

Family-Centered Education and Its Clinical Outcomes in Patients Undergoing Hemodialysis Short Running

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Background: Poor adherence to treatment in patients undergoing hemodialysis leads to many complications, including death of the patient.

Objectives: This study was aimed to investigate the effect of family-based training on common side-effects during dialysis.

Patients and Methods: The present randomized controlled trial study was conducted on 60 patients undergoing hemodialysis at hospitals of Tehran University of Medical Sciences, Iran, from May 2012 to October 2012. Samples were randomly divided into two groups of patient-education (n = 30) and education of patient associated with an active member of the family (n = 30). Blood pressure, chest pain, nausea, vomiting, headaches and muscle cramps were followed with a check list and a questionnaire. The frequencies of the above-mentioned complications at the mentioned intervals were recorded in three stages (before the intervention as well as two and four weeks after the intervention). Data analysis was performed using SPSS software, version 16, with chi-square test, Fisher's exact test and independent t-test.

Results: The mean ages of the patients in patient-centered and the family-oriented groups were 47.41 ± 10.31 and 48.16 ± 9.21 , respectively. The result showed that some of the variables such as chest pain ($P = 0.50$, $P = 0.01$), nausea ($P = 0.50$, $P = 0.01$), headache ($P = 0.81$, $P = 0.016$), and blood pressure ($P = 0.91$, $P = 0.016$) were statistically significant before and four weeks after the intervention.

Conclusions: According to the result of this study, the presence of families in a treatment plan could be essential to follow the treatment plan and subsequently reduced the complications of hemodialysis.

Keywords: Family-Centered Nursing; Patient-Centered Care; Complications; Hemodialysis

1. Background

Approximately 91% of patients diagnosed with end stage renal disease (ESRD) choose to perform hemodialysis as treatment (1). However, hemodialysis has many complications during and after the dialysis process (2). Mortality in patients undergoing hemodialysis has been reported as 16% according to the latest statistics, which often occurs following hemodialysis complications (3).

According to the Association for the Support of Kidney Patients report, from a total of 40000 patients with kidney complications, over 15000 undergo hemodialysis and about 1500 cases die due to the disease symptoms (1), complications such as hypotension, headache, chest pain, etc. each year, of which hypotension is the most common acute complication in hemodialysis, occurring in 20 - 30% of patients and causing problems such as nausea, vomiting and muscle cramps (4).

Despite recent advances in hemodialysis, muscle cramps

are still a major problem among these patients (5). In addition to being painful, this condition leads to restriction of patient movements (6), increased levels of serum creatine phosphokinase, shortened effective time of dialysis (7), and thus, increased mortality rate of patients (8).

Approximately 42% of deaths in patients undergoing hemodialysis are due to cardiovascular complications; the rate is three times higher than patients with non-uremic kidney complications. Ischemia and the resulted cardiac arrhythmias and chest pain, hypotension and sudden death are among the cardiovascular complications during dialysis (9).

According to previous studies, the factors affecting the incidence of cardiovascular events during dialysis include hypotension, electrolyte and blood volume changes, inactivity, anemia, and poor diet (10). On one hand, one of the concerns of patients with advanced and

chronic renal failure is gastrointestinal complications, ranging from mild abdominal pain to severe gastrointestinal bleeding. However, the most common gastrointestinal symptoms during hemodialysis are nausea and vomiting with higher prevalence in patients undergoing hemodialysis than others, as now these patients are treated symptomatically (11). Headache is another acute complication of hemodialysis which is usually caused in patients with increased fluid volume due to increased speed of dialysis and hypotension (12). The mentioned complications not only lead to fatigue and malaise during dialysis (13), but may cause insufficient removal of excess fluids from the body (14) and increased need for nursing care for frequent checking on patient's condition, administering fluids and medications, oxygen therapy, positioning, reducing the ultra-filtration, and finally discontinuing the dialysis earlier than the scheduled program (15).

