurology and rehabilitation, to evaluate muscle strength, monitor changes over time, and plan appropriate treatments and interventions. The MRC muscle power scale typically ranges from 0 to 5, with each level representing a specific degree of muscle strength. It's important to note that the MRC muscle power scale is a subjective assessment and relies on the examiner's expertise (23).

For functional status assessment we used Barthel Index (BI) as a validated tool and SSEQ-RO, which underwent psychometric validation.

The SSEQ-RO was the main functional status instrument in this study, and it was created by Jones et al. to assess self-efficacy in stroke survivors (9). It consists of 13 questions regarding the individual's confidence in performing functional activities of daily living and self-management. Each question can be answered on a 4-point Likert scale, with 0 being "not at all confident" and 3 representing "extremely confident." The overall score goes from 0 to 39 points; the higher the score, the stronger the individual's self-efficacy. The scale can also be divided into two subscales, with items 1 through 8 showing an activity scale and items 9 through 13 showing a self-management scale (9, 24).

Barthel Index (BI) was the other measure of functional status used in the psychometric validation. BI is a very reliable and widely used tool in the rehabilitation field. It measures a person's ability to perform activities of daily living (ADLs) (25). The Barthel includes 10 personal activities. Each of these items is assigned a score based on the individual's level of independence, and the scores are then summed to provide an overall assessment of the person's functional status. The total score ranges from 0 to 100, in steps of 5, with a higher score indicating a higher level of independence in activities of daily living. Lower scores represent a greater degree of dependence and impairment in performing a specific task (26). BI is also an advantageous scoring system for predicting the prognosis of individuals with acute stroke (27).

Inflammation status was documented with serum C reactive protein (CRP).

2.3 Sample size estimation, statistical analysis and psychometric tests

Considering that the SSEQ questionnaire has 4 possible answers and 10 patients are needed for each possible answer (28), we enrolled 50 patients to have a sufficient number even in the case of missing data. The sample size was consistent with other similar studies (11, 12).

For data analysis we used MedCalc® Statistical Software version 22.001 (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2023) and IBM SPSS Statistics (version 20, Chicago, USA). Relevant baseline features were assessed with descriptive statistics.

Construct validity was evaluated with both convergent and divergent validity. We calculated the Pearson's correlation coefficients between SSEQ-RO and relevant variables (see below). Responsiveness was assessed as a capacity to show contrast between different severity groups according to NIHSS score categories (29). Reliability (internal consistency) was evaluated with Cronbach's alpha. A value between 0.70 and 0.95 is considered acceptable (30). Repeatability (test-retest reliability) was evaluated with the intraclass correlation coefficient (ICC).

3. Results

Table 1 summarizes the socio-demographic and relevant baseline data of the sample used to validate the SSEQ-RO questionnaire. The total sample included 50 stroke survivors with a mean age of 65.1 years, 28 (56%) being male and 22 (44%) female. Figure 2 shows that the baseline SSEQ-RO total score correlates inversely proportional with age

($r = -0.51$, $p < 0.0001$). When we analyzed the impact of age category on the SSEQ score we found that in the elderly (at least 65, $n=27$ patients) compared to the non-elderly (aged less than 65, $n=23$ patients) results showed a mean SSEQ total score at baseline of 15.33 ± 8.62 for the former category versus 23.78 ± 9.74 , for the latter ($p=0.002$). The self-efficacy baseline levels did not significantly vary according to the stroke subtypes (19.85 ± 9 for hemorrhagic type versus 19.11 ± 10.25 for ischemic type, $p = 0.85$) or according to gender (20.22 ± 10.97 for females versus 18.42 ± 9.31 for males, $p = 0.53$) (Figure 3). Most of the patients experienced an ischemic stroke, with only 7 (14%) events being hemorrhagic. Stroke duration was, on average, 19.04 (± 22.6) months. The prevalence of comorbidities was 84% for hypertension, 15% for atrial fibrillation, and 28% for diabetes.

