The Effects of Cool Dialysate on Vital Signs, Adequacy and Complications during Hemodialysis

Abstract

Background: Cooling the dialysate is an important factor that contributes to the hemodynamic stability in patients during hemodialysis. The aim of this study was to determine the effect of cool dialysate on vital signs, and the adequacy and common complications of hemodialysis. Materials and Methods: The present crossover, triple-blind, clinical trial was performed on 62 dialysis patients, who were selected through stratified block randomization. First, one group underwent hemodialysis using a cool dialysate (35°C), and the other received routine hemodialysis (36.5°C). Each patient received a total of eight hemodialysis sessions. Then, treatment methods were swapped, and each group received the other group’s method. The patients’ blood pressure, pulse rate, and temperature were measured before dialysis, and in the first, second, third, and fourth hours of dialysis. The frequency of common complications of hemodialysis and dialysis efficacy were measured. The marginal model and Generalized Estimating Equations (GEE) were used to analyze the data. Results: The participants’ systolic ($p = 0.01$) and diastolic blood pressures significantly increased with a decrease in temperature ($p = 0.005$). The patients’ pulse rate ($p = 0.143$), adequacy of dialysis ($p = 0.922$), and common complications of hemodialysis did not significantly differ between the two temperatures ($p > 0.05$). Conclusions: Reducing dialysate temperature from 36.5 to 35°C led to hemodynamic stability; the blood pressure of the patients undergoing hemodialysis was more stable with the cool dialysate method and the number of drops in the blood pressure during the hemodialysis was reduced.

Keywords: Cold temperature, hemodialysis solutions, vital Signs

Introduction

Hemodialysis is the most common Renal Replacement Therapy (RRT) in Iran and worldwide.[1] More than 2 million people worldwide undergo hemodialysis. In Iran, more than 26,000 people undergo hemodialysis,[2,3] with a 15% annual increase.[4] Despite many technological and technical advances in the field of hemodialysis, significant problems remain during and after hemodialysis.[5,6] Hypotension and its related symptoms including fatigue, nausea, vomiting, dizziness, headache, and muscle cramps are among the main factors that aggravate patients during dialysis.[7,8] The hemodialysis nursing personnel spend much of their time dealing with and treating dialysis-induced complications, and in some cases, these complications frequently disrupt the process and even lead to premature termination of dialysis, and cause reduced clearance and removal of waste, which ultimately reduce the adequacy of dialysis.[9,10] Therefore, preventing these complications is one of the main responsibilities of dialysis personnel, especially nurses.[1] The important issue for these patients is the adequacy of dialysis. With inadequate hemodialysis, the patient’s blood toxins and clinical symptoms are not fully controlled, which leads to increased patient disability and mortality.[10]

Given that better dialysis leads to the patient’s higher quality of life, greater life expectancy, and fewer complications, it is important to identify the factors affecting improved dialysis adequacy and ways to enhance this adequacy.[11,12] One way to maintain the patients’ hemodynamic stability during hemodialysis is by reducing the temperature of the hemodialysis solution to below 36.5°C.[11] Some studies have shown that a dialysate temperature...
between 34 and 35.5°C causes hemodynamic stability during hemodialysis without adversely affecting dialysis adequacy.\[13,14\] Cardiovascular stability is better maintained during cool dialysis because more catecholamine is released and the resistance of peripheral vessels and tonicity of the veins are increased.\[15\] Despite many advances in the dialysis technology, dialysate temperature has not been well addressed in patients undergoing long-term dialysis.\[16\] Cooling the dialysate is still not used as a practical technique, which may be due to the fear of the patient feeling cold and shivery, and also the concern about the fact that reducing the dialysate temperature may lead to reduced dialysis adequacy due to the entrapment of the peripheral blood following the contraction of larger vessels.\[12,16\]

Previous studies have confirmed the safety and effectiveness of cool dialysis in cardiovascular stability.\[8,17\] Nevertheless, its effect on dialysis adequacy and other complications such as muscle cramps, nausea, and vomiting is not clear. Given that conventional dialysis has such complications as muscle cramps, headache, hypotension, nausea, and vomiting,\[8,12,18,19\] and due to the particular importance of dialysis adequacy,\[5,6\] the conflicting results reported in the previous studies,\[12,18,20\] and the simple and low-cost use of cool dialysis, further and more careful assessment of the factors that reduce complications and improve the adequacy of dialysis is necessary. Therefore, the present study was designed and conducted to determine the effect of cool dialysate on vital signs, and adequacy and common complications of hemodialysis.

