

1 **DOI: <https://doi.org/10.47391/JPMA.3151>**

2
3 **Translation and validation of stroke impact scale-16 in Urdu for**
4 **Pakistan**

5
6 **Umair Ahmed¹, Hossein Karimi², Syed Amir Gilani³, Ashfaq Ahmad⁴**

7 **1,2** University Institute of Physical Therapy, The University of Lahore, Lahore, Pakistan;

8 **3,4** Department of Allied Health Sciences, University of Lahore, Lahore, Pakistan.

9 **Correspondence:** Umair Ahmed. **Email:** umairahmedpt@gmail.com

10
11 **Abstract**

12 **Objective:** To translate and validate the Urdu version of stroke impact scale-16 for
13 Pakistani society.

14 **Method:** The prospective cohort study was conducted from February 2018 to
15 February 2020 after approval from the ethics review board of The University of
16 Lahore, Lahore, Pakistan, and comprised patients with mild to moderate stroke who
17 were recruited from five public and two private hospitals of the Punjab province.
18 Established guidelines were followed to translate the Stroke Impact Scale-16. The
19 patients were concurrently evaluated on Barthel Index, Stroke Rehabilitation
20 Assessment of Movement, Modified Rivermead Mobility Index, Modified Rankin
21 Scale, Short Form 36 Health Survey Questionnaire and the Hospital Anxiety and
22 Depression Scale to assess the validity of Stroke Impact Scale-16, and Spearman
23 correlation coefficient was used to determine the correlation among the scales.
24 Analysis of variance was employed to determine the discriminant validity. Intraclass
25 correlation coefficient, weighted kappa, Cronbach's alpha and item-total correlation
26 were calculated to establish the stability and consistency of Stroke Impact Scale-16.
27 Data was analysed using SPSS 25.

28 **Results:** Of the 90 patients, 50(55.5%) were females and 40(45.5%) were males. The
29 subjects were aged 50-80 years. The correlation of Stroke Impact Scale-16 was strong
30 with the established tools and ranged from 0.78 to 0.91. The discriminant validity was
31 also significant ($p<.001$) across all Modified Rankin Scale levels. The Intraclass
32 correlation coefficient was 0.94 and Cronbach's alpha was 0.91 for test-retest
33 reliability and internal consistency, respectively. All corrected item-total correlation
34 values exceeded the priori minimum standard (≥ 0.40) and ranged from 0.51 to 0.68.
35 The weighted kappa for item reliability also achieved priori criteria (≥ 0.40) and ranged
36 from 0.53 to 0.88.

37 **Conclusion:** With slight modifications, the Urdu version of Stroke Impact Scale-16
38 was found to have satisfactory psychometric properties and can be used in clinical and
39 research settings for stroke survivors in Pakistan.

40 **Key Words:** Stroke, Patient reported outcome measures, Quality of life.

41

42 **Introduction**

43 There is a pressing demand in neurorehabilitation and clinical research to include
44 subjective wellbeing as an essential health outcome. Although performance-based
45 functional tools are considered necessary,¹ self-reported physical functioning scales
46 are increasingly being valued in rehabilitation to design appropriate therapeutic
47 interventions for stroke patients.² Patient-reported physical functioning instruments
48 with suitable psychometrics are still scarce in Urdu language for Pakistani stroke
49 patients because such scales are mostly available in English or foreign languages.
50 Since only a small proportion of the Pakistani population can read and understand
51 English,³ their widespread use in clinical and research settings is limited. It is a well-
52 known fact that a simple translation does not warrant its use in clinical and research
53 settings and may lead to an instrument that is not equivalent to the original.^{4, 5}
54 Therefore, healthcare professionals face a dilemma; whether to develop a new
55 instrument in a native language or to test the psychometric properties of the well-
56 established outcome measure in the local environment and context.⁶ The development

57 of scale is a costly and laborious process.⁶ In contrast, the latter option is more
58 economical and allows comparison of results with national and international data.⁷
59 To cover the Nagi model domains, the clinicians and researchers usually combine the
60 Stroke Impact Scale-16 (SIS-16) with other health outcome measures due to its brevity
61 and good psychometric properties.⁸ SIS-16 is a disease-specific and self-reported
62 outcome measure used to capture stroke impact on survivors' physical functioning.^{9, 10}
63 SIS-16 demonstrated a better ability to capture stroke consequences, particularly in
64 mild to moderate stroke, compared to other scales, such as the Barthel Index (BI),
65 which have shortcomings of a severe ceiling effect.¹¹
66 The current study was planned to translate and validate the Urdu version of SIS-16 for
67 Pakistani patients. The stability of the reliability and validity of the Urdu version
68 would provide therapists working in neurological rehabilitation with an option to
69 select a patient reported outcome measure (PROM) that guide them to choose the most
70 appropriate interventions for their patients.

