Renal Replacement Therapy

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# Relationship between psychiatric symptoms and activities of daily living in patients undergoing hemodialysis

Yusuke Matsunaga[1,2*], Hiroki Takahashi[3], Yuta Suzuki[4], Shohei Yamamoto[4,5], Keigo Imamura[4], Shun Yoshikoshi[4], Juri Uchida[4], Takuya Nakajima[4], Narumi Fukuzaki[4], Manae Harada[6], Ryota Matsuzawa[7], Atsushi Yoshida[6], Kanako Ichikura[2], Yuko Fukase[2], Norio Murayama[8], Hanako Murase[2], Hirokuni Tagaya[2] and Atsuhiko Matsunaga[4]

## Abstract

**Background:** Accurately identifying the factors contributing to decline in activities of daily living (ADL) is important for preventing such decline in patients undergoing hemodialysis (HD). We studied the prevalence and number of overlapping psychiatric symptoms (depressive symptoms, apathy, and sleep disturbance) in patients undergoing HD and examined the relationship between psychiatric symptoms and ADL.

**Methods:** The study utilized a cross-sectional research design. The sample included 203 outpatients (median age: 69 years) undergoing stable HD treatment three times a week. Patient characteristics, including age, sex, body composition, dialysis vintage, primary kidney disease, comorbidity, and nutritional status, were collected from patients' medical records. Functional status was assessed based on the self-reported questionnaire that combined five basic and eight instrumental ADL items. Usual walking speed was used as an index of physical function. Additionally, the short version of the Center for Epidemiologic Studies Depression Scale was used to assess depressive symptoms. Further, apathy and sleep disturbance were assessed using the Motivation Score and the Athens Insomnia Scale, respectively.

**Results:** Overall, 59 (29.1%) patients demonstrated depressive symptoms, 100 (49.3%) reported apathy, 83 (40.9%) had sleep disturbance, 31 (15.3%) had three overlapping psychiatric symptoms, 43 (21.2%) had two overlapping psychiatric symptoms, 63 (31.0%) had only one symptom, and 66 (32.5%) had no psychiatric symptoms. Multiple logistic regression analysis showed that having two or three overlapping psychiatric symptoms was independently and significantly associated with ADL (functional status of 13 points for the ADL maintenance group, and of < 13 points for the ADL decline group, respectively), even after adjusting for patient characteristics and walking speed (odds ratio: 2.74, 95% confidence interval: 1.12–6.69, reference; no psychiatric symptoms).

**Conclusion:** The present study clarified that the overlapping symptoms, including depressive symptoms, apathy, and sleep disturbance, were independently associated with ADL decline in patients undergoing HD. It is useful to examine not only depressive symptoms but also other symptoms such as apathy and sleep disturbance to elucidate factors

*Correspondence: ymhealthscience@gmail.com

[1] Department of Clinical Psychology, Tsurukawa Sanatorium Hospital, 197 Shinkojimachi, Machida, Tokyo 195-0051, Japan
Full list of author information is available at the end of the article

associated with deteriorated ADL in chronic patients. Our findings provide a strong basis for targeted interventions to prevent functional dependence in the HD population.

**Keywords:** Hemodialysis, Activities of daily living, Depressive symptoms, Apathy, Sleep disturbance

## Background

Epidemiological studies in Japan indicate that the number of patients with end-stage renal failure receiving hemodialysis (HD) therapy is increasing at a rate of about 10,000 per year [1]. The mortality rate (10%) remains high, the duration of dialysis is becoming longer, and the population is aging. Furthermore, the focus of disease management has shifted to improving the quality of life (QOL).

Activities of daily living (ADL) is the collective term for everyday activities (basic ADL; BADL), such as getting up, moving, eating, and dressing, and more complex tasks (instrumental ADL; IADL), such as shopping, managing money, using public transportation, and other purposeful activities. BADL and IADL are important abilities for social participation and maintaining a healthy lifestyle. Therefore, when ADL declines, the scope of life may become limited, activities may be restricted, and independence in daily living may become difficult. On the other hand, it has been noted that declining ADL not only limits social participation and activities but also worsens life expectancy [2].

