Renal Replacement Therapy

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Measurement properties of the falls efficacy scale in patients on hemodialysis

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Abstract

Background The measurement properties of the falls efficacy scale have not been evaluated in patients on hemodialysis. This study determined the inter- and intrarater reliability, standard error of measurement, minimal detectable change, and limits of agreements of the falls efficacy scale in patients on hemodialysis.

Methods A cross-sectional study was conducted with 65 patients (57.5 ± 13.9 years, 63.1% male) on hemodialysis. The fear of falling was assessed by two previously trained raters using the falls efficacy scale. The intraclass correlation coefficient, standard error of measurement, minimal detectable change, and Bland–Altman plot were calculated to assess the inter- and intrarater reliability of the falls efficacy scale.

Results The interrater intraclass correlation coefficient was 0.91, and the intrarater intraclass correlation coefficient was 0.78, representing excellent interrater and good intrarater reliability. The standard error of measurement for inter- and intrarater assessments were 2.99 and 4.46, and the minimal detectable change for inter- and intrarater assessments were 9.26 and 12.33, respectively. The interrater mean difference score was 0.26 (95% limits of agreement: −8.01 to 8.53), and the intrarater mean difference score was −1.06 (95% limits of agreement: −13.39 to 11.27).

Conclusion In patients on hemodialysis, the falls efficacy scale showed excellent and good inter- and intrarater reliability, respectively. Additionally, standard error of measurement, minimal detectable change, and limits of agreements of the falls efficacy scale score were satisfactory.

Keywords Fear, Accidental falls, Chronic kidney failure, Renal dialysis, Observer variation

Background

Patients with end-stage renal disease on hemodialysis exhibit low physical function that contributes to physical frailty and sarcopenia all of which are strongly associated with adverse patient relevant outcomes such as disability, mortality, hospitalization, and increased risk of falls [1, 2]. The incidence of falls ranges from 1.18 to 1.60 falls/person-year in these patients, and the main consequences are fractures, functional impairments, and an increased fear of falling [2]. In a recent study, we showed that fear of falling was associated with history of falls in the retrospective 12-month interval in patients on

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hemodialysis [3]. Another study evaluated the impact of history of falls on fear of falling in elderly dialysis patients and showed that 68% of patients limited their activities, and 59% left home less frequently due to fear of falling when compared to patients without history of falls [4].

High fear of falling is prevalent in patients undergoing hemodialysis (63%), who exhibit greater concern about falling (41.7%) compared to a control group (17.5%) [5, 6]. Fear of falling is also associated with low levels of physical activity and worse physical function, postural balance, and quality of life in patients on hemodialysis [6–8]. Additionally, 37.2% of frail patients with chronic kidney disease reported very high or extreme concern about falling, whereas this proportion was 8.3% among nonfrail patients [9].

The fear of falling can be assessed by a simple question or using valid and reliable scales [10–13]. The Activities-specific Balance Confidence scale is suitable to detect loss of balancing confidence in mobility-related activities [11]. The Survey of Activities and Fear of Falling in the Elderly evaluates the link between fear of falling and activity restriction [12]. The Fall Efficacy Scale—International assesses concern about falling in a range of daily life and social activities [13]. The Fall Efficacy Scale (FES) was developed in 1990 considering the lack of standardization at that time, and it measures fear of falling based on the operational definition of fear as "low perceived self-efficacy or confidence at avoiding falls" [10]. This scale is valid and reliable for populations of patients with Parkinson's disease [14], stroke [15], and cognitive impairments [16], and it has been used in patients with end-stage renal disease on hemodialysis [8, 17–21].

The score of FES was associated with clinical conditions, such as anxiety and depression [10, 14]. Moreover, moderate and severe fear of falling measured by the Fall Efficacy Scale—International increased the risk of falling at 3 and 6 months in community-dwelling older patients [22]. In patients on hemodialysis, fear of falling evaluated by the Modified FES was independently associated with the number of steps and moderate to vigorous physical activity measured by accelerometry [7]. Another study with patients on hemodialysis showed that FES had a good diagnostic accuracy for screening frailty and fall risk [17].

Although the FES is quick and easy to apply and widely used in patients with chronic diseases, its measurement properties have not been described in patients on hemodialysis. Considering the important differences between chronic diseases and the hemodynamic instability due to dialysis, the evaluation of the measurement properties of the FES in patients on hemodialysis is necessary. Moreover, the interrater reliability and minimal detectable change (MDC) score of the FES has not been established. Therefore, the objective of this study was to describe the inter- and intrarater reliability, standard error of measurement (SEM), MDC, and limits of agreements of the FES in patients on hemodialysis.

