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Effect of Application of Cool Dialysate on Controlling Hypotension and Restless Leg Syndrome among Patients Undergoing Hemodialysis

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Abstract
Context: Hemodialys patients frequently experience the distressing side effects of restless legs syndrome and intradialytic hypotension. It may induce patients to experience discomforting symptoms, lead to vascular access thrombosis, and reduce the efficiency of dialysis. So, it is necessary to prevent this complication. **Aim:** The purpose of this research was to evaluate effect of application of cool dialysate on controlling hypotension and restless leg syndrome among patients undergoing hemodialysis. **Methods**: A purposive sample of 88 patients admitted to the Hemodialys department at Benha University Hospital Qalyoubia, Egypt, was subjected to a quasi-experimental research design (control group and study). Three tools were used, I: Structured Interviewing Questionnaires, II: and intradialytic hypotension Assessment, and III: International restless legs syndrome Severity Rating Scale. **Results** demonstrated that the incidence of intradialytic hypotension signs and symptoms after the second and fourth weeks of intervention differed significantly between patients in study and control groups, with a statistically significant P-value of 0.003. Also, that there were high statistically significant differences between patients of both groups regarding total level of restless legs syndrome post-intervention (2^{nd} and 4^{th} week), with a statistically significant P-value of <0.001** **Conclusion:** Application of cool dialysate controlled intradialytic hypotension and restless legs syndrome among study hemodialysis patient compared to control group. **Recommendations:** Similar studies should be replicated on a large sample size in different geographic areas in Egypt to generalize the findings.

Keywords: Cool dialysate, Intradialytic hypotension & Restless legs syndrome

Introduction
Hemodialysis is the most widely used form of renal replacement treatment (RRT) in Egypt and around the world. Hemodialysis is administered to approximately 2 million patients globally. Patients with end-stage kidney disease may benefit from this possibly life-saving medication. Despite a number of scientific and technological developments in the sector, there are still a lot of problems that might occur during and after HD **(Kalaveh et al, 2018).**
Negative side effects are common in HD patients; these include: blockage in vascular access site (entrance point), muscle cramps hypotension (low blood pressure) weakness, dizziness, or nausea and blood loss, which can be linked to the type of treatment they are receiving or to end-stage renal disease **(National Kidney Foundation, 2024).**
According to the European Best Practice Guidelines, IDH can be defined as a 10-mmHg drop in mean arterial pressure or a 20 mmHg drop in systolic blood pressure (SBP) during dialysis. Commonly occurring symptoms such as nausea, vomiting, abdominal pain, cramping in the muscles, pruritis, exhaustion, and lightheadedness also follow, necessitating the intervention of nurses **(Georgianos & Agarwal, 2019)**.
Moreover one of the side effects of HD is associated with neuromuscular problems, is a RLS that is typified by a strong need to move the legs while at rest as well as uncomfortable leg sensations like burning, throbbing, or creeping **(Kallenbach, 2022).** The International RLS Study Group has established specific criteria for the diagnosis of RLS. These criteria include the persistent need to move one's legs, symptom onset or worsening while at rest or immobile, symptom onset or worsening during the evening and night, and the ability to move momentarily to alleviate annoying symptoms **(Amrollahi, 2022).**
A straightforward, non-pharmacological way to avoid HD adverse effects is to lower the temperature of the dialysate. Dialysate that is 0.5 °C below body temperature is used in cold dialysis. IDH can be prevented using dialysate cooling (IDH). By producing vasoconstriction and stimulating the sympathetic nervous system, hemodynamic stability is maintained **(Salib et al, 2021).**
Cool dialysis lessens the damage that HD causes to the brain by sheltering the cerebral vascular beds from damaging perfusion. Long-term cold dialysis enhanced the heart's resting ejection fraction, decreased end-diastolic volumes and left ventricular

mass, and maintained aortic distensibility, all of which decreased the risk of subsequent cardiovascular events **(Elemshaty et al, 2023)**.

Hemodialysis nurses spend a great deal of time managing and treating complications that arise from dialysis. In certain situations, these complications can cause significant disruptions to the process, even resulting in an early termination of dialysis. They can also result in decreased waste clearance and removal, which ultimately lowers the effectiveness of dialysis. Thus, one of the key duties of dialysis staff, particularly nurses, is to prevent these problems **(Ahmadi et al , 2021).**

Significance of the study

Numerous problems, including IDH and RLS, are linked to HD. Globally; the incidence rate of IDH is thought to be between 20% and 30%, although an Egyptian study **Narouz & El-Sayed (2019)** indicated that it was 90%. In addition, it has been predicted that 20% to 80% of hemodialysis patients had RLS **(Amrollahi et al, 2022)**. In the most recent year (2023), 190 patients were admitted to the HD unit at Benha University Hospital **(Statistics office in Benha university hospital, 2023).**

Hemodialysis side effects, such as RLS and hypotension, increase the risk of vascular access thrombosis and the corresponding cardiovascular morbidity and death rates, they also reduce the effectiveness of HD therapy. Therefore, preventing them is a crucial component that supports patients' hemodynamic stability during HD. This study was performed to assess the effect of cool dialysate on the decrease of hypotension and RLS in HD patients.

Aim of study

The purpose of this research was to: - Evaluate the effect of application of cool dialysate on controlling hypotension and restless leg syndrome among patients undergoing hemodialysis

Research hypotheses:

Hypothesis (1): The mean score of IDH among dialysis patient could be decreased than their control after cool dialysate application.

