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CLINICAL RESEARCH

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Accepted	d: 2019.1 d: 2019.1 d: 2019.1	11.14	Validity and Reliability Physical Activity Ques Hemodialysis Patients China					
Authors' Cont Study D Data Colli Statistical An Data Interpre anuscript Prepa Literature S Funds Colli	Design A ection B nalysis C tation D ration E Search F		Xiaowei Lou Qiang He	 The Second Clinical Medical College, Zhejiang Chinese Medical University, Hangzhou, Zhejiang, P.R. China Department of Nephrology, Zhejiang Provincial People's Hospital, Hangzhou, Zhejiang, P.R. China People's Hospital of Hangzhou Medical College, Hangzhou, Zhejiang, P.R. China Chinese Medical Nephrology Key Laboratory of Zhejiang Province, Hangzhou, Zhejiang, P.R. China 				
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		Background:	in Chinese maintenance hemodialysis (MHD) patie	ity of the International Physical Activity Questionnaire (IPAQ) ents. These findings could help increase the validity of future				
Material/Methods:		ial/Methods:	MHD physical activity (PA) studies, both within China and throughout the world. A multicenter prospective cohort study including 320 patients was conducted in Zhejiang, China. Patients' PA was assessed by analyzing answers to the International Physical Activity Questionnaire Chinese version (IPAQ-C) during hemodialysis, and comparing the results with 1 week of pedometer data.					
		Results: Conclusions:	PA-related variables correlated significantly betwee stratified by sex, there was a significant correlation r=0.603 p<0.01 for men) and intensity between per relationships were observed among women, but si p<0.05, moderate PA partial $r=0.358 p<0.05$, walk This is the first study to test the reliability and value	t-retest stability (total ICC=0.84, 95%CI 0.76–0.89), and all even the IPAQ-C and pedometer data (r=0.280–0.561). When for total PA (Spearman r=0.468 p<0.01 for women; Spearman dometry and IPAQ-C. After adjustment for several factors, no ignificant relationships existed for men (total partial r=0.486 ing partial r=0.465 p<0.05, vigorous PA not significant). dity of the IPAQ-C in Chinese MHD patients. Overall, we con- ent for measuring PA in Chinese MHD patients, but possible				
MeSH Keywords: Full-text PDF:		H Keywords:	sex and age bias should be considered when interpreting these results. Exercise Therapy • Hemodialysis, Home • Motor Activity • Questionnaires					
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Background

End-stage renal disease (ESRD) is a primary cause of death in patients with chronic kidney disease (CKD) [1]. It is widely accepted that maintenance hemodialysis (MHD) is the primary therapeutic approach for the clinical treatment of ESRD [2,3]. While the continual development of hemodialysis technology has significantly prolonged the survival of patients on MHD, their quality of life still remains at a low level [4-6]. Efforts targeted at improving the quality of life and the long-term survival rates of patients underlie the goals and philosophy of modern dialysis [7]. As dialyzed patients grow older with the advancement of ESRD survival, their physical strength progressively declines and dialysis-related complications gradually appear [8]. The 2005 Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines advised that exercise training should be a part of the integrated management of MHD patients [9]. The 2016 British Association of Sport and Exercise Sciences (BASES) guidelines also state that regular and appropriate exercise is a foundation for ensuring good physiological function and quality of life [10].

Monitoring and surveying daily activity is of great importance for increasing the amount of exercise performed by hemodialysis patients [11]. Consequently, establishing a method to measure physical activity (PA) in large-cohort randomized controlled trials is desperately needed. Further, this method is needed to perform comparisons among different countries and across studies. Currently, questionnaires are practical and inexpensive instruments used to survey PA, and such questionnaires can have high reliability and validity among specific populations. Many physical activity questionnaires have been used in epidemiological studies [12]. Because the data format collected by the different questionnaires is not uniform, it is hard for clinicians to compare results across different studies. To solve this problem, the World Health Organization (WHO) and its partners have developed the International Physical Activity Questionnaire (IPAQ) for measuring and comparing PA in a variety of demographics and in different countries. The validity and reliability of the IPAQ has been tested in 12 countries [13] as well as in healthy Chinese citizens [14]. Although the IPAQ questionnaire has been extensively tested in the general population, it is rarely tested in patients receiving hemodialysis. In 2015, Rosa et al. confirmed the validity of the questionnaire in hemodialysis patients in English-speaking countries [15]. However, previous studies [14,16] have shown that cultural and language differences can affect the accuracy of the results when questionnaire language is altered.

