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Clinical assessment of fear of falling after stroke: validity, reliability and responsiveness of the Persian version of the Fall Efficacy Scale-International

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Abstract

Background: Fear of falling may be related to falling during stroke onset. The Fall Efficacy Scale-International (FES-I) with excellent psychometric properties, is an instrument developed to assess patients' concerns about fallings. The aim of this study was to determine validation of this scale in Iranian patients with stroke.

Methods: The "forward-backward" procedure was applied to translate the FES-I from English to Persian. One hundred-twenty patients who had suffered stroke, aged 40 to 80 years (55% male) completed the Persian FES-I, Geriatric Depression Scale-15 (GDS-15), General Health Questionnaire-28 (GHQ-28), Berg Balance Scale (BBS) and Timed up and Go (TUG) questionnaires. The interval time for the test-retest of the Persian scale was 7-14 days.

Results: The test-retest and inter-rater reliabilities of the Persian FES-I were excellent (ICC2,1=0.98, $p<0.001$) and the internal consistency was high (Cronbach's alpha=0.78). Factor analysis of the 16 items in the Persian scale showed only one significant factor. The total Persian FES-I score had a significantly negative correlation ($p<0.001$) with the BBS, but it had significantly positive correlation with the TUG, GHQ-28, and GDS-15. The difference in responsiveness scores across fallers and non-fallers yielded a large effect size (0.46), which indicated a good discriminating validity.

Conclusion: The Persian FES-I proved to be an effective and valuable measurement tool to assess stroke patients' fear of falling in practice and research setting.

Keywords: Fall Efficacy Scale-International (FES-I), Stroke, Reliability, Validity, Psychometric properties.

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Introduction

Fear of falling (FOF) or post-fall syndrome is an emergent and critical issue, and identifies as a risk factors for falling after stroke (1,2). Fear due to falling is introduced as a "debilitating spiral": loss of confidence and a decrease in physical activity that increase dependency (2). It can be followed by symptoms such as: anxiety, depressive symptoms, reduced self-efficacy in mental health status, social isolation and dependency, avoidance of environmental risks, decreased functional mobility and balance, and using walking aids in post-stroke. In previous studies, the incidence of FOF post-stroke was reported to be 12-92% and 12-65% in patients with and without a fall, respectively (2). Clinicians should be aware of FOF post-stroke symptoms as a primary barrier in recovery of functions because they can negatively affect rehabilitation, recovery (1), and the cost to the

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health care system (3). Early diagnosis of FOF in patients with stroke could help clinicians plan rehabilitation programs for them in order to prevent complications.

To assess FOF, different approaches have been developed over the years (4,5). In large scale surveys or prevalence studies, the Single Item Question is being commonly used, but this assessment does not ask about the intensity of FOF and make it hard to detect specific changes in FOF over time (2,4). The Fall Efficacy Scale (FES) was added to resolve these potential issues because it assessed the confidence of the patients while they did 10 basic activities of daily living without falling (6). However, this assessment did not measure FOF symptoms in social and highly physical activities (7), thus the result cannot be applied in different cultural contexts (5).

The Fall Efficacy Scale International (FES-I) has been found to be an excellent clinical tool for assessing concerns about falling in easy, difficult, and social activities (8). The FES-I was developed by Yardley et al. (9) at the Prevention of Falls Network Europe (ProFaNE) in UK. The FES-I has been translated in 14 different languages while maintaining a standard protocol. The reliability and validity of this test have been tested with elderly population (5,10), but it has never been used with stroke patients (11). On the other hand, use of an excellent psychometric international assessment tool helps researchers and clinicians to increase the possibility of participating of stroke patients in international clinical trials. Thus, the purpose of this study was to investigate the reliability, validity, and responsiveness of the Persian FES-I with stroke patients.

Methods

Participants: A total of 120 participants between the ages of 40 and 80 years who had suffered stroke within the past six to 60 months before participated in this study. They were all patients who had visited in neurological clinics at one of four different teaching hospitals affiliated the university with simple non-random sampling. The evaluations were conducted in the occupational therapy department of the rehabilitation hospital affiliated with the university campus in Tehran from October 2012 to June 2013. All of the participants were Persian speaking and lived in their own homes. The inclusion criteria were the ability to communicate and understand FES-I concepts and instructions (participants needed to obtain a score of 21 or more on Mini Mental State Examination); the ability to independently walk at least 10-meters (with or without an assistive device) four times a day; and they needed to be physically able to both read and write. The exclusion criteria included any other neurological, cardiovascular or major musculoskeletal impairments (e.g., lower extremity amputation) that could have prevented participants from completing the assessments. Participants that suffered another stroke between the test-retest times were also excluded.

