



The Effect of Reduced Dialysate Temperature on Dialysis Adequacy of Diabetic Patients (A Clinical Trial Study)

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Abstract

Background: Given that diabetes is the most prevalent cause of end-stage renal disease (ESRD) and that dialysis adequacy is an important factor in the survival of diabetic patients, prognosis of these individuals is predicated according to adequate and standard hemodialysis.

Objectives: The present study aimed at investigating the effect of lowering dialysate solution temperature on dialysis adequacy.

Methods: This was a clinical trial, in which 32 qualified patients were studied. The subjects were chosen by convenience sampling from patients, who had referred to Ali-Ibn Abitaleb Hospital of Zahedan in spring, 2018. Each patient underwent hemodialysis twice, in which the solution temperature was reduced by one temperature from 37°C to 36°C. Except for the temperature decrease, other conditions were identical during the study. To evaluate the adequacy of dialysis in each session, blood samples of patients were examined before and after dialysis. Data were analyzed in SPSS 21 using descriptive statistics and dependent *t*-test. The significance level was set below 0.05.

Results: The mean and standard deviation of age was equal to 60.2 ± 9.2 (year), duration of diabetes was 12.07 ± 7.25 years, duration of hemodialysis was 27.7 ± 21.8 (months), and weight gain between two sessions of dialysis was 1.6 ± 0.68 (kg). The mean and standard deviation of dialysis adequacy index equaled 1.14 ± 0.34 in the two cold sessions and 0.98 ± 0.20 in the routine session, suggesting significantly higher value in the cold sessions ($P < 0.001$).

Conclusions: Administering cold dialysis solution (36°C) positively influences dialysis adequacy. Therefore, if patients are not medically prohibited from using the cold solution, cold dialysis solution should be prescribed to hemodialysis patients.

Keywords: Cold Dialysis Solution, Dialysis Adequacy, Diabetic Patients, Hemodialysis, Chronic Renal Failure

1. Background

Kidney failure has turned to a major public health problem in Iran and the rest of the world (1, 2). The incidence and severity of end-stage renal disease (ESRD) is growing in Iran, with an annual rise of 6%. The mean incidence of ESRD is 680 people per one million, which is well beyond the global average (465 per one million). Specifically, the number of people affected by this condition in Iran has soared from 24,000 in 2008 to 40,000 in 2011. Considering the rising prevalence of diabetes and hypertension, it is anticipated that the number of kidney patients, dialysis patients, and kidney transplants will double by 2021 with at least 90,000 people struggling against these conditions (3, 4). Between 1997 and 2006, according to Aghighi et al., the number of ESRD patients skyrocketed by 130% in Iran, which highlights the urgent need for at-

tending to this disease (5). Approximately 29200 (95%) of these patients undergo hemodialysis, and 1,624 are treated by peritoneal dialysis. Hemodialysis is the most important dialysis treatment in these patients with an average 6% growth in Iran. By the end of 2016, it has been estimated that about 2648000 patients were treated at 39600 dialysis centers around the world, which means an average of 67 patients were admitted to each treatment center (Dialysis Ico, Tehran, Iran). Despite the many technological and technical advances in hemodialysis, there are still many problems during and after dialysis. Although hemodialysis can prolong the life span of patients, various complications associated with hemodialysis also jeopardize the health of these individuals (6, 7). Since diabetes is the cause of about 30% of kidney failure cases, the authors of the present research attempted to focus on this subject. Con-

sidering that complications such as hypotension during hemodialysis are more common in diabetic patients and that the need for high quality dialysis is extremely urgent in diabetic patients due to the negative effects of dialysis on controlling blood glucose (8), cardiovascular diseases and lack of dialysis adequacy are the main determinants of disability and mortality in patients undergoing hemodialysis (9).

The crucial issue for these patients is to ensure their dialysis adequacy. Typically, two methods of urea reduction ratio (URR) and modeling urea kinetic (Kt/v) are used to evaluate this adequacy (10). Based on the kidney disease outcomes quality initiative (KDOQI) issued by the National Kidney Foundation (NKF), the use of Kt/V is preferable to URR thanks to its more accurate assessment of urea removal (11).