In China, there has been some testing of the Chinese version of the IPAQ (IPAQ-C) among normal elderly people, as well as in certain clinical groups (e.g., people with hypertension [17] and diabetes [18]). However, no study has verified the validity of the IPAQ-C in Chinese hemodialysis patients. Therefore, it remains unknown how Chinese hemodialysis patients with little or no heavy physical activity will respond to the IPAQ-C. As such, the aim of our study was to test the validity and reliability of the IPAQ-C in Chinese hemodialysis patients.

Material and Methods

Patients and study design

Four centers of hemodialysis treatment in different cities of Zhejiang province participated in this cross-sectional and multicenter experiment. These cities were Hangzhou, Tiantai, Tongxiang, and Haining. Patients who met the inclusion criteria, did not meet the exclusion criteria, and were willing to wear a pedometer were included in our study.

The inclusion criteria were the following: (1) older than 18 years of age, (2) received hemodialysis treatment for more than 3 months, (3) undergoing hemodialysis 3 times a week, and (4) willing to answer the IPAQ-C and wear a pedometer.

The exclusion criteria were the following: (1) use of a wheelchair, physical handicap, or suffering severe cardiovascular or pulmonary disease causing impaired walking and (2) a diagnosis of Alzheimer's disease, intellectual disability, illiteracy, or other condition that might impair the patient's ability to answer the questionnaire.

We recruited 1280 patients, and 320 were subsequently enrolled in our study. After enrollment, patients completed the personal information study survey. Hemodialysis information and laboratory test results such as values of creatinine, hemoglobin, body mass index (BMI), nutrition indicators (albumin, triglyceride, cholesterol in whole blood), and inflammatory biomarkers (neutrophil count and C-reactive protein) were obtained from each patient's medical record. Pedometers were issued, and pedometer data were collected over a 1-week period, using previously published methods [19]. Patients answered the International Physical Activity Questionnaire (IPAQ; Chinese short version) when they returned their pedometer, and this questionnaire was completed again after 1 week as the reliability testing. Some patients participated in the baseline survey and wore pedometers, but did not participate in the second one-week survey. Therefore, while we obtained the pedometer data for 320 subjects, only 102 people agreed to take part in the second survey and were involved in the reliability testing of IPAQ-C. The entire enrollment process is shown in Figure 1.

The study protocol was authorized by the Ethics Committee of Zhejiang Provincial People's Hospital. The 4 hemodialysis

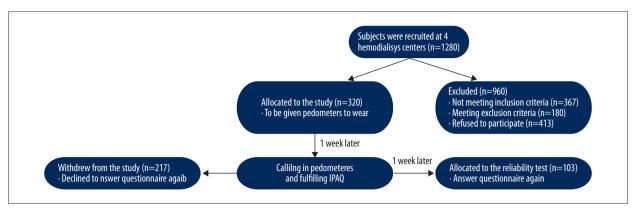


Figure 1. The entire enrollment process.

centers all belong to Zhejiang Provincial People's Hospital Health Alliance, and as such, while they are in different cities, they share the same Ethics Committee and follow the same ethics rules (approval number 2019KY030). Subjects have given their informed consent and the study protocol was approved by the institute's Committee on Human Research.