Hypothesis (2): The mean score of RLS scale among dialysis patient could be decreased than their control after cool dialysate application.

Materials and Methods:

Research design:

In order to achieve the purpose of the study, a quasi-experimental research design that included a study and a control group was employed. The aim of a quasi-experimental design is to show that an independent and dependent variable are causally related. A real experiment, however, is dependent on random assignment, but a quasi-experiment is not. **(Reichardt, 2019)**.

Study setting

This research was conducted in the Benha University Hospital's HD department in Qalyoubia, Egypt. The HD department is located in the medical building's second floor, is comprised of two massive halls, each of which is equipped with a dialysis machine and 18 beds. These halls are utilized by patients with chronic renal failure from throughout the governorate of Qalyoubia. It provides patients with medical care at cost-free.

Subjects:

Type: Purposive sample of 88 patient undergoing hemodialysis. The study sample was randomly assigned alternatively into two equal groups 44 patient for each (study and control).

Size: Using the census data of admissions to the dialysis department from the Benha University Hospital Census, 2023, the sample size was determined using the following formula: The formula for Stephen Thompson **(Fearon et al., 2017).**

$$n = \frac{N \times p\,(1-p)}{\left((N-1 \times (d^2 \div z^2)) + p\,(1-p)\right)} =$$

N= Population size is 190

D= the neutral property that the ratio offers is equal to 0.12.

d= the rate of error is 0.05.

z= Class standard answering with a significance level of 1.96

The Total sample size was 88 based on the following criteria:

Inclusion criteria: The study will involve both genders, with a range of 21 to 60 years, who can collaborate and communicate. In addition to having chronic renal failure, the patient must have experienced RLS and hypotension during HD during the last two months and not be on any medications or treatments that might increase these symptoms. The patient must be receiving four hours of HD three times a week.

Exclusion criteria were alterations in the frequency and hours of HD, fever, diabetic neuropathy, chronic infections, severe anemia, psychiatric patients, chronic hypotension, and a patient with a history of paralysis and physical disability (**Aliabadi et al, 2020)**.

Tool for data collection: The following tools were utilized to collect information:

Tool I: Structured Interviewing Questionnaires:

After reviewing relevant literature, the researchers created this tool. **(Halle et al, 2020; Aliabadi et al, 2020 ; Ahmadi et al, 2017& Kashani et al, 2019).**

It consisted of two primary components. Five questions covering demographic information, such as age, sex, education level, occupation, and place of residence, formed **the first part.**

The second part of the survey included nine inquiries on information regarding health. The main causes of HD, the existence of other chronic conditions, the last time antihypertensive medication was used prior to the HD session, smoking status, the length of time that RLS symptoms started during dialysis, and the history of taking medication to decrease RLS symptoms were all involved in these questions.

Tool II: IDH assessment:

This instrument was modified from **Elpasiony et al, (2022)** to assess how cooling the dialysate affects the reduction of IDH. The researchers filled out the instrument, which consisted of two primary components:

The first part consisted of a chart that was used to record the patients' blood pressure prior to the HD session, as well as charts that were utilized in the second week (6 sessions) and the fourth week (12 sessions) to identify and document IDH events.

The second part was used to evaluate IDH symptoms that indicated the onset of IDH, such as headache, chest discomfort, cramping, shortness of breath, dizziness, vomiting, nausea, sweating, gastrointestinal distress, chest pain and abdominal pain.

Tool II:(IRLSSRS):

The International RLS Intervention Group developed this scale **(Walters et al, 2003)** which was translated and adapted to the Arabic language to evaluate the severity of the patient's RLS symptoms. Ten questions formed it, and each one was scored from 0 (none) to 4 (extremely severe). Prior to the HD session, as well as during the second week (6 sessions) and the fourth week (12 sessions), the patient was asked to rate their restless legs. The rating criteria included the following: the degree of sleep disturbance, fatigue or drowsiness from RLS symptoms, the severity of RLS overall, the frequency of RLS symptoms, the severity of RLS symptoms on an average day, the degree to which RLS symptoms interfere with work performance, mood disturbance, leg and arm RLS discomfort, the need to move around due to RLS symptoms, and the relief from RLS symptoms from moving around.

The total scores

The range of the total scores was 0 – 40. According to statistics, this score was converted to the severity of RLs as follows:

- None RLS was indicated by 0.
- Mild RLS was indicated by 1–10.
- Moderate RLS was indicated by 11–20.
- Severe RLS was indicated by 21–30.
- RLS was extremely severe in 31–40.

Pilot study

Pilot study conducted on 88 patients, or 10% of the study sample, to assess the viability and clarity of the instruments utilized as well as the estimation of the time needed to finish them. No changes were made to the questionnaire. As a result, the pilot research sample was added to the full study sample.

Ethical considerations

Administrative design and ethical consideration: Benha University's department of nursing's scientific research and ethics committee (code: REC- MSN-P25) approval for this study's administration. The process was then legally approved by the dean of the nursing faculty and the director of the HD departments at Benha University Hospital.

The study considered all ethical considerations. Every patient was made aware of the goals and purpose of the study, as well as their right to withdraw at any moment. Patients who participated in the study provided further verbal consent. Researchers maintained subject confidentiality and anonymity. The patients who participated in the investigation were additionally required to provide oral consent.

