



## The Impact of the Gradual Reduction of Dialysate Sodium on Occurrence of the Hypotension and Plasma Sodium Level in Hemodialysis Patients

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### Abstract

**Background:** Dialysis is the most common method of caring end-stage kidney disease, but it has some complications despite its several advantages. The aim of study was to investigate the impact of the gradual reduction of dialysate sodium on occurrence of the hypotension and plasma sodium in hemodialysis patients.

**Methods:** 56 hemodialysis patients participated in this randomized triple-blind crossover clinical trial. The patients were randomly divided into two groups of A and B. The routine method (Sodium Dialysis solution) was performed on group A, whereas the gradual reduction of sodium dialysis fluid was given to group B for three sessions. These dialysis methods were again implemented three sessions, after one week of routine dialysis (wash out). The routine method (Sodium Dialysis solution) was performed on group B, and the gradual reduction of sodium dialysis fluid was performed on group A, for three sessions. Patients' blood pressure was measured three separate times: 15 minutes before dialysis, during dialysis (first, second, third and fourth hours of dialysis) and 15 minutes after of it. Moreover, Patients' sodium level was also measured before and after the intervention. In this way, the descriptive statistics and inferential statistics (repeated measure analysis of covariance) were utilized to implement data analysis.

**Results:** In the case of routine method, the percentages of the prevalence of hypotension in above mentioned different hours were declared 6.2%, 26.6%, 44.5%, 32.8%, respectively. On the other hand, in the case of the gradual reduction of sodium dialysis fluid, these corresponding percentages were cleared 2.3%, 1.7%, 5.31%, 44.46%, respectively. The mean differences of plasma sodium before and after dialysis in the mentioned methods were obtained as 0.58 in the case of routine method, whereas it is 2.36 in the case of gradual reduction of sodium dialysis fluid method. In this research, there was no significant difference between the rate of hypotension and plasma sodium in the gradual reduction of sodium dialysis fluid by the routine method under 80% powers.

**Conclusions:** The experimental results revealed that a gradual reduction of the sodium dialysis fluid did not play a significant role in the reduction of blood pressure during dialysis and plasma sodium in hemodialysis patients. However, either confirmation or rejection of this issue will require further studies and resolving the limitations.

**Keywords:** Sodium dialysis fluid, Hypotension, Plasma Sodium, Hemodialysis.

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## Introduction

Chronic renal failure is one of the major health problems in the world. Based on a high percentage of health interventions

in each country, this failure is one of the major causes of mortality worldwide.<sup>1,2</sup> The dialysis approach is one of the most common methods for the treatment of final-stage renal disease.<sup>3,4</sup> Although this approach contains several advantages, it has some complications, which may cause the problems such as reducing dialysis and adequacy Patients' discomfort, increasing the workload of nurses and doctors, imposing high costs on the treatment system and decreasing an acceptance for regular dialysis program. As a result, it is critical to control and prevent these complications.<sup>5,6</sup> Hypotension, muscle cramps, nausea and headache are the most common and critical of its complications, in which the popular complication of hemodialysis is hypotension, which is about 50% of treatment interventions.<sup>5,7</sup> Hypotension can cause more severe headaches, vomiting, and muscle cramps.<sup>8</sup> Another complication of hemodialysis is called hyponatremia, which can exacerbate the hypotension during dialysis. Besides, it can cause congestive heart failure. It should be noted that reducing the sodium dialysis fluid can exacerbate hypotension during dialysis.<sup>9,10</sup> Meanwhile, hyponatremia may increase the risk of Gram-negative bacilli infections, makes longer the length of hospital stay, which may result in death.<sup>11</sup>

In the hemodialysis patients, plasma sodium concentration is stable, which seems that the osmolarity point of these patients should be regulated. This is accomplished by adjusting the sodium dialysis fluid.<sup>12</sup> Compared to other cations, sodium plays a critical role in dialysis, based on which if it becomes either low or high, it can affect the death of patients. Furthermore, sodium plays an important role to regulate the blood pressure.<sup>13</sup> The advantage of sodium profiling is that the use of high concentrations of sodium in dialysis initiates, which may result in 1) facilitating the transfer of water from the intercellular space to the intravascular space, 2) maintaining the intravascular volume from hypotension and therefore, preventing muscle cramps. One of the criticisms of the step-by-step method is that the use of these profiles can increase the weight between dialysis sessions. Based on the results of the study by Ghafourifard et al. (2009),<sup>14-17</sup> the use of sodium profiles is preferred than the conventional methods, and does not have any complication.<sup>18</sup>