IPAQ (Chinese Short Version)

The International Physical Activity Questionnaire (IPAQ) was developed by the WHO in 1998 to access physical activity [13]. There are 2 versions available: the long form (IPAQ-LF) with 31 questions, and the short form (IPAQ-SF) with 9 questions. For hemodialysis patients, the scale needs be easy to use, so the short version was selected for testing in our study. In the results of the IPAQ-C, total physical activity is presented as metabolic equivalent (MET) minutes per day. The metabolic equivalent/minute (MET-min) was calculated using the formula [13]:

- Walking MET-minutes/week=3.3×minutes of walking×days of walking; Moderate MET-minutes/week=4.0×minutes of moderate intensity activity×days of moderate or vigorous activities;
- Vigorous MET-minutes/week=8.0×minutes of vigorous intensity activities×day activities with vigorous intensity.

Pedometer

The pedometers (OMRON HJ-328, Omron, Kyoto, Japan) used in our experiment were electronic motion sensors. The pedometer was worn on a backpack, which can record any displacement of the human body. This includes walking, jumping, climbing, and running. The validity of the Omron pedometers have been proven in many different populations [20–24] and under various walking conditions [25]. Compared with other pedometers, the Omron pedometers have superior performance, especially in step counting [26].

Statistical analysis

Normally distributed variables are demonstrated by means±SD and non-normally distributed variables are presented by median and interquartile intervals. Categorical data are represented by medians and quartiles. The Spearman's rank-order correlations and partial correlations were used to reveal the strength of relationships. All statistical analyses were conducted using SPSS (version 24.0, SPSS, Inc., Chicago, USA). P values of less than 0.05 were defined as a strong tendency towards statistical significance. R values [27] of 0.2, 0.5, and 0.8 were regarded as small, moderate, and large correlations, respectively.

Results

Baseline characteristics

Characteristics of the 320 patients are presented in Table 1. Information from 120 women and 200 men were collected. Their age range was 24–75.5 years. The average dialysis duration was 2.13 (1–11) years. Chronic glomerulonephritis accounted for the largest share of original disease (57.50%), followed by diabetic nephropathy (18.13%) and hypertensive nephropathy (3.44%). Some inflammatory indicators and nutritional indicators of patients were also collected for the partial correlation calibration model, and these data was also shown in Table 1.

Physical activity

As Table 2 presents, the total mean step counts per day were 3391.15 (women 3741 and men 3137.75). Total mean MET measured and calculated by IPAQ-C was 1533 (women 2152.5 and men 1400). When evaluated separately by sex, no significant difference was found in either index.

Table 1. Characteristics of the hemodialysis patients* (n=320).

Characteristic		Value
Age (years)	58.60	(24–75.50)
Sex – no. (%)		
Female	200	(62.50%)
Dialysis duration [#] – yr (%)	2.13	(1–11)
Body mass index – kg/m ²	21.33	(16.80–39.50)
Original diseases – no. (%)		
Chronic glomerulonephritis	184	(57.50%)
Diabetic nephropathy	88	(18.13%)
Hypertensive nephropathy	11	(3.44%)
Other or unknown	37	(11.56%)
Hemoglobin – g/L	106.33	(73–149)
Albumin – g/L	38.29	(29.63–66.81)
Triglyceride – mmol/L	4.01	(0–185)
Cholesterol – mmol/L	4.36	(0–7.86)
Neutrophil count – ×10 ⁹ /L	7.25	(1.90–77.40)
C-reactive protein	3.92	(0.50–29.10)

* Values are means (min–max); # dialysis duration is the years of dialysis.

Validity test of IPAQ-C

Table 3 demonstrates the Spearman's rank-order of the daily activity measured by pedometry and IPAQ-C. Total activity measured by the IPAQ-C was closely correlated to the pedometry data (Spearman r=0.561 p<0.01). After adjusting for sex, age, dialysis duration, hemoglobin, albumin, triglycerides, cholesterol, neutrophil count, and C-reactive protein, the correlation decreased slightly (partial r=0.388, P<0.01). The different intensities of PA assessed by pedometry and IPAQ-C had a moderate relationship, both before and after adjustment.

Table 2. Physical activity of the sample, stratified by sex.