Inadequate dialysis can lead to increased disease symptoms, increased duration of hospitalization, reduced patient's quality of life, and increased imposing costs for patients, their families and the health system, while a well-scheduled dialysis with few or no complications, in addition to reducing the costs can have an essential role in increasing the quality of life and survival of the patients (4).

Research has shown that hemodialysis complications occur mainly due to noncompliance with the treatment plan. In fact, poor adherence to the treatment plan will be associated with poor clinical outcomes; therefore, education of patients with chronic renal failure is highly crucial (16).

Nurses have the direct responsibility for the care of patients undergoing hemodialysis; they are responsible for educating the patients and their families (17). One of the main topics of the training is to follow the treatment plan (18). Given that the major factors affecting the clinical outcomes of patients with kidney failure occur outside of the health care system and in the home environment, family members who spend time with the patient at home play a role in care responsibilities and the patient's support (19). Positive effects of education are considered as one of the most important aspects of nursing activities (20), according to what was mentioned and with regard to the researcher's experience in care of patients during hemodialysis.

2. Objectives

This study aimed to answer two hypotheses: "hypotension in family-centered groups of patients is less than patient-centered groups" and "muscle cramps in family-centered group are less than patient-centered groups".

3. Patients and Methods

The current study was a quasi-experimental clinical trial with registration number IRCT201204161599N17, per-

formed on patients treated with hemodialysis referred to Imam Khomeini and Amir Alam hospitals affiliated to Tehran University of Medical Sciences between May 2012 and October 2012.

The sample size was determined by the following formula and confidence interval (CI) = 95%, and power of 80% (in each group $n = 30$) (Equation 1).

$$1) \quad n = \frac{\left(z_{1-\frac{\alpha}{2}} \sqrt{2pq} + z_{1-\beta} \sqrt{p_1q_1 + p_2q_2} \right)^2}{(p_1 - p_2)^2}$$

The inclusion criteria of patients were as follows; age from 18 to 65 years; undergoing hemodialysis three times a week, each time for 3 - 4 hours; history of chest pain or symptoms of headache, nausea or vomiting during the two weeks before the intervention, no cardiovascular, gastrointestinal and cerebral vascular diseases and not using cardiac, anti-headache, anti-nausea and anti-vomiting medications, and lack of uremia phase at the time of the research. During the study, if any patient was a kidney transplant candidate or faced with changes of food and pharmaceutical diets by the physician, was excluded from the study.

The inclusion criteria of the active member of the family were as follows; the main person with the highest participation in treatment issues and spending more time with the patient (according to the patient's opinion), being literate.

After conducting the administrative procedures and obtaining the approval of the University Ethics Committee, following the introduction and explaining the objectives of the research to the research units (with eligibility criteria to enter the study), the informed consent form was obtained from each patient and the study was performed.

Before the beginning of the intervention, the patients' blood pressures were taken and controlled for two consecutive weeks, three days per week and five times a day (immediately before the start of dialysis, one hour, two hours, three hours after it, and the final hour of dialysis), using the observation check list for recording blood pressure; with the first occurrence of hypotension in any of the above steps, the patient was enrolled.

In this study, hypotension during dialysis was defined as the time that the systolic pressure of patient decreased more than 30% compared to predialysis or was less than 100 mmHg, or a diastolic pressure below 60 mmHg (21, 22). Other complications were also recorded using the observation checklist for two weeks, three days per week and twice a day (at the middle and final half hour of the dialysis), when most of the symptoms occurred (13), and with the first occurrence of any of the above complications, the patient was included in the study.

According to the International Headache Society, headaches during dialysis are once considered when they start during dialysis and end 24 hours later. These

Table 1. Educational Content Provided to Patients and Their Families

Educational Intervention	Educational Content	Time Per Session, min
First session	Kidney disease; the causes of kidney failure; how to work with hemodialysis device; the number of hemodialysis sessions	30 - 45
Second session	Some descriptions and recommendations on nutrition and diet (appropriate diet, the importance of adherence to the diet, permitted values of food consumption, dietary restrictions)	30 - 45
Third session	Moving program (the importance of regular exercising and its time, etc.); medication plan (how to use the medications, their side effects and the reason of prescribing according to the physician's orders)	30 - 45

effects were observed and recorded by the researcher.