71

72 **Materials and Methods**

73 The prospective cohort study was conducted from February 2018 to February 2020 at
74 various hospitals in the Punjab province of Pakistan, and allowed data collection at
75 two time points (T1 and T2). The design assumes that a subclinical or no change
76 occurs between T1 and T2.

77 After approval from the ethics review board of The University of Lahore, the sample
78 size was calculated according to CONsensus-based Standards for the selection of
79 health status Measurement INstruments (COSMIN) guidelines for psychometric
80 testing of PROM.¹² The sample was raised using consecutive sampling technique from
81 five public-sector facilities, including district headquarter hospitals (DHQs) at Okara,
82 Sahiwal, Multan, Qasur and Pakpattan, and two private hospitals, including Al-Shafi
83 Hospital and the The University of Lahore Teaching Hospital. Those included were
84 patients of either gender aged 50-80 years with acute or chronic stroke regardless of its
85 hemorrhagic or ischemic or recurrent nature. They were able to read and write Urdu,

86 and had a minimum education up to 5th grade. Stroke patients with communication
87 difficulties, such as those with aphasia or reduced consciousness, and stroke survivors
88 with the inability to walk independently were excluded.

89 After taking consent from the patients, baseline data was collected regarding age,
90 gender, type of stroke and duration since diagnosis.

91 In the first phase, translation and back-translation of SIS-16 was done in line with
92 guidelines proposed by Beaton et al. in 2004 and the World Health Organisation
93 (WHO) in 2014.^{4, 13} This phase consisted of five progressive stages. In the first stage,
94 two independent bilingual translators with specialist knowledge of English and Urdu
95 were invited from the United Kingdom to translate the SIS-16 into Urdu. One
96 translator had a non-medical background, while the other was a physiotherapist with
97 more than 10 years of experience in stroke rehabilitation with the National Health
98 Services (NHS). The two translators and an observer then synthesised the results and
99 produced a consensus translation of SIS-16 in the second stage. Two back-translators
100 with a non-medical background were then invited to back-translate the Urdu version
101 of SIS-16 into the source language. They were blinded to the original version of SIS-
102 16 and had no prior understanding of the scale. An expert committee, consisting of
103 translators, methodologists and researchers, produced the Urdu version of SIS-16 for
104 cognitive testing. In the final stage of this phase, eight patients self-completed the SIS-
105 16. An expert with more than 6 years of experience in stroke rehabilitation cognitively
106 debriefed the scale on these stroke patients to investigate their understandability of the
107 Urdu version of the scale (USIS-16). A final version was then produced for field
108 testing (Appendix).¹⁴

109 The second phase of the study comprised testing of psychometric properties, like
110 internal consistency, item-domain correlation, test-retest reliability and construct
111 validity. The validity of the USIS-16 was calculated by administering the following
112 battery of outcome measures with USIS-16 at T1: to assess the convergent validity,
113 BI, Modified Rivermead Mobility Index (MRMI), Stroke Rehabilitation Assessment
114 of Movement (STREAM), Modified Rankin Scale (MRS) and Short Form 36 Health

115 Survey Questionnaire (SF-36) were employed. The MRS was also used to assess the
116 known-group validity of USIS-16. The patients enrolled in the study were reassessed
117 at T2 after a week to determine the test-retest reliability. The questionnaire and
118 permission to use for translation and validation of the SIS-16 were obtained from
119 Mapi Research Trust (Lyon, France) on behalf of copyright holders, The University of
120 Kansas Medical Centre, United States of America. The standardisation of the data-
121 collection procedure was achieved through prior training of therapists to administer
122 the functional stroke scales before formal data-collection.