**Materials and Methods**

The present crossover, triple-blind, randomized, controlled clinical trial (IRCT2017032633145N) was conducted on 70 patients undergoing hemodialysis between July and August 2017 at the hemodialysis center in the city of Arak in Iran. The sample size was estimated using the average comparison formula in two independent groups according to a previous article.\[12\] Considering a probability of 10% loss of the samples, the considered was about 35 people in each group (α = 0.05; B = 0.10; CI = 95%; μ1 -μ2 = 0.6; S1 = 0.9; S2 = 0.6).

The participating patients met all of the inclusion criteria. The inclusion criteria included a willingness to take part, a minimum history of hemodialysis of 3 months prior to the study,\[21\] no hypertension medication on the morning of dialysis, no particular cardiovascular disorders such as heart attack or having a pacemaker, older than 18 years of age, no cancer, no severe anemia, and no thyroid disorders.\[3,16\] Eight patients were excluded from the study due to migration,\[3\] transplantation,\[2\] and hospitalization;\[3\] there were four in the control group and four in the experimental group. Finally, 62 patients were studied. Moreover, 32 patients were hypertensive and were told not to take antihypertensive drugs on the day of hemodialysis and not to eat during the session according to the doctor’s order and the patients’ consent. The present study was registered at Iran’s Centre for Clinical Trials.

The patients entered the study following an introduction by a specialist and based on the inclusion and exclusion criteria. The study objectives were explained and informed consents was obtained. The patients were selected using stratified block randomization based on the table of random numbers by a statistic advisor. The two groups were matched in terms of gender, age group, and history of hemodialysis. The present study was a triple-blind study—the researcher, patients, and data analyst had no knowledge of the interventions. The vital signs were measured and recorded by the researcher. The nurse regulating the dialysis temperature was not a member of the research team, and thus, was not aware of the intervention type and random assignment, and only played the role of a decoder and immediately after adjusting the temperature, the temperature display was covered. Accordingly, at the time of recording the responses, the researcher and the patient were not aware of the dialysis temperature. The statistical consultant received and analyzed the temperature data in terms of A and B temperatures.

A multi-part checklist was used as the data collection tool in this study. The first part included a demographic information form. The second part of the checklist included a chart to record the blood pressure and pulse of the patients before dialysis in the first, second, third, and fourth hours of the dialysis. In the third part, the patient’s central temperature was recorded before and after dialysis, and in the first, second, and third hours during the dialysis. In the fourth section, complications were recorded during the dialysis, and in the final section, the patient’s blood urea was recorded at any temperature before and after the fourth session, which was recorded by the researcher.

In the present crossover study, first, one group underwent hemodialysis using a cool dialysate (35°C), and the other underwent conventional hemodialysis (36.5°C in this center). In the next stage, the treatment methods were swapped, and each group underwent the other group’s method. Each of these stages consisted of four consecutive sessions, and therefore, each patient received a total of eight hemodialysis sessions. The time intervals were the same for both groups and in both stages. All the patients underwent three sessions of hemodialysis per week, and each session lasted for 4 h. The dialysis parameters (blood flow rate, dialysate rate, dialysis filter, dialysis machine, and dialysis time), except for temperature, were the same for all the patients in the two stages of the study. A Formula 2000 dialysis machine (Model Formula 2000; Bellco, Mirandola, Italy) was used for all the patients. The blood flow rate (pump rpm) was set according to the patient’s condition between 200 mL/min and 400 mL/min, and the dialysate flow rate was adjusted at 500 mL/min.
A bicarbonate solution was used for all the patients. Prior to the study, all devices were calibrated by a technician.

