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Original Article

Applying Sodium Profile with or without Ultrafiltration Profile Failed to Show Beneficial Effects on the Incidence of Intra-dialytic Hypotension in Susceptible Hemodilaysis Patients

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Abstract

Introduction: Intra-dialytic hypotension (IDH) is a common complication during hemodialysis (HD) treatment. Previous studies have reported that modulating dialysate sodium concentration combined or not with modulation of ultrafiltration (UF) rate may reduce the incidence of IDH. The aim of the present study was to evaluate the effect of sodium and UF profiles on the occurrence of intra-dialytic complications and dialysis quality.

Methods: From a total of 64 patients, we selected 18 patients who suffered from recurrent IDH. Every patient received ten HD sessions utilizing each of the following treatments: (1) Control: constant sodium concentration and UF rates. (2) Sodium and UF profiles: a linearly decreasing sodium concentration combined with a linearly decreasing UF rate. (3) Sodium profile:decreasing sodium concentration with constant UF rate.

Results: Fourteen patients completed the study protocol. The incidence of IDH, mean inter-dialytic weight gain and the delivered dialysis dose were not different between the three treatments. However, symptomatic episodes of IDH were more commonand pre-dialysis systolic blood pressure was higher during the second and third treatment modalities compared to controls. Isolated sodium profile was associated with more malaise and less achievement of target session duration compared to the other two treatments. Isolated sodium profile was associated with less achievement of target UF while combined sodium and UF profiles were associated with more achievement of target UF compared to controls.

Conclusion: Our results indicate that sodium profile with or without UF profile does not have a beneficial effect on the incidence of IDH, achievement of target session duration or the delivered dialysis dose.

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Introduction

Hemodialysis (HD) is a worldwide common treatment for end-stage renal disease (ESRD). Although generally considered a safe procedure, it can have several adverse effects [1]. Intra-dialytic hypotension (IDH) is a common complication during dialysis and affects 20-33% of hemodialysis patients [2]. The pathophysiology of hypotension during dialysis is a decrease of circulating volume induced by ultrafiltration (UF). This is facilitated by the decline of extracellular osmolarity caused by the active removal of solutes, especially sodium. This results in transfer of fluids from outside to inside the cells, increasing the intracellular volume and lowering the extracellular volume [3].

Other complications that can occur during HD include cramps, nausea and vomiting, headache and malaise. Apart from patients' subjective discontents, these complications often require the early discontinuation of the dialysis session before prescribed time and/or fluid replacement. This can result in chronic volume overload and under-dialysis [4].

It has been suggested that modulating dialysate sodium concentration combined or not with UF profiling may better preserve circulating blood volume, and thus decrease the incidence of hypotensive episodes during dialysis [5-7].

Sodium profile is mainly applied with a higher dialysate sodium concentration during the first part of the dialysis

session, when the blood urea concentration and urea removal rates are high. This tends to lessen the inevitable decrease of plasma osmolality due to urea removal and reduce the resultant shift of fluids from the outside to the inside of cells. A lower dialysate sodium concentration during the remainder of the dialysis session avoids sodium accumulation [8, 9].

UF profile is usually designed to extract the major part of the total UF volume in the first part of the session when the patient is over-hydrated, to induce elevation of the plasma oncotic pressure and to provide a greater driving force for vascular refilling, and thus better blood volume preservation [10-12].

A combination of sodium and UF profiles was proposed to improve cardiovascular stability by increasing dialysate sodium concentration to enhance plasma refilling during periods of high UF rate and by decreasing dialysate sodium concentration when refilling appears less critical during periods of slow UF [12, 13].

Technological advances equipped modern HD machines with features that allow varying sodium concentrations in the dialysate and UF rates according to linear or stepwise models. There is controversy about the safety and efficacy of the routine use of these profiles. The aim of the present study was to evaluate the effect of sodium profile combined or not with UF profile on the occurrence of intra-dialytic complications and hemodynamic stability. Another goal was to test the hypothesis that using sodium profile would improve dialysis efficacy in terms of achieving targets such as UF volume, session duration and delivered dose of dialysis.

