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Measuring stroke impact with SIS: Construct validity of SIS telephone administration

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Abstract

Objectives: The purpose of this study was to examine the construct validity of the Stroke Impact Scale (SIS) using telephone mode of administration. *Methods*: Stroke patients were identified using national VA administrative data and ICD-9 codes in 13 participating VA hospitals. Stroke was confirmed by reviewing electronic medical records. Patients were administered SIS by telephone at 12-weeks post-stroke, and administered the Functional Independence Measure (FIM) and SF-36V at 16 weeks post-stroke. The instrument's convergent validity and its ability to differentiate between groups of stroke patients with different disability levels were examined using Pearson's correlations and Kruskal–Wallis one way ANOVA tests. *Results*: All the relevant relationships yielded high correlation coefficients with statistical significance: 0.86 for FIM-motor vs. SIS-ADL, and 0.77 for PF in SF-36V vs. SIS-PHYSICAL. The SIS presented better score discrimination and distribution for different severity of stroke than FIM and SF-36V without severe ceiling and floor effects. Kruskal–Wallis tests showed the Physical Component Score of SF-36V did not discriminate any disability levels. Physical functioning (PF) in SF-36V, FIM-motor, SIS-PHYSICAL, SIS-16, and SIS-ADL showed better discrimination in person's functioning. The pairwise comparisons showed that SIS-PHYSICAL, SIS-16, and SIS-ADL discriminated more Rankin levels than FIM-motor and PF in SF-36V. *Conclusions*: SIS telephone survey had superior convergent validity and was better at differentiating between groups of stroke patients with different disability levels than the FIM and SF-36V with no evidence of ceiling and floor effects. Telephone administration of SIS would be a useful and cost-effective method to follow-up community dwelling veterans with stroke.

Key words: Disability, Quality of life, Stroke, Stroke Impact Scale, Telephone administration, Validity

Introduction

Stroke is the leading causes of disability in the United States (US). Approximately 700,000–750,000 strokes occur in the US. It has been estimated that there are five million stroke survivors in the US with varying degrees of disability. The Veterans Health System also bears a significant stroke burden. Approximately 11,000 individuals are hospitalized in Veterans Health System facilities for acute stroke per year and based on the AHA ratio of stroke incidence and prevalence, up to 80,000 veterans may be stroke survivors [1]. Veterans Healthcare System's mission is to serve the needs of America's veterans by providing primary care, specialized care, and related medical and social support services. The Veterans Healthcare System serves over 5,000,000 veterans a year in over 160 hospitals and 330 outpatient clinics and centers located in all 50 states, operating the largest medical education, health professions training, and research in the US.

Stroke has a substantial impact on the physical and psychosocial aspects of well-being. The Agency for Health Care Policy and Research (AHCPR) [2] currently AHRQ, recommended using valid, reliable and sensitive instruments to measure stroke outcomes to measure the impact of stroke on person's well-being. The Barthel Index (BI) and the Functional Independence Measure (FIM) were recommended as ADL measures, Modified Rankin Scale (MRS) as a global disability measure, and Medical Outcomes Study (MOS) Short Form 36 (SF-36) and Sickness Impact Profile (SIP) were recommended as quality of life measures. The references for each instrument's validity and reliability can be found in the AHCPR guideline [2].

These instruments have been used in many clinical trials and epidemiological studies; however, ceiling or floor effects have been found that limit the ability of these instruments to evaluate stroke patient's disability prognoses or health outcomes over time. The SF-36 has shown floor effects while the ADL measures have shown ceiling effects, i.e., a large portion of patients are located in the highest or lowest possible score of the instrument, reducing the instruments' ability to detect change [3–5].

In this study, we used Veterans SF-36 (SF-36V), a short form health status scale for use among veterans. It was adapted from the MOS (Medical Outcomes Study) SF-36. The SF-36V measures eight concepts of health like SF-36: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health perceptions (GH), energy/vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). Items from each concept are summed and rescaled with a standard range from 0 to 100, where the score 100 denotes the best health. These eight concepts have also been summarized into two summary scores: a physical component summary (PCS) and a mental component summary (MCS).