Content validity and reliability:

The validity of the instruments was evaluated by a team of five experts from Benha University's Faculty of Nursing's medical-surgical nursing department. The modification was made according to the panel's assessment of the sentences' content, completeness, appropriateness, and clarity.. The panel's assessment of the data, completeness, appropriateness, and clarity of the sentences was followed in making the change. The Cronbach alpha test was used to evaluate the suggested tool's reliability. The Cronbach alpha test was used to evaluate the suggested tool's reliability (0.837, 0.689 & 0.748) for IDH assessment, signs and symptoms of IDH and restlessness leg syndrome scale respectively.

Fieldwork:

The four-month data collection process ran from early March 2023 to the end of July 2024. Purposive sampling was used to enroll patients who matched the inclusion criteria, and they were split equally between the study and control groups.

The study was conducted in four stages: planning, execution, assessment, and evaluation.

Assessment Phase:

The researchers utilized previous tools to acquire data from the HD department on three separate days per week (morning and afternoon) from 9:00 a.m. to 3:00 p.m. Each patient (control and study group) was interviewed individually to obtain their medical history and demographic information. The

researchers then collect demographic information from the patient. Using **Tool I,** each interview lasted approximately 5 to 10 minutes.

Planning phase:

At the beginning of the pre-intervention phase of the study, the intervention and control groups received HD using the conventional technique (dialysis with a dialysate temperature of 37°C) three times a week for four hours each, for a total of 12 sessions.

Implementation phase:

Dialysis machine setup, calibrate the dialysis machine to the desired parameters, including the reduced temperature for the dialysate (typically 35.5°C- compared to the stander 37°C). Over the course of one month, patients in the intervention group were treated with HD with cold dialysate (35.5°C) for four hours on three separate days. while stander dialysis (dialysis with a dialysate temperature of 37°C) which administered to patients in the control group during the same period.

During the HD sessions, the researchers employed tool II to compare the outcomes before and after the intervention and estimate the prevalence of IDH. The patient's systolic and diastolic blood pressures were recorded using a digital cuff sphygmomanometer prior to the dialysis procedure, as well as during the first, second, third, and fourth hours of the dialysis in the supine position. Additionally, the blood pressure of patients who reported experiencing at least one of the symptoms of hypotension (including nausea, vomiting, fatigue, dizziness, or muscle cramps) was evaluated and documented at that time.

Additionally, to assess the prevalence of RLS status at the beginning, before the application of cold dialysate, and at the second week (6 sessions) and fourth week (12 sessions) after the application of cool dialysate, the investigators used tool III during the HD sessions.

Evaluation phase:

- Patients in the control group were assessed three times at the same times as those in the trial group using tools II and III.
- Tools II and III were employed to evaluate study group patients on three separate occasions: prior to the application of cold dialysate, during the second week (6 sessions), and during the fourth week (12 sessions) following the application of cool dialysate. To determine the efficacy of the cool dialysate on IDH and RLS in HD patients, comparisons were conducted between two groups.

Statistical analysis

Software called SPSS (version 25) was used to analyze the data. The Kolmogorov-Smirnov test was used to examine whether the quantitative data had a normal distribution. The nominal variables in the two groups were compared using chi-square testing. Fisher's exact test was used in place of the chi-square test for smaller sample sizes where the frequency count was less than 5 for more than 20% of the cells. Fisher's exact test was used instead of the chi-square test for smaller sample sizes where the frequency count was less than 5 for more than 20% of the cells. The two categories' mean scores were compared using independent t-tests. The correlation between numerical variables was assessed using the Pearson method. Significant was defined as a p-value of less than 0.05, and extremely significant as a p-value of less than 0.001. Significant was defined as a p-value of less than 0.05, and extremely significant as a p-value of less than 0.001.

Result

Table (1): Distribution of both studied groups according to their personal data Study group (n= 44), and control group (n=44).

Personal data	Study group No=44		Control group No=44		X2	p-value
	(No.)	%	(No.)	%		
Age						
-<30	5	11.4	7	15.9		
-30- < 50	9	20.5	16	36.4	3.882	0.144 n.s
-50- 60	30	68.2	21	47.7		
Mean ± S	49.56 ± 0.69		49.31 ± 0.73		t-test= (1.633) p value = (0.106 n.s)	
Gender						
-Male	9	20.5	14	31.8	1.472	FEp 0.332 n.s
-Female	35	79.5	30	68.2		
Social status						
- Married	35	79.5	28	63.6	2.738	FEp 0.155 n.s
-Not married	9	20.5	16	36.4		
Residence						
-Rural	36	81.8	29	65.9	2.884	FEp 0.145 n.s
-Urban	8	18.2	15	34.1		
Education level						
-Can't read and write	5	11.4	2	4.5		
-Read and write	11	25.0	6	13.6	7.010	0.135 n.s
- Primary education	13	29.5	10	22.7		
-Secondary education	12	27.3	17	38.6		
-University education	3	6.8	9	20.5		
Occupation						
-Not working	13	29.5	7	15.9	2.369	0.306 n.s
-Working	15	34.1	17	38.6		
-Retired	16	36.4	20	45.5		

(n.s) Not Significant (P>0.05) *FEp: p value for Fisher exact for chi square*

Table (2): Distribution of both studied groups according to their medical history study group (n= 44), and control group (n=44).

