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Li-hui ZHAI¹, Yue-yue ZHANG^{1,2}, Yan XU^{2,†},
Wen-juan YIN², Lin LI², Gui-ling YUAN²

Impact of Sodium Profiling on Ambulatory Blood Pressure in Patients on Maintenance Hemodialysis

Утицај натријума на целодневни крвни притисак болесника на дуготрајној хемодијализи

¹Department of Nephrology, Qingdao University Affiliated Hospital, Qindao, China;

²Department of Nephrology, Shanghai General Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, China

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† **Correspondence to:**

Yan XU

Shinan distinct Jiangsu road 16

Qingdao, Shandong province, China

E-mail: xuyanqfy@126.com

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SUMMARY

Introduction/Objective Most patients with end-stage renal disease (ESRD) have hypertension. However, dialysis-related strategies to optimize blood pressure in these patients remain controversial.

The aim of this study is to investigate the influence of dialysate sodium profiling on ambulatory blood pressure (ABP) in patients on maintenance hemodialysis, when there is not adequate dialytic and economic resources and high patients' compliance.

Methods This prospective, single-center study enrolled 60 hypertensive ESRD patients. Subjects received maintenance dialysis with regular dialysate sodium concentration (140 mmol/L) during the initial 3 months after enrollment, and were randomly assigned to continue regular sodium dialysate (group A) or switch to sodium profiling (group B) during 3 months. ABP, heart rate (HR), pre-/postdialysis serum sodium levels, antihypertensive treatment dosages, and interdialytic weight gain (IDWG) were recorded after treatment assignment.

Results Thirty patients each were enrolled in groups A and B. The basic characteristics were not significantly different between the two groups. Compared to patients in group A 3 months later, patients in group B had lower systolic ABP ($p=0.02$), HR ($p=0.03$), IDWG ($p=0.04$), and antihypertensive medication dosages ($p=0.04$). Throughout the treatment duration, no significant inter-group differences were observed for pre-/post-dialysis serum sodium and intradialytic complications. Additionally, no significant correlation were found between systolic or diastolic ABP and other variables studied in this study.

Conclusion The dialysate sodium profiling successfully ameliorated hypertension and reduced BP medications without altering natremic levels or increasing complications among patients on maintenance hemodialysis.

Keywords: ambulatory blood pressure; end-stage renal disease; sodium profiling; hemodialysis

САЖЕТАК

Увод/Циљ Већина болесника са терминалном болести бубрега (ТББ) има хипертензију. Међутим, стратегија за дијализу везана за оптимизацију крвног притиска код ових болесника остаје контроверзна.

Циљ овог рада је да испита утицај подешавања натријума у дијализату на крвни притисак (КП) мерен целог дана код болесника на дугорочној хемодијализи у условима неодговарајућих дијализних и економских ресурса.

Метод Проспективна студија у једном дијализном центру са 60 хипертензивних болесника са ТББ. Прва три месеца сви су на дијализи са натријумом у дијализату од 140 mmol/L, а потом рандомизовано подељени у групу А (иста дијализа) и групу Б (подешен натријум у дијализату). Групе су дијализиране три месеца и праћени параметри: целодневни КП, пулс, натремија пре и после дијализе, дозе антипертензивних лекова (АЛ) и међудијализни прираст телесне масе (МДТМ).

Резултати Почетне вредности контролираних параметра нису се разликовале између група. После 3 месеца, болесници групе Б, у односу на групу А, имали су значајно нижи систолни КП ($p=0,02$) и пулс ($p=0,03$) у односу на њихове почетне нивое, мањи прираст МДТМ ($p=0,04$) и мање дозе АЛ ($p=0,04$). Нису уочене значајне разлике између група: пре и после дијализне натремија, систолни и дијастолни КП, учесталост интрадијализних компликација и других праћених варијабли у овој студији.

Закључак Подешавање натријума у дијализату успешно смањује хипертензију и дозе АЛ, без мењања натремије и повећања учесталости компликација дијализе.

Кључне речи: холтер крвног притиска; крајњи стадијума бубрежних болести; натремија; хемодијализа

INTRODUCTION

Hypertension is frequently observed in patients with advanced chronic kidney disease (CKD) and end-stage renal disease (ESRD). More than 90% patients with advanced CKD have hypertension, which persists even after progression to ESRD [1]. In addition, BP variability is a risk factor for adverse outcomes among hypertensive patients; patients on maintenance dialysis are more susceptible to adverse impact of BP fluctuations due to increased vascular stiffness and dialysis-related body fluid

shift. In 2009, a meta-analysis mostly incorporating randomized controlled trials found that reduction of BP is closely associated with lower risk of cardiovascular events, better all-cause mortality, and cardiovascular mortality among patients on maintenance dialysis [2].

