

Applicability of the Functional Assessment of Anorexia/Cachexia Therapy instrument to assess quality of life in maintenance haemodialysis patients with cachexia

Zhen Yang

First Affiliated Hospital of Guangxi Medical University

Haizhen Lu

First Affiliated Hospital of Guangxi Medical University

Baolin Zou

The First Affiliated Hospital of Guangx Medical University

Yixin Luo

School of Nuring,Sun Yat-sen university

Ping Zhao

First Affiliated Hospital of Guangxi Medical University

Li He

First Affiliated Hospital of Guangxi Medical University

Han Wang

First Affiliated Hospital of Guangxi Medical University

Guowei Chen

The First Affiliated Hospital of Guangxi Medical University

Yiping Wu

The First Affiliated Hospital of Guangxi Medical University

Yanlin Huang (✉ 2422560330@qq.com)

First Affiliated Hospital of Guangxi Medical University

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Abstract

Background Many patients on maintenance haemodialysis (MHD) eventually suffer from cachexia. The Functional Assessment of Anorexia/Cachexia Therapy (FAACT) is a tool used to evaluate the quality of life of patients with cachexia related to various diseases, but its suitability for use in MHD patients has yet to be verified. This study aims to explore the applicability of the FAACT in MHD patients by conducting reliability and validity tests.

Methods Qualified MHD patients were selected to complete the FAACT and Kidney Disease Quality of Life Short Form 36 (KDQOL-36) questionnaires, and their demographic data and biochemical test results were collected from electronic medical records. Then, statistical software was used to perform a reliability test, and Pearson correlation analysis was carried out with KDQOL-36 as the calibration scale. Finally, the patients were divided into groups to evaluate discriminant validity.

Results A total of 299 patients were included in this study. The Cronbach's alpha coefficients of the FAACT and its anorexia-cachexia subscale (ACS) were 0.904 and 0.842, respectively, and their test-retest reliability exceeded 0.85. The correlation coefficients between the FAACT and its items ranged from 0.146 to 0.631, and the correlation coefficients between the FAACT and KDQOL-36 dimensions ranged from 0.446 to 0.617. The effects of cachexia status (present or absent) on FAACT and ACS scores had effect sizes of 0.54 ($P < 0.001$) and 0.60 ($P < 0.001$), respectively. The FAACT and ACS also significantly discriminated between patients with and without inflammation ($P < 0.001$).

Conclusions The FAACT and ACS have acceptable reliability and validity in MHD patients and are suitable for measuring the quality of life of MHD patients with cachexia.

Background

Cachexia, a complex metabolic syndrome associated with various diseases, is characterized by muscle loss with or without fat loss^[1]. However, this syndrome is poorly defined in patients receiving haemodialysis and in patients with end-stage kidney disease (ESKD), who typically present with anorexia, muscular dystrophy, and protein-energy wasting (PEW)^[2,3]. These symptoms are consistent with those of cachexia observed in other chronic diseases, such as cancer, heart failure, and HIV^[3]. Anorexia, clinically defined as loss of appetite^[4], can exacerbate PEW in haemodialysis patients, resulting in malnutrition and increased mortality^[5]. Cachexia is the most severe stage of PEW, and many patients with PEW will eventually reach this stage^[3,6]. Up to 75% of patients with ESKD undergoing haemodialysis suffer from wasting or cachexia^[3]. Cachexia is generally similar in different diseases. The diagnostic criterion for cancer cachexia is weight loss greater than 5% or weight loss greater than 2% in individuals showing depletion according to current body weight and height (body mass index [BMI] <20 kg/m²) or skeletal muscle mass (sarcopenia)^[7].

However, a clinical tool to assess cachexia in maintenance haemodialysis (MHD) recipients is lacking. The FAACT is a tool used to assess the quality of life of patients with cancer, AIDS, and some chronic diseases^[8,9]. However, its applicability in MHD patients has not been demonstrated. The Kidney Disease Quality of Life Short Form (KDQOL-SF,)Kidney Disease Quality of Life Short Form 36 (KDQOL-36,) and Kidney Disease Questionnaire (KDQ) scales have been used to evaluate the quality of life of haemodialysis patients^[10-12], but they have no specific dimension for cachexia. The anorexia-cachexia subscale (ACS,) a component of the FAACT, is an effective assessment tool for the evaluation of cachexia patients. An ACS score ≤ 24 indicates a significant increase in the risk of cachexia in patients^[13], which may also provide a reference for the evaluation of cachexia in MHD patients.

