

#### ORIGINAL RESEARCH

# The Influence of an Unexpected Switch of Hemodialysis Facilities on the Quality of Life (QOL) in Hemodialysis Patients

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Background: We experienced a sudden breakdown of hemodialysis system during a clinical study of dermal itch and serum BNP concentrations.

Patients and Methods: Forty-eight hemodialysis patients were enrolled in the itch-related study. It was intended to improve itch by lowering BNP with supportive communication between the patients and the dialysis staff. We planned to collect data, including visual analogue scale (VAS), dermatology life quality index (DLQI), blood samples and QOL score (KDQOL-SF), four times over a four week interval. The first data was obtained just prior to switching facilities due to a breakdown. The patients underwent hemodialysis in other facilities for two weeks and underwent determination of their clinical data, including QOL scores, three

Results: While mean blood pressure showed no significant differences, serum albumin, iron and phosphate levels were worsened significantly between pre- and post-relocation. Serum BNP and DLQI showed no significant changes. VAS was significantly worsened. The mean values of the cognitive function in the KDQOL-SF and sleep and the role-physical, role-emotional, social function, dialysis staff's encouragement in SF-36 analysis were identified as statistically significant items by MANOVA. Both SF-12 physical and mental composites were also statistically significant. Although SF-12 physical composites were significant among the patients under 66 yrs of age (median), eight factors were significant among those over 66 yrs. Independent analyses revealed every item that was detected worsened significantly after the switch of facilities.

Conclusion: Unexpected switching of hemodialysis facilities severely impacts the QOL for a long duration as well as the patients' symptom and laboratory data.

Keywords: KDQOL-SF, switch of hemodialysis facilities, dermal itch

# Introduction

Most patients undergoing maintenance hemodialysis receive treatments at hemodialysis facilities close to their homes. Huge disasters including earthquakes, Tsunami, floods, hurricanes, etc., can force dialysis facilities to close and patients to evacuate from their living communities. After the Great East Japan Earthquake in 2011, following the Tsunami and Fukushima Daiichi nuclear power plant accident, about 10,000 hemodialysis patients evacuated from their hometowns and continued to undergo hemodialysis in surrogate facilities adjacent to their temporary housings.<sup>2,3</sup> Those who have relocated after disasters tend to exhibit various physical and mental symptoms. 4-6 The evacuated victims of the Great East Japan Earthquake undergoing hemodialysis also exhibited similar problems and lowering of their quality of life (OOL).<sup>7–9</sup>

While these studies have revealed the relationships between relocation of the living place and lowering of the QOL, the effects of unexpected changes of hemodialysis facilities have not been reported. We experienced an unexpected and temporal switching of hemodialysis patients to other facilities due to a sudden breakdown of the water supplying system. Just one week prior to this accident, we started a clinical study to examine the relationships between dermal itch and serum B-type natriuretic peptide (BNP). Visual analogue score (VAS) for itch, dermatology life quality index, blood samples, including BNP levels, and QOL score (KDQOL-SF) were obtained from each patient with the purpose of examining relationships between dermal itch, serum BNP and QOL. Two weeks after the accident, the patients returned to our facility and maintenance hemodialysis was reinitiated. According to the protocol, QOL scores were collected repeatedly three times over a one month interval.

# **Patients and Methods**

### **Patients**

Forty-eight patients undergoing maintenance hemodialysis in the Juntendo University Hospital were enrolled in this study. This group consisted of 29 males and 19 females, with a mean age of 65-yrs. Seventeen patients (39.6%) suffered from diabetic kidney disease. Additional demographic data are summarized in Table 1.