Rahman et al found that hypertensive ESRD patients had significantly higher blood volume, plasma volume, and extracellular fluid levels than normotensive patients with ESRD [3]. In ESRD patients undergoing maintenance hemodialysis, it is now recognized that refractory hypertension and sodium and fluid retention might result from impaired homeostasis associated with loss of renal function. Sodium and fluid retention plays an important role in the pathogenesis of hypertension in ESRD patients, and the sodium-potassium balance is crucial to endothelium-dependent vascular dilatation. Determinants of salt and water retention in ESRD patients primarily include dietary sodium intake, sodium gain from high-sodium dialysate, and the dialytic modality and schedule (usually thrice weekly) for sodium clearance [4,5].

Greater ultrafiltration during dialysis and dry weight lowering is beneficial for BP reduction, decreasing predialysis systolic BP, left ventricular volume, and antihypertensive medication dosage. A recent study lends support to this theory by showing that enhanced dialysis sodium removal can ameliorate arterial stiffness, left ventricular hypertrophy, and IDWG [6]. Thus, maintaining the balance of sodium and extracellular fluid plays an important role in IDWG modulation. Del Giudice and colleagues found that low dialysate sodium concentrations improved BP control among patients on maintenance dialysis [7]. But shorter duration of dialysis and increased ultrafiltration rate following technological advancements in the field of hemodialysis have brought about hypotension, disequilibrium syndrome, and muscle cramps. Adjustment of dialysate sodium concentration can be a potential approach to achieve this balance [8]. Sodium profiling is usually used in normovolemic patients with hypotension or normal blood pressure who are instable during dialysis session, and some researchers suggest that sodium profiles reduce dialysis complications and provide patient comfort. They thus believe that such procedures are beneficial to patients facing difficulty in reaching dry weight due to the adverse effects of dialysis.

In addition, recent studies suggest the superior prognostic importance of ambulatory BP (ABP) monitoring compared to single BP measurement and its facilitation of adequate BP control in patients on dialysis[9]. Guidelines from the American Heart Association (AHA) and European Hypertension Society (EHS) recommend ABP monitoring in all hypertensive patients [10].

People in Province Shandong of China usually have a dietary habit of high-salt, and the IDWG of our patients was between 0.5–3.5 kg or more. Large IDWG requires high ultrafiltration rate which is always followed by dialysis instability, some patients even could not eliminate the superfluous fluid in one dialysis course. But according to KDOQI guidelines, patient's interdialytic weight gain (IDWG) should not exceed 1 kg during the week and 1.5–2 kg during the weekend. IDWG of more than 4.8% (i.e., 3.4 kg in a 70 kg person) is a reflection of excessive sodium and water intake, and is associated with increased mortality.

A large percent of patients in our dialysis center was refractive hypertension, probably because of superfluous fluid and sodium. Although we prescribed them with restricted sodium and water diet, tried to use 138mmol/l or lower dialyzate sodium, normalize Kt/V, increase the frequency of dialysis etc, there was no ideal results, which might because of the low compliance with clinicians' advices. Additionally, for the limitation of our country in dialytic and economic resources, we neither have enough dialysis machine to meet longer dialysis session time nor can afford high flux dialyzers every time. In this dialysis center, the routine dialysis time was 4h, and the center has 3 courses every day, with no nocturnal hemodialysis, although it is well known that longer dialysis session time may cure dialysis hypertension, dialysis time should be at least 4 hours (KDOQI). Therefore, we performed this study and tried to find a suitable way to relieve their hypertension in our center.

There is a paucity of studies that evaluate the effectiveness of dialysate sodium profiling in controlling interdialytic ABP, and we sought to investigate this issue in patients on maintenance dialysis, to instruct clinical intervention. The primary endpoints of this effective study were changes in clinical parameters, including ABP, heart rate (HR), interdialytic weight gain (IDWG). Secondary endpoints included changes in antihypertensive treatment dosage, serum sodium, and dialysis adequacy in this study. Safety endpoints included intradialytic hypovolemia-related complications, such as hypotension and cramping events per months.

METHODS

Study population

The current study was approved by the institutional review board of Qingdao University, Shandong Province, People's Republic of China, and all participants provided written informed consent. The study was conducted with adherence to the principles of the Declaration of Helsinki.