There are various ways to either prevent or reduce the complication of hypotension in hemodialysis, which are as follows: changing the dialysis dose, changing the temperature of dialysis fluid, scheduled nursing care, gradual reducing of sodium dialysis, and changing in ultrafiltration. For these, it should be mentioned that some linear and stepped profiles have

been utilized,<sup>8,19-22</sup> for the treatment of hyponatremia, such as normal saline infusion.<sup>23</sup> Therefore, there is no the most effective theoretical agreement. Based on the mentioned above, it can be stated that the aim of this study is to determine the effect of gradual reduction of dialysate sodium on hypotension as well as the plasma sodium in the hemodialysis patients.

## Materials and Methods

The aim of study was to determine the effect of a gradual reduction of sodium dialysis fluid on the occurrence of hypotension as well as the plasma sodium in the hemodialysis patients.

This is a randomized clinical trial, triple-blind, cross over clinical study with Iranian registry of clinical trial number "IRCT2017040833295N1", which is carried out on 56 chronic renal failure patients referred to Shahroud Imam Hossein Dialysis center in 2017.

Inclusion criteria were 18-75 year-old patients with final-stage renal disease (ESRD). The condition of these patients was that they should have been undergoing hemodialysis for at least two months (2–3 times a week). Moreover, they are willing to participate in the plan. The exclusion criteria were considered as follows:

1. The patients' blood pressure had not been controlled
2. pre-dialysis blood pressure lowering medications had been used (the corresponding patients have prescribed blood pressure medication in consultation, with consulting the physician, after dialysis)
3. Myocardial infarction had been occurred in the last six months
4. The discharge fraction had been less than 30%
5. A pacemaker (pacemaker) had been existed

The records of patients suffering from a chronic renal failure were investigated. These patients underwent hemodialysis at the dialysis centers affiliated to Shahroud university of medical sciences. Then, 56 eligible patients were selected among them using consecutive sampling, based on the inclusion and exclusion criteria. It should be noted that a written consent was received from all of them. Subsequently, these patients were randomly assigned to either A or B groups using a quadruple blocking method.

In this study, the utilized data collection tools are demographic profile form (full name, age, gender, and weight), blood pressure checklist of patients at different time intervals (15 minutes before dialysis, 1, 2, 3 and 4 hours during hemodialysis and 15 minutes after dialysis) and laboratory measurement of Plasma Sodium.

To measure patients' blood pressure, an ALPK-2 barometer was used, manufactured in Japan. Plasma Sodium was measured by xdcib4 apparatus.

The method of intervention was implemented in such a way that the group patients (group A) were dialyzed using a routine method (138 milliequivalent per liter Sodium Dialysis solution and then keeping fix it duration of the dialysis). Moreover, the test group patients (group B) were dialyzed hemodialysis

patients using the gradual reduction of Sodium Dialysis. They were dialyzed for one week (three sessions). The Dialysis of group B was performed such that the reduction began with 150 milliequivalent per liter. This was carried out every 15 minutes per milliequivalent per liter, and it was continued until the concentration reached 138 milliequivalent per liter. Afterwards, both groups were dialyzed for one week using a routine method (wash out).<sup>24</sup> Then, Dialysis was performed using a crossover method, based on which the group B was dialyzed using the routine method, whereas group A was dialyzed using the gradual reduction of sodium dialysis, under three times. The type of Dialysis machine, nurse, pump dial and Dialysis strain used were constant for each patient during the period of study. The patients' blood pressure was measured 15 minutes before Dialysis, during Dialysis (first, second, third and fourth hours of hemodialysis) and 15 minutes after Dialysis in the supine position by a Japanese ALPK2 antimeter. Note that however, for patients undergoing four hours of Dialysis, the fifth time blood pressure was also measured. In this paper, the blood pressure was measured and then recorded from a hand that has not a fistula. Then, 5 ml venous clot samples were taken from all patients in order to measure and investigate the Sodium levels, and then the serum electrolyte levels were measured.