# **Itch-Related Study**

We previously reported that higher serum BNP concentrations were closely related to dermal itch in hemodialysis patients. As the next step, we intended to show causation by reducing the itch through attenuation of the serum BNP levels. Since serum BNP levels in hemodialysis patients are critical to body weight gain during dialysis interval and target dry weight settings, we planned a supportive communication method between patients and dialysis staff. An attending doctor and nursing staff were assigned to each patient. In each session, they reported the patient's body weight and any gain between dialysis intervals. When the weight gain was above 5% of the target dry weight, the staff gave a "yellow card", like in professional football games (Figure 1A). For those who exhibited elevated BNP concentrations, the staff attempted to reduce their target dry weight. The staff also discussed how the patients could improve their lifestyles, including diets, drinking and exercise. If necessary, they consulted experts, ie, nutritionists, physical therapists and clinical counselors. Thus, we enforced daily activities.

### Data Collection

In December 20XX, VAS for dermal itch, DLQI, blood samples and kidney disease-specific QOL score (KDQOL-SF) responses were collected for the first time (test 0). Supportive communication to reduce body weight gain and serum BNP was initiated simultaneously. The following week, the dialysis center was closed after the hemodialysis fluid supplying system was severely damaged. Every patient had to undergo hemodialysis in another facility. One week later, the fluid supplying system was fixed and the treatments at the dialysis center resumed. The patients returned to start maintenance hemodialysis. One month after collecting the first responses for KDQOL-SF, the second survey (test 1) administered. The third (test 2) and fourth surveys (test 3) were administered in one month intervals. During the evacuation, a male patient died due to acute coronary syndrome in the surrogate clinic. Two patients decided to continue hemodialysis at the alternative facilities since they lived more than 50 km from the conventional facility. Another male patient died of heart failure between the second and third surveys. Four patients refused to take the third survey and other four patients took the fourth (Figure 1B).

The KDQOL-SF is a modified version of SF-36 that was developed specifically for the dialysis patients<sup>12</sup> and was validated for Japanese patients.<sup>13</sup> The KDQOL-SF contains eight evaluation items: symptoms or problems, effects of kidney disease on daily life, burden of kidney disease, work status, cognitive function, quality of social interaction, sexual function and sleep. Additionally, SF-36 health survey including physical function, physical role, pain, general health, emotional well-being, emotional role, social function and energy/fatigue can be evaluated. A non-health related QOL survey including social support, dialysis staff encouragement and patient satisfaction was administered simultaneously.

Table I Patient's Background and Laboratory Data Pre- and Post- Evacuation

	Unit	Normal Range	Pre-Evacuation Mean±SD	Post-Evacuation Mean±SD	P-value
Age	Year		65.0±9.4		
Gender	Male/female		29/19		
Cause of ESKD	DM/non-DM		17/31		
Systolic blood pressure	mmHg	<140	150.8±19.2	152.4±17.9	0.44
Diastolic blood pressure	mmHg	<90	78.6±12.4	78.6±10.3	0.98
Duration of hemodialysis	Year		9.4±6.2		
Hemoglobin	g/dL	13–18	10.6±0.9	10.7±0.8	0.46
Hematocrit	%	40–52	32.7±2.6	32.4±2.6	0.46
Iron	mg/dL	60–200	62.9±28.4	54.9±27.1	0.01*
TIBC	mg/dL	250-410	290.3±46.5	292.8±46.4	0.53
Ferritin	ng/mL	20–280	80.6±63.7	72.6±68.0	0.48
Albumin	g/dL	3.7–5.5	3.73±0.3	3.67±0.33	0.04*
Calcium	mg/dL	8.2–10	8.9±0.5	8.9±0.6	0.83
Phosphate	mg/dL	2.5-4.5	5.l±1.l	5.5±1.2	0.04*
Intact-PTH	pg/mL	10–65	220.7±147.0	196.6±139.3	0.98
Urea nitrogen (pre-hemodialysis)	mg/dL	<20	63.8±16.1	63.8±18.0	0.43
Urea nitrogen (post-hemodialysis)	mg/dL	<20	22.1±10.5	21.1±7.8	0.43
Creatinine (pre-hemodialysis)	mg/dL	0.6-1.0	10.5±0.2	10.4±2.4	0.67
Creatinine (post-hemodialysis)	mg/dL	0.6-1.0	4.l±1.l	4.l±1.l	0.53
Beta2-microglobulin	mg/L	<23	27±6.6		
AST	IU/L	<40	13.4±5.9	14.0±5.4	0.2
ALT	IU/L	<40	8.6±4.8	8.8±3.8	0.7
Gamma-GTP	IU/L	<50	19.3±12.1	19.1±14.2	0.82
HbsAg	Positive/negative	Negative	0/48		
HCVAb	Positive	Negative	1/47		
Total bilirubin	mg/dL	<1.0	0.4±0.1		
Triglyceride	mg/dL	50-150	120.9±57.4	124.8±53.8	0.95
LDL-cholesterol	mg/dL	<140	81±21.1	80.5±3.6	0.85
C-reactive protein	mg/dL	<0.1	0.5±1.0	0.31±0.46	0.23
Cardio-thoracic ratio (X-ray)	%		49.1±5	48.6±5.7	0.11