A study (Dialysis Outcomes and Practice Pattern Study; DOPPS) examined the functional status (13 items) consisting of BADL (5 items) and IADL (8 items) of approximately 7000 patients undergoing dialysis (including 1700 Japanese) who were 65 years old and older [3]. It was reported that the risk of death increases dramatically in elderly patients when the number of independent items falls below eight. In addition, our previous study investigated the likelihood of independence and perceived difficulty in ADL, where we found that difficulty in mobility tasks was independently associated with all-cause mortality [4]. Therefore, accurately identifying the factors contributing to ADL decline for preventing ADL decline in patients undergoing HD is an extremely important intervention in disease management.

Previous reports examining factors contributing to ADL decline have shown that physical function is strongly associated with ADL decline in patients undergoing HD [5]. On the other hand, in the general elderly population living in the community, it has been noted that physical function and depressive symptoms are associated with ADL decline [6]. However, a definitive verdict on the relationship between ADL and depressive symptoms in patients undergoing HD has not yet been reached. One reason for this is that not enough research has been done to determine whether depressive symptoms are independently associated with lower ADL in patients undergoing HD, even when considering the effects of physical function.

In general, it has been noted that individuals with depressive symptoms have multiple psychiatric symptoms, including apathy (decreased motivation) and sleep disturbance [7, 8]. Previous reports on patients undergoing HD indicate that approximately 40% have depressive symptoms [9, 10]. However, the prevalence and overlap of psychiatric symptoms other than depression, such as apathy and sleep disturbances, is not clear. In addition, no study has examined in detail the relationship between these psychiatric symptoms and ADL in patients undergoing HD.

The purpose of this study was to assess the prevalence and number of overlapping psychiatric symptoms (depressive symptoms, apathy, and sleep disturbance) in patients undergoing HD and examine the relationship between these psychiatric symptoms and ADL.

## Methods

### Population and study design

This cross-sectional study enrolled clinically stable outpatients with end-stage renal disease at Sagami Circulatory Organ Clinic between April 2018 and March 2020. According to the Japanese Society for Dialysis Therapy guidelines, all patients at this center were undergoing maintenance HD therapy three times a week. Patients were excluded if: they had been hospitalized 3 months prior to the study, required assistance of another person for walking (even if using a cane, or a walker), had a recent myocardial infarction or angina pectoris, chronic heart failure (New York Heart Association classes III–IV), severe peripheral artery disease with intermittent claudication or critical limb ischemia, uncontrolled hypertension (systolic and diastolic blood pressure at rest > 180/110 mmHg), dialysis disequilibrium syndrome such as hypotension, nausea, or muscle spasm while receiving HD, or cognitive decline that made them unable to understand the questions. This study was conducted in accordance with the ethical standards of the 1975 Declaration of Helsinki, as revised in 2013, and was approved by the Research Ethics Committee of Kitasato University (2015-033). All patients provided written informed consent for their participation in the study.

### Clinical characteristics

Patients' data including: age, sex, time on HD, body composition (body mass index [BMI]), primary kidney disease, serum albumin, geriatric nutritional risk index (GNRI), comorbidities, and cognitive function, were collected from medical records at the time of enrollment in the study. BMI was calculated by dividing post-HD dry weight by height squared. To calculate GNRI, we used the formula: $[1.489 \times \text{albumin (g/L)}] + [41.7 \times \%\ \text{(bodyweight \{kg\}/ ideal bodyweight \{kg\})}]$. A comorbidity index developed for dialysis patients and consisting of primary causes for end-stage renal disease and 11 comorbid conditions was used to qualify comorbid illnesses [11]. The Mini-Mental State Examination (MMSE) score, an 11-question measure (a total score of 30 points) that tests orientation in time and space, word recording, attention, calculation, delayed recall, language, and executive function, was used to screen for cognitive deterioration.