The difference between SF-36 and SF-36V is in two role items (role limitations due to physical and emotional problems). The original items, dichotomized yes/no response choices, were changed to five point ordinal choices ('no, none of the time' to 'yes all of the time'). These changes to the role scales have increased the precision of the scales by more than 100% for the role-physical and 80% for the role-emotional scales, and lowered the floor and raised the ceiling of the metric as reflected in each of the scales' distributions. The modified scales have also improved precision of the physical and mental component summary scales by 5% [6].

Stroke Impact Scale (SIS) was developed with extensive psychometric test procedures. The most recent SIS, version 3.0 has 59 items in eight different domains: strength, hand function, ADL/IADL, mobility, emotion, memory, communication, and social participation. Through a course of our research to develop an instrument that has the capability to measure changes and follow the recovery of stroke patients, we showed that the Stroke Impact Scale (SIS) does not have significant ceiling or floor affects. The SIS also proved to have better discrimination among different levels of health status [7, 8].

Psychometric qualities of Stroke Impact Scale have already been published in a number of studies; however, those previous studies were based on in-person evaluation. Recently we completed a two-year project funded by HSR&D, Department of Veterans Affairs. The primary objective of this study was to assess the utility of the SIS in a community dwelling stroke survivors

with more realistic administration methods such as telephone and mail survey. We have published our findings on the response rate, response bias, reliability, data completeness, and internal consistency [9], showing that telephone administration is overall better administration method than mail. As a subsequent report, in this manuscript, we focus on the construct validity of telephone SIS administration.

Materials and methods

Subjects and data collection

This study used a prospective mixed (survey plus observational) design from 13 veterans hospital sites in the United States. Stroke patients were identified from the National Patient Care Database (NPCD) using International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes at discharge with a high sensitivity algorithm [1]. Stroke was confirmed by reviewing electronic medical records, radiology reports, neurology consults approximately 2–4 weeks following inpatient discharge. For confirmed stroke patients, discharge summaries and electronic medical records were reviewed to capture patients' age, gender, race, marital status, next of kin, provider specialty, stroke diagnosis source, stroke type and location, functional status at discharge, history of prior stroke, prior functional status, and prior neurological symptoms. Modified Rankin Scores (MRS; pre-stroke and post-stroke), cognitive impairment on discharge (dichotomous) and aphasia (dichotomous) were abstracted from patient medical records as well.

Telephone SIS administration

Patients with confirmed diagnosis of stroke received an introductory letter, informed consent with instructions and a stamped return envelope, telephone SIS survey instruction, at 10 weeks post-stroke. Two weeks later, at 12 weeks post-stroke, patients were contacted via telephone to obtain telephone consent, a cognitive screen, and the SIS survey. The estimated average length of telephone interview was approximately 30–40 min but varied for individual patients depending on their conditions. For the patients who were not reached by telephone, a SIS survey with instructions, informed consent, SF-36V, and stamped return envelope were mailed at 16 weeks post-stroke. At 16-weeks post-stroke, responders in both groups were re-administered a cognitive screen, FIM, and SF-36V survey via telephone.

Institutional review board and informed consent

The Veterans Health Administration requires informed consent to be signed by the patient and witnessed. A patient may complete the survey, however, this information cannot be used unless informed consent is completed and returned. To reconcile incomplete or non-returned consents, the investigators implemented a '3-attempt process'. This process was used to reconcile incomplete or non-returned consents. For patients whose consent was incomplete (e.g., missing witness signature), the consent was returned to the patient via mail asking for missing items. When the patient did not return the consent, an additional consent was forwarded to the patient asking for his/her completion. This was described in the previous publication [9].

Data analysis

Demographic information was captured from chart review, and statistical significance was determined via either chi-square or *t*-tests where appropriate. Two components in construct validity were examined. First, convergent validity with the correlations between SIS and FIM, and between SIS and SF-36V was examined with Pearson correlations. Second, the discriminating ability for dissimilar groups was compared among the three instruments in two ways. First, descriptive score distributions of the relevant domains in SF-36V, FIM, and the SIS such as the SIS PHYSICAL, SIS-16, and ADL/IADL domains, SF-36V PF, RP, and PCS, and FIM motor. Domain scores were examined for each MRS level, but MRS0 and MRS1 were combined due to small sample size of MRS0 ($n = 2$). Second, Kruskal–Wallis one way ANOVA and pairwise comparison tests were used to explore if the instrument discriminated different levels of disability. For this analysis we combined

MRS4 and MRS5 due to small sample size in MRS5 (n = 4 for FIM and SF-36V, and n = 5 for SIS domains).