When the data was separately analyzed by sex, there was a modest but significant correlation for total PA (female Spearman r=0.468 p<0.01; male Spearman r=0.603 p<0.01) and different intensity levels of PA between pedometry and IPAQ-C. After adjustment for age, dialysis duration, hemoglobin, albumin, triglycerides, cholesterol, neutrophil count, and C-reactive protein, no relationships were discovered between the pedometry and IPAQ-C measuring PA among women, but significant relationships were found for men (total partial r=0.486 p<0.05, moderate activity partial r=0.358 p<0.05, walking partial r=0.465 p<0.05), with the exception of vigorous activity.

Reliability test of IPAQ-C

The results of IPAQ-C Reliability testing are demonstrated in Table 4. The intraclass correlation coefficient (ICC) for each domain between test 1 and test 2 ranged from 0.62 to 0.99, and all domains had statistical significance (P<0.01). The highest ICC was the vigorous activity domain (0.99, 95% CI: 0.98–1.00), and the lowest one was moderate activity (0.62, 95% CI: 0.44–0.75).

Discussion

It is common knowledge that as MHD patients age, there is an increasing need for an effective treatment to maintain a high quality of life. A multitude of studies have shown that appropriate physical activity in MHD patients can improve cardio-pulmonary function [28], relieve fatigue [29–31], alleviate the inflammatory cascade [32], and improve quality of life [33]. To promote physical activity in these patients, a simple and effective questionnaire is greatly needed. Although the prevalence of chronic kidney disease in China is 10.8%, there is no questionnaire specifically designed for dialysis patients in China. Indeed, IPAQ has only been tested in dialysis patients in England [15]. To the best of our knowledge, this is the first study aimed at testing the reliability and validity of IPAQ-C that recruited large numbers of patients in multiple centers. Compared with previous studies, we used a pedometer instead

Measure	Total (n=320)		Fem	Females (n=120)		Males (n=200)	
IPAQ-C (MET-min/week)							
Vigorous activity	0.0	(0.0–0.0)	0.0	(0.0–840.0)	0.0	(0.0–0.0)	
Moderate activity	210.0	(0.0–1680.0)	840.0	(0.0–1680.0)	0.0	(0.0–1680.0)	
Walking	693.0	(346.5–1386.0)	693.0	(317.6–1386.0)	693.0	(346.5–1386.0)	
Total	1533.0	(693.0–4452.0)	2152.5	(676.4–5759.3)	1400.0	(606.4–3318.0)	
Pedometer (average steps per day)	3391.2	(1792.8–5117.4)	3741.0	(2315.8–5311.4)	3137.8	(1576.4–5038.8)	

Values are median (First Quartile, Third Quartile).

IPAQ	Total (n=320)	Females	; (n=120)	Males (n=200)		
(MET-min/week)	Spearman correlation r	Partial correlation r#	Spearman correlation r	Partial correlation r##	Spearman correlation r	Partial correlation r##	
Vigorous activity	0.280*	0.197*	0.398**	0.153	0.19	0.216	
Moderate activity	0.430*	0.271*	0.417*	0.128	0.412*	0.358*	
Walking	0.407*	0.380*	0.344+	0.267	0.481*	0.465*	
Total	0.561*	0.388*	0.468*	0.238	0.603*	0.486*	

 Table 3. Correlations between the IPAQ-C and the pedometry-measured activity.

[#] Adjusted variables include Sex, Age, Dialysis duration, Hemoglobin, Albumin, Triglyceride, Cholesterol, Neutrophil count, C-reactive protein; ^{##} adjusted variables include Age, Dialysis duration, Hemoglobin, Albumin, Triglyceride, Cholesterol, Neutrophil count, C-reactive protein. * Correlation is significant at the 0.01 level (2-tailed); ** correlation is significant at the 0.05 level (2-tailed).

Table 4. Reliability of IPAQ-C (n=102).