Therefore, this study aimed to assess the reliability and validity of the FAACT in evaluating the quality of life of MHD patients with cachexia.

Methods

Participants and data collection

This study recruited patients from three blood purification institutions; all participation was voluntary study. The participants were no younger than 18 years old, had undergone regular haemodialysis two or three times a week for at least 6 months, and could read and understand our questionnaire. Participants with non-chronic kidney disease, recent major surgery, or concurrent tumours were excluded. This study was approved by the ethics committee of the research institution, and all participants read and signed an informed consent form.

Based on the pre-survey and previous literature, the expected correlation of the questionnaire results in this study was 0.8^[14], and the software Pass11.0 was used to calculate the minimum necessary sample size assuming $\alpha=0.05$, $1-\beta=0.9$ and test error < 0.2 ^[15-18]. This calculation yielded a minimum sample size of 56.

The demographic and clinical characteristics of the participants were obtained from electronic medical records. The weight change of the participants over the past 6 months was determined on the basis of their records during each haemodialysis session. Then, participants with cachexia were identified in accordance with the evaluation criteria. The presence of infection was determined on the basis of C-reactive protein (CRP) concentration >8 mg/L, white blood cell (WBC) count $>10^{10}$ /L, and the most recent diagnosis. by a physician The participants completed the FAACT and KDQOL-36 questionnaires under the guidance of a researcher and a nurse. The FAACT questionnaire was re-administered to a subset of patients one week later to assess the test–retest reliability.

Assessment schedule

The FAACT is an instrument used to assess the quality of life of patients with anorexia and cachexia. This instrument includes 39 items in five dimensions: physical well-being (PWB; 7 items), social well-being (SWB; 7 items), emotional well-being (EWB; 6 items), functional well-being (FWB; 7 items), and the anorexia-cachexia subscale (ACS; 12 items)^[8]. Most of the items (PWB, SWB, EWB, and FWB) were drawn from the Functional Assessment of Cancer Therapy–General (FACT-G), a general chronic illness questionnaire^[9,19]. The ACS is the core evaluation of cachexia. In the FAACT All items were rated on a five-level scoring system: “not at all, “a little bit, “somewhat, “quite a bit”, and “very much”. Higher FAACT scores corresponded to better quality of life, and lower ACS scores corresponded to more severe cachexia^[8].

The KDQOL-36, a simplified version of the KDQOL-SF questionnaire, was used in place of the regular short form to enhance the completion rate of the questionnaire. The KDQOL is widely used to assess the quality of life of haemodialysis-treated patients, and it has been recognized as authoritative by many researchers^[20-22]. The validity of the Chinese version of the KDQOL-36 has also been verified^[23]. It comprises 36 items, including the generic 12-Item Short-Form Health Survey to provide two summary scores assessing impact on the physical and mental dimensions, along with 24 items to provide three disease-specific subscales: a symptom/problem list, the effects of kidney disease, and the burden of kidney disease^[24,25].

Statistical analysis

Patient characteristics were summarized using conventional descriptive statistical methods. Then, the reliability and validity of the FAACT were evaluated in all patients who completed the questionnaire. For reliability evaluation, standardized Cronbach's alpha coefficients were used to assess the internal consistency and test–retest. reliability of the FAACT The Cronbach's alpha coefficients were interpreted as follows: < 0.40 was weak, 0.40 to 0.74 was moderate, 0.75 to 0.90 was strong, and >0.90 was very strong^[26]. For validity assessment, the divergence and convergence of the questionnaire were evaluated by calculating the Pearson correlation coefficients among the FAACT, its dimension scales, and the five subscales of the KDQOL-36, including the correlation coefficients of the FAACT and its subscales with each of their own items. The patients were divided into different subgroups (i.e., infection and no infection, cachexia and no cachexia), and their summary scores were compared to analyse the discriminant validity of the FAACT. Then, independent t test-s were conducted. Data were analysed using SPSS 24.0 statistical software, and the criterion for statistical significance was set to $P < 0.05$.

