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Original Article

The effects of a home-based care model on fluid load in hemodialysis patients

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Abstract: Background: Fluid management in hemodialysis patients is critical, but there are no optimal care protocols. The aim of this study was to investigate the impact of a home-based care model on the fluid loads in patients undergoing sustained hemodialysis. Methods: This is a single-center, randomized, controlled clinical study. 124 patients who underwent maintenance hemodialysis were randomized into an experimental group (EG) and a control group (CG) (n=62 for each group). The EG underwent a home-based care model, and the CG was cared for using a routine nursing model. They were compared in terms of their blood pressure, BMI, pulse wave velocity (PWV), and N-terminal (NT)-pro hormone BNP (NT-proBNP) levels before the nursing and at 12 months of follow-up. Results: There was no significant difference in the baseline data between the two groups (P>0.05). At 12 months of intervention, the EG had better systolic blood pressure (139±9 mmHg vs. 144±13 mmHg, P=0.04) and NT-proBNP levels (6148 pg/ml vs. 8552 pg/ml, P=0.01) than the CG. There was no significant difference between the two groups in terms of BMI, DBP or PWV or in their adverse event rates. Conclusion: The home-based care model is beneficial for fluid management in hemodialysis patients.

Keywords: Hemodialysis, home-based care model, fluid load

Introduction

Persistent fluid overload is more common in patients with end-stage renal disease undergoing maintenance hemodialysis. Evidence shows that chronic fluid overload is strongly associated with complications such as hypertension, arrhythmias, left ventricular hypertrophy, heart failure, and cardiovascular-related death [1]. Fluid overload also leads to an increase in arterial stiffness (assessed by measuring pulse wave velocity) by expanding arterial dilation and increasing systolic pressure [2]. Arterial stiffness has been proven to independently predict mortality in patients with end-stage renal disease [3]. Blood pressure and NT-proBNP are both good indicators of fluid load in hemodialysis patients [4].

Proper management of fluid load requires, on the one hand, the multidisciplinary cooperation of the physicians, nurses, and dietitians, and, on the other hand, the active participation of the patients and their families is essential because dialysis patients require long-term, continuous, and timely monitoring and regulation of their fluid intake, their low-sodium diets, and their weight in their daily lives [5]. Home-based care is a patient-centered model. The medical team enables the patients' families to provide ongoing care for the patients by providing support and education. The effectiveness of this model of care has been demonstrated in pediatrics, critical care medicine, and neurology [6, 7]. This randomized, controlled study intends to explore the impact of the home-based care model on the above indicators.

Subjects and methods

Subjects

From May 2015 to May 2018, 124 patients who underwent maintenance hemodialysis in our hospital were recruited as the study cohort. Enrollment criteria: (1) age ≥ 20 years; (2) lived well on dialysis for 1-20 years; (3) three times of hemodialysis treatment a week, with each treatment lasting more than 3 hours; (4) a blood flow rate of 250~300 ml/min; (5) weight gain <7% during the last month of dialysis. Exclusion criteria: (1) patients with concomitant chronic obstructive pulmonary disease and pleural effusion; (2) patients with renal transplantation. Elimination criteria: (1) patients with a reduced dialysis frequency after enrollment; (2) patients who underwent kidney transplantation or who only received peritoneal dialysis after enrollment. Informed consent was obtained from all patients. This study was approved by the Ethics Committee of Wuhan Central Hospital. SAS software was used to generate a random number table, and the patients were numbered according to their medical record numbers, which corresponded to the random sequence numbers to determine the grouping.

Methodology

The experimental group (EG) was cared for using home-based care. 1) A follow-up file was established after each patient's enrollment, and the patients were followed up once a month in the outpatient clinic; 2) A nursing team composed of nephrology nurses, physicians from blood purification centers, and nutritionists provided nursing support during the follow-up period; 3) Lectures centered on hemodialysis and nursing knowledge were organized for the patients and their families once a month, covering weight monitoring, healthy diets (fluid intake and low-sodium diet), family care of dialysis access, and communication skills among family members, etc. 4) The families of 3-4 patients will form a mutual assistance group, exchanging and sharing their nursing experiences once a month.

The control group (CG) received routine care. After enrollment, a follow-up file was established for each patient, and a follow-up was performed once a month.

Outcome measurement

Baseline data: gender, age, dry weight, type of vascular access, duration of dialysis, primary disease, serum calcium, hemoglobin concentration, albumin concentration; sex, age, and literacy of the primary caregiver.

Endpoints: Body mass index (BMI), systolic blood pressure, diastolic blood pressure, NT-proBNP, measured using immunoassays (ECLIA Roche Diagnostics, GMBH Mannheim, Germany) and PWV, measured on the radial artery, femoral artery, and carotid artery by applanation tonometry with Sphygmo-Cor Vx software (AtCor Medical).