The patients were invited to participate in the study by telephone. Only four of the potential participants rejected to participate in the study. The remaining participants were visited in either one of two occupational therapy clinics by the researchers. All of the tests were administered by an occupational therapist with more than 15 years of experiences in both clinical and research settings. Distance time between test-retest of the FES-I was 7-14 days. The second interview was conducted by two different raters to verify inter-rater reliability. The second rater that was brought in to verify the inter-rater reliability for the FES-I was also an expert occupational therapist.

Information about ages, genders, family statuses, living arrangements, stroke types and sides, number of falls within the last year, and comorbid problems of participants were collected from their medical charts and questionnaire.

Permission to translate the FES-I to the Persian version was granted by ProFaNE. The Ethic Committee affiliated with the Iran University of Medical Sciences approved this study. All of the participants

signed an informed consent that was aware of the purpose of the study before participating. During the course study, participants were free to leave at any time if they felt uncomfortable.

Measurements: In addition to the FES-I, the other assessment tools used in this study were: the Single Item Question, Depression Scale-15 (GDS-15) (12), General Health Questionnaire-28 (GHQ-28) (13), Timed Up and Go (TUG) (14,15), and Berg Balance Scale (BBS) (5,16). The GHQ-28 is a psychological disorder screening tool with 4 subscales: somatic symptoms, anxiety/insomnia, social dysfunction, and severe depression. The TUG assessed the basic functional mobility of the participants. The BBS assessed the functional balance performance for 14 activities that are common in daily life. The Single Item Question scale took very a little time to complete and would have been easier for people with potential cognitive impairment to compete, which is common after stroke (1). That is why, it was considered as the gold standard in criterion validity for this study. The Single Item Question scale assessed FOF symptoms by asking: "In the past 12 months were you afraid of falling?" If the participants answered "yes", the questionnaire asked: "Do you avoid certain activities due to FOF?" If the participants answered "yes" again, the questionnaire asked "with limitation or without limitation?" (2). In previous studies, the Single FOF question had good test-retest reliability (0.66) and it also had a strong positive correlation with the FES-I (0.73) (11). To evaluate the convergent validity of the FES-I, the GDS-15, GHQ-28, TUG, and BBS scales were included. The order of assessments administered was randomized.

The FES-I is a questionnaire that provides information about how much fear patients have of falling during a range of basic and instrumental activities that are part of their everyday lives. The FES-I is comprised of 14-items, 10 from the original FES (with a few word change) and six new items. Each daily activity has a 4-point scale (1= not at all concerned, 4= very concerned). Total scores range from 16 (complete absence of concern) to 64 (extreme concern). The FES-I was administrated using face-to-face structured interviews (8,10). The participants were asked to only focus on their FOF symptoms from within the past 12 months.

Translation procedure of the FES-I: The study was conducted according to the 10-step FES-I protocol published on the ProFaNE (9) website (www.profane.eu.org). These 10-step start from forward translation from the original English version to the Persian version was performed independently by two Persian native speakers who were familiar with the concept of FOF. After that, the first consensus meeting was conducted to provide feedback and a provisional local version. Subsequently, each translator separately administered the provisional version to two patients with stroke to see if any of the items needed to be clarified. At the second consensus meeting with two experts in occupational therapy, the final Persian version was prepared. Backward translation from Persian to English was performed by two different native English language translators separately. The final Persian FES-I version was forwarded to ProFaNE for approval and is included in the Appendix.

Statistical analysis: Statistical analysis were conducted to find the mean, standard deviation (SD), frequency (n), and frequency percent (n [%]). Pearson's correlation coefficients (r) were conducted to measure the relationship between FES-I and the number of falls in the last year. The criterion, convergent, and internal structural coherence validity values were also calculated (17). The criterion validity between FES-I and Single FOF question was assessed by calculating Spearman's correlation coefficient (*rho*). The correlation between FES-I scores and other scores (TUG, BBS, GHQ-28, and GDS) were assessed by calculating Pearson's correlation coefficients (r) according to Monuro's guideline. According

to Monuro's guideline, Pearson or Spearman values between 0.70 and 0.89 indicate high reliability (5,9,18). Internal structural validity of the FES-I was simplified by factor analysis, using principal component analysis for the total matrix variance with Varimax rotation (5,19). To perform factor analysis, only eigenvalues greater than one were kept for further analysis.