**Notes**: The laboratory data of pre- and post-evacuation are expressed as the mean  $\pm$  SD. \*p<0.05.

Abbreviations: ESKD, end-stage kidney disease; TIBC, total iron binding capacity; PTH, parathyroid hormone; estimable; AST, aspartate aminotransferase; ALT, alanine aminotransferase; gamma-GTP, gamma-glutamyl transpeptidase; HBsAg, hepatitis B surface antigen; HCVAb, anti-hepatitis C virus antibody, LDL-C, low-density lipoprotein cholesterol.

Short form QOL surveys (SF-12 physical composite and mental composite) were also administered. A better QOL was indicated by a higher score of the KDQOL-SF.

### Clinical Data Collection

Clinical data of the patients, including age, gender, cause of end-stage kidney disease, and blood samples were collected from the electronic medical record system in the Juntendo University Hospital. Blood pressure and laboratory data, including hemoglobin, iron, total iron binding capacity (TIBC), ferritin, calcium, phosphate, intact-PTH, urea nitrogen, creatinine, AST, ALT, gamma-GTP, triglyceride, LDL-cholesterol and C-reactive protein (CRP), from blood samples at the time of first survey (test 0) and one month later (test 1) were also collected for statistical analysis. All blood samples were taken at the beginning of hemodialysis on Monday or Tuesday two days after the last session. Serum BNP was measured in samples obtained post-dialysis.

# Statistical Analyses

Data are expressed as the mean  $\pm$  standard deviation (SD). The data from blood samples between test 0 and test 1 were compared by paired-student's t test. The mean values between the four surveys were compared by multivariate





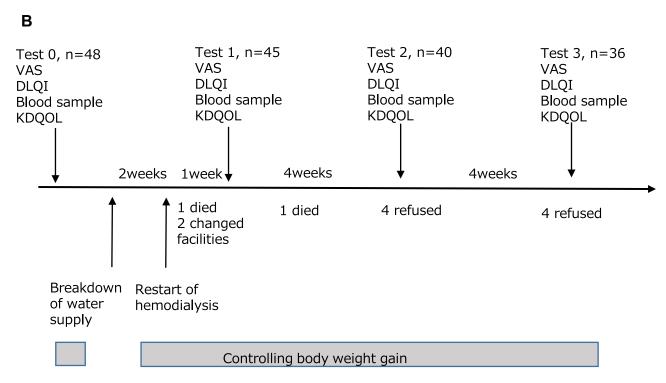


Figure I (A) The yellow card. The patients whose pre-dialysis weight gained more than 5% of the target dry weight during the hemodialysis interval received this card. The card informed the patients that they had increased their body weight too much and exceeded the limit (5% of the target dry weight). (B) The time course of this study. The time course of the study that intended to weaken dermal itch by lowering the serum BNP concentration and timing of the accident with the water supply system. The collection of data, including VAS, DLQI, Blood sample and KDQOL-SF and movement of the patients, are shown.