Results

The study procedure and response rates are presented in Figure 1. Sixty eight percent of patients responded to the 12-week SIS telephone survey. Considering completeness of Veterans Health Administration specific informed consent process, the response rate dropped to 48%. Issues related to getting patient informed consent and more detailed information on response rates were described in the previous publication [9].

Differences in demographic characteristics were examined in several ways. First, 12-week SIS responders (n = 136) and non-responders (n = 62) were examined. Table 1 summarized the results. No systematic difference was found between SIS responders and non-responders, except next of kin ($p = 0.026$). Second, there was no statistical difference between overall responders (n = 136 + 8) and non-responders (n = 7 + 47). Third, we examined if there were differences between 12-week responders (n = 136) and 16-week responders (n = 8), and found no statistical difference in their demographics. For the last comparison, however, due to the small sample size of eight, the power of the analysis may be questionable.

For the statistical analyses, we only included the 95 telephone responders. Table 2 summarizes the convergent validity of SIS against established measures, the FIM and the SF-36V. Correlation coefficients are presented for the relevant relationships. All the relevant relationships presented statistical significance (p-value ≤ 0.05).

Figure 2 presents the score distribution of SIS PHYSICAL, SIS-16, and ADL/IADL, FIM motor, SF-36V PF, RP, and SF-36V PCS. Three respondents did not have baseline MRS scores recorded, so these individuals were excluded from the analysis. The three domains of SIS, SIS PHYSICAL, SIS-16, and ADL/IADL, did not show ceiling or floor effects compared to the FIM motor or SF-36V, PF, RP, and PCS domains.

Figure 2g illustrates that FIM motor does not differentiate MRS(0 + 1), MRS2, and MRS3, and scores are clustered at the high end showing ceiling effects. Figure 2e shows that the PCS in SF-36 does not discriminate hardly any disability levels in MRS by putting the scores at the lower end. Figure 2d and f demonstrate that PF and RP in SF-36V perform better discrimination by spreading the scores wider compared to PCS, but the mean and median scores barely cover the lower half of the possible score range. Figure 2a, b, and c display that SIS PHYSICAL, SIS-16, and SIS-ADL/IADL scores cover whole score range without any indication of ceiling or floor effect that was observed in FIM or SF-36V.

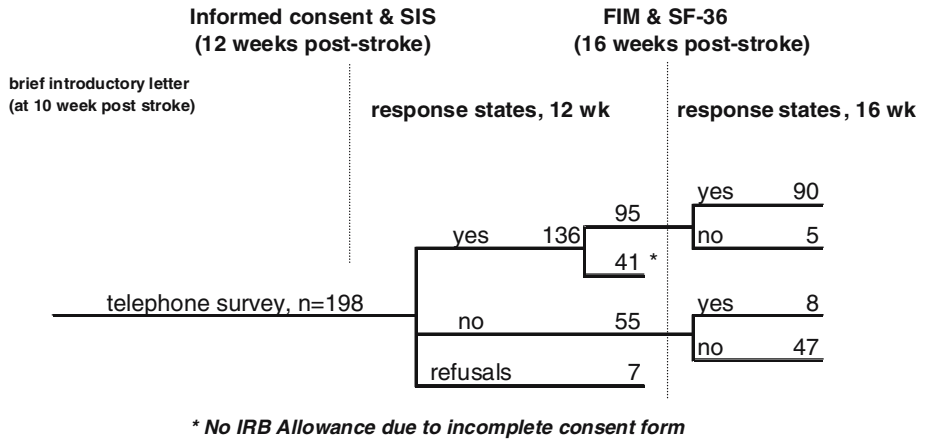

Figure 1. Instrument administration timeline for Modified Rankin Scale (MRS), Stroke Impact Scale (SIS), Functional Independence Measure (FIM), and MOS Short Form −36V (SF-36V).