Evidence suggests that cold hemodialysis improves cardiovascular tolerance, reduces hypotension during hemodialysis, prevents early termination of hemodialysis session, and enhances dialysis adequacy (12). Pathophysiologically, it is notable that when cold hemodialysis solution is used, a heat exchange occurs between the blood and hemodialysis solution, body temperature does not rise, and vascular contraction takes place; also, as a result of increasing the strength of heart contraction, oxygenation of tissues (especially skin) is improved, stimulation of the sympathetic nervous system decreases, and complement activity and the reactionary behavior of monocytes are diminished. Finally, most complications of hemodialysis are prevented and the hemodialysis adequacy is enhanced (13).

Since hemodialysis patients experience numerous problems due to their especial mental and physical conditions, the quality of dialysis is particularly important and it could mitigate a lot of these complications (14). In Iran, more than 60% of dialysis patients receive Kt/V of 1.2 (15, 16), and this inadequate dialysis is more frequent in diabetic patients than their non-diabetic counterparts (8).

A number of methods have been introduced for enhancing dialysis adequacy, one of which is administering cold dialysis solution. The results of multiple studies revealed that this is a simple and cost-effective method, which can reduce the amount and frequency of hypotension, stabilize hemodynamic indices and augment hemodialysis quality, and consequently promote quality of life and general health of diabetic patients undergoing hemodialysis (17-19).

2. Objectives

In view of the above-mentioned findings, this study was conducted to investigate the effect of reduced dialysate temperature on dialysis adequacy of type 2

diabetic patients, who had referred to Ali-ibn Abitaleb Hospital, affiliated with Zahedan University of Medical Sciences, during year 2018.

3. Methods

This was a quasi-experimental single-group study conducted in spring 2018 on hemodialysis patients in Ali-ibn Abitaleb teaching hospital. A total of 32 patients with type 2 diabetes, who had been admitted for hemodialysis and had the inclusion criteria were chosen as the study population via convenience sampling. The inclusion criteria were a history of dialysis for at least three months, no use of blood pressure reducers, weight gain up to 3 kg between hemodialysis sessions, and lack of anemia, malignant diseases, or thyroid disorders. Patients, who expressed their willingness to participate, were provided with necessary explanations regarding the procedure and purpose of the study. Besides, they were required to hand in their informed consent form. This research was approved by the Ethics Committee of Zahedan University of Medical Sciences and registered under the code of IR. ZA-UMS.REC.1396.292. It fulfilled the ethical considerations of medical research, including confidentiality of patients' information.

Patient registration form consisted of two parts. The first part covered demographic and clinical characteristics, including age, gender, marital status, education, occupation, weight, underlying disease, residence, vital signs, hemodialysis onset, hemodialysis frequency per week, hemodialysis length in each session (hour), duration of diabetes (year), duration of treatment with hemodialysis (month), weight loss during hemodialysis, results of blood tests, type of dialysis filter and solution based on examination, surveying the cases, and interviewing patients. The second part included measuring and ensuring the adequacy of dialysis of each patient during each session. The sample size was estimated at 14 by means of the following formula and taking in account the numerical values of the variables discussed by Beladi Mousavi et al., along with the confidence interval and test power of 95%. However, to ensure the adequacy of sample size, it was set at 30. Finally, considering the possible dropout and to obtain a greater certainty, 32 subjects were selected to be studied (20).

The study was performed in two stages. Initially, all patients underwent hemodialysis with the solution being set at 37°C (i.e., the routine solution, which is the usual hemodialysis temperature). Next, they were exposed to reduced dialysate temperature of 36°C (the cold solution). The sequence of dialysis with cold or routine solutions for each patient was randomly determined using a blue and a green ball, so that each patient was asked to choose a ball

from a box containing 16 blue balls and 16 green balls. In the first stage, the blue and green balls were used to signify the cold and routine solutions, respectively. This was reversed in the second stage.