Table 1. Baseline characteristics of the enrolled stroke patients

Variable/parameter	Total (n = 50)
Age, mean (SD)	65.1 (10.05)
Gender, n (%)	
• Male	28 (56)
• Female	22 (44)
Stroke type, n (%)	
• Ischemic	43 (86)
• Hemorrhagic	7 (14)
Comorbidity, n (%)	
• Hypertension	42 (84)
• Diabetes Mellitus	14 (28)
• Atrial fibrillation	15 (30)
SSEQ score baseline, mean (SD)	19.22 (10.01)
SSEQ score 10 days, mean (SD)	17.48 (9.55)
VAS EQ-5D-5L baseline, mean (SD)	48.78 (23.78)
NIHSS score baseline, mean (SD)	5.98 (3.02)
mRS score baseline, mean (SD)	3.18 (1.25)
MRC score baseline, mean (SD)	2.38 (1)
BI score baseline, mean (SD)	61 (25.67)
Serum CRP (mg/dl)	1.2 (1.53)
BMI	28.55 (5.66)

n = number of participants, SD = standard deviation, SSEQ = Stroke Self-Efficacy Questionnaire, BI = Barthel Index, CRP = C reactive protein, BMI = body mass index, VAS EQ-5D-5L: visual analogue scale of the EQ-5D-5L questionnaire

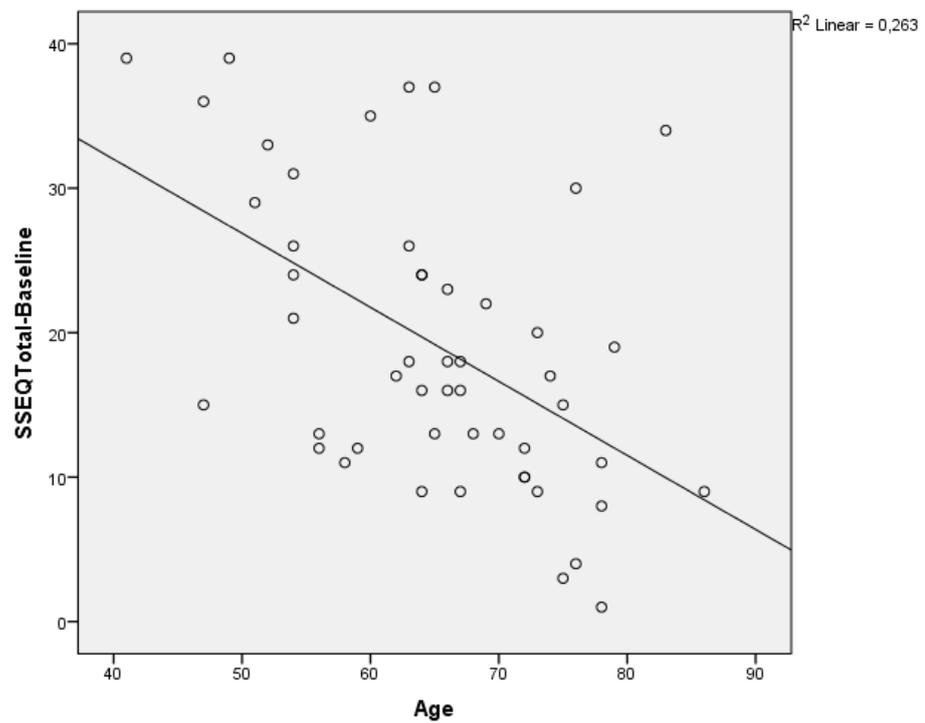


Figure 2. Relation between Baseline SSEQ-RO Total Score and Age ($r = -0.51$, $p < 0.0001$)