Table 1. Responder and non-responder characteristics from chart review

Variable	Tel responders, N = 136		Tel non-responders, N = 62		*p*-value
Age (SD)	68.04 (12.0)		68.05 (12.5)		0.673
Gender – female	3	2.2%	0	0.0%	0.234
Race					
White	90	66.2%	42	67.7%	0.177
Black	14	10.3%	13	21.0%	
Hispanic	2	1.5%	0	0.0%	
Asian	5	3.7%	0	0.0%	
Other	4	2.9%	2	3.2%	
Missing	21	15.4%	5	8.1%	
Marital status					
Married	69	50.7%	29	46.8%	0.996
Divorced/separated	26	19.1%	12	19.4%	
Widowed	12	8.8%	5	8.1%	
Never married	5	3.7%	2	3.2%	
Missing	24	17.6%	14	22.6%	
Next of kin					
Spouse	65	47.8%	27	43.5%	0.026
Child	24	17.6%	2	3.2%	
Sibling	13	9.6%	12	19.4%	
Parent	8	5.9%	5	8.1%	
Other	19	14.0%	9	14.5%	
Missing	7	5.1%	7	11.3%	
Stroke type – ischemic	128	94.1%	60	96.8%	0.429
Prior functional status by MRS*					
0	67	49.3%	24	38.7%	0.62
1	26	19.1%	14	22.6%	
2	20	14.7%	8	12.9%	
3	8	5.9%	7	11.3%	
4	3	2.2%	1	1.6%	
5	1	0.7%	0	0.0%	
Missing	11	8.1%	8	12.9%	
Prior living status – community	129	94.9%	57	91.9%	0.69
Prior stroke	44	32.4%	23	37.1%	0.559
Prior stroke neurological symptoms	19	14.0%	14	22.6%	0.091
Discharge MRS*					
0	6	4.4%	1	1.6%	0.856
1	25	18.4%	11	17.7%	
2	24	17.6%	9	14.5%	
3	39	28.7%	19	30.6%	
4	30	22.1%	12	19.4%	
5	7	5.1%	5	8.1%	
Missing	5	3.7%	5	8.1%	
Cognitive deficit at discharge	30	22.1%	18	29.0%	0.219
Aphasia	30	22.1%	15	24.2%	0.715

* MRS = Modified Rankin Scale.
0: No symptoms at all, 1: No significant disability despite symptoms; able to carry out all usual duties and activities, 2: Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance, 3: Moderate disability; requiring some help, but able to walk without assistance, 4: Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance, 5: Severe disability; bedridden, incontinent and requiring constant nursing care and attention.

Table 3 shows the results of the Kruskal–Wallis one way ANOVA and *post-hoc* pairwise comparisons. SF-36V PCS was not able to make a distinction for any pair of disability levels. PF and RP in SF-36V, however, showed discrimination for two pairs of disability levels: the

Table 2. Convergent validity of SIS – correlations with established measure

	SIS domains								
	Strength	Memory	Emotion	Communication	ADL/IADL[a]	Mobility	Hand function	Social participation	PHYSICAL
FIM[b]									
FIM-M	0.404*	–	–	–	0.858*	0.738*	0.659*	0.588*	0.773*
FIM-C	–	0.501*	–	0.637*	–	–	–	0.549*	–
SF-36V [c]									
PF	0.477*	–	–	–	0.732*	0.755*	0.682*	0.667*	0.768*
RP	0.533*	–	–	–	0.711*	0.724*	0.631*	0.750*	0.750*
RE	–	–	0.504*	–	–	–	–	0.583*	–
SF	–	–	–	–	–	–	–	0.655*	–
BP	–	–	–	–	–	–	–	–	–
MH	–	–	0.713*	–	–	–	–	0.601*	–
VT	–	–	–	–	–	–	–	0.593*	0.529*
GH	0.460*	0.378*	0.460*	0.362*	0.503*	0.574*	0.470*	0.531*	0.576*
PCS	0.520*	–	–	–	0.586*	0.632*	0.628*	0.539*	0.687*
MCS	–		0.692*		–	–	–	0.618*	–