The educational intervention began at the end of the second week. Therefore, education of both groups (patient-centered and family-centered) was conducted as individual face-to-face training with regard to the patient's training needs, in three areas of diet, exercise program and medication diet on patient's bed. In the patient-oriented group, the educational content was provided only to the patients individually, while in the family-centered group, in addition to the patient, one active member of the family attended to the training sessions. The educational content of each session is described in Table 1.

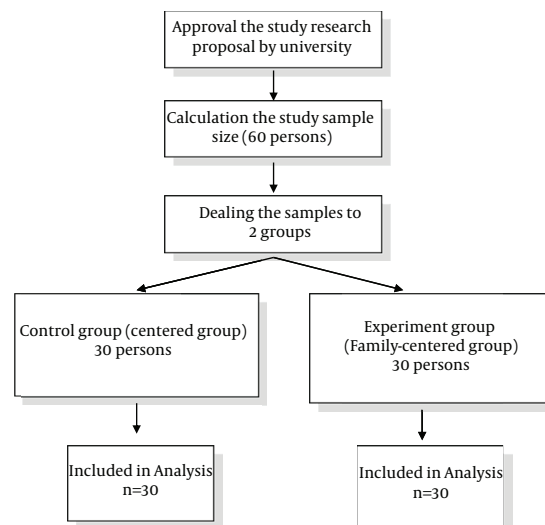
At the end of the sessions, the pamphlet of each session was provided to the participants. The researcher's contact number was also given to the participants in case of any questions.

In the second and fourth weeks after the intervention, the episodes of hypotension, muscle cramps, chest pain, headache, nausea and vomiting were re-evaluated in both groups. Therefore, these factors were examined for a week, three days per week and two times a day (in the middle and the final half hour of dialysis).

Data collection tool included a questionnaire and an observation checklist. The questionnaire consisted of two parts: individual information of patients (demographic information) and information about the disease. The observing checklist included hypertension, muscle cramps, chest pain, headache, nausea and vomiting with 50 questions. Content validity method was used to determine the scientific validity of the researcher-made questionnaire. Therefore, after reading the books, the scholarly new and the relevant articles, similar studies and internet searching as well as collecting the faculty and advisors opinions and comments, data collection toll was prepared. Thereafter, it was presented to 10 faculty members of Tehran University of Medical Sciences to determine the content validity. After collecting their feedbacks, modifying and suggested comments by the faculty members were applied by help of the advisors and the experts. In addition, content validity ratio (CVR) and content validity index (CVI) were measured. Content validity ratio was deter-

mined by the Lawshe table ($P < 0.05$). Content validity index was determined with CVI score of Waltz and Bausell ($> 0.79 =$ appropriate item, $0.70 - 0.79 =$ needs to be revised, $< 0.79 =$ unacceptable).

The questionnaire reliability was estimated using Cornbrash's alpha coefficient as 0.75 and the observation checklist reliability was confirmed by simultaneous observation and agreement factor of one. Data were analyzed using SPSS software version 16, statistical independent t-test, Fisher's exact test and chi-square test.

**Figure 1.** Study Diagram Plan

4. Results

During the study, 30 subjects were included in each group and none were excluded. The mean age of patients in the patient-centered and the family-oriented groups were 47.41 ± 10.31 and 48.16 ± 9.21 , respectively. Other demographic characteristics are listed in Table 2.

Table 2. Demographic Characteristics of Patients Undergoing Hemodialysis Treatment in the Two Groups ^{a,b}