This was carried out both before and after the intervention (at the end of third session of dialysis). It is worthwhile to mention that 56 patients who were undergoing hemodialysis in the Dialysis ward of Imam Hossein hospital in Shahroud were registered by the first author using sequential sampling among the eligible patients. Afterwards, they were entered to the research after understanding the objectives of the study and receiving a written consent. Then, the patients were randomly divided into two groups (group A and group B) using a predetermined random pattern based on the quadratic blocks. In this matter, the researcher distinguished 28 series of A and B cards based on a 4-block random block pattern. These cards were provided to the hemodialysis ward supervisor in separate envelopes. In this way, the patients were assigned into two groups A and B, in the blind concealment envelope. Data were collected by a Dialysis nurse who was unaware of the patients' placement in the groups. In the current research, the patients, collector, and analyzer were unaware of the type of intervention in the groups ILJMH A and B until the end of the study. A consent form was received from all patients after necessary explanation of the research aims. It is worthwhile to mention that this study was approved by the Ethics Council of the university of medical sciences under code "ir.shmu.rec.1396.35".

The collected data were then analyzed through the descriptive statistics (e.g. mean, standard deviation, absolute and relative frequency) and inferential statistics (ANOVA via repeated measure).

## Results

The mean age of the patients was  $16.7 \pm 57.6$  years, in which most of the patients were male. Their percentage was 57%, based on which the mean and standard deviation of these patients were  $11.9 \pm 65.9$ kg.

The computational results indicate that the rate of hypotension during routine dialysis in the first, second, and

third hours of dialysis was measured to 6.2%, 26.6%, and 44.5%, respectively, and at the end of it, the value was 32.8%. The prevalence of hypotension during hemodialysis with gradual reduction of sodium dialysis fluid during the first, second, third hours of dialysis was 7.03%, 31.2%, 46.1%, respectively. Moreover, this was calculated to 44.5%, at the end of dialysis.

The impact of the proposed treatment was compared using the GEE regression model, which was not observed any significant effects. In other words, the prevalence of hypotension was not significantly different between the routine method and gradual reduction of dialysis solution. It should be

noted that the sequence of interventions also had no significant impact on the occurrence of hypotension during dialysis (Pvalue > 0.05) (see table 1).

Meanwhile, the mean difference of the plasma sodium before and after dialysis in the routine method was obtained as 0.58, whereas it was 36.2 in gradual reduction of dialysis solution method. In other words, there was no significant difference in the plasma sodium levels between two proposed groups (Pvalue = 0.52) (see table 2).

Ultimately, the experimental results confirmed that the treatment sequence, type of treatment, and treatment time had no significant effect on plasma sodium levels (see table 3).

**Table 1. Investigating the impacts of sequencing and treatment of hemodialysis patients using GEE regression to compare the prevalence of hypotension during dialysis**

	Significance level	Standard deviation	Coefficient E (B)	Confidence interval E (B)	
				Lower bound	upper bound
Sequence effect	0.01	0.2	1.83	2.87	1.58
Treatment effect (group)	0.29	0.33	0.7	1.36	0.36

**Table 2. Results of comparison of mean plasma sodium difference before and after dialysis in two methods**

Test result	Standard deviation difference	Mean difference	Method
T = 1.96	5.3	0.58	Routine
df = 104	3.7	2.36	Gradual reduction of dialysis liquid sodium
P = 0.52			

**Table 3. Effect of sequence, treatment and time on comparison of sodium levels in a crossover clinical trial**

Significance level	F	MS	
0.6	0.3	4.81	Sequence effect
0.8	0.03	0.22	Treatment effect (group)
0.5	0.31	2.31	Time effect