A digital scale (Sanjesh Sabet Co., Barkhar, Isfahan Province, Iran) with a precision of 0.5 kg was used for measuring the patients’ dry weight. The dialysis technique used on all the patients was conventional hemodialysis; no patient was on hemodiafiltration. The patient’s weight was recorded before and after the dialysis. The fluid removal was calculated as the difference between the patient’s weight before and after a dialysis session. The patient’s systolic and diastolic blood pressures and pulse rate were measured using a digital cuff sphygmomanometer (Omron Corp., Osaka, Japan; the device was used for the first time and had previously been calibrated by the manufacturer) before the dialysis, and the first, second, third, and fourth hours of the dialysis in the supine position.[22] Moreover, the blood pressure of patients complaining of at least one of the symptoms of hypotension (such as muscle cramps, nausea, vomiting, fatigue, or dizziness) was measured and recorded at that moment. The patient’s temperature was measured and recorded in every session using a digital thermometer (Macrolife, Switzerland) in both the ears before the dialysis, and in the first, second, third, and fourth hours of the dialysis, and the mean temperature was taken into account. To match the environmental factors, the ambient temperature was controlled throughout the study. Since eating and drinking hot or cold liquids during the dialysis can affect the patient’s vital signs, the type of nutrition used and time of its use were kept the same for all the patients; therefore, all the patients took only a simple snack in the first 2 h of the dialysis. The frequency of common complications of hemodialysis (hypotension, and muscle cramp, nausea, and vomiting) was recorded in a checklist. The temperature was changed through the dialysis machine only during the dialysis, and the effect of reducing the temperature of the solution was not seen in the next session; therefore, there was no need to determine the wash-out period. To assess the dialysis adequacy, blood samples were taken before and after the dialysis on the fourth and eighth sessions by an assistant researcher and sent to the laboratory. Before collecting the blood samples at the end of the dialysis, the blood flow rate was reduced to 50 mL/min for 30 s and the samples were obtained from the arterial set. The urea reduction ratio (URR) was calculated using the formula: urea pre-urea post/urea pre × 100%. The dialysis efficacy was assessed using the second generation logarithmic (Daugirdas) equation: Kt/V = -ln (R-0.008 × t) + (4 - 3.5 × R) × 0.55 × UF/V urea.

Where R is the ratio of post-dialysis BUN (BUN post) divided by pre-dialysis BUN (BUN pre), t is the dialysis session duration in hours, UF is the ultrafiltration volume in liters, and V urea is the estimated volume of distribution of urea.[22]

Data were analyzed using descriptive methods such as frequency distribution tables and mean and standard deviation indices in the SPSS software (version 22; IBM Corp., Armonk, NY, USA). For univariate comparison of the two groups, Chi-square and Fisher’s exact tests were used. For multivariable modeling of the data, the marginal longitudinal model and Generalized Estimating Equations (GEE) were used because the data were not normally distributed. \( p < 0.05 \) was considered as significant. It is worth mentioning that the identity link function and exchangeable covariance matrix are used in the GEE model. Furthermore, for the multivariable modeling of the cross-sectional data (such as Kt/V and URR), generalized linear models with identity link functions were used.

**Ethical considerations**

The present study was approved by the ethics committee of the Lorestan University of Medical Sciences, Iran, (LUMS. REC.2017.262). The study objectives were explained to the participants and informed written consents were obtained from them.

**Results**

The present study was performed on 62 patients undergoing hemodialysis [Figure 1], including 31 (50%) women, 44 (71%) married and 32 (51.60%) illiterate individuals, and 40 (64.50%) individuals with arteriovenous fistula [Table 1]. The temperature had a significant effect on mean systolic blood pressure \( (p = 0.01) \). According to the marginal model, the dialysis temperature and dialysis time had a mutually significant effect on mean systolic blood pressure \( (p = 0.016) \) [Table 2], meaning the difference between the two dialysis temperatures was time-dependent and increased during the dialysis. The mean systolic blood pressure at 35°C was higher compared to 36.50°C during dialysis time \( (p = 0.01) \), and these differences are especially pronounced in the second stage, in the second, third, and fourth hours of the dialysis, and are statistically significant [Figure 2]. The mean diastolic blood pressure at 35°C was significantly higher compared to 36.5°C \( (p = 0.005) \).

The hemodialysis time had a significant effect on the mean diastolic blood pressure \( (p = 0.047) \). The diastolic blood pressure in the second stage was greater than in the first stage. The patient’s mean heart rate did not significantly differ between the two dialysate temperatures \( (p = 0.143) \). The marginal model showed that the dialysis time did not have a significant effect but had a considerable effect on the mean heart rate \( (p = 0.052) \); the lowest heart rate was observed at the end of the second hour and the highest at the end of the fourth. The mean (SD) of the heart rate at baseline after 1, 2, 3, and 4 h was 71.97 (12.86), 71.94 (2.82), 71.63 (12.15), 71.84 (12.54), and 72.69 (12.35), respectively.