Methods

This was a prospective study conducted in our dialysis unit from July to December 2010. Out of a total of 64 adult ESRD patients who underwent maintenance HD in the center, we selected 18 patients who were prone to IDH. These were stable patients who had been maintained on thrice-weekly HD for more than one year and who suffered from IDH in more than 30% of HD sessions over the previous three months. IDH was defined as a decrease in systolic blood pressure by more than 30%. Exclusion criteria were cardiac failure, antihypertensive medications, blood transfusion during hemodialysis, active bleeding, a poorly functioning arteriovenous fistula and excessive food consumption before HD session. All patients gave their informed consent to participate in the study.

The target weight was evaluated and readjusted if necessary by the attending nephrologists who were not involved in the design or analysis of the study. Dry body weight was determined individually based on blood pressure (BP), absence of peripheral and/or pulmonary oedema and echocardiography data.All treatments were performed using FMC 4008S (Fresenius Medical Care AG, Bad Homberg, Germany), polysufone low flux dialysers and bicarbonate buffered dialysate (sodium 139 mmol/l, potassium 2 mmol/l, calcium 1.50 mmol/l, magnesium 0.5 mmol/l, bicarbonate 29 mmol/l). Blood flow rate was individualized from 250 to 320 ml/min. Dialysate flow rate was 500 ml/min. Dialysate temperature was 37°C. During the study, dialyser surface area, blood flow rates, anticoagulation during the session and the dosage of erythropoietin were maintained unchanged.If inter-dialytic weight gain was <1.6% of dry weight (corresponding to 1 Kg of weight gain for 60 Kg of dry weight) the dialysis session was excluded from data analysis.

Each one of the following treatment modalities was applied during ten HD sessions for each patient. First modality (control): constant sodium concentration of 139 mmoL/L with constant UF rate. Second modality (sodium and UF profiles): linearly decreasing sodium concentration with the initial sodium concentration set at 147 mmoL/L falling to 131mmol/l at the end of dialysis, combined with a linearly decreasing UF rate. Third modality (sodium profile): the same model in the second modality with constant UF rate. Clinical parameters were measured for all sessions.We used the same electronic scale (Seca) for measuring weight throughout the study. Blood pressure (BP) was measured in the supine position 5 min before the session, every 30 minutes during the session, at the end of the session just before extracorporeal volume infusion and if symptoms of hypotension occurred. BP was measured using Fresenius BP monitor. Symptomatic hypotension was defined as IDH accompanied by hypotensive symptoms such as dizziness, frequent yawning or perspiration, or an event that required immediate intervention. Delivered HD dose was presented by Kt/V according to the ionic dialysance method using the on-line clearance monitor (OCM). The achievement of target UF and session duration were represented by a ratio according to the following formulae:

Target UF achieved = (actual UF volume / inter-dialytic weight gain) x 100

Target session duration achieved = (actual session duration / planned session duration) x 100

Data was analyzed using the Statistic Package for Social Sciences software for Windows (SPSS version 10.0). Quantitative variables were expressed as mean ± standard deviations. Qualitative variables were expressed as numbers and percentages. A value of $P<0.05$ was

considered statistically significant. Quantitative variables of paired data were compared by analysis of variance with repeated measures. Percentages of paired data were compared by the Cochrane Q test.

Results

Among 18 patients included in the study, only 14 patients completed the three different treatment modalities of the study. The remaining patients did not complete the study protocol because they were transferred to another HD center. Clinical and demographic characteristics of patients are shown Table-1. A total of 420 dialysis sessions were conducted during this study. Table-2 shows the measured parameters of the three treatment modalities. There was no difference in terms of occurrence of IDH between the three treatment modalities. However, the use of sodium profile as monotherapy or in combination with an UF profile was significantly associated with an increased frequency of symptomatic IDH compared to control treatment. The pre-dialysis systolic blood pressure increased significantly during treatment with sodium profile alone or in combination with UF profile compared to control treatment. Post-dialysis systolic BP was significantly lower during sodium profile treatment compared to both other treatment modalities. Post-dialysis diastolic BP was significantly lower during the sodium and UF profiles treatment compared to control treatment. Inter dialytic weight gain and dry weight were not changed during sodium profile treatment, combined or not with UF profile. Episodes of malaise were significantly more frequent during the use of sodium profile compared to control treatment. These episodes were also more frequent during sodium profile treatment in comparison with sodium and UF profiles treatment. The frequency of other intra-dialytic complications was similar during the three treatment modalities.