123 Data was analysed using SPSS 25. An intraclass correlation coefficient (ICC) (2-way
124 random model with agreement) and weighted kappa (quadratic) were calculated for
125 test-retest and individual item reliability, respectively. A priori criteria of ICC ≥ 0.70
126 and weighted kappa ≥ 0.40 were deemed appropriate for test-retest and item reliability,
127 respectively.^{15, 16} The internal consistency of the USIS-16 was determined with
128 Cronbach's alpha, and a value of ≥ 0.70 was considered standard for PROM.¹⁷ Internal
129 consistency was further assessed by conducting an item-to-total correlation; that is,
130 how each item on the test relates to the instrument as a whole. This approach avoids
131 creating an unduly extended test, and values ≥ 0.40 for item-to-total correlation were
132 deemed appropriate.¹⁸ Concurrent criterion validity compares the measure to a gold
133 standard at the same point in time. It was hypothesised that USIS-16 would have a
134 strong correlation (>0.70 or above) with BI as the gold standard.¹⁹ The convergent
135 validity indicates the extent to which the tool is believed to reflect the same underlying
136 phenomenon and correlates to outcome measures of a similar construct.²⁰ In contrast,
137 divergent validity assumes that different outcome measures assess unlike constructs
138 and lack correlation.²¹ It was hypothesised that STREAM, MRMI and physical
139 domain of SF-36 would show a moderate (0.30 to 0.59) to high correlation (0.60 or
140 more) with USIS-16. In contrast, a low correlation ($r_s=0.30$) was expected with the
141 Hospital Anxiety and Depression Scale (HADS). Spearman's rank correlation
142 coefficient (r_s) was used to determine the convergent and divergent validity. The
143 discriminant or known-group validity assesses the ability of the scale to distinguish

144 between different classes of patients. Based on the MRS scale, stroke patients were
145 subgrouped into slight, mild, moderate and moderately severe disabilities. It was
146 hypothesised that a significant difference would exist when the mean USIS-16 score
147 based on MRS stages would be compared. Analysis of variance (ANOVA) was used
148 to calculate the significance of differences $P < 0.05$ was set as the marker of
149 significance.

150

151 **Results**

152 Of the 90 patients, 50(55.5%) were females and 40(45.5%) were males. The subjects
153 were aged 50-80 years. Of the total, 63(70%) had ischemic stroke and 27(30%) had
154 haemorrhagic. Mean values of all the scales used in the study were noted (Table 1).

155 The correlation of SIS-16 was strong with the established tools and ranged from 0.78
156 to 0.91. The discriminant validity was also significant ($p < 0.001$) across all MRS
157 levels. The ICC was 0.94 and Cronbach's alpha was 0.91 for test-retest reliability and
158 internal consistency, respectively. All corrected item-total correlation values exceeded
159 the priori minimum standard (≥ 0.40) and ranged from 0.51 to 0.68. The weighted
160 kappa for item reliability also achieved priori criteria (≥ 0.40) and ranged from 0.53 to
161 0.88.

162 The criterion and convergent validity of USIS-16 were acceptable and demonstrated a
163 significantly strong correlation between USIS-16 and other functional scales
164 (BI= $r=0.88$, STREAM= $r=0.91$, MRMI= $r=0.92$, and MRS= $r=0.78$). The USIS-16 score was
165 significantly correlated with the physical functioning of SF-36 at a higher level
166 ($r=0.84$). However, the physical component summary (PCS) demonstrated a moderate
167 correlation (0.67) with the USIS-16 (Table 2).

168 The known-group validity of USIS-16 was satisfactory as the mean score of USIS-16
169 tended to decrease significantly with the severity of the stroke based on MRS (Table
170 3).

171

172

173 **Discussion**

174 To the best of our knowledge, the current study is the first to translate and test the
175 psychometric properties of SIS-16 into Urdu language for Pakistani stroke survivors.
176 The findings are fairly consistent with studies that found psychometric properties of
177 SIS-16 adequate in diverse cultures and contexts.²²⁻²⁴

178 A significant proportion of stroke patients in the current study failed to complete one
179 item owing to cultural differences and local variability in the relevance of this item as
180 the item, 'heavy household chores', was not usually relevant for males in Pakistani
181 society because 66% of participants reported that they were never involved in
182 household chores and, therefore, this item did not apply to them. This finding is not
183 surprising considering that Pakistan is a relatively gender-segregated society where
184 household chores are considered a part of female responsibility. However, SIS-16
185 provides a way to replace the missing data to estimate what they might be.