Table 2 Analyses of Dermal Itch-Related Values

Factors	0 Month (Test 0)	I Month (Test I)	2 Months (Test 2)	3 Months (Test 3)	df	F value	P value
BNP	311±370	247±251	256±268	268±267	29	0.19	0.16
VAS	1.6±2.3	2.7± 2.7	2.8±2.9	1.9±2.4	42	1.3	<0.0001***
DLQI	2.1±2.6	2.1±2.4	2.3±2.7	2.4±2.8	20	0.14	0.43

**Notes**: Repeated collection of the dermal itch related values were analyzed by MANOVA. \*\*\*p<0.0001. **Abbreviations**: BNP, B-type natriuretic peptide; VAS, visual analogue scale; DLQI, dermatology life quality index.

analysis of variance (MANOVA). Dunnett's test was applied for each test separately in the analyses of the differences between control data, the first survey (test 0) and the other tests. To examine the effect of age, independent analyses were performed using all patients, patients under 66-yrs of age (median) and over 66-yrs. Statistical significance was considered at p<0.05. All statistical analyses were performed using JMP 7.02 (SAS Institute Inc., Cary, NC) software.

# **Results**

# Laboratory Data

The mean blood pressure of the patients did not change after switching of the dialysis facilities. Serum albumin, iron and phosphate levels were worsened between pre- and post-switch of hemodialysis facilities (Table 1).

# Itch Related Study

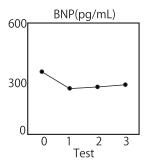
Although supportive communication was maintained to control the patient's weight gain, except for during the evacuation period, serum BNP levels did not change significantly. Skin condition QOL score (DLQI) showed no significant change throughout the whole studying period. While VAS for itch suggested a significant change, it was worsened after evacuation until test 2 (Table 2, Figure 2)

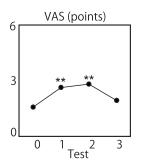
# MANOVA of KDQOL-SF

Among the kidney disease-specific QOL items, the mean values of cognitive function and sleep were significantly different (0.031, 0.045, respectively). The SF-36 health survey revealed that the values of role- physical (p=0.029), pain (p=0.018), role emotional (p=0.039), social function (p=0.038) changed significantly during the surveys. Among the items of the non-health related QOL surveys, dialysis staff encouragement revealed significant changes. Both of the SF-12 physical and the mental composite revealed any significant changes of the patients' QOL (p=0.013, p=0.034) (Table 3).

# Independent Analyses

All of the items for patients' QOL selected by MANOVA showed that the scores worsened after the first survey. All of the patient's values for sleep, role-physical, social function, SF-12 physical and mental composite in tests 1, 2, 3 were significantly





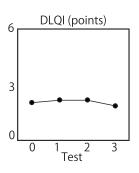


Figure 2 Controlling BNP and itch was failed. The mean values of each test is shown and tests 1, 2 and 3 were compared with the pre-relocated data, test 0 using MANOVA (\*\*\*p<0.01). The supportive method did not change the patient's serum BNP concentration or DLQI scores. VAS was worsened after switching facilities.