Health related data	Study group (n=44)		Control group (n=44)		X2	p-value
	(No)	%	(No)	%		
Presence of comorbidities						
- DM	23	52.3	16	36.3		
- HTN	14	31.8	18	40.9	3.042	0.385 n.s
-Heart disease	5	11.4	5	11.4		
- liver disease	2	4.5	5	11.4		
The main cause for hemodialysis						
-Hypertension	6	13.6	12	27.3	3.467	0.177 n.s
-Renal failure	34	77.3	26	59.1		
-Systemic lupus	4	9.1	6	13.6		
Smoking						
-Yes	5	11.4	10	22.7	2.009	0.156 n.s
-No	39	88.6	34	77.3		
Time since complaint with restless leg syndrome						
- 1 - < 6 months.	6	13.6	2	4.5	5.467	0.056 n.s
- 6- <12 months	6	13.6	14	31.8		
- 1 year and more	32	72.8	28	63.7		
Using medication for restless leg syndrome						
-Yes	9	20.5	11	25.0	0.259	0.611 n.s
-No	35	79.5	33	75.0		

Health related data	Study group (n=44)		Control group (n=44)		X2	p-value
	(No)	%	(No)	%		
If yes, the type of medication	(n=9)		(n=11)			
-Oral tablets	5	55.5	4	36.4	0.988	0.610 n.s
-Injection	4	44.5	7	63.6		
The last time taking hypertension medication						
- At night	30	68.4	26	59.1		
- 2 hours before hemodialysis session	7	15.9	8	18.2	5.238	0.155 n.s
- Directly before hemodialysis session	2	4.5	8	18.2		
- Didn't receive any medication	5	11.4	2	4.5		
Type of venous access for hemodialysis						
-Central venous catheter	4	9.1	7	15.9	0.935	0.334 n.s
-Fistula	40	90.9	37	84.1		
Type of dietary regimen						
- Low salt	25	56.8	16	36.4		
- Low fluid volume	8	18.2	18	40.8	7.014	0.071 n.s
- High salt	3	6.8	5	11.4		
- High fluid volume	8	18.2	5	11.4		

(n.s) Not Significant (P>0.05)

Table (3):Comparison of both studied groups according to their intradialytic blood pressure {pre, after 2nd week, and 4th week} of hemodialysis session Study group (n= 44), and control group (n=44).

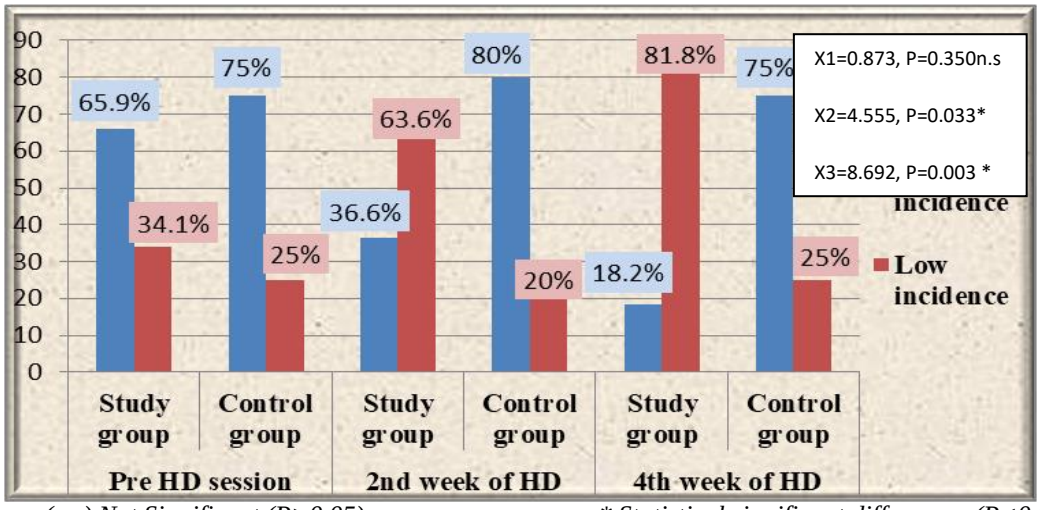
Intradialytic blood pressure		Study phases: (pre- intervention) Pre-hemodialysis session		(post intervention): 2nd week of hemodialysis (post 6 sessions)		4th week of hemodialysis (post 12 sessions)		t test P value (1)	t test P value (2)	t test P value (3)
		Study group	Control group	Study group	Control group	Study group	Control group			
First hour	Systolic pressure	120.86± 0.34	120.79±0.40	120.59±0.94	100.20± 0.40	120.20±0.40	100.56±0.50	0.844 0.401$^{n.s}$	-6.327 <0.001**	-13.998 <0.001**
	Diastolic pressure	80.86 ± 0.34	80.79 ± 0.40	80.63 ± 0.48	70.20 ± 0.42	80.22 ± 0.42	70.56 ± 0.50	0.844 0.401$^{n.s}$	-6.074 <0.001**	-13.552 <0.001**
Second hour	Systolic pressure	120.93 ±0.25	120.88±0.32	120.40 ±0.65	100.20± 0.40	120.38 ±0.49	100.56±0.50	0.735 0.464$^{n.s}$	-6.931 <0.001**	-13.552 <0.001**
	Diastolic pressure	80.93 ± 0.25	80.88 ± 0.32	80.36 ± 0.61	70.22 ± 0.42	80.20 ± 0.40	60.00 ± 0.00	0.735 0.464$^{n.s}$	-7.683 <0.001**	-11.157 <0.001**
Third hour	Systolic pressure	110.86± 0.34	100.93±0.25	120.20 ± 0.40	90.00 ± 0.00	120.20 ±0.40	90.00 ± 0.00	1.050 0.297$^{n.s}$	-29.188 <0.001**	-29.188 <0.001**
	Diastolic pressure	70.86 ± 0.34	70.93 ± 0.25	80.20 ± 0.40	60.00 ± 0.00	80.20 ± 0.40	60.00 ± 0.00	1.050 0.297$^{n.s}$	-29.188 <0.001**	-29.188 <0.001**
Fourth hour	Systolic pressure	120.75 ±0.43	120.72±0.45	120.34 ± 0.47	90.00 ± 0.00	120.06 ±0.25	90.00 ± 0.00	1.774 0.080$^{n.s}$	-22.952 <0.001**	-50.257 <0.001**
	Diastolic pressure	70.93 ± 0.25	60.00 ± 0.00	80.34 ± 0.47	60.00 ± 0.00	80.06 ± 0.25	60.00 ± 0.00	1.774 0.080$^{n.s}$	-22.952 <0.001**	-50.257 <0.001**