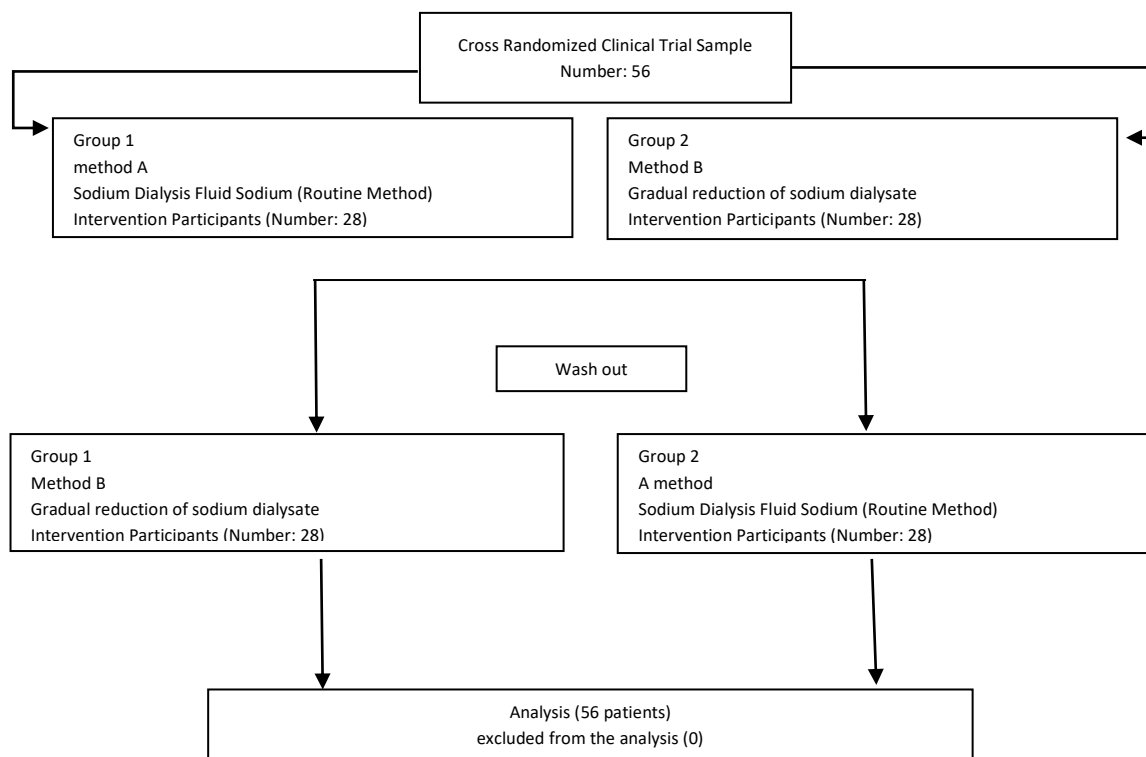


Figure 1. Study process diagram

## Discussion

The aim of study was to investigate the gradual reduction of dialysate sodium on occurrence hypotension as well as the plasma sodium levels in the hemodialysis patients.

In the current research, the prevalence of hypotension during dialysis in the routine method, in the first, second, third and fourth hours, it was calculated to 6.2, 26.6, 44.5, and 32.8%, respectively. Molaee et al. (2012) stated that the rate of occurrence of hypotension during the routine dialysis was calculated to 10.27, 20.12, 32.32, and 29.66, respectively in the mentioned hours.<sup>25</sup> Furthermore, the prevalence of hypotension during dialysis in the gradual reduction of sodium dialysis fluid method, in the first, second, third and fourth hours, was measured to 67.03%, 31.2%, 46.1%, 44.5%, respectively. In this regard, Molaee et al. (2012) described that the rate of occurrence of hypotension during this reduction was measured to 9.09, 17.80, 25 and 31.06, respectively, in the mentioned hours.<sup>26</sup>

The results indicated that the incidence of hypotension during dialysis was not significantly different between two proposed methods. Saeedi et al (2017) investigated that the gradual reduction of sodium dialysis fluid may lead to reduce the hypotension during hemodialysis.<sup>26</sup> The reason for the differences in the obtained results of these mentioned studies and the current research is that in our paper, both the number of statistical samples and the number of dialysis sessions are low.