The patient’s mean body temperature reduced during the dialysis at 35°C compared to 36.5°C, and the interaction of the dialysis temperature and time on the body temperature was significant \( (p < 0.001) \). The study stage also had a significant effect on the body temperature \( (p < 0.001) \), and
these differences in the temperature are especially pronounced in the second stage, in the second, third, and fourth hours of dialysis, and are statistically significant [Figure 3].

The results of the Poisson regression revealed no significant difference in the incidence rate of hypotension between the dialysis temperatures of 35 and 36.5°C ($p = 0.095$); the relative rate of hypotension incidence was 2.160 times more in the dialysis temperature of 36.5°C compared to 35°C (Rate Ratio = 2.16; 95% Confidence Interval = 0.87-5.33). It is worth noting that, based on the Poisson regression model, the effects of the dialysis period (study stage) and the order of receiving the intervention on the incidence rate of hypotension were not significant. Moreover, based on Fisher's exact test, the effects of the dialysis stage, dialysis temperature, and order of intervention on the muscle cramp were not significant. The effects of dialysis stage, dialysis temperature,
and order of intervention on the incidence of nausea were not significant. Finally, the effects of dialysis stage, dialysis temperature, and order of intervention on the incidence of vomiting were not significant. The results of the generalized linear model revealed that the effects of the dialysis stage, dialysis temperature, and the order of intervention on dialysis adequacy were not significant. In addition, the difference in the URR between the two dialysate temperatures was not significant [Table 3].

**Discussion**

The present study showed that both the systolic and diastolic blood pressures were significantly higher and showed less variation in the cool dialysate method compared to the conventional method. The mean systolic blood pressure at 35°C was higher compared to 36.5°C during the dialysis period; these differences were especially pronounced in the second period in the second, third, and fourth hours of dialysis. This finding was in line with the findings of Moujerloo et al.[23] In the study by Moujerloo et al.,[23] the prevalence of hypotension in the routine method was higher than the intervention method, and these differences are especially pronounced in the second stage in the second, third, and fourth hours of dialysis.

In a similar study conducted on two groups of five individuals (the first consisting of five patients known to have hypotension during dialysis, and the second of five

| Period | Temperature | Kt/V Mean (SD) | URR Mean (SD) |
|--------|-------------|----------------|---------------|
| First  | 35°C        | 1.32 (0.29)    | 0.65 (0.08)   |
|        | 36.5°C      | 1.30 (0.31)    | 0.65 (0.08)   |
| Second | 35°C        | 1.29 (0.25)    | 0.64 (0.07)   |
|        | 36.5°C      | 1.32 (0.31)    | 0.65 (0.09)   |
| *p-value 1*** | 0.922* | 0.892* |
| *p-value 2**** | 0.769* | 0.977* |
| *p-value 3***** | 0.716* | 0.662* |

*Kt/V: Kinetic modeling time/V urea, **URR: Urea Reduction Ratio, ***Denotes the significance of the dialysis period (a comparison between the first and second periods of dialysis), ****Denotes the significance of the dialysis temperature (a comparison between 35 and 36.5°C), *****Denotes the significance of the intervention effect (a comparison between patients who, first, experienced a temperature of 35°C, and then, the temperature of 36.5°C and patients who, first, experienced the temperature of 36.5°C, and then, the temperature 35°C, Generalized linear models with identity link function patients with stable blood pressure during dialysis) at 36.5 and 35°C, the mean arterial blood pressure significantly increased with cool dialysate in the first group, and the frequency of drop in blood pressure reduced.[15] In the present study, the blood pressure was more stable during dialysis with cool dialysate. Although our patients were non-selective, a greater number of patients participated.
In a study by Azar, the patients were assessed over six dialysis sessions at 35 and 36.5°C, and higher systolic blood pressure was reported with cool dialysate. In the present study, both systolic and diastolic blood pressures were higher with cool dialysate. Notably, the diastolic blood pressure was higher in the second stage compared to the first.

In a study conducted by Borzou et al. with the reduction of dialysate temperature, the patients’ systolic blood pressure increased slightly, but this increase was not statistically significant. In the present study, both systolic and diastolic blood pressures were higher with cool dialysate. A greater number of patients participated in the present study compared to the study by Borzou et al. The patients’ mean heart rate reduced with cool dialysate, but this reduction was not significant. In similar studies, the patients’ heart rate reduced with a reduction in the dialysate temperature. In several other studies, no change was observed in the mean heart rate with cool dialysate.