Methods

Participants

This cross-sectional study is an exploratory analysis of an expanded project that investigates risk of falls in patients on hemodialysis, and was conducted between September 2021 and March 2022. Participants were recruited from the Pro-Renal Center (Barbacena, Minas Gerais, Brazil). The study protocol followed the ethical principles of the Declaration of Helsinki and was approved by the Barbacena School of Medicine Research Ethics Committee (N° 3.741.115/2019). All participants signed an informed consent form.

The convenience sample included patients aged at least 18 years with end-stage renal disease under hemodialysis treatment for at least three months, conducted in three weekly sessions of four hours each.

Patients were excluded if they presented any of the following conditions: a physical limitation that compromises the activities daily living; use of gait assistance; wheelchair use; uncorrected visual impairments; psychiatric or cognitive disorders [23]; severe and unstable comorbidities; hospitalization in the past three months; and incapable of being interviewed during the hemodialysis session.

Study protocol

The interviews for the application of the FES questionnaire were conducted during dialysis sessions by two previously trained raters. The assessment of interrater reliability occurred ten minutes after the first interview. The intrarater reliability was assessed by a single rater and investigated between 10 and 14 days after the first interview.

Sociodemographic, clinical and laboratory data

Age, sex, educational level, time on dialysis, body mass index, comorbidities (hypertension, cardiovascular disease, diabetes mellitus, dyslipidemia, and neurological disease), laboratory data, and the history of falls in the previous year were collected from medical records and participant interviews. A fall was defined as an "unexpected event in which the individual comes to rest on the ground, floor or lower level" [24], and a positive history of falling was defined as having experienced at least one fall in the previous 12 months.

Fear of falling

The fear of falling was assessed by the FES which includes the following 10 items: take a bath or shower; reach into cabinets or closets; prepare meals not requiring carrying heavy or hot objects; walk around the house; get in and out of bed; answer the door or telephone; get in and out of a chair; get dressed and undressed; light housekeeping; and simple shopping [10, 25]. The level of confidence in each item is scored from 1 (low confidence) to 10 (high confidence), and total score ranges from 10 to 100 [25].

Statistical analyses

Normality distribution of data was determined using the Shapiro–Wilk test. Continuous variables are summarized as mean ± standard deviation or median (interquartile range) for normally and not-normally distributed variables, respectively. Categorical variables are expressed as number of participants (percentage).

The inter- and intrarater reliability were calculated based on the intraclass correlation coefficient (ICC) considering a two-way mixed effects model, single measurement or rater and absolute agreement. ICC was classified as excellent (> 0.90), good (0.75–0.90), moderate (0.50–0.74), or poor (< 50) [26].

The SEM was calculated with the following formula: $SEM = SD \times \sqrt{(1-ICC)}$, where SD is the standard deviation of the FES score from the mean of all patients. The MDC was calculated with the following formula: $MDC = SEM \times 1.96 \times \sqrt{2}$. The MDC is also expressed as a percentage ($MDC_{\%}$): $MDC_{\%} = (MDC/mean) \times 100$ [26].

Ceiling and floor effects were determined as more than 20% of the participants at the highest and lowest scores. .

The inter- and intrarater agreement limits of the FES score were investigated by Bland–Altman plots, plotting individual mean difference scores against their means while considering 95% limits of agreement at 1.96 SD above and below this mean [26].

The comparisons between the FES score assessed by rater 1 and rater 2 on the first evaluation day, and by rater 1 on different days were performed using the paired t-test to assess any systematic bias between the assessments.

Statistical analyses were performed using SPSS software, version 22.0. A p value < 0.05 was considered statistically significant.

Results

Of the 160 patients assessed for eligibility, 95 were excluded, and 65 were analyzed because they completed the second interview (Fig. 1).

The sociodemographic, clinical, and laboratory data of the participants are shown in Table 1. The mean age of the participants was 57.5 ± 13.9 years, 63.1% were male, and the most prevalent comorbidities were hypertension and cardiovascular disease. All patients were well dialyzed with hemodialysis efficiency index values more than 1.2.

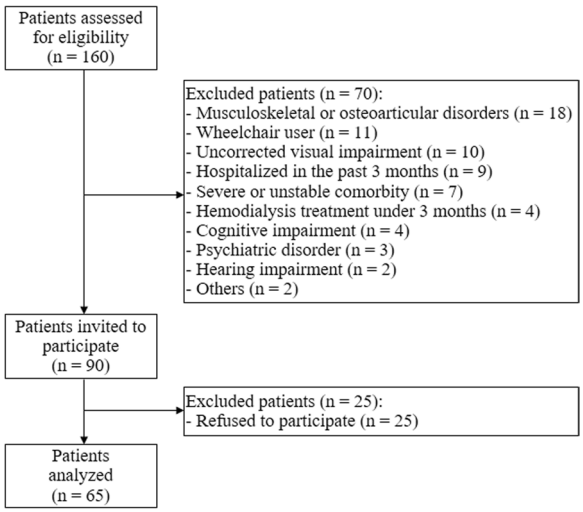

Fig. 1 Flow diagram of the inclusion of participants

Table 1 Sociodemographic, clinical, and laboratory data of the participants (n = 65)