### Activities of daily living (ADL)

Functional status was assessed based on the self-reported questionnaire that combined five BADL items (eating, getting dressed, bathing, using the toilet, and transferring from bed to chair) and eight IADL items (using the telephone, getting places beyond walking distance, grocery shopping, preparing a meal, doing housework, doing laundry, taking medications, and managing) using the Katz index [12] and the Lawton scale [13], respectively. Both scales have been validated in the general population. In BADL, a score of 1 was given if the person was independent in an item, and a score of 0 if assistance was needed. As for the IADL, a score of 1 was given if the person was independent or needed some assistance in an item, and a score of 0 if the person was unable to do it at all. Therefore, each individual could be assigned a possible total score of 13 for each functional status. We assigned patients to two groups: ADL maintenance group (functional status score = 13) and ADL decline group (functional status score < 13).

### Psychiatric symptoms

The presence of depressive symptoms, apathy, and sleep disturbance was assessed to understand the psychiatric symptoms.

#### *Depressive symptoms*

The Center for Epidemiologic Studies for Depression (CES-D) scale is widely used to evaluate depressive symptoms in the general population and patients with chronic diseases, including patients undergoing HD in clinical settings [14–17]. We used the short, 10-item version of the CES-D translated into Japanese (the Japanese version of the CES-D10) to assess depressive symptoms in the week before the study. Its accuracy and validity have been reported among patients undergoing HD [18, 19]. Each item is rated on a scale ranging from 0 to 3; the total CES-D10 score was calculated as the sum of all item scores and ranged from 0 to 30. Higher scores indicated greater depressive symptoms; the presence of depressive symptoms was defined as a score ≥ 10.

#### *Apathy*

Apathy was assessed using the Japanese version of the Apathy Scale [20, 21]. This scale was developed to assess decreased motivation in patients with neurological diseases such as stroke and Parkinson's disease and has recently been used to assess decreased motivation in patients with chronic kidney disease [22]. Each item is rated on a scale ranging from 0 to 3; the total Apathy Scale score was calculated as the sum of all item scores and ranged from 0 to 42, with the higher scores indicating greater apathy. Presence of apathy was defined as a score ≥ 16.

#### *Sleep disturbance*

Sleep disturbances were assessed using the Japanese version of the Athens Insomnia Scale (AIS), a self-assessment scale for insomnia developed by the Global Project on Sleep and Health established by the World Health Organization, and have been confirmed to be highly reliable and valid [23, 24]. The AIS consists of eight items: five to evaluate sleep disorders (falling asleep, moderate nighttime arousal, early morning arousal, total sleep time, and sleep quality) and three to evaluate daytime dysfunction (daytime mood, daytime activity level, and daytime sleepiness) [25]. Each item is rated on a scale ranging from 0 to 3; the total AIS score was calculated as the sum of all item scores and ranged from 0 to 24. Higher scores indicated greater insomnia, and the presence of insomnia was defined as a score ≥ 6.

### Physical function

Physical function was evaluated by measuring the usual walking speed along a 10-m walkway before dialysis on a dialysis day. The most reliable and valid method for assessing walking ability and walking speed is strongly associated with the onset of disability, severe mobility limitation, and mortality in several populations, including healthy elderly and patients with neurological disorders, orthopedic dysfunction, cardiovascular disease, and kidney disease [26–30]. More recently, the usual walking speed was adopted to screen for sarcopenia and frailty [31, 32]. In our study, the self-selected walking speed was measured once and expressed in meters/minute.