Quality control

Targeted trainings provided for health care professionals were included in the study, including an introduction to the background of the topic, grouping, randomization protocol, standardized follow-up, and documentation.

Statistical analysis

All the data were entered and cross-checked by two specialist nurses from the research team. SPSS 25.0 software was used for the data analysis and Prism 7.0 was used for the chart making. The comparisons of the categorical variables between the groups was performed using chi-square tests. Continuous variables conforming to a normal distribution were expressed as the "mean ± SD" and were compared using independent sample t tests. The continuous variables that did not conform to a normal distribution were expressed as "median (interquartile range)", and rank sum tests were used for the comparisons between groups. $P<0.05$ indicated a significant difference.

Results

Enrollment of 124 cases

During the follow-up period, 3 (1 received a kidney transplantation, 2 switched to peritoneal dialysis) and 4 (2 received a kidney transplantation, 1 switched to episcleral dialysis, 1 showed a decreased dialysis frequency) were excluded from the EG and the CG, respectively. Ultimately, a total of 124 patients completed the follow-up, with 62 patients in the EG and 62 patients in the CG. The inclusion and exclusion processes are shown in **Figure 1**. The differences in the baseline data between the patients who withdrew from the groups and those who completed the study were not significant.

Baseline data of the patients and the primary caregivers

Except for their plasma albumin concentrations, the differences between the EG and CG

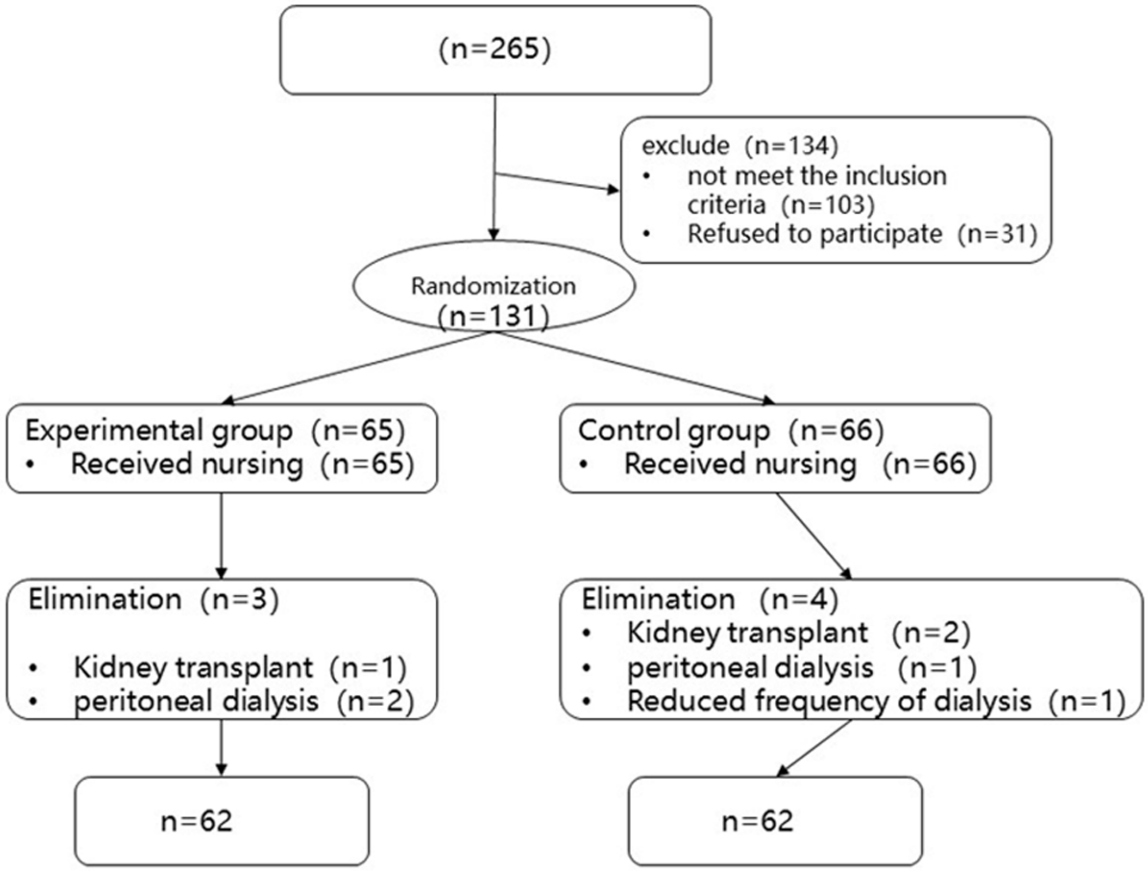

Figure 1. Enrollment process.

were not significant (**Table 1**). The primary caregivers of the two groups were also comparable (**Table 2**).