N = 89 for PCS vs. SIS, and MCS vs. SIS; N = 90 for the rest.
–, correlation is not relevant in nature.
*$p < 0.001$.
[a]ADL/IADL, Activities of Daily Living & Instrumental Activities of Daily Living.
[b]FIM, Functional Independence Measure. FIM-M, Motor component of Functional Independence Measure; FIM-C, Cognitive component of functional Independence Measure.
[c]SF-36V, Short Form-36 for Veterans. PF, physical functioning; RP, role physical; RE, role emotion; SF, social functioning; BP, bodily pain; MH, mental health; VT, vitality; GH, general health; PCS, physical component summary score; MCS, mental component summary score.

highest functioning, MRS(0,1) vs. lowest functioning level, MRS(4,5), and MRS2 vs. MRS(4,5) by taking account the borderline significance level ($0.05 < p < 0.07$). The FIM showed similar results to SF-36V PF. Three domains of SIS showed best performance among tested instruments by discriminating three pairs of disability levels.

Discussion

The development of Stroke Impact Scale and its performance as a stroke outcome measure with traditional in-person interview has been presented and published in previous works [8, 10–18]. This manuscript was prepared based on our project titled, 'Quality of Life in Veterans with Stroke' that was focusing on the feasibility and validity of telephone and mail administration of SIS in the community dwelling stroke survivors. We reported our findings that the telephone administration is superior to mail in response rate, data completeness, and internal consistency, with 2.2 times the cost of the mail survey [9].

In this study we evaluated the construct validity of SIS compared to the FIM and SF-36V with telephone administration methods. We found that the SIS held convergent validity when compared to the FIM and SF-36V, and showed better performance in discriminating stroke patient's physical functioning compared to SF-36V and FIM based on the baseline MRS, which was documented at hospital discharge.

The SIS domain scores in physical functioning context were significantly different across four MRS levels. Because of the small sample size in each extreme, MRS0 and MRS5, we were only able to demonstrate four different levels of MRS by collapsing MRS0 and MRS1, and MRS4 and MRS5. The better performance in discriminating physical functioning has been consistent with the previous studies [7, 8].

We recorded patient's MRS score at hospital discharge, SIS at 12 week post-stroke, and FIM and SF-36V at 16 week post-stroke. Ideally, engaged instruments may be administered at the same time to avoid any potential bias or alternative hypothesis. In fact, from our study design, it is