Group Characteristics	Patient-Centered	Family-Centered	Result
Gender			$\chi^2 = 1.08$; df = 1; P = 0.29
Male	11 (36.7)	15 (50)	
Female	19 (63.3)	15 (50)	
Occupation			Fisher's exact test; P = 0.07
Unemployed	4 (13.4)	3 (10)	
Housewife	16 (53.3)	16 (53.4)	
labor	1 (3.3)	1 (3.3)	
Employee	5 (16.7)	1 (3.3)	
Retired	2 (6.7)	9 (30)	
Self-employed	2 (6.7)	0	
Income rate			Fisher's exact test; P = 0.16
Sufficient	2 (6.7)	5 (16.7)	
Partially Sufficient	18 (60)	21 (70)	
Insufficient	10 (33.3)	4 (13.3)	
Residential place			$\chi^2 = 1.08$; P = 0.78
Urban	20 (66.7)	19 (63.3)	
Rural	10 (33.3)	11 (36.7)	
Education level			Fisher exact test; P = 0.80
Illiterate	20 (66.7)	19 (63.3)	
Below high school diploma	12 (40)	14 (46.7)	
High school diploma	9 (30)	9 (30)	
University degrees	1 (3.3)	2 (6.7)	
Marital status			Fisher's exact test; P < 0.001
Married	7 (23.3)	26 (86.7)	
Single	7 (23.3)	2 (6.7)	
Widowed	11 (37.7)	2 (6.7)	
Divorced	5 (16.7)	0	

^a Abbreviation: df, Degree of freedom.

^b Data are presented as No. (%).

The two groups were similar regarding the demographic variables, except for marital status and lifestyle, which were not associated with compliance based on the independent t-test and were not considered interventional (association of marital status with dieting: P = 0.49; medicinal: P = 0.11; motor (movement): P = 0.49; the relationship between lifestyle and diet: P = 0.31; medicinal: P = 0.25; motor (movement): P = 0.16). Diabetes was the major cause of dialysis factor in both patient-centered (43.3%) and family-centered (43.3%) groups; most of the patients in both patient-centered (46.7%) and family-centered (43.3%) groups had been undergoing dialysis for one to five years. During the two weeks

of the study before the intervention, the two groups had no significant differences regarding the frequency of hypotension with P = 0.91 and the mean change of 1.60 (1.30) as well as the frequency of muscle cramps with P = 0.50 and the mean change of 1.06 (1.01). However, in the second and fourth weeks after the intervention, significant differences between the two groups were observed regarding the frequency of hypotension, respectively with P = 0.016 and the mean change of 0.70 (0.70) and P = 0.02 with the mean change of 0.86 (0.62), muscle cramps with P = 0.01 and the mean change of 0.46 (0.86) and P = 0.02 with the mean change of 1 (1.05). Other complications are listed in Table 3.

Table 3. Comparison of Education Effects on Complications During Hemodialysis in the Two Groups ^{a,b}

Complication	Before the Intervention		Second Week After the Intervention		Fourth Week After the Intervention	
	Patient-Centered	Family-Centered	Patient-Centered	Family-Centered	Patient-Centered	Family-Centered
Chest pain						
0	0	0	3 (30.3)	10 (81.4)	3 (30.3)	9 (72.1)
1	6 (75)	8 (70)	6 (60.3)	2 (18.6)	6 (60.3)	2 (18.6)
2	2 (25)	3 (30)	1 (9.3)	0	1 (9.3)	1 (9.3)
Mean ± SD	1.06 ± 1.01	0.9 ± 0.92	0.46 ± 0.86	0.06 ± 0.25	1 ± 1.05	0.05 ± 0.62
t-test results	T = 0.66 df = 58; P = 0.50		T = 2.4 df = 58; P = 0.01		T = 2.23 df = 58; P = 0.02	
Headache						
0	0	0	4 (12.4)	10 (58)	6 (26.7)	9 (63.3)
1	4 (27.6)	3 (24)	12 (73.3)	7 (32.7)	8 (46.6)	6 (26.7)
2	10 (48.4)	9 (47.6)	4 (13.4)	3 (9.3)	6 (26.7)	3 (10)
3	3 (24)	6 (28.4)	0	0	0	0
Mean ± SD	1.58 ± 1.30	1.61 ± 1.21	0.70 ± 0.70	0.30 ± 0.53	0.84 ± 0.58	0.43 ± 0.64
T-test results	t = 0.10 df = 58 P = 0.81		t = 2.4 df = 58 p = 0.01		t = 0.10 df = 58 p = 0.81	
Nausea						
0	0	0	4 (12.4)	10 (58)	6 (26.7)	10 (58)
1	4 (34)	3 (24)	12 (73.3)	7 (32.7)	8 (46.6)	5 (32.7)
2	9 (47.6)	9 (47.6)	4 (13.4)	3 (9.3)	6 (26.7)	3 (9.3)
3	3 (24)	6 (28.4)	0	0	0	0
Mean ± SD	1.68 ± 1.28	0.74 ± 0.74	0.30 ± 0.53	0.84 ± 0.58	0.43 ± 0.64	0.74 ± 0.74
t-test results	t = 0.15; df = 58; P = 0.67		t = 2.6; df = 58; P = 0.03		t = 1.58; df = 58; p = 0.01	
Vomiting						
0	0	0	3 (30.3)	10 (81.4)	3 (30.3)	9 (72.1)
1	6 (87.5)	6 (78.75)	6 (60.3)	2 (18.6)	6 (60.3)	2 (18.6)
2	1 (12.5)	3 (21.25)	1 (9.3)	0	1 (9.3)	1 (9.3)
Mean ± SD	1.08 ± 1.15	0.94 ± 0.95	0.46 ± 0.86	0.06 ± 0.25	1 ± 1.05	0.05 ± 0.62
t-test results	t = 0.68; df = 58; P = 0.48		t = 2.4; df = 58; P = 0.01		t = 2.23; df = 58; P = 0.02	