186 Internal consistency of USIS-16 was satisfactory according to the recommended
187 standards (>0.70).⁵ This finding is consistent with the original and translated versions
188 of SIS-16.^{23,24} Congruent to previous researches²³⁻²⁵, the Urdu version of SIS-16
189 demonstrated a high correlation with the established tool. Similarly, the test-retest,
190 item reliability and item-domain correlation were also adequate.

191 The current study is not without limitations. The sample consisted of high functioning
192 patients with mild to moderate stroke, limited to community-dwellers. The findings,
193 therefore, should be applied with caution to patients with severe stroke. Further testing
194 is needed with a larger sample size, including patients with severe disabilities.

195

196 **Conclusion**

197 The Urdu version of SIS-16 was found to have satisfactory test-retest reliability,
198 internal consistency, construct and discriminant validity. The scale has robust
199 psychometric properties and can be used in clinical and research settings.

200

201

202 **Disclaimer:** The text is based on a PhD research thesis.

203 **Conflict of interest:** None.

204 **Source of Funding:** None.

205

206 **References**

207 1. Traversi E, Springhetti I, Melazzini M, Giorgi G. The ICD-ICF clinical model
208 of hospital care. *G. Ital. Med. Lav. Ergon.* 2019;41:70-7.

209 2. Rodríguez-Nogueira Ó, Morera Balaguer J, Nogueira López A, Roldán Merino
210 J, Botella-Rico J-M, Del Río-Medina S, et al. The psychometric properties of the
211 person-centered therapeutic relationship in physiotherapy scale. *PLoS One.*
212 2020;15:e0241010. doi: 10.1371/journal.pone.0241010. PMID: 33156867; PMCID:
213 PMC7647106.

214 3. Haidar S, Fang F. English language in education and globalization: A
215 comparative analysis of the role of English in Pakistan and China. *Asia Pacific Journal*
216 *of Education.* 2019;39:165-76.

217 4. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process
218 of cross-cultural adaptation of self-report measures. *Spine (Phila Pa 1976).*
219 2000;25:3186-91. doi: 10.1097/BRS.0000000000001891. PMID: 27607311.

220 5. Streiner DL, Norman GR, Cairney J. Health measurement scales: a practical
221 guide to their development and use: Oxford University Press, USA; 2015.

222 6. Arafat SY, Chowdhury HR, Qusar M, Hafez M. Cross cultural adaptation &
223 psychometric validation of research instruments: A methodological review. *J Behav*
224 *Health.* 2016;5:129-36.

225 7. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural
226 adaptation of questionnaires could not bring out a consensus. *J. Clin. Epidemiol.*
227 2015;68:435-41. doi: 10.1016/j.jclinepi.2014.11.021. PMID: 25698408.

228 8. Ward I, Pivko S, Brooks G, Parkin K. Validity of the stroke rehabilitation
229 assessment of movement scale in acute rehabilitation: a comparison with the