** Statistical significant differences (P<0.05)*
*** Highly statistical significant differences (P<0.001).*
P^1. difference in intradialytic blood pressure between both groups pre sessions
P^2. difference in intradialytic blood pressure between both groups post 2nd week of sessions
P^3. difference in intradialytic blood pressure between both groups post 4th eek of sessions

Table (4): Comparison of both studied groups according to their incidence of signs and symptoms of intradialytic hypotension, {pre, after 2nd week, and 4th week} of hemodialysis session, Study group (n= 44), and control group (n=44).

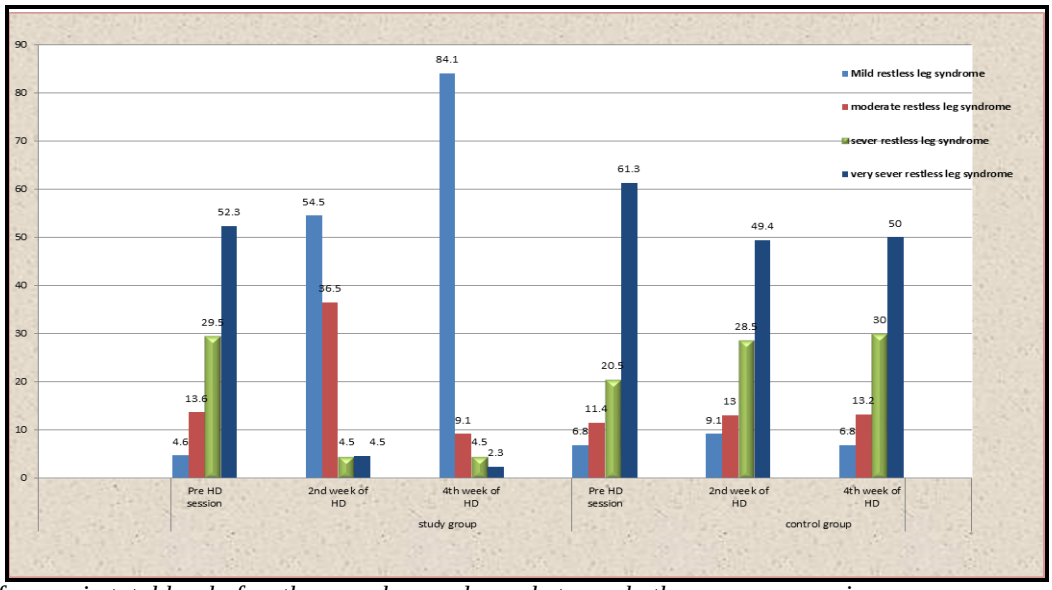
Signs and symptoms of intradialytic hypotension	Study group (n=44)			Control group (n=44)			X2 p-value (1)	X2 p-value (2)	X2 p-value (3)
	Pre-hemodialysis with cool dialysate	4th week of hemodialysis with cool dialysate	2nd week of hemodialysis with cool dialysate	Pre-hemodialysis with a dialysate temperature of 37°C	4th week of hemodialysis with a dialysate temperature of 37°C	2nd week of hemodialysis with a dialysate temperature of 37°C			
	No (%)	No (%)	No (%)	No (%)	No (%)	No (%)			
Fatigue	42(95.5)	18(40.9)	3(6.8)	44(100.0)	32(72.7)	27(61.4)	2.047 0.153 n.s	9.078 0.003*	29.131 <0.001**
Cramps	44(100.0)	14(31.8)	18(40.9)	44(100.0)	44(100.0)	39(88.6)	0.715 0.398 n.s	16.649 <0.001**	21.963 <0.001**
Sweating	36(81.8)	6(13.6)	3(6.8)	29(65.9)	20(45.5)	18(40.9)	2.884 0.089 n.s	10.700 <0.001**	14.072 <0.001**
Dizziness	38(86.4)	18(40.9)	15(34.1)	32(72.7)	30(68.2)	25(56.8)	2.514 0.113 n.s	6.600 0.010*	4.583 0.032*
Nausea	38(86.4)	13(29.5)	9(20.5)	43(77.3)	32(72.7)	30(68.2)	1.222 0.269 n.s	16.418 <0.001**	20.308 <0.001**
Vomiting	32(72.7)	10(22.7)	5(11.4)	27(61.4)	34(77.3)	15(34.1)	1.286 0.257 n.s	26.182 <0.001**	6.471 0.011*
Shortness of breath	15(34.1)	1(2.3)	0(0.0)	8(18.2)	6(13.6)	5(11.4)	2.884 0.089 n.s	3.880 0.049*	5.301 0.021*
Headache	42(95.5)	14(31.8)	6(13.6)	38(86.4)	28(63.6)	23(52.3)	2.200 0.138 n.s	8.928 0.003*	14.864 <0.001**
Abdominal discomfort	25(56.8)	5(11.4)	0(0.0)	20(45.5)	13(29.5)	10(22.7)	1.137 0.286 n.s	4.470 0.034*	11.282 0.001**