The blood pressure of the patients undergoing hemodialysis was more stable with the cool dialysate method, which improves hemodynamic stability during dialysis. Cool dialysate causes hemodynamic stability during dialysis through various mechanisms, including constant body temperature, increased activity of the sympathetic nervous system, and the subsequent increase in heart contractility, and resistance of the peripheral vessels followed by an increase in the central blood circulation and cardiac output.

In the present study, the mean body temperature of the patients before dialysis was 35.82°C, which is in agreement with the findings of the previous studies showing that dialysis patients have a lower body temperature than normal people (less than 36°C). In the studies conducted by Teruel et al. and Azar, the patients’ body temperature reduced following cool dialysis. The present study also showed that using cool dialysate reduces the body temperature during the dialysis session, and the difference between the two dialysis temperatures is time-dependent and increases during dialysis. Moreover, the body temperature reduced in the second stage compared to the first.

In the present study, no significant difference was found in the dialysis adequacy between cool dialysis and conventional dialysis. Therefore, cool dialysate had no effect on reducing urea or dialysis efficiency. However, Azar showed that cool dialysate increases dialysis efficiency. In a study conducted by Borzou et al., the dialysis adequacy significantly increased at 35°C. This lack of a significant difference in the dialysis adequacy between cool and normal dialysate may be attributed to many factors such as malnutrition, the premature ending of the dialysis session due to hypotension or other technical reasons, noncompliance of the patients, inappropriately low dialysate flow rate, and dialyzer leaks, inadequate blood flow from the vascular access, and blood clotting during the dialysis, which reduces the effective dialyzer surface area.

Many studies have concluded that cool dialysate does not change dialysis adequacy or urea removal. In the present study, no change was observed in these variables. Since cool dialysate increases the resistance of peripheral vessels, there is a concern that this hemodynamic effect may reduce dialysis adequacy by entrapping peripheral blood following the contraction of the larger vessels, which
is unfounded.\textsuperscript{[12]} Cool dialysis leads to blood pressure control during and after hemodialysis, with no adverse effect on dialysis adequacy.\textsuperscript{[14,19,29]}

In a study by Moattari \textit{et al.},\textsuperscript{[30]} the mean frequency of vomiting and muscle cramp due to a drop in the blood pressure during dialysis was higher, and the frequency of nausea was lower with cool dialysate compared to the conventional method. In the present study, the patients were non-selective in terms of hypotension and side effects, while in the study by Moattari \textit{et al.},\textsuperscript{[30]} in 30% of dialysis sessions, the patients had at least one of the symptoms of vomiting, nausea, and muscle cramp.

Many studies have shown that using cool dialysate has positive effects, increases the energy level, improves general health, and reduces nursing interventions and extra costs.\textsuperscript{[20,24,31]} However, in this study, no significant change was observed in the efficacy of dialysis by decreasing the dialysate temperature, but cool dialysate caused hemodynamic stability. No complications caused by cool dialysis have been reported to date.\textsuperscript{[32]} Cool dialysis has been recognized as an effective intervention for all dialysis patients, especially patients older than 55 years, those with cardiovascular diseases and low body strength, and women.\textsuperscript{[33]} The strengths of the present study included its block randomization, triple-blind design, and crossover nature, and specifically, the type of analysis used and the measurement of the core body temperature. The limitation of this study was the small sample size. It is recommended that this study be conducted with larger sample size and in larger centers.

\textbf{Conclusion} 
Reducing dialysate temperature from 36.5 to 35°C leads to hemodynamic stability, the blood pressure of the patients undergoing hemodialysis was more stable with the cool dialysate method and the number of drops in the blood pressure during the hemodialysis was reduced. Cool dialysis has no effect on the adequacy of the dialysis. Other complications (muscle cramp, nausea, and vomiting) were very slight, and no significant difference was observed between the two temperatures in this regard. Given that cool dialysis is a simple intervention that can be performed in all centers worldwide, it is recommended that the dialysate temperature not be fixed for all patients and that it be adjusted in every dialysis session according to the patient’s condition.

\textbf{Acknowledgments} 
The authors would like to express their gratitude to all the participating patients and to those who helped design and carry out this study. The current article was based on a thesis sponsored by Lorestan University of Medical Sciences, Khorramabad, Iran (coded 434).

\textbf{Financial support and sponsorship} 
Lorestan University of Medical Sciences

\textbf{Conflicts of interest} 
Nothing to declare.

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