IPAO-C	Adminis	stration one	Adminis	stration two	Intraclass	
(MET-min/week)	Mean±SD	Median (p25-p75)#	Mean±SD	Median (p25-p75)#	correlation coefficient (ICC)	95% CI
Vigorous activity	82.35± 326.32	0 (0–0)	83.73± 332.08	0 (0–0)	0.99*	0.98, 1.00
Moderate activity	699.31± 1282.72	0 (0–840)	920.98 <u>+</u> 1957.47	0 (0–1295)	0.62*	0.44, 0.75
Walking	1376.49 <u>+</u> 1551.49	693 (346.50–1905.75)	1385.43± 1586.79	693 (346.50–1905.75)	0.90*	0.85, 0.93
Total	2158.15 <u>+</u> 2083.05	1459.50 (517.56–3249.75)	2386.60 <u>+</u> 2636.65	1459.5 (682.50–3517.5)	0.84*	0.76, 0.89

* Values are the median (First Quartile, Third Quartile); * correlation is significant at the 0.01 level (2-tailed).

of an accelerometer as the standard. As the pedometer was lighter, we obtained a larger sample size, which made the results more reliable. Moreover, we added reliability testing to confirm the credibility of the questionnaire. By conducting studies in different hemodialysis centers of different regions, and using a series of statistical methods, we excluded many factors influencing exercise, such as the location of dialysis centers, nursing interventions, and nutrition and inflammatory status.

We found that the IPAQ-C showed good reliability with all ICC values greater than 0.60. For the all groups, PA measured by IPAQ-C and pedometer showed a moderate correlation (r=0.280–0.561), but when stratified by sex, this correlation was only found in male patients (r=0.216–0.486). Unfortunately, there are no other data from other studies of Chinese MHD patients for validation of our findings. However, when comparing our result to studies carried out in other populations and countries, we found both similarities and discrepancies. First, the correlations conducted in our study are similar to the results of a 12-country study (r=0.30) [13]. However, data from the only other study similar to ours, conducted in the

UK, contradict our results. In that study, investigators found a significant correlation for total PA in females (r=0.551) but not in males. This result is also similar to that found in an earlier study among older adults; however, it should be noted these were healthy subjects [34]. This suggests that further is needed, and that there may be differences in the findings of the IPAQ-C in healthy subjects when compared to dialysis patients, and across cultures.

Interestingly, Swedish scholars [35] found no differences between females and males when comparing 2 methods of PA measurement. In a study using accelerometers, the correlation was generally lower in men, and in studies using pedometers, it was generally lower in women. There is evidence that the accelerometer may underestimate the patient's activity in low-intensity walking [36,37], while the pedometer may not be able to recognize other activities beyond walking. It has been noted that there are sex-based differences activities; men are more likely to walk, while women do housework more frequently. Thus, the use of accelerometers underestimated the amount of activity in men, while pedometers underestimated the amount of activity in women. This explanation is consistent with the experimental results found in our study and that of other scholars. Therefore, it is reasonable to believe that the reduced correlation after sex stratification found in our study is not attributable to the IPAQ-C questionnaire, but is in fact due to bias caused by the reference measurement device.

Our study has certain limitations that need to be addressed. It relied on a single pedometry measure to quantify physical activity, and an accelerometer, considered to be the criterion standard for measuring daily physical activity, was not used due to its size and cost. There were 413 eligible patients who refused to participate, largely due to the inconvenience of wearing a pedometer for a 1-week period of recording. There was no significant difference in the distribution of patients who refused to participate compared to our study group. To improve recruitment, similar studies need to be conducted across China an internationally.

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Conclusions

This study was a robust test of the validity and reliability of IPAQ-C in a Chinese hemodialysis patient group. The high intraclass correlation coefficients demonstrate the reliability of the IPAQ-C, and the significant correlations between daily physical activity measured by IPAQ-C and pedometry further strengthen the IPAQ-C validity. In conclusion, we provide evidence that the IPAQ-C is a useful, simple, and efficacious instrument for generating physical activity data in Chinese patients undergoing hemodialysis.

Conflict of interest

None.

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