Moreover, this result is also different from the results founded by Akedag et al. (2015) in which the effect of low sodium dialysis on the blood pressure in hemodialysis patients was investigated. In this study, the incidence of hypertension was significantly lower in the test group (137 mEq/l Sodium Dialysis) than in the control group (140 mEq/l Sodium Dialysis).<sup>9</sup> The possible reason for this difference may be interpreted due to the different follow-up time in two mentioned studies. In other words, in the above study, the patients were evaluated up to 6 months after the investigation, and then both their systolic and diastolic blood pressure were measured during this period, at dialysis and at home. Nevertheless, in the current research, the patients' blood pressure was measured during three hemodialysis sessions (five sessions each) for each intervention. Besides, the results of Shah Ghaliyan et al. (2015) were not the same as ones obtained by our study. Meanwhile, the impacts of a gradual reduction of sodium dialysis fluid concentration and individual dialysis sodium concentration on the blood pressure in hemodialysis patients were investigated. Their results confirmed that the rate of systolic blood pressure changes in steady-state sodium dialysis was higher than one of the gradual sodium dialysis.<sup>27</sup> The possible reason for this difference may be interpreted due to the different duration of assessment that patients had been assessed before the intervention.

In the current research, there was no significant difference in the mean plasma sodium before and after the intervention between two proposed groups. In this regard, Sayar livglou et al. (2007) provided that for the patients via a plasma sodium of less than 137 milliequivalent (pre-Dialysis), Sodium Dialysis fluid of 135 milliequivalent could be prescribed, whereas for

those patients via a plasma higher than 137 milliequivalent, the Sodium Dialysis fluid of 137 milliequivalent could be prescribed. After 8 weeks, they observed a significant decrease in the pre-Dialysis systolic blood pressure  $17.7 \pm 151.7$  versus  $179 \pm 24.8$  and  $16.4 \pm 132.3$  systolic blood pressure versus  $28.8 \pm 141.4$ .<sup>28</sup> These experiment results are also inconsistent with ones of our study. The possible causes of differences in the results may be interpreted that in their study, the level of Sodium Dialysis fluid was specified for each patient based on their Plasma Sodium level. In the current research, however, both patients were treated through a gradual reduction of Sodium Dialysis fluid and fixed Sodium, which had no relationship with the pre-Dialysis Plasma Sodium. It should be noted that the use of crossover method is one of the strengths of this paper. The restrictions of the patient evaluation sessions (three sessions per intervention) and the low number of patients were considered as some limitations of this study. No correlation was found between the Plasma Sodium and blood pressure. This result is different from the results of the Zahed et al. (2015). Their paper is discussed about the relationship between the Sodium Dialysis fluid concentration and blood pressure in chronic renal failure patients. Their study was carried out on 266 hemodialysis patients suffering from ESRD for various reasons. They were on Lohman Hakim, Ashrafi Isfahani and West of Tehran. In this study, the systolic blood pressure was measured before and after Dialysis and Sodium Dialysis fluid for one month. It is worth noting that the systolic blood pressure changes before and after Dialysis are significantly correlated with changes in dialysis fluid Sodium, based on which this relationship is independent of all other factors affecting on the blood pressure and direction. This study was contrary to the results of the study by Zahid (2015).<sup>29</sup> The possible reasons for the differences between the results of this study and our study could be interpreted due to the differences in the sample size of the two studies, the duration of evaluation before and after the intervention, and the number of study centers. The finding is different from the results of Yasser al-Shawawi et al. (2013). Their paper was developed about the relationship between Sodium concentration and blood pressure in the hemodialysis patients. Their study was implemented on about 40 hemodialysis patients during 12 months. Moreover, this paper was a cross-sectional and single-blind study, in which the entered patients were hemodialyzed for 36 sessions. The systolic blood pressure changes before and after dialysis were significantly correlated with sodium changes and were one of the factors affecting on the blood pressure.<sup>30</sup> The possible reasons for the differences between the results of this study and our paper may be interpreted due to some differences in the evaluation period.

One of the strengths points of this study are the use of crossover method. The limitations of patient evaluation sessions (three sessions per intervention) and the low number of patients may be some other limitations of this study. This study revealed that a gradual reduction in the Sodium Dialysis fluid had no significant role to decrease the blood pressure during Dialysis and Plasma Sodium in the hemodialysis patients. It should be noted that either rejection or confirmation of this issue requires further studies. Moreover, as the blood pressure drops significantly during Dialysis, nurses need to be aware of this issue and should try to reduce it.



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## Conflict of Interest

The authors declare that they have no conflict of interest.

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