This prospective, single-center study enrolled patients undergoing maintenance hemodialysis at the blood purification center of the affiliate hospital for Qingdao University. Inclusion criteria were age 18 or older, dialysis for more than 12 months, mean hemoglobin 110–120 g/L with stable erythropoietin dosage, and daily residual urine output less than 100 mL. Subjects were included when mean systolic ABP levels was above 150 mmHg. Patients with history of arrhythmia (atrial fibrillation or frequent premature complexes), major cardiovascular or cerebrovascular events within the 3 months preceding enrollment, active infection or concurrent malignancy, and prominent subcutaneous edema or pericardial effusion on cardiac ultrasonography were excluded.

Study procedure

All participants underwent a washout period of 3 months with regular dialysate sodium concentration (140 mmol/L) before commencing study treatment. All patients were prescribed to low salt, limited fluid intake before this trial, and did not perform any alterations in dietary habits or new dietary instructions. All subjects underwent maintenance hemodialysis using polysulfone-based

membrane thrice weekly for 4 hours, low flux dialyzers routinely and high dialyzers twice a month. Subjects were randomly assigned to either regular sodium dialysate (group A) or sodium profiling (group B) groups. Dialysate for group A patients comprised a bicarbonate-based formula, with a fixed sodium, potassium, and calcium levels of 140, 2.5, and 1.5 mmol/L, respectively. Dialysate for group B patients consisted of an adjustable formula, which comprised: an initial sodium level of 148 mmol/L and a linear reduction to 132 mmol/L over the treatment period and potassium and calcium levels of 2.5 and 1.5 mmol/L, respectively. The blood flow rate for each patient ranged between 200 and 280 mL/min; dialysate flow rate and temperature were 500 mL/min and 37°C, respectively, with anticoagulation using unfractionated or low-molecular-weight heparin.

In study subjects, pre- and post-dialytic serum sodium and urea were measured once a month at the central laboratory of the hospital. The formula Kt/V was utilized to evaluate the adequacy of each dialysis session. Kt/V was calculated according to a natural logarithm formula: $Kt/V = \ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times UF/W$, where R is postdialysis blood urea nitrogen and predialysis blood urea nitrogen, t is session length in hours, UF is ultrafiltration volume in liter, and W is postdialysis weight in kg [11].

Study endpoints

Parameters included in primary and secondary endpoints were monitored. On the interdialytic day of the first week of each month, sitting BP and HR were measured after patients rested for 10 minutes at three time points (morning, noon, and evening) and the mean of the three measurements was recorded as the value for that day. Mean values of ABP and HR were documented from data obtained on consecutive interdialytic days in that week. Patients were censored if their ABP decreased to less than 130/80 mmHg during the intervention period or after 3 months of treatment.

Antihypertensive medication dosage was quantified with the defined daily dose (DDD) approach [6] for each type of medication. For patients on more than one antihypertensive medication, we calculated the sum of DDD from all medications to represent the antihypertensive dosage. IDWG was calculated from the difference between body weight measured after one dialysis and that measured before the next session, which was divided by their dry weight and the mean of measurements from consecutive interdialytic days of the first week of each month was calculated.

Safety endpoints included intradialytic hypovolemia-related complications. We recorded the monthly frequency of dialysis-related hypotension and muscle cramping. Dialysis-related hypotension was defined as a decrease in systolic BP of more than 20 mmHg or a decrease in mean BP of more than 10 mmHg, accompanied by symptoms of hypotension requiring clinical interventions. Muscle cramping referred to intradialytic painful muscle contractions unaccompanied by hypotension, amenable to improvement by local massage and saline infusion.

Statistical analysis

We used SPSS v17.0 for statistical analysis. Continuous variables are expressed as mean \pm standard deviation, normal distributions of the variables were examined. Comparison of data normal distributions was done by Student's independent *t*-test. Blood urea nitrogen, DDD, IDWG were not normal distributions and were tested by Mann-Whitney *U*-test. Categorical data were analyzed by chi-square test. Pearson analysis and multi-factor regression analysis were performed to find the correlation between ABP and other variables. A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

Sixty patients: male, 27; mean age, 45 \pm 12.3 (25.5–65 years) on maintenance hemodialysis were enrolled. The mean duration of dialysis was 5.7 \pm 2.6 years (1.5–10.5 years). ESRD etiologies in these patients were: 35 (58.3%) chronic glomerulonephritis, 10 (16.7%) diabetic nephropathy, and 15 (25%) hypertensive glomerulosclerosis.