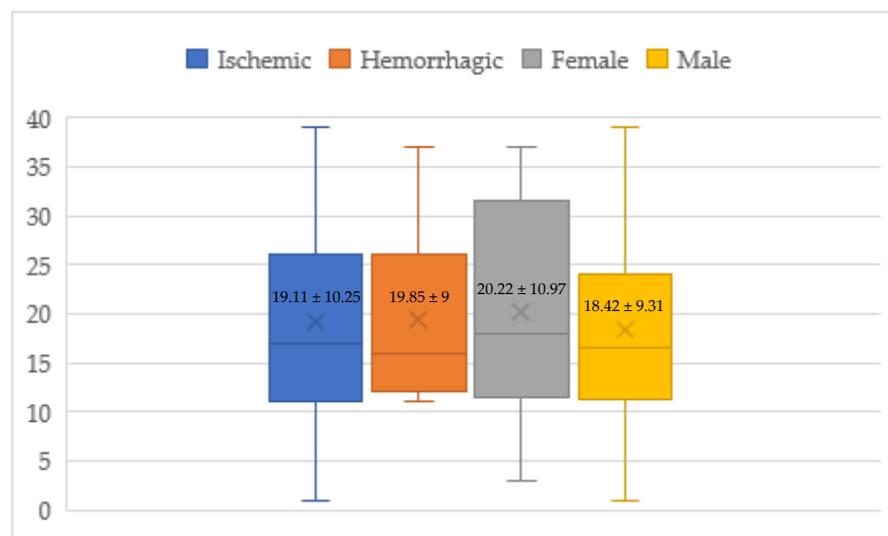


Figure 3. Impact of gender, respectively of stroke type, on baseline SSEQ score

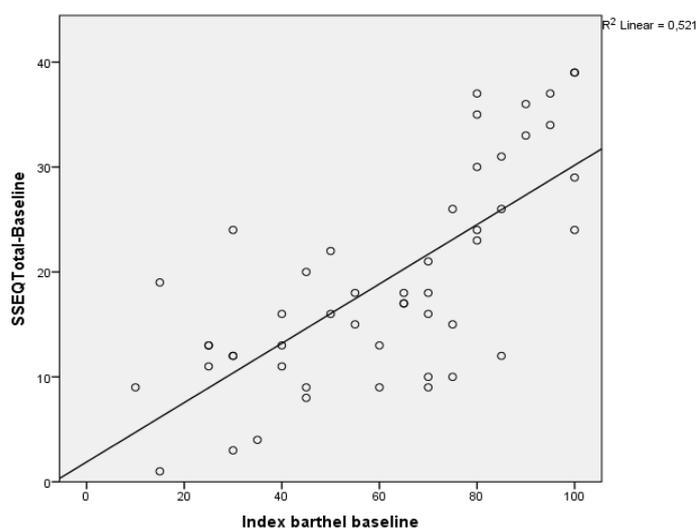
3.1. Construct validity

To determine convergent validity, we assessed the correlation between the SSEQ-RO on one side with quality of life, scores of stroke severity, and functional status on the other side. Table 2 summarizes these results and demonstrates that the strongest correlation was manifested with the BI score (see also Figure 4).

Table 2. Convergent validity for baseline SSEQ-RO score

	BI	MRC	NIHSS	mRS	VAS EQ-5D-5L
Sample size	50	50	50	50	50
Correlation coefficient r	0.7177	0.4662	-0.4585	-0.6732	0.5111
Significance level	P<0.0001	P=0.0006	P=0.0008	P<0.0001	P=0.0001
95% Confidence interval for r	0.5491 to 0.8302	0.2158 to 0.6590	-0.6534 to 0.2065	-0.8014 to 0.4859	-0.2713 to 0.6911

BI: Barthel Index; MRC: Medical Research Council; NIHSS: The NIH Stroke Scale; mRS: modified Rankin scale; VAS **EQ-5D-5L**: Visual Analog Scale of the EQ-5D-5L questionnaire

Figure 4. Relation between baseline SSEQ Total Score and baseline Barthel Index score ($r = 0.71$, $p < 0.000$)

Divergent validity was used to ensure that SSEQ-RO did not measure something unintended. For this purpose we chose to assess SSEQ-RO correlations with baseline serum C reactive protein, respectively with BMI. There were no correlations between baseline SSEQ-RO score with baseline serum C reactive protein or with baseline BMI ($r = -0.108$, $p = 0.45$ for the former, $r = 0.191$, $p = 0.18$ for the latter – Table 3). Our results suggest a direct proportionality between BMI and SSEQ-RO scores, which is in opposition to other studies that showed an inverse proportionality between self-efficacy levels and BMI (31).