### Statistical analysis

Data were presented as median (25th–75th percentile) or numbers (percentage). Multiple logistic regression analysis was conducted to examine the relationship between ADL, presence or absence of psychiatric symptoms, and the number of overlapping psychiatric symptoms, with functional status as the dependent variable (ADL maintenance group = 13 points; ADL decline group < 13 points). The independent variables were patient characteristics, except primary kidney disease (age, sex, BMI, time on hemodialysis, comorbidities, serum albumin, GNRI, and MMSE), walking speed, and psychiatric symptoms. Comorbidity index was employed as a representative of comorbidities for the independent variables to avoid model overfitting. Analyses were performed using JMP Pro 15 software (SAS Institute Inc. Cary, NC, USA).

## Results

### Patient characteristics and physical function

After including the patients who met the study's selection criteria, 203 outpatients undergoing HD were enrolled in this study. Their characteristics are summarized in Table 1. The median participant age was 69 years, 61.6% were males, and the median BMI was 21.3 kg/m$^2$. The median time on HD was 6.0 years. The most common underlying kidney disease was diabetes (34.5%), followed by glomerulonephritis (GN)/cystic kidney disease (30.0%). The most common comorbidity was diabetes (45.3%), followed by atherosclerotic heart disease (26.1%). The median comorbidity index, GNRI, serum albumin level, and MMSE score were 6, 95.1, 3.7, and 27, respectively. Furthermore, the median walking speed as a physical function was 1.2 m/ms.

**Table 1** Summary of patient characteristics

| | **All (*n*) = 203** |
|---|---|
| Age (years) | 69 [61, 76] |
| Male (%) | 125 (61.6) |
| Time on hemodialysis (years) | 6 [2, 14] |
| BMI (kg/m$^2$) | 21.3 [18.8, 24.6] |
| Primary kidney disease (%) | |
| Diabetes | 70 (34.5) |
| GN/cystic kidney disease | 61 (30.0) |
| Hypertension | 20 (9.9) |
| Others | 52 (25.6) |
| Comorbidity (%) | |
| Atherosclerotic heart disease | 53 (26.1) |
| Congestive heart failure | 33 (16.3) |
| CVA/TIA | 52 (25.6) |
| Diabetes | 92 (45.3) |
| Comorbidity Index (point) | 6 [4, 9] |
| Serum albumin (g/dL) | 3.7 [3.6, 3.9] |
| GNRI | 95.1 [90.3, 98.6] |
| MMSE score | 27 [24, 29] |
| Usual walking speed (m/s) | 1.2 [0.9, 1.4] |

Data are shown as the median [interquartile range] or number of patients (percentage)

*BMI* body mass index, *GN* glomerulonephritis, *GNRI* geriatric nutritional risk index, *CVA/TIA* cerebrovascular accident/transient ischemic attack, *MMSE* Mini-Mental State Examination

### Activities of daily living

Figure 1 shows a histogram of the functional status of all subjects. The median functional status of all subjects was 13 points. Of the 203 participants, 94 (46.3%) were in the ADL maintenance group and 109 (53.7%) were in the ADL decline group.

### Psychosomatic symptoms

The prevalence and number of overlapping psychiatric symptoms for all participants are shown in Fig. 2. The prevalence of each psychiatric symptom was 59 for depression, 100 for apathy, 83 for sleep disorders (with overlap), 63 (31.0%) for only one symptom, 43 (21.2%) for only two symptoms (8 for depression and apathy, 23 for apathy and sleep disorder, 12 for depression and sleep disorder), and 31 (15.3%) for three symptoms, accounting for almost 40% of all participants. A total of 66 (32.5%) participants had no psychiatric symptoms.

### Factors related to ADL

The dependent variable was the presence or absence of ADL decline, i.e., functional status 12 or less (decline group) vs. full score of 13 (ADL maintenance group). The presence or absence of psychiatric symptoms and the number of overlaps were independent variables, adjusted for age, gender, BMI, dialysis history, comorbidity Index, GNRI, serum albumin level, MMSE score, and walking speed. Multiple logistic regression analysis results are shown in Tables 2 and 3.