Comparisons of the BMI, blood pressure, PMV, NT-proBNP, and adverse events between two groups

The baseline values of the five outcome measurements were comparable in the two groups; at the end of 12 months of follow-up, there were no significant differences between the two groups in terms of their BMI, diastolic blood pressure, or PMV (**Table 3**). The mean systolic blood pressure (139±9 mmHg) in the EG was lower than it was in the CG (144±13 mmHg, P=0.04) (**Figure 2**); the median NT-proBNP level of 6148 (3043-11160) pg/ml in the EG was lower than the 8552 (5600-12377) pg/ml in the CG (P=0.01) (**Figure 3**). In addition, there was no significant difference in incidences of adverse events during the follow-up between the two groups (**Table 4**).

Discussion

Home-based care is a model of care that places the patient and their family at the center of the health care decisions [8]. This concept emerged in the 1850s when pediatricians found that children who allowed their mothers to visit or even enter the room with them were less likely to have serious emotional and behavioral problems after discharge [9, 10], and then the concept was extended from family care of hospitalized children to home care of discharged children [11], and further promoted to ICU patients and to adult patients. In the context of the transformation of nursing from "curative" to "caring", this model has been widely applied as it promotes collaboration between the patient, the family, and the members of the health care team and empowers the patient's family to provide continuous and effective care, so it has wide versatility [6, 7]. This clinical study adopted the home-based care model which integrates hemodialysis

Table 1. Baseline data

Item	Total (124 cases)	experimental group (62 cases)	control group (62 cases)	Statistics	P
Age (years)	50±10	51±8	49±12	0.76	0.45
Male	73 (58.9%)	34 (54.8%)	39 (62.9%)	0.83	0.36
Dry weight (kg)	61.6±7.4	61.0±6.7	62.2±8.7	-0.93	0.35
Duration of dialysis (months)	55±41	57±44	54±38	0.31	0.76
Dialysis access				1.04	0.60
Autologous arteriovenous fistula	112 (90.3%)	55 (88.7%)	57 (91.9%)		
Long-term central venous access	8 (6.5%)	4 (6.4%)	4 (6.4%)		
Graft vascular access	4 (3.2%)	3 (4.8%)	1 (1.6%)		
Primary disease				0.72	0.95
Chronic nephritis	46 (37.1%)	25 (40.3%)	21 (33.9%)		
Diabetes	20 (16.1%)	9 (14.5%)	11 (17.7%)		
hypertension	13 (10.5%)	6 (9.7%)	7 (11.3%)		
Polycystic kidney	11 (8.9%)	5 (8.1%)	6 (9.7%)		
unknown	34 (27.4%)	17 (27.4%)	17 (27.4%)		
Serum calcium (mmol/L)	2.09±0.26	2.12±0.25	2.06±0.26	1.29	0.20
Albumin (g/L)	41.8±2.9	41.2±2.8	42.3±3.0	-2.13	0.04
Hemoglobin (g/L)	113±12	113±11	114±14	-0.47	0.64

Table 2. Comparison of the primary caregivers

Item	Experimental group (62 cases)	Control group (62 cases)	Statistics	P
Age (years)	36±12	38±12	-0.89	0.37
Male	42 (67.7%)	37 (59.7%)	0.87	0.35
Literacy			1.16	0.76
Primary school and below	30 (48.4%)	32 (51.6%)		
Lower secondary school	15 (24.2%)	12 (19.4%)		
High school	11 (17.7%)	14 (22.6%)		
College and universities	6 (9.7%)	4 (6.5%)		

patients with caregivers under the same care framework. The medical care team holds health lectures, conducts family follow-ups, and organizes communications among mutual assistance groups to help the patient's family members find shortcomings in the care process, establish a reasonable care plan, and enrich and improve the patient's family's disease knowledge and nursing ability [12, 13].

On the other hand, maintaining a reasonable volume state is one of the key goals of hemodialysis, but there is no universally accepted optimal protocol [14] Mihai et al. divided hemodialysis patients into a fluid overload group (>17.4%, 22 cases) and a normal group (≤17.4%, 135 cases) based on the cut-off point for relative fluid overload: 17.4%, with a median follow-up period of 66.2 months. A significantly higher mortality rate was observed in the overload group than in the normal group (45.5% vs. 21.5%). A multifactorial Cox survival analysis showed a risk ratio of 2.72 (95% CI: 1.60-4.63) for death in the overload group, demonstrating the adverse effects of fluid overload on hemodialysis patients [15].