- 230 functional independence measure and stroke impact scale-16. *PM&R*. 2011;3:1013-
231 21. doi: 10.1016/j.pmrj.2011.08.537.
- 232 9. Richardson M, Campbell N, Allen L, Meyer M, Teasell R. The stroke impact
233 scale: performance as a quality of life measure in a community-based stroke
234 rehabilitation setting. *Disabil. Rehabil.* 2016;38:1425-30. doi:
235 10.3109/09638288.2015.1102337.
- 236 10. Ahmed U, Karimi H, Gilani SA, Ahmad A. Translation and validation of the
237 stroke impact scale 3.0 into urdu for Pakistan. *NeuroRehabilitation*. 2021;1-12. doi:
238 10.3233/NRE-210064.
- 239 11. Vellone E, Savini S, Fida R, Dickson VV, Melkus GDE, Carod-Artal FJ, et al.
240 Psychometric evaluation of the stroke impact scale 3.0. *J. Cardiovasc. Nurs.*
241 2015;30:229-41. doi: 10.1097/JCN.0000000000000145.
- 242 12. Mokkink LB, De Vet HC, Prinsen CA, Patrick DL, Alonso J, Bouter LM, et al.
243 COSMIN risk of bias checklist for systematic reviews of patient-reported outcome
244 measures. *Qual. Life Res.* 2018;27:1171-9. doi: 10.1007/s11136-017-1765-4.
- 245 13. World Health Organization. Process of translation and adaptation of instruments.
246 http://www.who.int/substanceabuse/research_tools/translation/en/. 2014.
- 247 14. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al.
248 Principles of good practice for the translation and cultural adaptation process for
249 patient-reported outcomes (PRO) measures: report of the ISPOR task force for
250 translation and cultural adaptation. *Value Health*. 2005;8:94-104. doi: 10.1111/j.1524-
251 4733.2005.04054.x.
- 252 15. Vanbelle S. A new interpretation of the weighted kappa coefficients.
253 *Psychometrika*. 2016;81:399-410. doi: 10.1007/s11336-014-9439-4.
- 254 16. Koo TK, Li MY. A guideline of selecting and reporting intraclass correlation
255 coefficients for reliability research. *J. Chiropr. Med.* 2016;15:155-63. doi:
256 10.1016/j.jcm.2016.02.012.
- 257 17. Connelly LM. Cronbach's alpha. *Medsurg Nurs*. 2011;20:45-7.

- 258 18. Green SB, Yang Y. Evaluation of dimensionality in the assessment of internal
259 consistency reliability: Coefficient alpha and omega coefficients. *Educational*
260 *Measurement: Issues and Practice*. 2015;34:14-20.
- 261 19. Souza ACd, Alexandre NMC, Guirardello EdB. Psychometric properties in
262 instruments evaluation of reliability and validity. *Epidemiol Serv Saude*.
263 2017;26:649-659. doi: 10.5123/S1679-49742017000300022.
- 264 20. Salinas J, Sprinkhuizen SM, Ackerson T, Bernhardt J, Davie C, George MG, et
265 al. An international standard set of patient-centered outcome measures after stroke.
266 *Stroke*. 2016;47:180-6. doi: 10.1161/STROKEAHA.115.010898.
- 267 21. Jewell DV. *Guide to evidence-based physical therapist practice*: Jones &
268 Bartlett Publishers; 2014.
- 269 22. Kunsman S. Abstract T P125: Does the Stroke Impact Scale-16 (SIS-16)
270 positively correlate with the functional independence measure (FIM) during
271 acuteinpatient rehabilitation following stroke? *Stroke*. 2015;46:ATP125-ATP. doi:
272 10.1161/STROKEAHA.115.010898.
- 273 23. Katzan IL, Thompson N, Uchino K. PROs in Clinical Practice: SIS-16 Better at
274 Detecting Change in Functional Status Than the Modified Rankin. *Stroke*.
275 2016;47:A186-A.
- 276 24. Chou C-Y, Ou Y-C, Chiang T-R. Psychometric comparisons of four disease-
277 specific health-related quality of life measures for stroke survivors. *Clin. Rehabil*.
278 2015;29:816-29. doi: 10.1177/0269215514555137
- 279 25. Coppers A, Möller JC, Marks D. Psychometric properties of the short form of
280 the Stroke Impact Scale in German-speaking stroke survivors. *Health Qual Life*
281 *Outcomes*. 2021;19:1-13. doi: 10.1186/s12955-021-01826-5.

282
283 -----

284
285
286

287 **Table 1: Sample characteristics (n=90)**

Demographic and risk factors	N (%)	Functional Scales	Mean ±SD
Female	50 (55.50)	SF-36	
Male	40 (44.40)	Physical function	55.44± 20.03
Socio-economic Status		Emotional role	65.21± 35.71
Low-income	20 (22.22)	Body pain	53.25 ± 27.09
Middle-income	38 (42.22)	Social functioning	50.13 ± 23.43
Higher-income	32 (35.50)	Vitality	55.94 ± 26.59
Stroke type		General health	67.61 ± 19.86
Ischemic	63 (70.00)	Role limitations	59.16 ± 27.14
Hemorrhagic	27 (30.00)	Mental health	66.94 ± 18.70
Risk Factors		BI	62.83 ± 12.65
Smoking	28 (31.10)	MRMI	10.33 ± 01.74
Ischemic heart disease	23 (25.50)	SIS 16	66.28 ± 11.41
Obesity/overweight	17 (18.80)	MRS	02.51 ± 00.73
Hypertension	16 (17.70)	HADS-A	11.28 ± 04.66
Diabetes mellitus	11 (12.20)	HADS-D	10.65 ± 04.03

288 SF-36: Short form-36, BI: Barthel index. MRMI: Modified Rivermead mobility index, SIS-16:
 289 Stroke Impact Scale-16, MRS: Modified Rankin scale, HADS: Hospital anxiety and depression
 290 scale.