^a Data are presented as No. (%).^b Abbreviation: df, Degree of freedom.

5. Discussion

Although hemodialysis administration in ESRD patients is currently considered as the most common treatment method, it has numerous side effects on body organs, including the cardiovascular system, the nervous system and the gastrointestinal system and high mortality due to hemodialysis complications is still a serious problem (21).

The findings showed that within the two weeks of the study before the intervention in both groups, the highest frequency of hypotension was twice the highest hypotension occurred at the final hour of hemodialysis. Therefore, the two groups were not significantly different in the frequency of hypotension and were homogeneous. However, in the second and fourth weeks after the intervention, education of patient associated with the active family member significantly reduced the frequency of hypotension. Therefore, in the family-oriented

group, in the second and fourth weeks after the intervention, respectively 73.3% and 63.3% of patients did not develop the mentioned complication, while in patient-centered group in the second and fourth weeks after the intervention, respectively 73.3% and 60% of the patients developed hypotension once. Within the two weeks of the study before the intervention, the highest number of muscle cramps in both groups was once and the majority of cramps had occurred at the final half hour of hemodialysis. Therefore, the two groups had no significant difference in the frequency of muscle cramps and were homogeneous. However, in the second and fourth weeks after the intervention, the education of patient associated with the active family member significantly reduced the frequency of muscle cramps, so that in the family-oriented group in the second and fourth weeks after the intervention, respectively 81.4% and 72.1% of the patients

did not develop the complication, while in the patient-centered group in the second and fourth weeks after the intervention, respectively 60.3% and 60.3% of the patients developed muscle cramps once. In addition, the findings revealed that during the two weeks of the study before the intervention in both groups, the highest frequency of occurred chest pain and vomiting was once, while headaches and nausea occurred twice, all of which were often in the last half hour of hemodialysis. Therefore, the two groups had no significant difference in the frequency of complications and were homogeneous. However, in the second and fourth weeks after the intervention, education of patient associated with the active family member significantly reduced the frequency of chest pain, headache, nausea and vomiting, so that in the family-oriented group in the second and fourth weeks after the intervention, the patients did not develop the complications as follows: 81.4% and 72.1% in chest pain episodes; 58% and 63.3% in headache episodes; 58% and 58% in nausea episodes; and 81.4% and 72.1% in vomiting episodes; while, in the patient-oriented group in the second and fourth weeks after the intervention, the situation of complications occurrence was as follows: chest pain: 60.3%; headaches: 73.3%; nausea: 46.6%; vomiting: 60.3%.