Results

Descriptive analysis

Among 310 patients, 299 were included in the study. The other 11 patients did not finish the questionnaire and thus were excluded. The demographic and clinical characteristics of the patients are listed in Table 1. The most common primary disease in MHD-treated patients was chronic glomerulonephritis (44.1%), followed by hypertensive nephropathy (21.4%) and diabetic nephropathy (16.1%). Approximately 28.1% of the patients were determined to be infected on the basis of their CRP concentration, WBC count, and doctor's diagnosis, and 19.4% of the patients were diagnosed with cachexia. The average age of all patients included in the analysis was 54.6 years old, and their average BMI was 22.4.

Reliability

Table 2 presents the standardized Cronbach's alpha coefficients and test–retest reliability. The Cronbach's alpha coefficients of PWB, EWB and FWB were lower than 0.74, whereas the other Cronbach's alpha coefficients were acceptable and indeed strong^[26], at 0.842 for the ACS and 0.904. for the FAACT After a week, 100 patients were randomly selected for retesting, and the test–retest reliability of FAACT and the ACS exceeded 0.8.

Clinical validity

As shown in Table 3, the structural validity of the FAACT was evaluated by calculating the Pearson correlation coefficients between all subscales and their own items. Except for items GP1, GP7, GS7, GF5, and ACT13, whose correlation coefficients of with the FAACT and its dimensions were all less than 0.3, the coefficients for the remaining items (34 in total) were between 0.3 and 0.7, and the correlation coefficients with the ACS exceeded 0.5 for all items except the ACT11 and ACT13. The correlation coefficients between the FAACT and all its subscales exceeded 0.5, and the coefficient between the ACS and the FAACT was 0.814.

All subscales of the KDQOL-36 were moderately correlated with the FAACT, with correlation coefficients greater than 0.4, and moderately correlated with the ACS. The specific results are listed in Table 3.

Tables 4 and 5 list the results of additional analyses based on the different symptoms of haemodialysis patients. The FAACT and ACS showed high discriminant validity in patients with cachexia ($P < 0.001$), with effect sizes of 0.54 and 0.6, respectively. In the presence of inflammation, all scales except SWB and FWB were statistically significant, among which the FAACT and ACS showed good performance ($P < 0.001$).

Discussion

Cachexia is an important factor affecting the quality of life of patients on MHD^[27]. Many MHD patients suffer from anorexia, PEW, malnutrition, and eventually cachexia. At present, few studies have evaluated

cachexia in patients with ESKD, and a standard evaluation tool for these patients is lacking. Therefore, exploration of the evaluation tools for cachexia in MHD patients is of high clinical significance. The FAACT has been verified as a tool to measure the quality of life of patients with cachexia related to many diseases^[8,9]. This study may serve as a reference for the evaluation of cachexia in MHD patients and for the development of the FAACT scale.

This study assessed the reliability and validity of the FAACT in MHD patients. In terms of reliability (Table 2), Cronbach's alpha was acceptable, but PWB, EWB and FWB had reliability of less than 0.74, whereas the overall FAACT and the ACS outperformed other disease detection instruments^[8,28]. The repeatability of the FAACT was also outstanding, with the test–retest reliability of all dimensions exceeding 0.8. In particular, the test–retest reliability of the EWB, FACT-G, and FAACT scales exceeded 0.9. These results demonstrated the stable internal consistency of FAACT. Therefore, the FAACT and ACS are stable, reliable scales for measuring the quality of life of MHD patients.

In terms of validity, moderate correlations were found between each subscale (PWB, EWB, SWB, FWB, and ACS) and its items, and the items of each subscale were more correlated with that subscale than with other scales. However, low relevance was found between individual items, such as the ACS and ACT13, in MHD recipients with a chronic illness, relatively stable condition, and a low frequency of large fluctuations in health. In general, the of convergent validity the FAACT is acceptable in this population but not as high as in patients with cancer^[28]. In addition, correlations were found between PWB, EWB, SWB, FWB, and the ACS (0.158–0.526), and the correlation between PWB and the ACS was 0.526. Quality of life should be evaluated in various aspects; thus, the presence of correlation is understandable. Cachexia can greatly affect the bodily function of haemodialysis patients^[29,30]. This result explains the relatively strong correlation between PWB and the ACS. The KDQOL-36 is an authoritative scale to measure the quality of life of haemodialysis patients. This scale correlated with the FAACT in all dimensions. A strong correlation was also found between KDQOL-36 and the FAACT in similar dimensions, confirming the clinical applicability of the FAACT.