(n.s) Not Significant (P>0.05) **Statistical significant differences (P<0.05)*
*** Highly statistical significant differences (P<0.001).*
P[1]. difference in Signs and symptoms of intradialytic hypotension between both groups pre sessions



(n.s) Not Significant (P>0.05) ** Statistical significant differences (P<0.05)*
P[1]. difference in incidence of signs and symptoms of intradialytic hypotension between both groups pre sessions
P[2]. difference in incidence of signs and symptoms of intradialytic hypotension between both groups post 2nd week of sessions
P[3]. difference in incidence of signs and symptoms of intradialytic hypotension between both

Figure (1): Comparison of incidence of signs and symptoms of intradialytic hypotension between the studied groups throughout different study periods {pre, after 2nd week, 4th week} of hemodialysis sessions. Study group (n=44) & control group (n=44)



P^1. difference in total level of restlessness leg syndrome between both groups pre sessions
P^2. difference in total level of restlessness leg syndrome between both groups post 2^{nd} week of sessions
P^3. difference in total level of restlessness leg syndrome between both groups post 4^{th} week of sessions

Figure (2): Comparison of total level of restless leg syndrome between the studied groups throughout different study periods {pre, after 2nd week, 4th week} of hemodialysis sessions. Study group (n=44) & control group (n=44)

Table (5): Comparison of restless legs syndrome between both studied groups throughout different study periods {pre, after 2^{nd} week, 4^{th} week} of hemodialysis sessions study group (n= 44), and control group (n=44).

Study phases / Restless legs syndrome	Intervention group (n=44)			Control group(n=44)			t-test P value (1)	t-test P value (2)	t-test P value (3)
	Pre-HD session	2nd week of HD (6 sessions)	4th week of HD (12 sessions)	Pre-HD session	2nd week of HD (6 sessions)	4th week of HD (12 sessions)			
	X ±SD	X ±SD	X ±SD	X ±SD	X ±SD	X ±SD			
Rate of the RLS discomfort in legs or arms	3.68±0.47	1.00±0.80	0.59±0.49	3.61±0.57	3.97±0.15	3.95±0.30	0.606 0.546 n.s	-24.05 <0.001**	-38.362 <0.001**
Rate of the need to move around because of RLS symptoms	3.45±0.90	1.04±0.83	0.45±0.58	3.40±0.89	3.45±0.90	3.36±1.03	0.237 0.813 n.s	-13.016 <0.001**	-16.189 <0.001**
Relief of RLS arm or leg discomfort from moving around	1.11±0.81	0.36±0.48	0.04±0.30	0.93±0.25	0.88±0.81	1.00±0.91	0.1.415 0.161 n.s	-3.659 <0.001**	-6.572 <0.001**
Sleep disturbance from RLS symptoms	3.63±0.65	0.72±0.97	0.54±0.50	3.68±0.73	1.95±0.30	2.02±0.15	-0.306 0.760 n.s	-7.990 <0.001**	-18.638 <0.001**
Tiredness or Sleepiness from RLS symptoms	3.00±0.00	0.31±0.47	0.40±0.49	3.06±0.72	2..97±0.15	3.02±0.15	-0.621 0.538 n.s	-35.656 <0.001**	-33.360 <0.001**
Severity of RLS as a whole	3.93±0.25	0.36±0.48	0.50±0.59	4.00±0.00	3.97±0.15	3.97±0.15	-1.774 0.080 n.s	-47.053 <0.001**	-37.840 <0.001**
Frequency of getting RLS symptoms	3.90±0.29	1.04±0.83	0.86±0.97	3.86±0.34	3.90±0.29	3.88±0.32	0.666 0.507 n.s	-21.506 <0.001**	-19.468 <0.001**
Severity of RLS symptoms on an average day	3.45±0.50	0.63±0.94	0.63±0.48	3.54±0.50	3.00±0.00	3.00±0.00	-0.847 0.400 n.s	-16.638 <0.001**	-32.220 <0.001**

Study phases / Restless legs syndrome	Intervention group (n=44)			Control group(n=44)			t-test P value (1)	t-test P value (2)	t-test P value (3)
	Pre-HD session	2nd week of HD (6 sessions)	4th week of HD (12 sessions)	Pre-HD session	2nd week of HD (6 sessions)	4th week of HD (12 sessions)			
	X ±SD	X ±SD	X ±SD	X ±SD	X ±SD	X ±SD			
Severity of impact of RLS symptoms on ability to carry out daily affairs	3.52±0.50	0.68±0.47	0.95±0.21	3.61±0.49	3.00±0.00	3.00±0.00	-0.855 0.395 n.s	-32.637 <0.001**	-64.393 <0.001**
Severity of mood disturbance due to RLS symptoms	3.36±0.48	1.04±0.83	0.54±0.50	3.43±0.50	3.02±0.15	3.00±0.00	-0.648 0.519 n.s	-15.475 <0.001**	-32.325 <0.001**

*HD) Hemodialysis (n.s) Not Significant (P>0.05) ** Highly statistical significant differences (P<0.001).*
P^1. difference in restlessness leg syndrome between both groups pre sessions
P^2. difference in restlessness leg syndrome between both groups post 2nd week of sessions
P^3. difference in restlessness leg syndrome between both groups post 4th week of sessions

Table (6): Correlation between the studied groups intradialytic blood pressure, signs and symptoms of intradialytic hypotension and restless leg syndrome at 4th week of hemodialysis session, Study group (n= 44), and control group (n=44).