Baseline parameters: inter-group comparison

Of the 60 participants, 30 were assigned to group A (46.7% male) and 30 to group B (43.3% male). Mean age and duration of dialysis were 45.4 \pm 13.1 and 5.8 \pm 2.7 years for group A, 44.7 \pm 11.6 and 5.7 \pm 2.6 years for group B. No significant inter-group differences existed for baseline characteristics, including hemoglobin, total protein, albumin, calcium, phosphates, potassium, urea, creatinine, total protein, antihypertensive medication dosage, IDWG status, intradialytic hypotension,

Table 1 Patients' baseline characteristics ($\bar{x}\pm$ SD).

	Group A	Group B	<i>p</i> -value
Hemoglobin(g/l)*	97.3 \pm 8.6	99.1 \pm 9.4	0.442
Total Protein(g/l) *	67.4 \pm 5.2	65.3 \pm 4.2	0.090
Albumin(g/l) *	35.5 \pm 3.5	36.6 \pm 2.9	0.190
Calcium(mmol/l) *	2.22 \pm 0.47	2.35 \pm 0.36	0.234
Phosphates(mmol/l) *	1.65 \pm 0.23	1.54 \pm 0.31	0.124
Potassium(mmol/l) *	5.0 \pm 0.8	4.9 \pm 1.2	0.705
Blood Urea Nitrogen (mmol/l) #	25.5 \pm 10.4	22.7 \pm 12.5	0.349
Serum Creatinine (umol/l) *	890.2 \pm 150.9	907.5 \pm 143.7	0.651
Estimated Dry Weight (kg)*	60.5 \pm 10.7	59.2 \pm 8.4	0.602
<i>Kt/V</i> *	1.36 \pm 0.10	1.41 \pm 0.11	0.070
Pre-dialysis serum sodium (mmol/L) *	138.7 \pm 3.8	139.3 \pm 3.3	0.516
Post-dialysis serum sodium (mmol/L) *	135.8 \pm 3.8	137.6 \pm 3.4	0.052
Antihypertensive medication dosage (DDD)#	4.5 \pm 1.9	4.5 \pm 2.1	1.000
Intradialytic hypotension (event/month) ‡	16	20	0.503
Intradialytic cramping (events/month) ‡	12	16	0.448
Interdialytic weight gain (%)#	4.32 \pm 1.25	4.39 \pm 1.49	0.8444
Systolic blood pressure (mmHg) *	152.67 \pm 17.53	154.48 \pm 16.4	0.6811
Diastolic blood pressure (mmHg) *	104.34 \pm 15.49	109.46 \pm 13.2	0.1735
Heart rate (/min) *	76 \pm 7	78 \pm 9	0.168

*Data were normal distributions and comparison were done by Student's independent *t*-test.

#Data were not normal distributions and comparison were done by Mann-Whitney *U*-test.

‡Data were categorical and comparison were analyzed by chi-square test. A *p*-value of less than 0.05 was considered statistically significant.

and muscle cramping (Table 1). Pretreatment ABP, HR, pre- and postdialysis serum sodium, and *Kt/V* did not differ between group A and B patients.

Endpoints

After dialysate sodium profiling for 3 months, group B patients did not have significant alterations in their pre-/postdialysis serum sodium, dialysis

adequacy measures, IDWGs, and intradialytic hypotension/muscle cramping compared to group A (Table 2).

Table 2. Inter-group comparison of parameters at post-assignment.

	Group A	Group B	P-value
<i>Kt/V</i> *	1.38±0.10	1.40±0.10	0.442
Pre-dialysis serum sodium (mmol/L) *	139.5±2.8	138.7±2.9	0.281
Post-dialysis serum sodium (mmol/L) *	136.5±2.8	136.3±3.0	0.790
Antihypertensive medication dosage (DDD) #	4.4±2.3	3.3±1.7	0.039
Intradialytic hypotension (event/month) †	20	12	0.156
Intradialytic cramping (events/month) †	8	16	0.102
Interdialytic weight gain (%)#	4.44±1.17	3.80±1.18	0.039
Systolic blood pressure (mmHg) *	154.67±18.32	138.00±18.19	0.000
Diastolic blood pressure (mmHg) *	109.47±14.88	85.34±12.90	0.000
Heart rate (/min) *	78±6	75±8	0.039

*Data were normal distributions and comparison were done by Student's independent *t*-test.

#Data were not normal distributions and comparison were done by Mann-Whitney-U test.

†Data were categorical and comparison were analyzed by chi-square test. A *p*-value of less than 0.05 was considered statistically significant.