In a study by Mottahedian Tabrizi et al. (17), a checklist for recording the complications was used to examine the complications. They concluded that planned nursing care during dialysis significantly decreased nausea from 33.3% to 3.3%, reduced vomiting from 16.7% to zero with $P < 0.02$, reduced muscle cramps from 50% to 6.7% with $P = 0.001$, and decreased hypotension from 66.7% to 10% ($P < 0.001$). Complications checklist was also used in the current study and the conducted family-centered training led to adherence to the treatment plan at home (especially observing the fluid restriction) and reduced the frequency of nausea, vomiting, muscle cramps and hypotension during the hemodialysis. Lee and Kim concluded that with proper training on nutrition in patients undergoing hemodialysis, gastrointestinal symptoms significantly improved and ultimately led to their improved quality of life ($P < 0.01$) (23). In the other study the importance of families to improve the quality of life of patients and their families, as well as the treatment outcomes were pointed out (24). In a systematic review by Lockett et al. the use of advanced care planning, including the use of family members in the treatment of patients with chronic kidney disease (CKD) due to their more knowledge of the care needs of the patient was recommended (25). In the present study, with the active participation of families in teaching various issues, we tried to improve the clinical outcomes, including reducing the unpleasant side-effects during hemodialysis. In a study by Sandra et al. it was concluded that families' education and their participation in treatment led to a significant increase in adherence to the diet ($P = 0.04$) and medication ($P = 0.029$) plans (26). In a systematic review by Denhaerynck et al. 30 - 74% of patients had muscle cramps

due to noncompliance with the treatment plan based on fluid restriction and dieting (27). In the present study, we tried to investigate other common side-effects during hemodialysis with educating the health plan.

In a study by Setiani Agus et al. (28), the majority of patients undergoing hemodialysis developed hypophosphatemia (53.1%) and needed to learn the proper use of their medications, especially phosphorus bonding agents, their significance, and effects of not using their medications. According to the results of Smith et al. study (29), it was found based on the statements of patients that they needed a source for protection and support and to become sensitive to follow the treatment plan and increase their knowledge in this regard (29). According to the present study and the importance of compliance with treatment plan, as well as its impact on clinical outcomes in patients undergoing hemodialysis, it was tried with families attending and increasing their participation in treatment; the rate of compliance with the treatment plan will be increased, and thereby, the common intradialytic complications would be reduced.

At the end, according to the results, the percentage of hypotension in the family-centered group in the second and fourth weeks after the intervention was significantly lower than in the patient-centered group ($P = 0.016$ and $P = 0.02$, respectively). Therefore, the first hypothesis of the study: "hypotension in the family-centered group is less than the patient-centered group" was accepted.

Furthermore, the percentage of muscle cramp in the family-centered group in the second and fourth weeks after the intervention was significantly lower than the patient-centered group ($P = 0.01$ and $P = 0.02$, respectively). Therefore, the second hypothesis of the study: "muscle cramps in the family-centered group are less than the patient-centered group" was accepted.

5.1. Limitations of the Study

The questionnaires were filled through self-report; thus, there were inaccuracies in recording of the data reported. In addition, different psychological and individual characteristics were effective on patients' adherence to the treatment plan. The durations of control and follow-up were short (four weeks); thus, it is recommended to conduct a study with a larger sample size and a longer duration for better results.

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Authors' Contributions

Study concept and design: Parvaneh Asgari, Fatemeh Bahramnezhad. Acquisition of data: Parvaneh Asgari, Pouya Farokhnezhad Afshar. Analysis and interpreta-

tion of data: Fatemeh Bahramnezhad, Mitra Zolfaghari. Drafting of the manuscript: Parvaneh Asgari, Fatemeh Bahramnezhad. Critical revision of the manuscript for important intellectual content: Fatemeh Bahramnezhad, Mitra Zolfaghari. Statistical analysis: Parvaneh Asgari, Fatemeh Bahramnezhad. Administrative, technical, and material support: Parvaneh Asgari, Fatemeh Bahramnezhad, Pouya Farokhnezhad Afshar, Study supervision: Mitra Zolfaghari.

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