The three reliability scores calculated in this study were: the test-retest, inter-rater and internal consistency (17). The inter-rater and test-retest reliability of the FES-I were calculated with Intraclass Correlation Coefficients (ICC); where an ICC≥0.8 indicates excellent reliability (20,21). The Standard Error of Measurement (SEM) and Minimum Detectable Change (MDC) values were calculated for both of the coefficients. As a rule of thumb, if an SEM value is less than 10% of the maximum score of the scale or small scale, the absolute level of reliability is desired and acceptable. The MDC measured the minimal detectable of change needed to be 95% confident that the observed changed between the two measures reflected real change and not measurement error (22,23). Cronbach's alpha was calculated to evaluate the internal consistency of the results, where an alpha value greater than 0.80 indicates excellent reliability (20). Inter-item correlations were assessed by calculating Pearson's r values (17).

Responsiveness scores on the FES-I test were compared between the fallers and non-fallers within the last year (17) and they were calculated by averaging the means of the effect sizes between the fallers and non-fallers (9). Those scores were also equal to the ratio of the means differences of the total FES-I scores between the two groups divided by the standard deviation of the base line group (24). An effect size greater than 0.80 indicates large validity between this subgroup (24).

There were no missing values in the dataset, and all of the data were tested to see if they had normal distribution using a Kolmogorov-Smirnov test. For all of the statistical comparisons within the dataset, the level of significance was set at ≤0.05. All analyses were conducted with SPSS for Windows, version 13.0.

Results

Descriptive statistics: The mean age of the participants was 60.1 years (SD=10.7). The mean score on the MMSE was 25.01 (SD=3.76), and the mean time since the participants had suffered stroke was 25.82 (SD=15.06) months. The mean score on the

Table 1. Nominal characteristics of the Persian stroke participants (n[%])

Variables	Entire participants	Fallers	Non-fallers
Gender			
male	66(55)	43(57.3)	23(51.1)
female	54(45)	32(42.7)	22(48.9)
Family status			
single	6(5)	5(6.7)	1(2.2)
married	101(84.2)	62(82.7)	39(86.7)
widowed/divorced	13(10.8)	8(10.7)	5(11.2)
Living arrangements			
alone	5(4.2)	3(4)	2(4.4)
with spouse/relative	115(95.8)	72(96)	43(95.6)
Co-morbid problems			
dizziness	29(24.9)	20(26.7)	9(20)
poly-pharmacy≥4	103(85.8)	66(88.0)	37(82.2)
walking with aid	37(30.8)	27(36)	10(22.2)
Falls over last year			
0	45(37.5)	-	-
1	17(14.2)	-	-
2	22(18.3)	-	-
>2	36(30)	-	-
FOF			
no	61(50.8)	43(57.3)	18(40)
yes	59(49.2)	32(42.7)	27(60)

Table 2. Mean, standard deviation, median, factor analysis of the Persian FES-I

Item	Mean(SD)	Median	One factor loadings	Commu-nality	Correlation item to total
1.Cleaning the house (e.g. sweep, vacuum or dust)	2.03(1.20)	1	0.94	0.88	0.93
2.Getting dressed or undressed	2.03(1.14)	1.5	0.92	0.84	0.91
3.Preparing simple dishes	1.98(1.23)	1	0.93	0.87	0.92
4.Bathing or showering	2.23(1.24)	2	0.93	0.87	0.93
5.Going to the store	2.07(1.20)	1	0.94	0.89	0.94
6.Sitting down or standing up from a chair	1.97(1.19)	1	0.95	0.90	0.94
7.Going up or down the stairs	2.33(1.27)	2	0.93	0.76	0.92
8.Walking in the neighborhood	2.14(1.29)	1	0.97	0.93	0.97
9.Reaching to take something above your head or on the ground	2.02(1.17)	1	0.92	0.84	0.91
10.Go to the phone and answer it before stopping its ringing	1.78(1.04)	1	0.88	0.78	0.87
11.Walking on a slippery surface (e.g. wet or icy)	2.40(1.29)	2	0.92	0.85	0.92
12.Meeting a friend or relative	2.02(1.20)	1	0.93	0.86	0.92
13.Walking in a crowded place	2.23(1.30)	2	0.95	0.90	0.94
14.Walking on an uneven surface (e.g. cobble-stone, unsuitable pavement or ground covered with gravel)	2.38(1.27)	2	0.94	0.88	0.94
15.Going up or down a slope	2.37(1.29)	2	0.93	0.86	0.93
16.Going out to a social event (e.g. religious cere-mony, family gathering or cultural center)	2.02(1.19)	2	0.92	0.84	0.91
Total	33.88(18.08)				