However, group B patients had significantly lower systolic ($p<0.01$), diastolic ABP ($p<0.01$) and HR ($p=0.04$) compared to patients in group A.

Antihypertensive medication dosage

also decreased significantly in group B patients compared to group A ($p=0.04$) (Table 1).

IDWG for group B patients decreased from 4.4±1.5 kg at baseline to 3.8±1.2 kg at 3 months, with a significantly lower level at 3 months than in patients in group A ($p=0.04$) (Table 2).

Correlation analysis

We performed Pearson analysis and multi-factor regression analysis, but did not find any significant relation between systolic or diastolic ABP and other variables (data not show).

DISCUSSION

This is an effective study designed to compare the effect of sodium profiling with sodium dialyzate concentration 140 mmol/l, which is the routine sodium dialyzate concentration in our dialysis center, as well as many centers in our country, maybe some countries else. This study tried to use adjustable sodium dialysis, adjusted the ultrafiltration according to the IDWG and the tolerance of each patient, to exclude more fluid in one dialysis course, get near to the dry weight, lowering the ABP, without increasing dialysis adverse events. We previously found that dialysate sodium profiling can reduce postdialysis BP in hypertensive patients on maintenance hemodialysis [12]; in the current study, we further identified that dialysate sodium profiling, compared to regular dialysate sodium status, effectively decreases interdialytic ABP and use of antihypertensive medication. Another study similarly showed that low-sodium dialysate can reduce morning and night ABP over a period of 6 months [13]. Inrig et al conducted a randomized study, comparing hemodialysis patients receiving low- and high-sodium dialysate for 3 weeks, and found that low-sodium dialysate leads to a mean 9-mmHg decrease in systolic BP, consistent with our findings [14]. Our study extends their findings by demonstrating the similarly favorable effect of dialysate with adjustable sodium on ABP parameters, antihypertensive medication dosages, and IDWG in patients on maintenance hemodialysis.

In sodium profiling, hyphenatremic dialysates are used at the beginning of the dialysis process. Sodium content of the dialysate is then gradually reduced to allow excess sodium to be removed from the blood. High sodium concentration in this method facilitates the movement of water from the interstitial space into the intravascular space and results in better maintenance of intravascular volume and fewer adverse effects during dialysis. In this study, we used high-sodium dialysate (148 mmol/L) initially during each session, and linearly reduced dialysate sodium concentrations over time (finally to 132 mmol/L) to facilitate removal of excessive sodium. This maneuver did not affect serum sodium and intradialytic BP after 3 months; the systolic, diastolic ABP, and HR all significantly improved after dialysate sodium profiling, whereas these parameters did not alter in the control group.

Intradialytic complications such as hypotension and muscle cramping are frequently associated with dialysis intolerance, the reduction of blood flow and dialysis duration, leading to lower dialysis adequacy (Kt/V) [15]. From this study, we found that compared to regular dialysate sodium group, dialysate sodium profiling did not increase these complications significantly, which is consistently with results from previous studies [11]. However, despite the fact that there are already multiple studies addressing the effect of dialysate sodium profiling on improving hypertension in patients on maintenance hemodialysis, some believe that high concentrations of sodium in sodium profiles will lead to not only increased thirst and interdialytic weight gain (which means the need for removing greater volumes of fluids to reach dry weight and higher frequency of hypotension) but also hypertension^[11]. Thus, sodium in sodium profiles nowadays should only be used in short time, with adequate assessment of patients' response. Once there is improve in fluid load and ABP, dialysis mode should be back to routine mode, and enhance education of low-salt, less fluid intake.

Therefore, more studies, especially those with large sample size, conducted at multiple centers, and of longer duration are needed to verify the benefit of this approach. Other issues such as ultrafiltration profiling and individualized sodium profiling regimens also await further investigation. Our study is limited in several aspects. The case number is modest, and cardiac as well as vascular stiffness parameters were not collected during study. However, our findings have merit because adjustable sodium dialysate for BP control is scarcely addressed in the literature.

CONCLUSION

This study found that, in patients on maintenance hemodialysis, adjustable sodium dialysis can reduce ABP, HR, antihypertensive medication dosage, and IDWG. These findings contribute to the current literature by showing that adjustable dialysate sodium has a beneficial effect on hemodynamic parameters similar to that with low-sodium dialysate in patients on hemodialysis, and we did not increase dialysis adverse events in the 3 months. Further study is needed to confirm our results.

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NOTE

ZHANG Yue-yue and ZHAI Li-hui should be viewed as co-first author.

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