This study explored whether a home-based care model is beneficial for the management of fluid load in hemodialysis patients. After 12 months of follow-up, although the differences between the two groups in three outcome measures (BMI, diastolic blood pressure and PWV) did not show any significant differences, the systolic blood pressure and NT-proBNP were lower in the patients using the home-based

Table 3. Comparison of the outcomes

Item	Baseline data				End of 12 months of follow-up			
	Experimental group (62 cases)	Control group (62 cases)	Statistics	P	Experimental group (62 cases)	Control group (62 cases)	Statistics	P
BMI (kg/m^2)	23.4±3.1	23.0±2.9	0.70	0.48	23.8±2.7	23.1±2.8	1.43	0.16
Systolic pressure (mm Hg)	145±15	142±17	1.10	0.27	139±9	144±13	-2.09	0.04
Diastolic blood pressure (mm Hg)	76±8	78±9	-1.57	0.12	79±7	81±12	-0.83	0.41
PMV (m/s)	7.67±1.97	8.14±2.10	-1.30	0.19	7.82±1.67	8.10±2.11	-0.81	0.42
NT-proBNP (pg/ml)	5023 (2843-7654)	5777 (4204-10003)		0.59	6148 (3043-11160)	8552 (5600-12377)		0.01

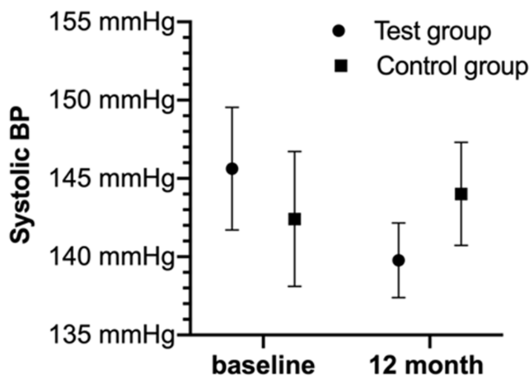

Figure 2. Mean systolic pressure (mmHg).

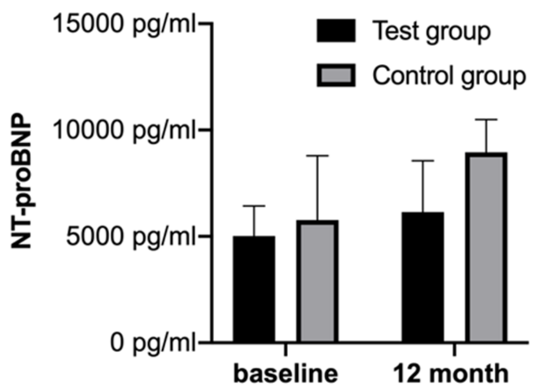

Figure 3. Changes in the median NT-proBNP (pg/ml) values.

care model than in the patients receiving conventional care. The present study was inconclusive as to whether the aforementioned reductions in systolic blood pressure and NT-proBNP can translate into improved final outcomes; however, based on previous studies, it is reasonable to speculate that there is a possibility [16-19]. Although there is no consensus on the target blood pressure in hemodialysis patients, an analysis of the HEMO data shows that in young patients on hemodialysis (mean age 54.9 years, similar to the age of patients in this group), the risk of death was lowest in those with a systolic blood pressure between 120-130 mmHg, and arterial stiffness was an important and independent predictor of survival [20, 21]. Another CORD study involving 47 European dialysis centers covering 1,084 patients showed that for every 1 m/s increase in the PWV, the risk of death increased by 15% [3]. Finally, NT-proBNP was found to be an independent risk factor for death in HD patients [22].

It was demonstrated that aortic stiffness is an independent predictor of cardiovascular event-related death and all-cause death in hemodialysis patients [23-25], but this study did not show a significant difference in the PWV between the two groups, which may be related to the small sample size. However, it must also be noted that this study focused on indirect surrogate endpoints (blood pressure, PWV, and NT-proBNP) and did not gather sufficient data on the clinical endpoints such as cardiovascular events or mortality, which influenced the strength of the conclusions and should be followed up to further investigate the correlation between the home-based care model and the clinical endpoints.

In medical resource-limited areas like China, families work as a very important part of the health system, especially for patients with chronic diseases, playing the part of nurse to some extent. And in some non-western cultures, the natural family connectedness improves the quality of patient care when family members are involved [26], which may partially explain the results of the present study.

As the first randomized, controlled, clinical study to explore the effect of the home-based care model on fluid load in hemodialysis patients, the study demonstrated that this care model is beneficial to the management of fluid load and may help reduce the incidence of cardiovascular events and mortality in hemodialysis patients by using outcome measures such as blood pressure, PMV and NT-proBNP, and the conclusion has some value for clinical application. The present study does have some limitations. First, ideally future studies should involve more than one center and an correspondingly larger patient cohort with better external validity. Second, future studies will be more accurate if they quantify the interventions applied to the EG.

Disclosure of conflict of interest

None.

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Table 4. Average number of negative events during the follow-up period

Adverse events	experimental group (62 cases)	control group (62 cases)	t-value	P
Hypotension, spasticity	5.0±1.2	5.2±1.9	-1.45	0.15

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