Table 3 Chronological Changes in Subscales of KDQOL-SF

Quality of Life Domain	Data Collection					MANOVA	
	0 Month (Test 0)	I Month (Test I)	2 Months (Test 2)	3 Months (Test 3)	df	F value	P-value
Kidney disease quality of life							
Symptom problem list	85.1 ± 9.7	81.9 ± 11.3	79.8 ± 14.5	80.4 ± 13.3	35	0.75	0.528
Effect of kidney disease	84.8 ± 12.4	78.5 ± 15.9	75.9 ± 18.2	78.5 ± 15.6	35	1.7	0.186
Burden of kidney disease	42.0 ± 21.6	33.0 ± 18.3	33.6 ± 20.0	35.9 ± 21.9	35	0.15	0.178
Work status	63.0 ± 33.2	59.8 ± 38.9	54.8 ± 42.5	56.6 ± 42.2	35	0.004	0.987
Cognitive function	96.5 ± 7.3	91.2 ± 10.2	89.5 ± 12.2	88.6 ± 18.5	34	0.29	0.031*
Quality of social interaction	64.9 ± 5.2	62.6 ± 6.2	61.9 ± 7.1	63.1 ± 6.9	34	0.16	0.157
Sexual function	ND	ND	ND	ND			
Sleep	74.5 ± 17.3	67.9 ± 17.2	65.0 ± 19.5	65.5 ± 19.4	35	0.26	0.045*
SF-36 health survey							
Physical function	79.6 ± 17.2	72.2 ± 19.6	69.5 ± 23.3	68.2 ± 25.1	35	0.13	0.226
Role-physical	81.0 ± 34.8	57.0 ± 44.0	52.4 ± 43.4	55.9 ± 45.2	35	0.29	0.029*
Pain	80.4 ± 24.7	66.5 ± 25.7	66.8 ± 24.6	66.8 ± 23.0	35	0.24	0.056
General health	45.1 ± 13.2	43.2 ± 12.3	42.3 ± 14.1	44.7 ± 14.2	35	0.05	0.662
Emotional wellbeing	82.1 ± 17.8	72.7 ± 13.7	72.7 ± 18.0	73.2 ± 18.3	33	0.25	0.056
Role-emotional	90.7 ± 27.8	74.6 ± 43.4	69.8± 44.7	61.4 ± 48.7	35	0.27	0.039*
Social function	91.8 ± 18.3	76.6 ± 27.3	78.0 ± 26.2	79.5 ± 23.9	33	0.29	0.038*
Energy/fatigue	59.8 ± 22.9	55.1 ± 20.3	54.5 ± 20.4	55.7 ± 25.0	35	0.04	0.675
Non-health related QOL							
Social support	85.3 ± 16.7	80.4 ± 20.9	79.0 ± 20.2	80.7 ± 17.6	34	0.11	0.328
Dialysis staff encouragement	87.0 ± 16.7	80.7 ± 21.7	81.0 ± 20.7	77.0 ± 24.7	34	0.29	0.031*
Patient satisfaction	5.3 ± 8.5	12.0 ± 15.2	11.9 ± 18.1	10.6 ± 14.4	33	0.14	0.213
SF-12 composite score							
Physical composite	46.5 ± 6.4	42.2 ± 9.0	39.9 ± 9.5	42.6 ± 8.4	25	0.53	0.013*
Mental composite	56.8 ± 8.8	50.8 ± 9.9	48.4 ± 11.4	50.1 ± 12.1	25	0.41	0.034*

Notes: The values of subscales are expressed as the mean ± SD. \*p<0.05.

Abbreviations: SF-36, short-form 36-item Health Survey; SF-12, short-form 12-item health survey; QOL, quality of life; MANOVA, multivariate analysis of variance; df, degrees of freedom; ND, not done.

lower than those of test 1. The scores of cognitive function, role-emotional and dialysis staff encouragement were gradually reduced and showed significant lowering two or three months after evacuation (Figure 3A).

The patients under 66-yrs of age exhibited significant reduction of the SF-12 physical composite. The scores of test 3 were recovered and showed reduced significance compared to those of test 0 (Figure 3B).

The patients over 66-yrs of age showed significant worsening in multiple subscales of KDQOL-SF. Most of the scales for test 1 were significantly lower than test 0. Dialysis staff encouragement showed a pattern similar to that of all of the patients. With the exception of the effect of kidney disease, the values of test 3 remained significantly lower compared to those of test 0 (Figure 3C).