Variables	Values
Age (years)	57.5 ± 13.9
Male (*n*, %)	41 (63.1)
Educational level (years)	6.0 (5.5)
Time on dialysis (years)	1.9 (2.9)
Body mass index (kg/m^2)	23.4 (5.2)
Comorbidities (*n*, %)	
Hypertension	64 (98.5)
Cardiovascular disease	44 (67.7)
Diabetes mellitus	26 (40.0)
Dyslipidemia	22 (33.8)
Neurological disease	9 (13.8)
History of falls (*n*, %)	31 (47.7)
Laboratory data	
Hemodialysis efficiency index	1.5 (0.4)
Hemoglobin (g/dL)	9.8 ± 2.1
Albumin (g/dL)	3.8 (0.4)
Calcium (mg/dL)	8.7 (0.9)
Phosphorous (mg/dL)	5.3 ± 1.5
Parathyroid hormone (pg/mL)	620.0 (693.0)
Vitamin D (ng/mL)	29.9 ± 11.2
C-reactive protein (mg/L)	65.3 ± 22.4

Continuous data are expressed as the mean ± standard deviation or median (interquartile range) according to the Shapiro–Wilk test

Categorical data are expressed as number of participants (percentage)

The ICC, SEM, MDC, floor or ceiling effect, and comparisons between assessments of the FES score are presented in Table 2. The interrater ICC was 0.91, and the intrarater ICC was 0.78, representing excellent interrater and good intrarater reliability. FES presented ceiling effects of 40% and 41.5% for inter- and intrarater assessments, respectively.

Figure 2 shows the inter- and intrarater agreements of the FES score using a Bland–Altman plot. The interrater mean difference score was 0.26 (95% limits of agreement: −8.01 to 8.53), and the intrarater mean difference score was −1.06 (95% limits of agreement: −13.39 to 11.27). The majority of points fall within the 95% limits, with scores evenly spread across low and high FES scores.

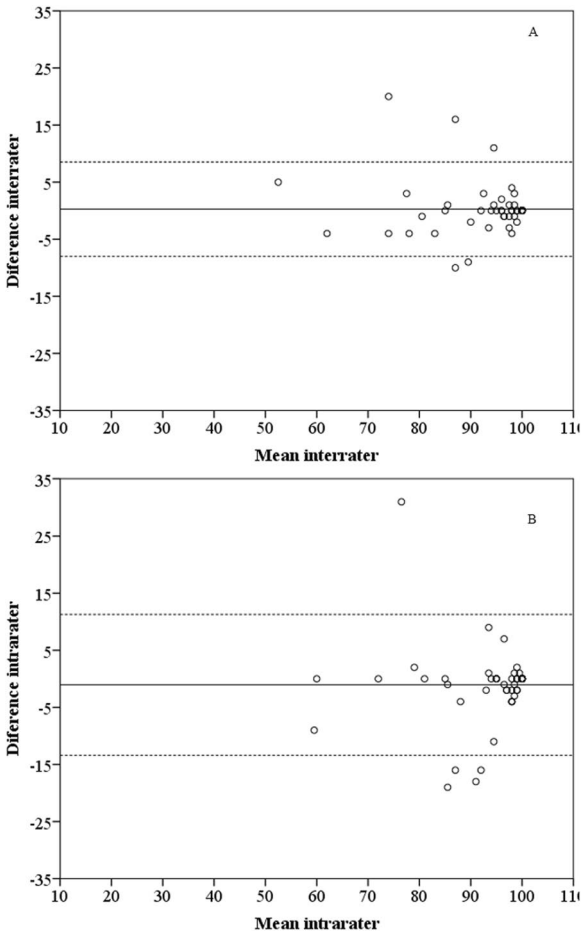

Fig. 2 Bland–Altman plots of the FES score for interrater (**A**) and intrarater (**B**) reliability. The solid line indicates the reference of the mean difference, and the dashed lines represent the upper and lower limits of agreement

Discussion

To the best of our knowledge, this is the first study to evaluate the reliability and measurement properties of the FES in patients on hemodialysis. The main results of this study were as follows: the inter- and intrarater reliability of the FES were excellent and good, respectively; the SEM, MDC, and limits of agreements of the FES score were satisfactory. The measurement properties of the instrument were suitable for the population of interest according to recommendations of COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) [27], which demonstrates that the FES is adequate to evaluate the fear of falling in patients on hemodialysis.