Comparison of the FAACT scores of MHD patients in different states showed that all dimensions except SWB and EWB were statistically significant in different cachexia states ($P<0.05$); the ACS and FAACT were the best performers ($P<0.001$) in this respect, with effect sizes of 0.60 and 0.54, respectively. FWB also performed excellently, with an effect size even greater than those of the ACS and FAACT. This result indicated that cachexia significantly affected the physical conditions of MHD patients, which further proves the above conclusion. However, FWB had unsatisfactory internal consistency and poor reliability in the evaluation of patients with cachexia only. Inflammation is an important factor causing cachexia. In fact, cachexia is usually accompanied by inflammation^[31-33]. Therefore, the presence and severity of inflammation are important indicators of cachexia. Comparison of the results in haemodialysis patients according to their inflammatory state revealed that all dimensions except SWB, FWB, FAACT, and KDQOL-36 varied significantly by inflammatory status and that the ACS and FAACT also performed well

($P < 0.001$). These data demonstrate that the ACS and FAACT have high discriminant validity in MHD patients with anorexia.

The FACT-G and its dimensions measure common aspects of quality of life in chronic disease. The FACT-G, SWB, and EWB in MHD patients show good reliability and have been verified to be valid in some diseases, especially cancer^[9,28]. However, their discriminant validity for inflammation group was not high as that of similar dimensions of the KDQOL-36 (Table 5). Thus, the KDQOL-36 is a good choice for assessing the conventional dimensions of quality of life. The FACT-G and its dimensions are not recommended as the only tool for evaluating the quality of life of MHD patients.

This study has some limitations. First, the international consensus on cancer cachexia was used as a basis because a standard diagnostic criterion for patients with cachexia is unavailable. The patients' skeletal muscle loss was not calculated because of their clinical conditions, which can cause slight deviation. Second, only a cross-sectional survey was performed, and the influence of changes in the condition of MHD patients on the FAACT score was not analysed. Finally, only the application of the Chinese version of the FAACT in haemodialysis patients was analysed, which may affect the generalizability of the present results.

Conclusion

The assessment of MHD patients with cachexia has great clinical significance, and the FAACT and ACS have good reliability and validity. Thus, the FAACT and ACS are suitable for measuring the quality of life of MHD patients with cachexia in different states. In the future, a large-scale, multi-centre, multilingual version of this longitudinal study may be performed to further confirm the applicability of FAACT in MHD patients.

Abbreviations

MHD: maintenance haemodialysis; FAACT: Functional Assessment of Anorexia/Cachexia Therapy; KDQOL-36: The Kidney Disease Quality of Life Short Form 36; ESKD: end-stage kidney disease; PEW: protein energy waste; EZ: effect size; PWB: physical well-being; SWB: social well-being; EWB: emotional well-being; FWB: functional well-being; ACS: anorexia-cachexia subscale SF12-PCS: 12-Item Short-Form Physical Component Summary; SF12-MCS: 12-Item Short-Form Mental Component Summary

Declarations

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Consent of publication:

Not applicable

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Authors' contributions

ZY participated in research design, data collection and manuscript writing. Guidance of YH's participation in the research; BZ and YL provided guidance in the process of revision; HL and PZ participated in analysis; LH, HW, GC and YW participated in the data collection and entry. All authors have read and approved the manuscript.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Prior to the study, this study was approved by the Ethics Committee of the First Affiliated Hospital of Guangxi Medical University, with the approval number 2019 (KY-E-33). All researchers signed informed consent.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1		
Demographics and clinical characteristics of MHD-treated patients (n = 299)		
Variable	n	%
Gender		
Female	111	37.1
Male	188	62.9
Primary disease		
Chronic glomerulonephritis	132	44.1
Hypertensive nephropathy	64	21.4
Diabetic nephropathy	48	16.1
Others	55	18.4
Inflammatory status		
Inflammatory	115	71.9
No inflammatory	58	19.4
Cachexia status		
Yes	Mean(SD)	Range
No	54.6(15.4)	19–91
Clinical characteristics	22.4(3.7)	14.1–40.01
Age, years	60.0(12.3)	29.6–86.4
Body mass index	60.9(12.6)	28.6–87.4
Body weight, kg		
Body weight 6 months ago		