### **Discussion**

Since we read a report that BNP was a candidate of stimulator for itch transmission, <sup>14</sup> we have studied the relationships between BNP and itch in hemodialysis patients. <sup>11</sup> Our observational study suggested serum hyper-BNP related daytime itch in non-diabetic patients. Then, we attempted to control itch by lowering serum BNP. By ethical restriction, we could perform the supportive communication method and the protocol was approved by ethics committee of the Juntendo University. Unfortunately, owing to water-supply system breakdown, our hemodialysis unit was closed just after starting study. But the member of our group adhered to the protocol.

Returned patients showed lowering serum albumin, iron and elevated phosphate. Most of the surrogate facilities have close relationships and collaborate with ours. Every patient's protocol of hemodialysis was sent and the records from

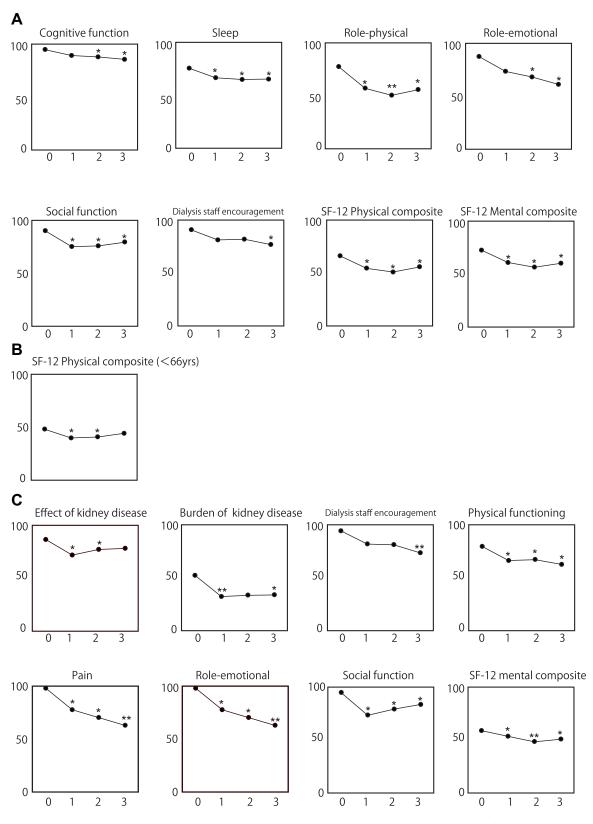


Figure 3 Significantly changed subscales of KDQOL-SF during the study. The mean values of each test are shown. The values of tests 1, 2, 3 were compared with test 0 using MANOVA (\*p<0.05, \*\*p<0.01). (A) The analyzed data from all of the patients. (B) The analyzed data from the patients under 66 years (median) old. Only SF-12 Physical composite was significantly different. (C) The analyzed data from the patients over 66 years old.

surrogate facilities showed that the patients were given adequate dialysis. The change of serum albumin and phosphate might be driven by changing dietary habits. It was possible that lowering iron was due to stopping supplementation.

Our plan for reducing weight gain and serum BNP was failed. Patient's itch was worsened. These phenomena might reveal the limitation of the supportive methods or shortage of study period. While the itch was worsened, DLQI was not changed. Although the VAS score significantly elevated after the switch of dialysis facilities, the patients had mild itch with mean VAS score was 1.6 at the beginning of the study. The elevated mean VAS score was 2.7 (Table 2). Previous validation studies revealed that the heavier intensity of itch gave the more impact on patient's QOL scores. <sup>15,16</sup> Thus, the increase of the VAS score influenced subtle impact on DLQI DLQI limits to show the impact of skin troubles on QOL, the dissociation between DLQI and KDQOL suggests the impact of sudden switch of dialysis facilities.