None of the independent variables (psychiatric symptoms: depressive symptom, apathy, and sleep disorder) were significantly associated with the ADL decline (Table 2). In contrast, the presence of two or more psychiatric symptoms was an independently significant factor (odds ratio: 2.74, 95% confidence interval: 1.12–6.69, $p$ value = 0.027) with or without ADL decline, even after adjustment for patient background factors and physical function (walking speed), based on absence of psychiatric symptoms (Table 3).

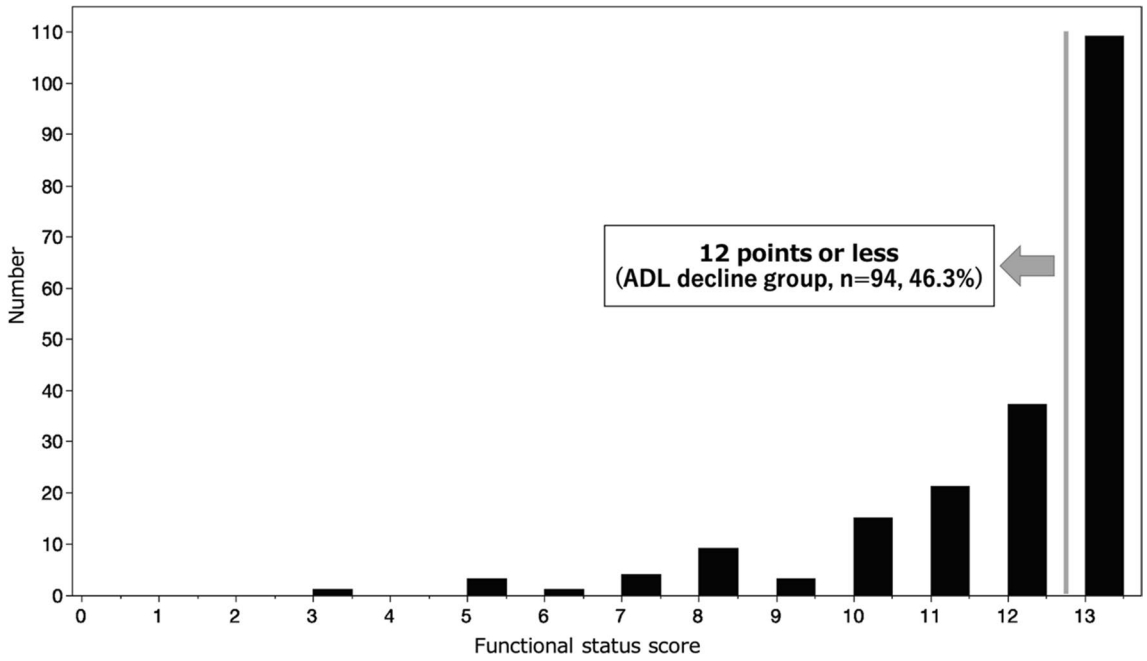


**Fig. 1** Histogram of functional status score of all subjects ($n = 203$)

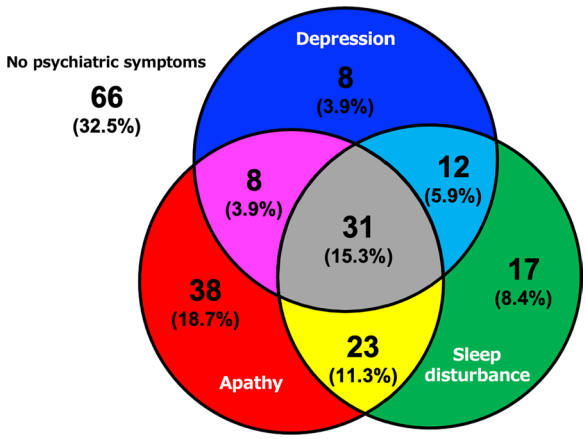


**Fig. 2** The number and proportion of overlap and non-overlap among psychiatric symptoms (depression, apathy, and sleep disturbance). Three circles indicate the prevalence of depression, apathy, and sleep disturbance, respectively. The percentage of the population in the single and overlapped domains is also shown. The rate is about the total cohort ($n = 203$)