In order to provide identical conditions, hemodialysis variables were the same in both cases, except for the solution temperature. All patients were dialyzed three times per week for three to four hours each session. The average body temperature of patients was set at 37°C before hemodialysis. For all patients, R5 polysulfone dialyzers (Soha Co.) were used with the same high-flux ultrafiltration coefficient and bicarbonate hemodialysis solution (bicarbonate sodium 650 g 35 Meq/L, Pharmed Medical Industries co.), which was fixed during the study. All instruments, including dialysis machines equipped with ultrafiltration control system (Fresenius model 4008-B), scale (Seca), and pressure gauge were tested and approved. Dialysate flow rate was constant at 500 mg/minute. The rate of fluid harvest for each patient was calculated based on the difference in weight before dialysis and after dialysis (i.e. dry weight). The blood flow was calculated at 300 mL/minute, and needle tip size 16 was used.

All parameters were maintained on the device until the end of the dialysis session. To measure BUN before dialysis, arterial blood sample was immediately collected before hemodialysis. After the end of the hemodialysis session, to prepare the blood sample, the pump flow was first reduced to 100 cc/minute. After 15 seconds, another arterial sample was collected. All samples were evaluated by the hospital laboratory, and the results were collected. Once the samples were measured, dialysis adequacy was assessed through the Kt/V method, using the Daugirdas II formula, which is internationally acceptable (21). In this formula, Ln is the natural logarithm, R is the ratio of post-dialysis to pre-dialysis urea, T is the duration of each hemodialysis per hour, UF is the volume of ultrafiltration, and V is the post-dialysis weight (22). The Kt/V index was equal to or more than 1.2 represented good dialysis and less than 1.2 indicated dialysis with poor adequacy. Thus, the more the Kt/V values exceeded 1.2, the greater the adequacy of dialysis would be. By the same token, even as this value recedes from 1.2, dialysis adequacy diminishes accordingly.

$URR = \frac{BUN_{pre} - BUN_{post}}{BUN_{post} \times 100}$ (BUN = Blood urea nitrogen)

$$KT/V = -\ln(R - 0/008 \times T) + (4 - 3/5T) \times 0/55UF/V$$

$$KT/V = \ln(1 - URR)$$

Finally, the data were analyzed in SPSS 21. The descriptive statistics of mean, frequency, and standard deviation were used to describe the data. Subsequently, the effect of cold dialysis on the adequacy of dialysis was evaluated using the dependent *t*-test. The level of significance was considered below 0.05.

4. Results

Of the 32 patients enrolled in the study, one individual was excluded due to travel to another place, and the remaining 31 were examined. The majority of subjects were married and their education was below high school diploma. The demographic and clinical characteristics of participants are given in Tables 1 and 2.

Table 1. Demographic and Clinical Features of Hemodialysis Patients

Variable	No. (%)
Gender	
Male	14 (45.2)
Female	17 (54.8)
Marital status	
Married	26 (83.9)
Widow	5 (16.1)
Education	
Below high-school diploma	25 (80.7)
High school diploma	5 (16.1)
Above high-school diploma	1 (3.2)
Occupation	
Self employed	8 (25.8)
Employed	5 (16.1)
Unemployed	3 (9.7)
Housewife	14 (45.2)
Retired	1 (3.2)
Underlying disease	
Yes	19 (61.5)
No	12 (38.5)

The results of dialysis adequacy of cold dialysis compared with routine dialysis are presented in Table 3. It could be observed that there is a significant difference between the two methods ($P < 0.001$), with greater adequacy occurring in the cold dialysis method.

5. Discussion

One of the essential aspects of dealing with ESRD patients, who undergo hemodialysis, is to evaluate the adequacy of their dialysis. Today, it has been well-documented that inadequate dialysis is one of the leading factors in reducing the life expectancy of these people. The standard dialysate temperature is between 36.5 and 38°C. A dialysis solution with body temperature can increase the body temperature of the patient. This is followed by peripheral vasodilatation and subjecting the person to cardiovascular

Table 2. Mean and Standard Deviation of Disease Indicators in the Study Samples

Variable	No.	Min.	Max.	Mean \pm SD
Age, y	31	43	78	60.26 \pm 9.21
Duration of diabetes, y	31	45	400	12.7 \pm 7.25
Duration of hemodialysis, m	31	3	95	27.74 \pm 21.82
Weight gain between two dialysis sessions, kg	31	0.5	3.00	1.64 \pm 0.68

Table 3. Results of Dialysis Adequacy in Cold Dialysis and Dialysis With Routine Temperature

Dialysis method	Mean \pm SD	Result
Cold	1.14 \pm 0.34	P: 0.001
Routine	0.98 \pm 0.20	P: 0.001

instability and hypotension. Therefore, proper adjustment and modification of dialysate temperature from 37 to 34 - 35°C can improve cardiovascular stability in hemodialysis patients (18, 19). Conventionally, 37°C is selected as the standard dialysate temperature. Although there is the possibility of shivering when using cold dialysis, most patients tolerate it well and studies have also shown its effectiveness and safety (23-25).