291
 292
 293
 294
 295
 296
 297
 298
 299
 300
 301
 302
 303
 304
 305
 306

307 **Table 2: Convergent validity of Stroke Impact Scale-16 (SIS-16).**

Scales	r_s
BI	0.88*
STREAM	0.91*
MRMI	0.92*
MRS	-0.78*
HADS-A	-0.16*
HADS-D	-0.20*
SF-36	
Physical Functioning	0.84*
Physical Role	0.43*
Pain	0.29*
Social Function	0.31*
Mental Health	0.28*
Emotion	0.24*
Vitality	0.30*
General Health	0.33*
PCS	0.67*
MCS	0.21*

308 *Spearman correlation (r_s) is significant with p-value < .001, BI: Barthel index, STREAM: Stroke
 309 rehabilitation assessment of movement, MRS: Modified Rankin Scale, HADS: Hospital depression
 310 and anxiety scale, PCS: Physical component summary, MCS: Mental health component summary.

311

312 -----

313

314 **Table 3: Known-group validity.**

MRS	N	Mean ± SD*
1	25	80.80 ± 05.11
2	27	65.53 ± 07.29
3	21	54.69 ± 05.68
4	17	25.43 ± 10.11

315 MRS: Modified Rankin scale; N: Number of stroke patients.

316 Analysis of variance (ANOVA) was used to determine the significant difference between stroke
 317 patients who are at different stages of severity of the disease determined by MRS score;

318 *p<0.01.

319

320 -----

321

322

ایس آئی ایس -16 فالج کے اثر کا پیمانہ ورژن 3.0

بالکل مشکل نہ تھا	ذرا مشکل تھا	تھوڑا سا مشکل تھا	کافی مشکل تھا	بالکل نہ بو سکا	1. پچھلے 2 ہفتوں میں آپ کے لیے کتنا مشکل تھا...
5	4	3	2	1	الف۔ جسم کے اوپر والے حصے پر لباس پہننا؟
5	4	3	2	1	ب۔ خود سے نہانا؟
5	4	3	2	1	پ۔ لیٹرین وقت پر پہنچنا؟
5	4	3	2	1	ت۔ پیشاب پر قابو پانا (کپڑوں کا خراب نہ ہونا)؟
5	4	3	2	1	ث۔ پاخانہ پر قابو پانا (کپڑوں کا خراب نہ ہونا)؟
5	4	3	2	1	ج۔ جسمانی توازن کھوئے بغیر کھڑے رہنا؟
5	4	3	2	1	چ۔ شاپنگ کرنا؟
5	4	3	2	1	چ۔ گھر کے بھاری کام کاج کرنا (مثلاً وکیوم کلیئر یا جھاڑو سے صفائی کرنا، کپڑے دھونا، صحن میں کام کاج کرنا)؟
5	4	3	2	1	ح۔ جسمانی توازن کھوئے بغیر بیٹھ رہنا؟
5	4	3	2	1	خ۔ جسمانی توازن کھوئے بغیر چلنا؟
5	4	3	2	1	د۔ بستر سے کرسی تک جانا؟
5	4	3	2	1	ڈ۔ تیز چلنا؟
5	4	3	2	1	ذ۔ ایک منزل تک سیڑھیاں چڑھنا؟
5	4	3	2	1	ر۔ ایک بلاک (150 میٹر) تک چلنا؟
5	4	3	2	1	ڑ۔ گاڑی میں سوار ہونا اور اس سے باہر نکلنا؟
5	4	3	2	1	والا سامان مثلاً (چیزیں بھاری سے ہاتھ متاثر زیادہ اٹھانا)؟ تھیلا