## Discussion

Our study revealed the prevalence and overlap of depressive symptoms, apathy, and sleep disturbances in patients undergoing HD and showed that psychogenic symptoms are independently associated with the ADL decline. Furthermore, our study is the first to demonstrate that these psychophysiological symptoms are independently associated with the ADL decline, even after accounting for the influence of physical function (walking speed).

In a previous study of 216 patients undergoing HD, walking speed as physical function and age were found to be significantly and independently associated with ADL difficulty levels. In addition, an association was found between depressive symptoms and ADL levels in the group of patients with preserved physical function. In contrast, no significant association was found between depressive symptoms and ADL levels in the group of patients with impaired physical function [33]. In other words, the results of this previous study indicate that poor physical function is a predominant factor defining ADL in patients undergoing HD. Considering the results of this study, deteriorated physical function may mask the effect of psychosomatic illness on ADL.

Conversely, this study suggests that the combination of two or more psychosomatic illnesses may be a major factor influencing ADL decline in patients undergoing HD. Previous reports have shown that having depressive symptoms, apathy, or sleep disturbances leads to activity and behavior limitations. Depressive symptoms have been noted to cause modulation or reduction of emotional symptoms, such as discomfort and pleasure, and symptoms that limit behavior and activity, such as fatigue [34]. Apathy is characterized by decreased interest and a concomitant decrease in spontaneous and goal-directed behavior, which leads to limitation of behavior and activity [35, 36]. In addition, sleep disturbances particularly

**Table 2** Multivariate logistic regression analyses on the associations between ADL and psychiatric symptoms

| | Units of increase | OR | 95% CI | *p* value | OR | 95% CI | *p* value | OR | 95% CI | *p* value |
|---|---|---|---|---|---|---|---|---|---|---|
| Depression | Presence | 1.85 | 0.86–4.00 | 0.115 | – | – | – | – | – | – |
| Apathy | Presence | – | – | – | 1.50 | 0.71–3.15 | 0.287 | – | – | – |
| Sleep disturbance | Presence | – | – | – | – | – | – | 1.40 | 0.68–2.87 | 0.362 |
| Age | 1 year | 1.06 | 1.02–1.11 | 0.009 | 1.07 | 1.02–1.12 | 0.005 | 1.07 | 1.02–1.12 | 0.005 |
| Male | | 2.07 | 0.92–4.64 | 0.078 | 2.03 | 0.91–4.54 | 0.085 | 2.13 | 0.94–4.79 | 0.068 |
| BMI | 1 kg/m$^2$ | 1.02 | 0.88–1.18 | 0.809 | 1.04 | 0.90–1.20 | 0.617 | 1.03 | 0.89–1.20 | 0.669 |
| Time on hemodialysis | 1 year | 1.03 | 0.99–1.07 | 0.133 | 1.03 | 0.99–1.07 | 0.163 | 1.03 | 0.99–1.08 | 0.121 |
| Comorbidity Index | 1 point | 1.19 | 1.06–1.34 | 0.002 | 1.19 | 1.06–1.34 | 0.002 | 1.19 | 1.06–1.33 | 0.002 |
| Serum albumin | 1 g/dL | 1.78 | 0.13–24.33 | 0.665 | 2.10 | 0.16–28.20 | 0.577 | 1.80 | 0.13–24.00 | 0.657 |
| GNRI | 1 point | 0.97 | 0.83–1.14 | 0.724 | 0.96 | 0.82–1.12 | 0.603 | 0.97 | 0.83–1.13 | 0.654 |
| MMSE | 1 point | 1.02 | 0.90–1.15 | 0.768 | 1.03 | 0.91–1.17 | 0.608 | 1.01 | 0.90–1.15 | 0.815 |
| Usual walking speed | 1 m/s | 0.11 | 0.03–0.41 | 0.001 | 0.11 | 0.03–0.43 | 0.001 | 0.10 | 0.02–0.38 | 0.000 |