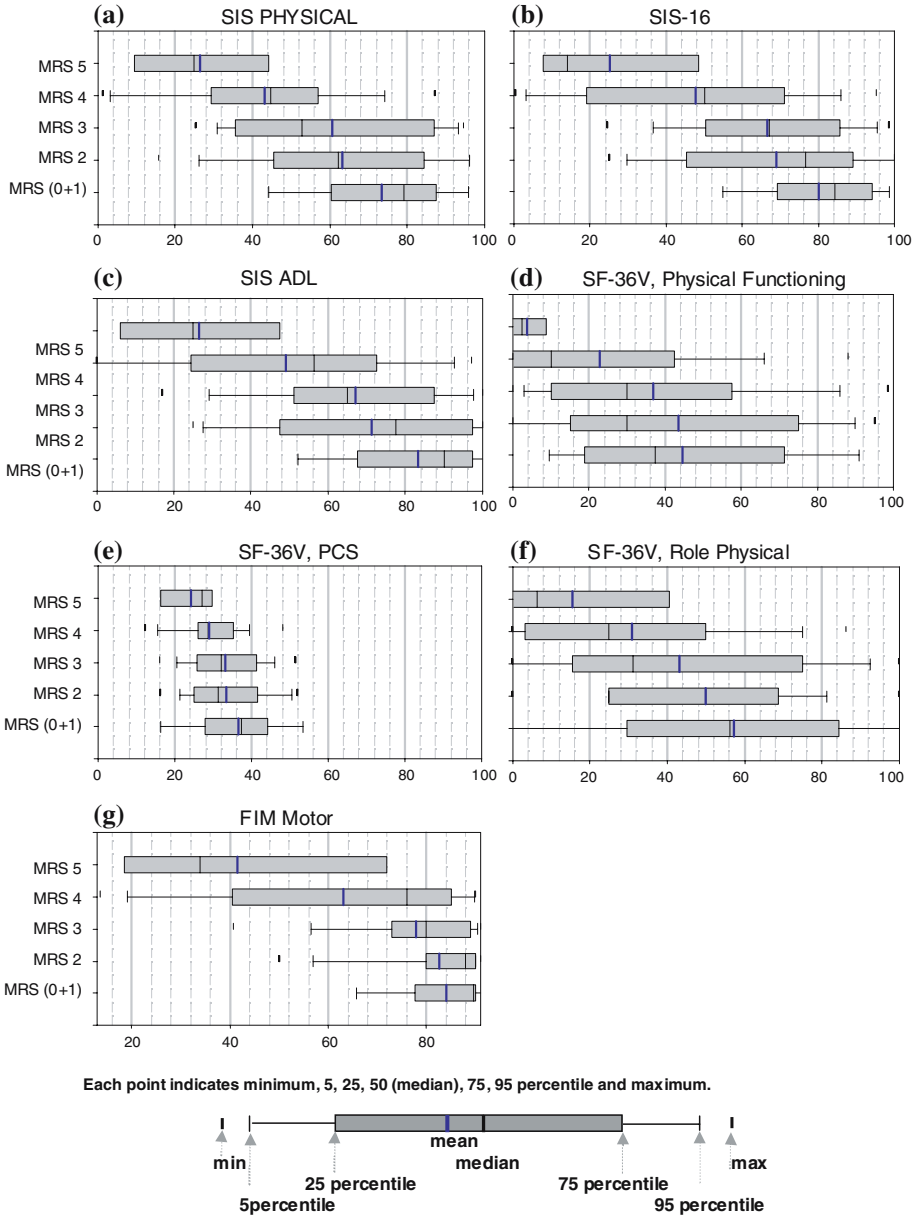

Figure 2. Score distribution for MRS.

possible to hypothesize that the ceiling/floor effects of FIM/SF-36V were caused by the 4-week time difference between the two administration points that might allow patients to recover more physical functioning. If this is the case, the better performance of the SIS in discriminating person's functioning reflects the natural recovery process rather than the discriminating ability of the instrument itself. However, we discarded the alternative hypothesis as there is evidence suggesting that the motor recovery in stroke patients occurs mostly within the first ninety days after stoke onset regardless of their severity of stroke. In other words, the 4 weeks difference after 12 weeks' post-stroke would not significantly change their physical functioning scores [7, 19].

Therefore, our results are consistent with other stroke outcomes research identifying a ceiling