Table 2			
Cronbach's alpha coefficients (standardized) and test-retest reliability			
Instrument	Item number	Cronbach's Alpha	Test-retest reliability
PWB	7	0.675	0.840
SWB	7	0.867	0.868
EWB	6	0.734	0.906
FWB	7	0.629	0.827
ACS	12	0.842	0.858
FACT-G	27	0.868	0.928
FAACT	39	0.904	0.921

Table 3								
Item-subscale correlation and correlation among subscales (n = 299)								
FAACT	Item-own scale correlation(range)	PWB	SWB	EWB	FWB	ACS	FACT-G	FAACT
PWB	0.384-0.633	1	0.158	0.404	0.354	0.526	0.667	0.692
SWB	0.530-0.850		1	0.238	0.324	0.217	0.658	0.551
EWB	0.384-0.633			1	0.350	0.424	0.710	0.677
FWB	0.366-0.722				1	0.363	0.729	0.663
ACS	0.192-0.770					1	0.543	0.814
FACT-G	0.171-0.595						1	0.930
FAACT	0.146-0.631							1

Table 4

Correlation between FAACT and KDQOL-36 (n = 299)

FAACT	PWB	SWB	EWB	FWB	ACS	FACT-G	FAACT
Symptom/problem list	0.543	0.231	0.348	0.302	0.609	0.505	0.617
Effects of kidney disease	0.509	0.126	0.336	0.420	0.440	0.489	0.531
Burden of kidney disease	0.421	0.154	0.397	0.283	0.483	0.444	0.519
SF12-PCS	0.436	0.057	0.158	0.385	0.446	0.361	0.446
SF12-MCS	0.346	0.176	0.522	0.265	0.362	0.465	0.481

Table 5

Means (standard deviation) of the symptom and quality of life instruments by MHD cachexia category, at baseline

Instrument	Cachexia (n = 58)	Non- cachexia (n = 241)	Total (n = 299)	<i>P</i>	Effect size
PWB	16.2(4.0)	18.8(3.8)	17.5(3.8)	<i>0.004</i>	0.68
SWB	15.4(4.6)	16.1(4.7)	15.9(4.7)	0.283	0.15
EWB	13.4(3.7)	14.2(4.1)	14.1(4.1)	0.186	0.19
FWB	9.2(3.7)	10.8(4.1)	10.5(4.1)	<i>0.011</i>	0.39
ACS	26.3(7.8)	30.7(6.9)	29.8(7.3)	<i>0.001</i>	0.60
FACT-G	54.3(10.9)	58.9(11.5)	58.0(11.5)	<i>0.006</i>	0.40
FAACT	80.5(16.2)	89.6(16.3)	87.8(16.6)	<i>0.001</i>	0.54

Effect size was calculated as (non- cachexia mean – cachexia mean)/SD of the total sample. Italicized numbers denote statistical significance at a threshold of $P < 0.05$

Table 6

Means (standard deviation) of the symptom and quality of life instruments by MHD inflammation category, at baseline

Instrument	Inflammation(n = 84)	No inflammation(n = 215)	<i>P</i>
PWB	16.0(4.1)	18.1(3.6)	<i>< 0.001</i>
SWB	15.8(5.1)	16.0(4.5)	0.675
EWB	12.8(4.2)	14.6(3.9)	<i>0.001</i>
FWB	9.8(4.2)	10.7(4.0)	0.073
ACS	25.7(7.8)	31.5(6.4)	<i>< 0.001</i>
FACT-G	54.4(13.0)	59.4(10.6)	<i>0.001</i>
FAACT	90.9(15.0)	80.0(18.2)	<i>< 0.001</i>
Symptom/problem list	67.6(11.9)	74.5(11.2)	<i>< 0.001</i>
Effects of kidney disease	48.3(11.6)	53.3(11.9)	<i>0.001</i>
Burden of kidney disease	10.0(11.8)	17.2(14.1)	<i>< 0.001</i>
SF12-PCS	33.0(6.3)	35.6(6.4)	<i>0.002</i>
SF12-MCS	34.3(5.2)	37.7(5.5)	<i>< 0.001</i>

Table 5

Means (standard deviation) of the symptom and quality of life instruments by MHD cachexia category, at baseline

Instrument	Cachexia (n = 58)	Non- cachexia (n = 241)	Total (n = 299)	<i>P</i>	Effect size
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Italicized numbers denote statistical significance at a threshold of $P < 0.05$

Supplementary Files

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