Table 3. Divergent validity for baseline SSEQ-RO score

	CRP	BMI
Sample size	50	50
Correlation coefficient r	-0.108	0.191
Significance level	P=0.45	P=0.18
95% Confidence interval for r	0.5491 to 0.8302	0.2158 to 0.6590

CRP: C Reactive Protein; BMI: Body Mass Index

3.2 Responsiveness

As a responsiveness equivalent, we hypothesized that the SSEQ-RO score could be an indirect marker of disease burden. We assessed the disease burden in this study with the baseline NIHSS scores, considering that stroke burden was lower if baseline NIHSS score was not more than 4 (minor stroke) and that it was higher if scores at least 5. When comparing baseline SSEQ-RO scores for the two disease burden levels, we found that the baseline SSEQ-RO score corresponding to a lower stroke burden was significantly higher than that corresponding to a higher stroke burden (24.09 versus 15.68, $p=0.002$).

3.3 Construct reliability

The Cronbach's alpha calculated for the baseline SSEQ-RO score was 0.92, and with this value, it is considered highly reliable. Cronbach's alpha calculated for the original SSEQ version was reported to be 0.90, a value that is comparable to ours (9). Moreover, according to our analysis, the removal of any question would result in a lower Cronbach's alpha which means that each question is well-defined in the questionnaire construction.

In addition, no floor and ceiling effects for the baseline scores were observed; only one patient had a maximum total score on the SSEQ-RO, with none of the patients scoring 0 points.

3.4 Repeatability

Repeatability (test-retest reliability) assessed with interclass correlation coefficient (ICC) was found to be 0.91 ($p < 0.001$), which is above 0.90 value, indicating an excellent repeatability (scores stability over short periods).

4. Discussion

This study aimed to validate SSEQ-RO in stroke patients undergoing rehabilitation. Based on the results above presented, we demonstrated that this scale is a reliable instrument that can be used from now on in Romanian stroke patients to document functional status and even disease physical burden over the disease course and as a result of various therapies applied, or as a result of complications development.

As mentioned above, several versions were also validated before, starting from the original one.

The Chinese version (10) of SSEQ was validated on a sample of 135 stroke survivors with a lower mean age (58.8 years, SD 9.75) and a higher mean stroke duration (6 years) compared to our study. SSEQ-C showed a high internal consistency (Cronbach's alpha 0.92), similar to our value, but the ICC for the test-retest reliability was lower with a value of 0.52. For construct validity SSEQ-C was compared with Frenchay Activities Index (FAI), a measure of instrumental activities of daily living, a significant positive correlation being reported. We also compared SSEQ-RO with a measure of ADL, but we chose Barthel Index (BI) and the results showed a high positive correlation, which means that SSEQ-RO could be used as a measurement of functional status. Unlike Frenchay Index which measures instrumental ADLs, Barthel index focuses on basic ADLs and therefore better captures the true severity of functional status impairment in stroke, and potentially the need for palliative care measures (32).

Topcu Serpil and Oguz Sidika recruited 130 subacute stroke patients to validate the Turkish version of SSEQ. Despite of sample characteristics, Cronbach's alpha was 0.93 and the test-retest reliability score was $r = 0.80$ (15).

The Italian validation sample consisted of 149 patients with a mean age of 69.3 years and with an average of 16.6 days poststroke. Their results showed that SSEQ could measure two dimensions of self-efficacy, activity and self-management, both of them being strongly related to recovery and independence after stroke (14). While the original study described that all questions focus on a single domain (9), the two dimensions model was also supported by a Rasch analysis (24) and other validation studies of SSEQ (11, 14). Because of this interesting scale behavior described above, we chose to test SSEQ-RO as a one-domain questionnaire, but we contemplate considering the Italian approach in a subsequent study.