Confirming the hypothesis that dialysis adequacy differs in routine and cold dialysis methods, the results of this study demonstrated that using the cold solution enhances dialysis adequacy. This finding coincided with the study by Azar et al. (7). Borzou et al.'s study was in line with the present study, concerning the positive impact of cold solution on dialysis adequacy and comfort of patients (15). However, the results of the current research are not compatible with those of Ayoub and Finlayson, who reported that the use of cold dialysis solution does not amplify hemodialysis adequacy, and only ultrafiltration, which refers to the volume of fluid obtained in dialysis, has a positive impact on raising the quality of dialysis (17).

In the present study, the adequacy of dialysis was obtained at Kt/Veq of around 1.14. Compared with the ideal 1.2, it is clear that during hemodialysis, patients with the same dialysis length had a good clearance. Similar to the present research, Azar et al. (7) reported a significantly enhanced adequacy as acquired using the Kt/Veq method. Considering that the use of cold dialysate solution in that study brought about a positive effect on the hemodynamic situation and dialysis tolerance, it can be inferred that cold dialysis gives rise to vascular and hemodynamic stability. In a systematic review on 22 researches studying the effect of lowering hemodialysis temperature in 408 patients, Selby and McIntyre observed no evidence suggesting adequacy reduction caused by cold dialysate solution (26).

Kaufman et al. concluded that even decreasing body temperature can help stabilize patient's blood pressure and reduce the need for therapeutic interventions (27). Selby and McIntyre proposed that while bringing down hemodialysis temperature could help control the reduction of blood pressure during hemodialysis, it does not have a considerable effect on the adequacy of dialysis (26). Hussein and Malik investigated the influence of dialysate temperature on stabilizing hemodynamic conditions of 40 patients. Each of their subjects underwent three dialysis sessions at 37°C and three sessions at 35°C. The results showed that the lower temperature of dialysis solution did not influence hemodialysis adequacy, nevertheless, since cold dialysis leads to a better hemodynamic condition in patients and alleviates complications, such as hypotension and fatigue, it is preferable to dialyze using either the conventional temperature or body temperature (28).

Therefore, it is recommended for cold dialysate solution to be administered to dialyze patients unless they have certain restrictions concerning this type of solution. Regarding the limitations of this study, it should be stated that it was only carried out on patients with type 2 diabetes. Therefore, the results cannot be generalized to all dialysis patients.

5.1. Conclusions

Due to the increasing prevalence of chronic diseases, such as diabetes and hypertension, the number of hemodialysis patients has escalated and the shortage of dialysis machines and experienced personnel has become a public concern. Hence, it is essential for effective therapeutic interventions to be devised to explore factors, which influence dialysis adequacy so as to improve the quality of dialysis, prevent unnecessary medical costs, and ultimately promote the quality of life hemodialysis patients. According to the findings of this study, confirming the positive effect of cold solution on the adequacy of dialysis and patient's comfort, it is suggested that not every patient should be dialyzed at a fixed temperature, and the dialysis solution temperature should be adjusted based on the patient's unique clinical situation. Furthermore, unless there is a prohibition in certain cases, the use of cold dialysis should be standardized for patients, who are prone to

hypotension. It will be illuminating if future studies conduct a similar research between two groups and another on hemodialysis patients with hypertension.

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Footnotes

Authors' Contribution: Fatemeh Kiyani: Study design, article composition; Husain Sarbaz: Data collection; Asadollah Keikhaei: Statistical analysis and editing; Salehoddin Bouya: Collaboration in collecting data.

Clinical Trial Registration: This study was registered under the code IRCT20171009036675N2 in the Iranian Registry of Clinical Trials.

Conflict of Interests: The authors reported no conflict of interests for this project.

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