*OR* odds ratio, *CI* confidence interval, *BMI* body mass index, *GNRI* geriatric nutritional risk index, *MMSE* Mini-Mental State Examination

**Table 3** Multivariate logistic regression analysis on the associations between ADL and number of overlapping psychiatric symptoms

| | | OR | 95% CI | *p* value |
|---|---|---|---|---|
| No psychiatric symptoms | | Reference | – | – |
| Only one psychiatric symptom | | 2.49 | 0.98–6.31 | 0.054 |
| Two or more psychiatric symptoms | | 2.74 | 1.12–6.69 | 0.027 |
| | Units of increase | | | |
| Age | 1 year | 1.07 | 1.02–1.12 | 0.002 |
| Men | | 2.32 | 1.01–5.33 | 0.047 |
| BMI (kg/m$^2$) | 1 kg/m$^2$ | 1.04 | 0.90–1.21 | 0.608 |
| Time on hemodialysis | 1 year | 1.03 | 0.99–1.08 | 0.116 |
| Comorbidity Index | 1 point | 1.17 | 1.04–1.32 | 0.006 |
| Serum albumin | 1 g/dL | 1.59 | 0.11–22.81 | 0.731 |
| GNRI | 1 point | 0.97 | 0.83–1.14 | 0.743 |
| MMSE | 1 point | 1.04 | 0.92–1.18 | 0.548 |
| Usual walking speed | 1 m/s | 0.13 | 0.03–0.50 | 0.002 |

*OR* odds ratio, *CI* confidence interval, *BMI* body mass index, *GNRI* geriatric nutritional risk index, *MMSE* Mini-Mental State Examination

decreased sleep efficiency and associated changes in daytime arousal rhythms and are known to cause decreased daytime activity [37, 38]. It is easy to imagine that a combination of psychiatric symptoms such as depression, apathy, and sleep disturbances can lead to ADL limitation (decline). Furthermore, it has been noted that when depressive symptoms become more severe, sleep disturbances also occur [39], and the overlap itself could lead to any of the psychosomatic symptoms becoming more severe, leading to a decline in ADL.

Another important finding of this study is the prevalence and overlap of psychosomatic disorders in patients undergoing HD. Of the 203 patients included in the study, 59 (29.1%) had depressive symptoms, 100 (49.3%) had anhedonia, and 83 (40.9%) had sleep disturbances. The prevalence of depressive symptoms was lower, and the prevalence of apathy and sleep disorders was higher than previously reported [3]. Most notably, 74 patients (36.5%) had two or more comorbid psychiatric symptoms. These results suggest that when assessing psychosomatic symptoms for detecting ADL-lowering factors, it is extremely important to evaluate multiple psychosomatic symptoms rather than just one of them to determine if there is an overlap. The DOPPS in 2016 indicated that patients undergoing dialysis with a total score of < 13 in functional status had a greater risk of mortality than patients with a maximum total score of 13 when adjusting for known mortality risk factors including age and comorbidities. This shows that functional dependence was a strong and consistent predictor of mortality [3] and indicates that our findings may provide useful information for disease management in patients undergoing HD.