Table 3. Discrimination of disability in SIS, FIM, and SF-36V

	PCS	PF	RP	FIMMOTOR	SIS16	SIS-PHYSICAL	SIS-ADL
Mean (25th–50th–75th percentile)							
MRS (0,1)	**36.43** (28.12, **37.22**, 42.78) N = 18	**44.44** (20, **37.5**, 70) N = 18	**57.29** (31.25, **56.25**, 81.25) N = 18	**84** (78, **89.5**, 90) N = 17	**80.12** (70.31, **84.38**, 93.75) N = 18	**73.36** (60.49, **79.29**, 86.98) N = 18	**83.19** (67.5, **90.0**, 97.5) N = 18
MRS2	**33.49** (25.08, **31.27**, 41.46) N = 19	**43.42** (15, **30**, 75) N = 19	**50** (25, **50**, 68.75) N = 19	**82.58** (80, **88**, 90) N = 19	**68.91** (45.31, **76.56**, 89.06) N = 19	**63.17** (45.56, **62.15**, 84.38) N = 19	**71.32** (47.5, **77.5**, 97.5) N = 19
MRS3	**33.24** (26.30, **31.95**, 39.79) N = 25	**36.8** (10, **30**, 55) N = 25	**43.25** (18.75, **31.25**, 75) N = 25	**77.88** (76, **80**, 88) N = 25	**66.57** (50.78, **67.19**, 85.16) N = 28	**60.68** (35.69, **52.88**, 86.77) N = 28	**66.96** (52.5, **65**, 87.5) N = 28
MRS(4,5)	**28.2** (26.09, **28.58**, 31.59) N = 24	**19.8** (0, **10**, 35) N = 25	**28.5** (0, **25**, 50) N = 25	**59.64** (33, **74**, 83) N = 25	**43.58** (10.94, **46.88**, 67.19) N = 27	**39.98** (24.97, **39.58**, 54.86) N = 27	**44.81** (22.5, **45**, 72.5) N = 27
Kruskal–Wallis test							
Observation (N)	86	87	87	87	92	92	92
Kruskal–Wallis statistic	6.33	11.63	10	17.83	19.17	18.39	18.79
p value	0.9650	0.0088	0.0185	0.0005	0.0003	0.0004	0.0003
p-values for-pairwise comparisons (Dwass–Steel–Chritchlow–Fligner)							
MRS (0,1) vs. MRS 2	0.7478	0.9949	0.803	0.9217	0.5094	0.5198	0.6815
MRS (0,1) vs.MRS 3	0.7857	0.7973	0.4916	0.3239	0.1862	0.4462	0.1145
MRS (0,1) vs. MRS (4,5)	0.0791	**0.0146**	**0.0257**	**0.0028**	**0.0004**	**0.0002**	**0.0004**
MRS 2 vs. MRS 3	$p > 0.9999$	0.9376	0.8702	0.4885	0.9869	0.9569	0.8816
MRS 2 vs. MRS (4,5)	0.4276	**0.0552**	**0.0626**	**0.0049**	**0.0308**	**0.0202**	**0.0244**
MRS 3 vs. MRS (4,5)	0.3786	0.0766	0.4192	0.0650	**0.0286**	**0.0537**	**0.0594**

effect of the FIM, and a floor effect of the generic quality of life measure, SF-36V when it is administered in stroke patients. The SIS scores, however, displayed no evidence of ceiling or floor effects, making the instrument more sensitive to evaluating stroke recovery.

Following patient's health status after discharge from acute hospitalization is becoming recognized as an important aspect of stroke care. From a societal perspective, stroke burden will only increase in the future due to the aging population, increasing stroke incidence trend, and high prevalence of stroke risk factors in population such as obesity and diabetes. Even though stroke case mortality has been decreasing over several decades because of the advances in medical technology, the societal burden is increasing due to increases in stroke survivors. Currently recommended and widely used measures in practice and research, however, may not be adequately evaluating stroke survivors' health status.

The findings of this study have important implication. The SIS proves its capability in following stroke patient's recovery trajectory without severe ceiling and floor effects. In practice, this will assist clinicians and researchers to follow the recommendations in the stroke guidelines regarding follow-up assessment. The Stroke Guideline by Agency for Healthcare Research and Quality [2] recommends to follow patients after discharge from rehabilitation within a month. The new Veterans Health Administration's stroke guideline, VA/DoD Clinical Practice Guideline for The Management of Stroke Rehabilitation, requires that patients who received rehabilitation services receive a follow-up evaluation with rehabilitation professional at 3–6 months after discharge [20]. Even though guidelines require follow-up evaluations, considering the high resource demand of traditional in-person stroke outcome measure, it is not always possible for practitioners to comply with these recommendations. Using the SIS telephone mode of administration, better patient care could be facilitated with significantly reduced resource use compared to the traditional in-person interview.

The authors acknowledge several limitations in this study. This study sample population is selected from the veteran population, and unfortunately, females are not well represented in this study. Thus, the application to the general population may be limited. We only examined physical functioning domain scores, without addressing other domains such as mental, emotional, participation domains that often affected by stroke. In addition, the study protocol did not include individuals' depression states, which may affect the outcomes.

In a future study, we will present the relationship between domains of SIS and health care utilization. This follow-up study will establish the utility of this measure in supporting decision making in the veterans health care system.

Conclusion

We concluded that the SIS has convergent validity compared to the existing and widely used instruments such as FIM and SF-36V, and better ability in discriminating dissimilar groups in terms of physical disability among stroke patients. We validated the SIS with telephone administration for the community dwelling stroke survivors, and this opens the possibility of practical use of SIS to measure the outcomes in community dwelling stroke survivors to achieve better patient care.

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