Variables	Studied groups	Restless leg syndrome	
		R	P value
Intradialytic systolic blood pressure during fourth hour	Intervention group	**-0.311**	**0.040***
	Control group	**-0.545**	**<0.001****
Intradialytic diastolic blood pressure during fourth hour	Intervention group	**-0.311**	**0.040***
	Control group	**-0.545**	**<0.001****
Incidence of Signs and symptoms of intradialytic hypotension	Study group	**0.515**	**<0.001****
	Control group	**0.592**	**<0.001****

(*) Statistically significant at ≤0.05 (**) Highly statistically significant at

Table (1): Demonstrated that: with ages ranging from 50 to 60 years, the study group's 68.2% of patients and the control group's 47.7% had respective means of 49.56 ± 0.69 and 49.31 ± 0.73 years. Also, 79.5% of the study group and 68.2% of the control group were females. Additionally, the percentage of married patients in both groups was 79.5% and 63.6%, respectively. Moreover, 81.8% of the study group and 65.9% of the control group lived in rural areas. Additionally, 29.5% of the study group had attained primary education, whereas, 38.6% of control group had secondary education. Also, 36.4% and 45.5% of both groups were retired. Importantly, there were statistically insignificant differences between patients of both groups regarding their personal data.

Table (2): Illustrates that, 52.3% of patients in the study group suffered from diabetes mellitus whereas, and 40.9% of patients in control group suffered from hypertension. Additionally, 77.3% and 59.1% of both groups stated that, renal failure was the main cause for HD. Furthermore, 88.6% and 77.3% of both groups were non-smokers. Moreover, 72.8% and 63.7% of both groups complained from RLS for 1 year and more. While, only 20.5% and 25.0% of both groups use medications for RLS and 44.5% & 63.6% of them take injection as treatment of restless leg syndrome. Also, 68.4% & 59.1% of both groups took hypertension medication last time at night. Moreover, 90.9% and 84.1% had fistula as venous access for HD. In addition, 56.8 % of patients in the Study group follow low salt dietary regimen whereas, 40.8% of the control group follow Low fluid volume dietary regimen. Additionally, it was observed that the medical histories of the patients in the two groups did not differ statistically. Additionally, it was observed that the medical histories of the patients in the two groups did not differ statistically.

Table (3): Reveals that, there were statistically insignificant differences between mean score of intradialytic blood pressure of both groups pre-intervention in the first, second, third, and fourth hours of observation. In contrast, a statistically

significant P-value of less than 0.001** was found for the mean intradialytic blood pressure score of the two groups in the first, second, third, and fourth hours of observation following the intervention (2nd and 4th week).

Table (4): Demonstrated that, there were statistically insignificant differences between mean score of incidence of signs and symptoms of intradialytic hypotension of both groups pre-intervention. Whereas, there was a highly statistically significant difference between mean score of incidence of signs and symptoms of IDH of both groups post-intervention in the 2nd week for signs of cramps, sweating, nausea and vomiting. Additionally, a statistically significant P-value of <0.001** was found for the mean score of incidence of signs and symptoms of IDH in the fourth week after the intervention for both groups, including fatigue, cramps, sweating, nausea, and headache.

Figure (1): Displays that, prior to intervention, The prevalence of IDH signs and symptoms was high in 65.9% of study group patients and 75% of control group patients.. However, in the 2nd week post intervention, these percentages changed to low incidence represented by 63.6% for the study group and 80% high incidence for the control group. In addition, , these percentages changed in the 4th week of intervention to low incidence represented by 81.8% for the study group and 75% high incidence for the control group, indicating a significant improvement in lowering incidence of signs and symptoms of IDH in the study group post intervention.

It was also noted that there were statistically insignificant differences between patients of both groups regarding incidence of signs and symptoms of IDH pre intervention. However, a statistically significant P-value of 0.003* indicated that the occurrence of signs and symptoms of IDH after the second and fourth weeks of intervention differed significantly between patients in the two groups.

Figure (2): Displays that, restless leg syndrome in the study group was 52.3% very severe and 4.6% mild severity pre intervention which changed to be 4.5% very severe & 54.5 % mild severity in the 2nd week post intervention and 2.3% very severe & 84.1%mild severity in the 4th week post intervention. But, the control group had 61.3% very severe and 6.8% mild severity pre intervention which changed to be 49.4% very severe & 9.1 % mild severity in the 2nd week post intervention and 50% very severe & 6.8% mild severity in the 4th week post intervention. Additionally, it was demonstrated that there was no statistically significant difference in the two groups' patients' pre-intervention total RLS levels. However, with a statistically significant P-value of less than 0.001**, there was a significant difference between the two groups' patients' overall levels of RLS after the second and fourth weeks of the intervention.