The achievement of target UF rate was significantly higher during sodium and UF profiles treatment compared to control treatment. This rate was significantly lower during sodium profile treatment compared to control treatment. The achievement of session duration was significantly decreased during sodium profile treatment compared to both other treatment modalities.The delivered dialysis dose was similar during the three phases of the study.

Discussion

Intra-dialytic complications, particularly hypotension, remain frequent despite continuous improvements in dialytic technologies. Dialysis-induced hypovolemia is considered the major causal factor. Change in effective blood volume depends on the equilibrium between fluid moving outside the body by UF and vascular refilling from the interstitial space. Sodium profile combined or not with UF profile was designed to improve vascular refilling and thereby dialysis tolerance. The results of our study showed no difference in terms of occurrence of IDH between the three treatment modalities. However, sodium profile alone or in combination with UF profile was significantly associated with more episodes of symptomatic IDH. Indeed, episodes of malaise were significantly more frequent during the use of sodium profile compared to control treatment.

Sodium profile alone has been frequently reported as a useful tool to improve dialysis tolerance [8, 9, 14-16]. Tang *et al* reported 62% reduction in the frequency of hypotension with the linearly decreasing sodium profile in 13 patients [17]. Many authors also evaluated the effect of sodium profile combined with UF profile on IDH. Using sodium and UF profiles in a linear model, Zhou *et al* and, and more recently Shahgholian *et al*, have demonstrated a significant reduction of IDH compared to conventional hemodialysis [2, 18]. A beneficial effect on IDH has also been reported with sodium profile combined with UF profile using a gradual model [19]. However, other authors have shown that the use of a sodium profile (combined or not with UF profile) did not improve the incidence of IDH. Iselin *et al* reported no effect on the occurrence of hypotension or the preservation of blood volume with a linearly decreasing sodium profile (sodium concentration from 145 to 133 mmol/L) adapted to a linearly decreasing UF profile [20]. A study by Zhou and his colleagues concluded that during a similar model of sodium and UF profiles, hypotensive episodes were significantly reduced, but sodium profile or UF profile as mono-therapy had no beneficial effect on intra-dialytic hemodynamics [21].In contrast with our results, several studies described no changes in pre-dialysis and post-dialysis systolic and diastolic blood pressures with the use of variable sodium profiles [3, 5, 16, 22].In some studies, inter-dialytic weight gain and estimated dry weight were not changed with sodium profile (combined or not with UF profile) [16, 22, 23], while other studies had reported a significant increase in weight gain [7, 24, 25]. In this study, we did not evaluate sodium gain with the use of sodium profile.

In our study, malaise was significantly more frequent with the use of sodium profile in comparison with control treatment. The frequency of other intra-dialytic complications was similar in the three treatment modalities in agreement with previous studies [1, 25]. Al-Hillali *et al* evaluated the effect of combining sodium and UF profiles on intra-dialytic symptoms. The results of their study don't support our findings. They reported intra-dialytic symptoms in 29 patients before applying the profiles and in only 21 patients after using the profiles

Table 1: Clinical and demographic characteristics of studied patients (n=14)

Variable	Summary
Age in years (mean ± SD)	45.2 ± 11.4
Females (number, %)	7 (50%)
Duration on HD in months (mean ± SD)	35.3 ± 15.9
VascularAccess (% arteriovenous fistula)	14 (100)
Dialysis time per week (% twelve hours)	100
Etiology of ESRD:	
Diabetes, n	10
Hypertension nephropathy, n	1
Unknown, n	3

Table 2: Results of the different parameters measured during the three phases of the study