There are several research limitations to this study. First, the study was conducted at a single institution, and the study population was small ($n=203$). Also, it is impossible to refer to a causal relationship between psychiatric symptoms and ADL declined because it was a cross-sectional study. Further, the method used to assess psychosomatic symptoms was a questionnaire, which did not collect objective information supporting psychosomatic symptoms or treatment details (e.g., medication information), as well as information on the severity of each psychosomatic symptom. It was not possible to determine the severity of the disease. Therefore, in addition to objective information indicating the presence or absence of each psychosomatic symptom, it is necessary to correlate this information with the content of the treatment. Furthermore, we needed to consider the impact of dialysis-related amyloidosis and CKD-related mineral and bone disorders in order to investigate their association with ADL decline, but we did not have sufficient data to diagnose these diseases in our study. Therefore, based on the previous reports that these comorbidities can lead to physical dysfunction and physical frailty [40–42], we adjusted the relationship of psychiatric symptoms with ADL decline using walking speed, which is an important marker to capture physical dysfunction and physical frailty. Finally, this study did not examine the characteristics of the participants, such as whether they had returned to work, whether they had family (roommate) support, or whether they used social support services. The impact of these data on the relationship between psychosomatic symptoms and ADL will need to be examined in detail in the future.

## Conclusions

Our evidence indicates that the overlapping symptoms, including depressive symptoms, apathy, and sleep disturbance, were independently associated with basic and instrumental ADL in patients undergoing HD. Furthermore, they support the usefulness of examining not only depressive symptoms but also other symptoms such as apathy and sleep disturbance to elucidate factors associated with deteriorated ADL in patients with chronic disease. Our findings provide a strong basis for targeted interventions to prevent functional dependence in the HD population.

#### Abbreviations

HD: Hemodialysis; ADL: Activities of daily living; QOL: Quality of life; BADL: Basic activities of daily living; IADL: Instrumental activities of daily living; DOPPS: Dialysis Outcomes and Practice Pattern Study; GNRI: Geriatric nutritional risk index; CES-D: Center for epidemiologic studies for depression; MMSE: Mini-Mental State Examination; AIS: Athens Insomnia Scale.

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#### Author contributions

Yusuke Matsunaga, Hiroki Takahashi, Yuta Suzuki, Shohei Yamamoto, Keigo Imamura, Shun Yoshikoshi, Manae Harada, Ryota Matsuzawa, Atsushi Yoshida, Kanako Ichikura, Yuko Fukase, Norio Murayama, Hanako Murase, Hirokuni Tagaya, and Atsuhiko Matsunaga analyzed and interpreted the patient data for psychiatric symptoms and activities of daily living and contributed to the preparation of the manuscript. Juri Uchida, Takuya Nakajima, and Narumi Fukuzaki performed psychiatric symptoms and activities of daily living measurements. All authors read and approved the final manuscript.

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#### Availability of data and materials

We decided not to share the data in our study because all data are thoroughly described and reflected in the accompanying tables and figures. (All relevant data are within the paper.)

## Declarations

#### Ethics approval and consent to participate

This study was conducted in accordance with the ethical standards of the 1975 Declaration of Helsinki, as revised in 2013, and was approved by the Research Ethics Committee of Kitasato University (2015-033). All patients provided written informed consent for their participation in the study.

#### Consent for publication

Not applicable.

#### Competing interests

The authors declare that they have no competing interests.

#### Author details

[1]Department of Clinical Psychology, Tsurukawa Sanatorium Hospital, 197 Shinkojimachi, Machida, Tokyo 195-0051, Japan. [2]Department of Health Science, Kitasato University School of Allied Health Sciences, Sagamihara, Japan. [3]Department of Rehabilitation, Shonan kamakura General Hospital, Kamakura, Japan. [4]Department of Rehabilitation Sciences, Kitasato University Graduate School of Medical Sciences, Sagamihara, Japan. [5]Department of Epidemiology and Prevention, Center for Clinical Sciences, National Center for Global Health and Medicine, Tokyo, Japan. [6]Department of Rehabilitation, Sagami Circulatory Organ Clinic, Sagamihara, Japan. [7]Department of Physical Therapy, School of Rehabilitation, Hyogo Medical University, Kobe, Japan. [8]Faculty of Humanities and Social Sciences, Showa Women's University, Tokyo, Japan.

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