The 36-items which show functioning and well-beings were assessed by KDQOL-SF. Among whole patients, they were significantly disturbed in cognitive function, sleep, role-physical, role-emotional, social function, dialysis staff encouragement, SF-12 physical and social composites (Figure 3A). The role-physical and role-emotional reflect the interference on the job and daily activities by physical and mental troubles, respectively. Social function suggests the effect on the relationships among the patients and their family members, neighbors and friends. SF-12 physical and mental composites are summarized the change of QOL by physical and mental disturbances. The physical and mental dimensions between SF-12 and SF-36 exhibit excellent correlation.

Older patients (>66-yrs) significantly interfered on Effect of kidney disease, burden of kidney disease, physical functioning, pain, role-emotional, social function and SF-12 mental composite (Figure 3C). The effect means the direct effect of kidney disease on daily life. "Burden" does time, money or efforts of patients and families to maintain daily life. The decrease of the physical functioning suggested the patients felt more difficulty for daily activities including taking a bath, changing clothes etc.<sup>12</sup> They showed long physical and mental interference while social function gradually improved. This suggested the effect of returning to the home facility.

We learned that there are six infrastructures that are indispensable to maintaining daily hemodialysis: 1) buildings, 2) hemodialysis equipment, 3) electrical power supply, 4) water supply, 5) dialysis materials and 6) dialysis workforce, after the experiences of the Great East Japan Earthquake on March 11, 2011. If one of these essential infrastructures is lacking, the patients cannot receive adequate treatment. Especially, a lack of electric power or water supply can put a hemodialysis center out of order for a long time. In this situation, transient switching of dialysis facilities is one of the solutions for continuing treatment.

After the Great East Japan Earthquake, many hemodialysis patients in Tohoku district were evacuated from their hometown to Niigata, Hokkaido, Chiba and Tokyo and underwent hemodialysis in unfamiliar environments.<sup>2</sup> The patients worried about their families who were left behind, their homes, evacuating methods, financial costs, the duration and joining unfamiliar patients when they were told the necessities of evacuation.<sup>19</sup> Relocation after disasters is considered to be associated with increased mental health problems.<sup>20</sup> Studies among the earthquake survivors have reported various symptoms, including post-traumatic stress disease (PTSD), PTSD-like and depression.<sup>21,22</sup> Relocation after disasters is also considered to be associated with increased mental health problems.<sup>20</sup> Post-traumatic stress and depression are negatively associated with QOL after disaster.<sup>23</sup>

Compared to these studies, our experience is unique since the cause of the physical and mental distress was limited to the unexpected switching of hemodialysis facilities. Every patient received adequate treatment and did not experience home re-location. The most severe impact on each of the patient's mental condition might be induced by a lack of human communication with the dialysis staff and other patients. One study examining satisfaction with dialysis treatment and QOL revealed that communication between the care provider and the patients plays a favorable role for the QOL.<sup>24</sup> Test separately study of KDQOL-SF subscales toward the patients over or under 66-yrs old showed aging related vulnerability for sudden change of surrounding circumstances.

Recent studies have revealed that social networking services enable hemodialysis patients and their families to share information in managing dialysis.<sup>25</sup> For young people suffering from mental health problem, social networking service-based interventions were found to be useable, engaging and supportive.<sup>26</sup> The lack of communication between the patients and care-providers can be overcoming by developing various communication tools. As such, user-friendly devices are anticipated.

# **Conclusion**

The unexpected switching of hemodialysis facilities severely impacts the patient's QOL for a long duration as well as the patients' symptom and laboratory data.

# **Data Sharing Statement**

The data that support the findings of this study are available on request from the corresponding author, YS. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

# **Ethics Approval Statement**

This study was approved by the Ethics Committee of the Juntendo University Hospital with declaration of Helsinki (No. 14-124). Written informed consent was obtained from the patients.

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### **Author Contributions**

All authors made a significant contribution to the work reported, whether that is in conception, study design, execution, acquisition data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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### **Disclosure**

The authors declare no conflicts of interest associated to this manuscript.

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