	Control (n=140)	Sodium + UF profiles (n=140)	Sodium profile (n=140)	P	P1	P2	P3
Inter-dialytic weight gain (g)	2095 ± 509	2107 ± 470	2209 ± 476	0.098	-	-	-
Pre-dialysis systolic BP (mm Hg)	134 ± 13	139 ± 16	138 ± 14	0.003	0.004	0.041	1
Post-dialysis systolic BP (mm Hg)	128 ± 16	128 ± 17	124 ±13	0.046	0.93	0.029	0.035
Pre-dialysis diastolic BP (mm Hg)	66 ± 12	67 ± 12	64 ± 12	0.081	-	-	-
Post-dialysis distolic BP (mm Hg)	65± 10	60 ±19	64 ± 10	0.015	0.024	1	0.056
Hypotension (n, %)	49 (35)	50 (35.7)	49 (35)	0.99	-	-	-
Symptomatic hypotension (n, %)	9 (6.4)	20 (14.3)	21 (15)	0.049	0.031	0.02	0.866
Asymptomatic hypotension (n, %)	40 (28.6)	30 (21.4)	28 (20)	0.418	-	-	-
Malaise (n, %)	14 (10)	20 (14.3)	43 (30.7)	< 0.001	0.272	< 0.001	0.001
Headache(n, %)	3 (2.1)	3 (2.1)	1 (0.7)	0.559	-	-	-
Nausea and/or vomiting (n, %)	1 (0.7)	0	1 (0.7)	0.605	-	-	-
Cramps(n, %)	4 (2.9)	6 (4.3)	9 (6.4)	0.351	-	-	-
UF (ml)	2147 ± 514	2268 ± 435	2184 ± 434	0.081	-	-	-
Target UF achieved (n, %)	0.96 ± 0.05	0.99 ± 0.01	0.92 ± 0.08	< 0.001	0.001	<0.001	< 0.001
Delivered dose (Kt/V)	1.25 ± 0.11	1.22 ± 0.09	1.23 ± 0.09	0.075	-	-	-
Target session duration achieved	0.99± 0.01	0.99 ±0.01	0.95 ± 0.04	<0.001	1	<0.001	<0.001
Dry weight (kgs)	62.14 ±7.5	61.96± 7.5	62.02 ± 7.3	0.848	-	-	-

P1 = P value comparing control treatment versus sodium and UF profiles
P2 = P value comparing control treatment versus isolated sodium profile
P3 = P value comparing isolated sodium profile treatment versus combined sodium and UF profiles

(P<0.05) [26]. Song *et al* demonstrated that a step-down sodium profile in 11 patients failed to improve dialysis tolerance. When sodium profile was combined with the stepwise decreasing UF profile, they obtained a reduction of intra-dialytic malaise [15].

Song *et al* [12] extended their evaluation to the delivery of dialysis dose, maintenance of session duration, and UF performance. Sodium profile used alone was beneficial in these terms. When combined with UF profile, it reduced the incidence of dialysis failure (defined as discontinuation of the session before 75% of planned time). The combination of these profiles was associated with less weight gain, better UF performance and a post-dialysis weight that was closest to the patient's dry weight. In our study, the achievement of session duration decreased significantly when sodium profile was used alone. This finding can be explained by the higher number of malaise episodes associated with earlier discontinuation of the dialysis session during this treatment modality. This difference, however, had no effect on the delivered dialysis dose.

There are methodological differences in the present study as compared with some previous studies.We evaluated the effects of sodium and UF profiles not only on the incidence of intra-dialytic complication sbut also on delivered dialysis dose and UF performance. The patients and their attending nephrologists dealing with dry weight and UF targets were both blinded to the assigned treatments modality. We do understand that there are several limitations to the present study. The relatively small number of cases might mean that the study is not sufficiently powered to detect significant difference in some parameters. The estimated values of dry weight might not be accurate. Dry weight was estimated essentially on the basis of subjective criteria. Inter-dialytic problems and sodium gain were not evaluated. Currently, blood volume controlled feedback systems are available [27, 28]. These systems directly monitor the change in blood volume during HD and maintain stable blood volume by adjusting the UF rate and dialysate conductivity. These technological developments could guarantee better intra-dialytic hemodynamic stability in the future.

Conclusion

Our results indicate that sodium profile alone or in combination with UF profile is not an efficient approach to decrease dialysis-related hypotension. Sodium profile also failed to reduce the incidence of other intra-dialytic complications or improve the achievement of targeted UF and session duration.

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