In the study reporting the validation of the SSEQ Portuguese version performed on a sample of 40 chronic stroke survivors, high intra-examiner reliability (ICC 0.86), acceptable internal consistency (Cronbach's alpha 0.68), and positive relationship between SSEQ-B and a stroke-specific quality of life measure were reported. In our study, we also identified a significant correlation of SSEQ-RO scores with EuroQol-VAS .

Regarding floor effect, previous studies reported similar results, but the ceiling effect varied between 7.5% and 61% for ceiling effect (11, 12, 15). Taking into consideration the variability of stroke chronicity in these studies, we can assume that SSEQ-RO could be a reliable measure regardless of the recovery stage.

Other examples of self-efficacy scales that can be used in stroke research include the General Self-Efficacy Scale (GSE) or The Self-Efficacy Scale for Exercise (SSE) (33, 34). However, both are generic instruments, the latter (SSE) rather being focused on age-related impairments in functional status. Therefore we consider that in the particular stroke setting SSEQ is most suitable for our purpose because of its disease specificity, good construct validity and reliability, and for its straightforward application technique. Moreover, database research did not report any other self-efficacy measurement tools related to stroke patients.

The main limitation of our validation study is the fact that we were not able to completely assess the responsiveness of the scale in stroke inpatients undergoing rehabilitation because of the limited duration of hospitalization and the lack of sensitivity and relevance of measurements done over shorter periods. While the original study did not report a retest of SSEQ questionnaire on their study group, other studies advise performing the retest 2 to 6 weeks apart, periods which in our study were not possible to be taken into account (15). Another limitation was the inability to measure the minimal clinically important difference, this parameter requiring a larger sample and a slightly different methodology

Finally, a good aspect of our study could be that we enrolled patients with different post-stroke periods, ranging from one week to more than five years, this aspect also being underlined as a necessity by the original article (9).

Because we demonstrated in this analysis that SSEQ-RO can be reliably used in Romanian stroke patients, we plan to use self-efficacy as a marker of palliative care need in these patients. This is a new research direction able to identify a potentially unexpected use of such a scale in stroke setting.

5. Conclusions

In conclusion, SSEQ-RO is a valid, reliable and stable instrument, concurrent validity with quality of life, functional status, motor deficit or stroke severity being demonstrated. It's important to note that self-efficacy can change over the recovery period and can be influenced by various factors, including personal experiences, social support, and the effectiveness of rehabilitation programs. This instrument might be beneficial in documenting the self-efficacy impairments factors in stroke survivors and the related disease burden and therefore could be used in various stages of stroke course, including those with contemplated palliative care. The good correlation between SSEQ-RO and Barthel Index could be translated into clinical practice by using SSEQ to assess the functional status of stroke patients. Moreover, by detecting such impairments, targeted therapeutic interventions can be developed to accelerate recovery and improve the life quality of such patients.

Author Contributions: Conceptualization, S.A.A. and I.A.C.M.; methodology, S.A.A.; software, S.A.A, L.B.; validation, I.A.C.M., S.A.A and D.A.; statistics, L.B.; investigation, I.A.C.M.; resources, D.A.; data quality check, L.B.; writing—original draft preparation, I.A.C.M and S.A.A.; writing—review and editing, I.A.C.M, S.A.A., B.E.I, L.P.; visualization, B.E.I.; supervision, S.A.A.; project administration, I.A.C.M., D.A.;. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded with the Ioan Alexandru Chirap Mitulschi PhD Doctoral contract nr. 2297 from 2022 issued by the University of Medicine and Pharmacy "Grigore T. Popa" Iasi, Romania.

Acknowledgment: We would like to thank Professor Fiona Jones for the permission granted to translate and validate this scale and for her valuable recommendations.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors declare no conflict of interest.

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