This study found excellent and good inter- and intrarater reliability of the FES, respectively, demonstrating that the scores of the scale were similar between the assessments. Furthermore, according to COSMIN, reliability represents the degree to which the measurement is free from measurement error, and an ICC of at least 0.70 is considered a good measurement property [27]. These results were similar to those of previous studies that evaluated the test–retest reliability of the FES in patients with Parkinson's disease (ICC = 0.795) [14], patients with stroke (ICC = 0.900) [15], and geriatric patients with (ICC = 0.807) and without (ICC = 0.844) cognitive impairment [16].

In this study, the SEM and MDC of the FES scores for inter- and intrarater were 2.99 and 4.46 and 9.26 (8.8%) and 12.33 (13.0%), respectively. A study of patients with

Table 2 The ICC, SEM, MDC, floor or ceiling effect, and comparisons between FES score ($n = 65$)

	ICC (95% CI)	SEM	MDC	$MDC_{\%}$	Floor/ceiling effects (%)	Assessment 1	Assessment 2	*p* value
Interrater	0.91 (0.85–0.94)*	2.99	8.26	8.8	0/40.0	94.3 ± 9.5	94.0 ± 10.1	0.619 [a]
Intrarater	0.78 (0.66–0.86)*	4.46	12.33	13.0	0/41.5	94.3 ± 9.5	95.3 ± 9.4	0.178[b]

FES Falls Efficacy Scale, *ICC* Interclass correlation coefficient, *SEM* Standard error measurement, *MDC* Minimal detectable change, $MDC_{\%}$ Minimal detectable change expressed as a percentage; *95% CI* 95% confidence interval

* $p < 0.001$ for F-test

[a] Comparison of FES score assessed by rater 1 and rater 2 on the first evaluation day

[b] Comparison of FES score assessed by rater 1 on different days

Parkinson's disease showed that the SEM was 3.4 and MDC was 42.7 (33.0%) in test–retest evaluation. However, this study applied an FES modified for neurologic disease clinic context with a total score ranging from 0 to 130, which could explain the differences in the SEM and MDC between the studies [28]. The SEM represents variability between trials due to random error, and MDC is the minimal amount of measured change required to eliminate the possibility that measurement error is solely responsible [26]. Thus, these values are useful to interpret the results of the FES, in which the values that include the SEM reflect random error and the MDC values indicate some important change for the patient.

The Bland–Altman limits of agreement of the FES score were satisfactory in this study. However, limits of agreements were narrower and less narrow for inter- and intrarater assessments, respectively, indicating no systematic bias because scores were distributed above and below the mean difference. The ceiling effect represented 40.0% and 41.5% for inter- and intrarater assessments, respectively. This effect was 17.8% in patients with Parkinson's disease [28] and 57.1% in older adults [29] in test–retest evaluation.

Considering the clinical application of the FES to evaluate fear of falling in patients on hemodialysis, this scale presents adequate clinimetric properties and requires less time from the patients. We contributed to the interpretability of this scale by helping to identify important changes beyond those that can be expected from error measurement. In this context, the implementation of the assessment of fear of falling of patients on hemodialysis can be important to create strategies to decrease the fear of falling, encouraging patients in fall prevention self-management [30].

This study has limitations. First, the participants were selected by convenience sampling, which can contribute to the presence of the ceiling effect. Second, even though this study did not include only elderly patients that present higher fear of falling, the results of the measurement properties of the FES could improve the external validity of this scale in patients on hemodialysis, including elderly and adult patients. Third, our results should be carefully interpreted because the study was conducted in a single hemodialysis unit. Forth, construct validity and responsiveness analyses were not performed. Finally, future longitudinal studies should verify whether the FES can predict adverse outcomes, such as serious falls and physical function impairments, in patients on hemodialysis.

Conclusions

In patients on hemodialysis, the FES presented excellent and good inter- and intrarater reliability, respectively. The SEM for inter- and intrarater assessments were 2.99 and 4.46, respectively. The MDC of the FES score was 9.26 (8.8%) and 12.33 (13.0%) to inter- and intrarater, respectively. Limits of agreements of the FES score were satisfactory in these patients.

Abbreviations

FES	Falls efficacy scale
ICC	Intraclass correlation coefficient
MDC	Minimal detectable change
$MDC_{\%}$	Minimal detectable change expressed as a percentage
SD	Standard deviation
SEM	Standard error of measurement

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Author contributions

Conception and design of the study: LASJ, BVP, PK, LMFL, and MMR. Supervision: BVP, LMFL, and MMR. Acquisition of data: LASJ, ABLA, LFFC, GMR, MAMJ, and MBCJ. Analysis and interpretation of data: all authors. Drafting and final approval of the manuscript: all authors.

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Availability of data and materials

All data generated or analyzed are within the manuscript.

Declarations

Ethics approval and consent to participate

Approval of the institutional review board of the Barbacena School of Medicine Research Ethics Committee (N° 3.741.115/2019). Informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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