

1 **Reliability and validity of the Swiss Spinal Stenosis Questionnaire for Iranian**
2 **patients with Lumbar Spinal Stenosis**

3 **Abstract**

4
5 **Background:** The purpose of this study was validation of the Persian translation of
6 the Swiss Spinal Stenosis Questionnaire in order to be used by Iranian researchers.

7 **Methods:** A total of 104 patients with spinal stenosis diagnosis, who were
8 candidates for operative treatment were entered into the study. The patients
9 completed the translated questionnaire in the 1st and the 7th days of admission and 6
10 months after surgery. Visual analogue scale was used to determine the severity of
11 the pain in the 1st day and the 6th month. Discriminant validity, convergent validity,
12 test-retest reliability, internal consistency, ability to detect changes and sensitivity
13 to clinical changes were assessed for the statistical purposes.

14 **Results:** Cronbach's α was more than 0.9 for all the items. ICC was about 0.9 for
15 all the items. For symptoms, physical and total items, Cronbach's α was 0.942,
16 0.957, 0.926 and Intraclass correlation were 0.891, 0.918, 0.862, respectively.
17 Paired t-test was significantly different between the 1st day and the 6th month
18 questionnaire. There was a positive correlation either between the first VAS and
19 the 1st day questionnaire (1st day Q) ($r=0.892$, $P=0.000$) or between the 6th month

20 VAS and 6th month Q ($r=0.940$, $P=0.000$). The Pearson's correlation between the
21 difference of the total scores of the 1st day and the 6th month and satisfaction score
22 after surgery showed negative correlation ($r= -0.746$, $P=0.000$). The effect size was
23 2.55.

24 **Conclusion:** The Iranian version of the Swiss Spinal Stenosis has excellent
25 internal consistency, excellent reliability, good ability to alter with changes,
26 especially parallel with clinical improvement, excellent ability to detect changes,
27 and well either convergent or discriminant validity.

28 **Keywords:** validity, reliability, questionnaire, and spinal stenosis.

29 **Introduction:**

30 Spinal stenosis is one of the most common disorders that conducts patients to orthopedics and
31 spine clinics. Degenerative spinal stenosis is the most common form of spinal stenosis and
32 usually affects elderly population. The most common symptoms of the disease are low back pain,
33 sciatica and intermittent neurogenic claudication (1, 2). Diagnosis of the disease is clinical but
34 radiography, CT scan and specially MRI are useful in confirming the diagnosis and rolling-out
35 other differential diagnosis and are helpful in planning treatment of the disease (1, 3).

36 For making standard documentation and communication between publics, we need a uniform
37 language and various questionnaires are our tools for this purpose. So these questionnaires must
38 be standard and reliable in each nation. One of the most useful ones is Swiss Spinal Stenosis that
39 was introduced by Stucki in 1996(4) and its reliability and validity have been challenged in many
40 studies(5, 6). Accordingly, we decided to translate and validate it in order to provide a standard
41 questionnaire for Iranian researchers.

42 Swiss questionnaire has 18 questions. The first 7 questions are related to patient's symptoms.
43 The first three questions are related to pain (severity, frequency and back pain) and the last four
44 questions are related to neuroischemic symptoms (numbness or tingling, weakness and balance
45 disturbance). Each question is scored from 1 to 5. Thus the maximum score, which can be
46 achieved from this domain, is 35. The next 5 questions are related to physical activity of patients,
47 and each question is scored from 1 to 4 (maximum 20 scores). Higher score means more severity
48 of the disease. The last 6 questions are about satisfaction of patients after surgical treatment, and
49 each is scored from 1 to 4. Higher score means less satisfaction from the surgery.

50

51 **Materials and Methods:**

52 All patients with lumbar spinal stenosis who were candidates for surgical treatment were
53 included in the study. Patients completed the translated forms of the Swiss Spinal Stenosis
54 Questionnaire in the first day of admission (1st day Q). These forms were completed again after
55 one week but before surgery (7th day Q). And finally, the patients completed the questionnaires
56 and satisfactory questions 6 months after surgery (6th month Q). Visual analogue scale (VAS)
57 was used for detecting the severity of the pain on the first day and the 6th month after surgery.
58 All the analyses were performed using SPSS 22.

59 **Translation process:** For face and content validity of the Iranian translated questionnaire, it was
60 presented to our spine surgeons and neurosurgeons co-workers to ensure used terminologies in
61 the questionnaire are the same as the usual idioms employed by patients in clinics and were
62 consistent with terminologies written in textbooks. Then this questionnaire was back-translated
63 to English by an English master in our university, familiar with medical terminologies but un-
64 aware of the original Swiss Questionnaire. Subsequently, the back-translated copy was compared
65 with the original copy in order to resolve differences, so the final translated copy was prepared
66 for validation.

67 **Validity:** To evaluate discriminant validity, paired t-test was used between the 1st day Q and the
68 6th month Q (7). 0.05 was used as the significance level. For convergent validity, the 1st day Q
69 and the 6th month Q were compared with the corresponding VAS using Pearson correlation(8).

70 **Reliability:** Test-retest reliability was detected by the intraclass correlation coefficients (ICCs)
71 and 95% confidence interval using the two pre-operative questionnaires (1st day Q and 7th day Q).
72 Internal consistency was assessed by Cronbach's α using the 1st day Q.

73 **Ability to detect changes:** Effect size was used to detect the ability of the questionnaire to
74 determine clinical changes as it is one of the most common methods for this purpose (9). The 1st
75 day Q and the 6th month Q were used to calculate it. The value of 0.2 or less represents low, and
76 value of 0.8 or more represents high ability to detect changes (10).