BBS, the TUG, the GHQ-28 and the GDS-15 were 48.05(SD=8.77), 22.8(SD=21.76), 23.93(SD=14.79) and 6.52(SD=4.20), respectively. According to their medical charts, the participants had suffered a total of 108 (90%) ischemic and eight (6.7%) haemorrhagic stroke. Four participants' type of stroke remained unknown. Sixty-four (53.3%) participants were experiencing right and 56 (46.7%) left hemiparesis. Seventy-five (62.5%) of the participants had falls history in the past year. The demographic characteristics of the participants are presented in Table 1. There was no significant correlation between FES-I scores and the number of falls in the past year (r= -0.13, p=0.15).

Validity: The Spearman's correlation showed a significantly high validity between the Persian FES-I and Single FOF question (*rho*=0.84, p<0.001). Convergent validity of the Persian FES-I correlation with the GHQ-28 (r=0.79, p<0.001), GDS (r=0.89, p<0.001), and TUG (r=0.31, p<0.001) demonstrated a significant positively association. It also had a significant negative correlation with BBS (r= -0.27, p<0.001). Factor analysis of the 16-item Persian FES-I yielded only one factor (Table 2). The eigenvalues for this one factor was 13.8. This factor accounted for 88.50% of matrix variance in the database. Item-total correlations ranged from 0.87 to 0.97 which indicated high to excellent correlation (Table 2). Table 2 illustrates the mean, standard deviation and median scores for each item of the Persian FES-I. Item 11 (walking on a slippery surface) had the highest mean score, followed by items 14 and 15.

Reliability: The test-retest reliability for the $ICC_{2,1}$ value was 0.98 (p<0.001, 95%CI=0.97 to 0.99). Its reliability values with the SEM, SEM%, MDC, and MDC% were 2.41, 7.14%, 6.69, and 19.7%, respectively. Inter-rater reliability yielded an $ICC_{2,1}$ value of 0.98 (p<0.001, 95%CI=0.98 to 0.99) with SEM, SEM%, MDC and MDC% values were values of 2.42, 7.13%, 6.71, and 19.7%, respectively. Internal consistency with Cronbach's alpha was 0.78. Inter-item correlations ranged from 0.75 to 0.97 (mean=0.86). The range for Cronbach's alpha after deletions of each item was 0.76 to 0.77, which was very close to the overall alpha value.

Responsiveness: The responsiveness of the Persian FES-I across fallers and non-

fallers showed a medium effect size (0.46).

Discussion

In this study, the Persian FES-I was administered according to the 10-step protocol published in ProFaNE (9). The results from the present study suggested that the Persian FES-I had high reliability and a good discriminating validity between faller and non-faller patients with stroke.

This study found that the correlation between the Persian FES-I scores and the Single FOF question was strong. Therefore, it can be expected that the FES-I could be used to assess the confidence in performing activities with or without falling. This finding was in agreement with previous criterion on validity studies in the UK, the Netherlands, and Greek versions that gold standard was the same question (4,10).