77 **Sensitivity to clinical changes:** Pearson's correlation was used in order to determine the ability
78 of the questionnaire to change after treatment. For this purpose, the difference between the total
79 scores of the 1st day Q and the 6th month Q was calculated, and its correlation and score of
80 satisfaction from surgery were determined. Negative correlation represented the sensitivity to
81 clinical changes because the higher score of satisfaction questions means the less satisfaction
82 from surgery.

83

84 **Results:**

85 A total of 104 patients (68 women and 36 men) with mean age 58.96 ± 1.07 years (39 – 85) with
86 lumbar spinal stenosis diagnosis were entered into the study. All the patients have been
87 performed conservative treatment with no satisfactory results. Thus, they stood as candidates for
88 surgical treatment. Standing radiography and MRI were requested for all the patients and other
89 para-clinic evaluation such as CT scan, bone densitometry and electrodiagnostic studies were
90 requested if indicated for confirming the diagnosis and **rolling-out** other differential diagnosis
91 and performing operative plane.

92 The mean scores of the questionnaires are summarized in Table 1. The mean score of VAS of the
93 1st day Q and the 6th month Q were 7.33 ± 0.65 (6 – 9) and 4.92 ± 7.33 (4 – 6), respectively.

94 The Cronbach's α of the symptom and physical scales were above 0.9 and the details are listed in
95 Table 2.

96 The results of the test-retest and intraclass correlation coefficient between the 1st day Q and the
97 7th day Q are summarized in Table 3.

98 The results of the paired t-test between the 1st day Q and the 6th month Q in order to determine
99 discriminant validity showed significant difference in all the items as shown in Table 4. About
100 convergent validity, there was a positive correlation either between the first VAS and the 1st day
101 Q ($r=0.892$, $P=0.000$) or between the 6th month VAS and the 6th month Q ($r=0.940$, $P=0.000$).

102 The mean total score of the 1st day Q and the 6th month Q was 40.23 and 24.38, respectively.

103 And the standard deviation of the total score of the 1st day Q was 6.22. Thus, 2.55 is the
104 calculated effect size in order to determine the ability to detect changes.

105 Pearson's correlation between the difference of the total scores of the 1st day Q and the 6th month
106 Q and satisfaction score after surgery was used in order to determine the sensitivity of the
107 questionnaire to clinical changes. The result was negative in correlation with a significant
108 difference ($r= -0.746$, $P=0.000$).

109

110 **Discussion:**

111 Degeneration of the intervertebral disc is the most common cause of low back pain (11) and the
112 final sequence of it, is degenerative lumbar spinal stenosis. Low back pain, sciatica and
113 intermittent neurogenic claudication are the most common complaints of patients (12). Treatment
114 may be nonsurgical but according to the degenerative nature of the disease, it is usually

115 progressive and surgical intervention **may be required** finally **as spinal stenosis is one of the most**
116 **common reason of spinal surgery among older population in the United State(13). In order to**
117 **communicate** between researchers, we need a standard language. Thus, classifications and
118 outcome questionnaires become important. Swiss Spinal Stenosis Questionnaire, also named
119 Zurich claudication questionnaire and Brigham spinal stenosis questionnaire is one of the most
120 common tools for this purpose. As a result, we tried to test its reliability and validity when
121 translated in Persian language.

122 We used Cronbach's α for internal consistency of our translated questionnaire (14). It looks the
123 questionnaire for homogeneity of the questions. 0.7 or higher values mean satisfactory reliability
124 for comparing the two groups, however, for clinical purposes, the value of 0.9 or above is usually
125 needed (15). This is the result obtained from our study in all domains of the questionnaire.

126 Repeated reliability means that the questionnaire must lead approximately the same results over
127 a period of time, when completed by the same patient. It is tested with test-retest and intraclass
128 correlation coefficient and the result is a number between 0 and 1. Bigger number, gives the
129 greater reliability. Generally, the value between 0.6 to 0.8 means good and the value greater than
130 0.8 means excellent reliability (16). Portney and Watkins believed that ICC must reach 0.9 for
131 clinical purposes (17). Our translation is very near to this criterion. Thus, Iranian version of the
132 questionnaire has excellent reliability.

133 Surgical treatment of lumbar stenosis usually is successful and satisfactory for patients. The 6th
134 month Q was different significantly from the 1st day Q and this means Iranian version has good
135 ability to alter with changes and to clarify if these changes are parallel to improvement of
136 symptoms of patients, we used satisfactory questions of the questionnaire. There was a negative
137 correlation between the difference of 1st day and 6th month questionnaire and satisfaction of the

138 patients. Increase in the score of satisfaction after surgery means less satisfaction of patients
139 from treatment. Therefore, the larger the difference between 1st day Q and 6th month Q results,
140 more improvements, and less score of satisfactory questions.

141 The effect size is a tool to clarify the ability to detect changes. The value of 0.2 or less means
142 low ability, but value of 0.8 or more means high ability to detect changes (7). The effect size in
143 our study was 2.55, and this means excellent ability to detect changes.

144 We used VAS for detecting convergent validity, but it was better to use other questionnaires
145 related to spinal stenosis such as Shuttle Walking Test, Oxford spinal stenosis score, and the
146 Oswestry disability index, but unfortunately none of them have been validated in Iranian version.
147 The results from our analyses shown well either convergent or discriminant validity of the
148 Iranian version of the questionnaire.

149

150 **Conclusions:** The Iranian version of the Swiss Spinal Stenosis Questionnaire has excellent
151 internal consistency, excellent reliability, good ability to alter with changes, especially parallel
152 with clinical improvement, excellent ability to detect changes and well either convergent or
153 discriminant validity.

154

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158

159 **Patient consent:** Our informed consent was obtained from the study participants.

160

161 **Disclosure:** The authors report no conflict of interest concerning the materials or methods used
162 in this study or the findings specified in this paper.

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