Convergent validity was assessed by calculating the power and direction of the relationship between the Persian FES-I version scores and the BBS, TUG, GHQ-28 and GDS-15 scores. There was a positive correlation between the Persian FES-I scores and the TUG scores. This finding suggested that lower the Persian FES-I scores, the more rapid ambulation and good functional mobility the patient had. Similarly, Ulus et al. (5) and Billis et al. (10) found a positive correlation of the Turkish and Greek versions of the FES-I with TUG. The TUG has been indicated to have good discriminative measure for predicting stroke patients who are at risk of falling (25). Thus, this result supports the advantage of FES-I. It was also observed that patients with higher BBS scores had better balance and it is expected a negative correlation between the Persian FES-I scores and BBS. In this study, lower the Persian FES-I scores were correlated with more BBS scores; similar result to the Ulus et al. (5) study. There was a strong positive correlation between the Persian FES-I scores and GHQ-28 scores that indicated a relationship between the Persian FES-I scores and the generic health questionnaire scores. This finding was similar to the significant associations observed in the Greek FES-I study with the GHQ-30 (10). The strong correlation of the FES-I with the generic health measure indicates the better sample perceived its health. A strong positive correlation was obtained between the Persian FES-I and GDS-15 scores. This result indicated that lower the Persian FES-I scores were associated with less depression. This is in line with previous study indicated that FOF might lead to general depression (8.18). FOF can be measured by examining a person's degree of self-confidence in performing everyday activities, both physical (such as slower habitual walking pace) and psychological factors (anxiety and depression). Also, post-stroke depression impacts negatively upon social activity and vice versa. The GDS-15 assess psychological factors especially in social activity and the FES-I assess physical and social activities. This means that the FES-I may have a high correlation with psychological constructs (26,27).

The factor analysis of the item–scores revealed that the Persian FES-I only assessed one main variable within the post-stroke group. Therefore, the result confirms the use of the Persian FES-I as a total-scale for which the derive measurement, the sum score of FES-I, is simply the total of 16-item score. It also suggested that the one main factor that explained most of the variance for the FES-I scores was simply measuring symptoms of FOF. However, in previous studies, the Swedish, Turkish, Brazilian, and Chinese versions of the FES-I in older people reported two factors as important (5,18,19,28). These difference could have been due to the variations between the cultures, types of populations that were sampled, and age differences.

The test-retest reliability of the Persian FES-I indicated an excellent reliability, which agreed with previous FES-I studies include the original FES-I (9), the Greek (10), Italian (29), FES-I (Ch.) (18), FES-I-Brazil (19), and the Netherlands versions (19). However, the German FES-I version was reported to only have a moderate reliability (4). The SEM value showed a desira-

ble and acceptable reliability for this dataset. In this study, the MDC% was 19.7. The calculated MDC% provides an assessment of a relative improvement or deterioration in the value of a parameter and could help clinicians decide whether performance had truly changed over time (23). The minimal detectable change in the current study was lower than that observed for the Greek FES-I (20.44%) (10).

The inter-rater reliability for the Persian FES-I for the total score indicated a very strong degree of association. This result agreed with the FES-I (Ch.) ($ICC_{2,1}$=0.95, 95%CI=0.89 to 0.98) (18) and FES-I-Brazil (ICC=0.91) (19). The SEM values also indicated desirable and acceptable reliability for the total score.

The analysis of internal reliability for total items indicated good and acceptable consistency. This result agreed with results of other studies ranged from 0.90 to 0.98 (4,5,9,10,18,19,28,29). All of the other previous studies investigated older people, while the current study investigated stroke patients with a mean age of 60 years old.

The responsiveness of the Persian FES-I across the fallers and non-fallers (at least one fall within the past year) subgroup indicated that it had good discriminant validity. This means that, the FES-I was able to detect changes in scores between the patients with stroke who had sustained at least one fall within the last year and those that had never fallen. This finding agreed with responsiveness observed with the Greek FES-I (10) and the original FES-I study (9) with older adults samples.

We acknowledge our study limitations. Previous studies indicated that there was a high risk of fall in ambulatory and independent living stroke patients, therefore, analyzing the results of FOF scores in detail was important for the well-being if these groups of patients (1,25,30). For this reason, ambulatory participants were invited to participate in this study. The data of this study were collected using face-to-face interviews, which likely minimized the measurement bias. Also in this study, the researchers only used the convenient sampling method to collect data. Therefore, it is possible that the patients with more severe symptoms of FOF were less keen to participate in this study. Further study is suggested to examine FOF in other health conditions.

Conclusion

The findings of this study suggested that the Persian FES-I demonstrated an adequate and acceptable assessment of FOF in patients who had suffered stroke. The FES-I could be used to address concerns about falling during physical and social activities. It could also be used in a clinical setting to determine whether clients have FOF.

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