Table (5): Reveals that, the mean score of the incidence of RLS in the two groups before to the intervention did not differ statistically significantly. However, a statistically significant P-value of less than 0.001** was found for the mean score of occurrence of RLS in the second and fourth weeks after the intervention, indicating a highly significant difference between the two groups.

According to table (6): It is evident that, among patients in both groups, there was a highly statistically significant negative connection between RLS and intradialytic systolic and diastolic blood pressure. As when blood pressure decreases, the possibility of RLS increases. The p-value was <0.001**. Whereas, among patients in both groups. RLS and the incidence of IDH symptoms were positively correlated in a highly statistically significant way. Below 0.001** was the p-value.

Discussion

Stress-strain may be experienced by HD patients during dialysis. Complications include bleeding, seizures, air embolism, and responses to the HD membrane, RLS dialysis disequilibrium syndrome, cardiac arrhythmias, and intradialytic hypotension. The primary treatment for end-stage renal disease (ESRD) is long-term HD. **Singh, et al., (2023).**

Personal data of the studied patients: According to this study about more half of the studied patients were found in be in the 50-60 age range, with mean age of 49.56 ± 0.69 years, more than three quarters of them were females, three quarters of them were married, more than one third of them were retired and more than three quarters of them lived in rural areas.

According to the researchers' view of point, this may be because as people age, their kidneys' structure and function deteriorate and change. Moreover, a person's glomerular filtration rate gradually decreases with age, dropping by 25% by the time they are 40, increasing their risk of renal impairment. In addition, married individual's high risk for renal failure due to factors often related to lifestyle such as increased risk of chronic diseases, health neglect and family responsibilities and economic and stress factors. Gender may also have that women higher risk for chronic kidney disease due to some factor as hormonal difference and urinary tract infection. Rural population may face higher exposure to certain environmental toxin, such as pesticides, herbicides, and contaminated water sources, which can damage the kidney over time.

This outcome was contested with **Ali et al., (2022),** who found that, a mean age of 45.51±13.29.and disagreed with **Fauzi & Triaswati., (2021)**, who showed that women made up more than half of the control group.

Also, the result in line with **Delshad & Aghajani., (2022)** who, found that three-quarters of the participants were married and in the same line with **Delshad & Aghajani., (2022)** whose results revealed with less than half were retired and were lived in rural areas. On the other hand this finding disagreement with **Fauzi & Triaswati., (2021)** whose results revealed with one quarter were employed.

The findings of this research indicated that the control and study groups demonstrated statistically insignificant differences in terms of clinical and demographic data. This indicated that the patients in both groups were homogeneously distributed and properly the results indicated that there was insignificant difference between the groups' demographic traits and disease-related data. Randomized, exhibiting identical characteristics. This finding were in aligned with **Kashani et al., (2019)** there was insignificant difference between the groups' demographic traits and disease-related data.

In relation to their medical background. This study's findings demonstrated that diabetes mellitus affected almost half of the participants in the study group. In contrast, hypertension affected over one-fifth of the control group. This could be because they were between the ages of 50 and 60, which is a frequent age range for chronic illnesses. This finding comes in agreement with **Long et al., (2024)** who found, about 25% of the participants in their study had hypertension, while nearly 33% had diabetes. However, this result was disagreed with **Ahmed et al., (2023)** who stated in their study, less than one fifth had diabetes, and one quarter had hypertension.

In addition, the present study found that, **renal failure was the main cause** for HD in more than three quarters of the study group and more than half of the control group. This result was disagreed with **Elpasiony, et al., (2022)** who found that, hypertension was the main cause for HD in nearly three quarters of patients.

Concerning smoking, the results of this study demonstrated that most of patients in the study group and more than half of the control group were nonsmokers. This result comes in aligned with **Hussaire, et al., (2024).** In their research, they found that more than half of the patients had never smoked, according to a study on the epidemiology of tobacco use among dialysis patients in France and a survey of nephrologists' involvement in tobacco cessation counseling.

Moreover, this result agreed with Joshi**, et al., (2024),** demonstrated that, less than one fifth of participants in the control group were current smokers while, more than one third of the study group were previous smokers and more than two thirds of the study group and more than three quarters of the control group were never smokers.

Concerning onset of RLS, Nearly three-quarters of the study group and roughly two-thirds of the control group reported having RLS for a year or more, according to the current study. This result was in the same line with **Kashani, et al., (2019),** stated that nearly half of tha intervention group and more than one third of that study group had complained from RLS for 1 year and more. Also, this result was agreed with **Aliabadi, etal., (2020)** stated that, nearly three quarters of the intervention 1 group had experienced RLS complaints for a year or longer.

Moreover, this study demonstrated that, nearly quarter of both groups use medications for RLS while less than half of the study group and nearly two thirds of the control group take injection as treatment of RLS. This result was disagreed with **Aliabadi, et al., (2020),** who stated that, more than half of both groups (intervention 1,2) took oral medication to relieve RLS symptoms.

In relation to last time taking hypertension medication, more than half of both groups took hypertension medication last time at night. This result was agreed with **Elpasiony, et al., (2022),** who reported that more than half of patients took hypertension medication last time at night post intervention.

Concerning type of venous access for hemodialysis, the most of patients in both groups had fistula. This may be due to it is most common and easy access. This result was aligned with **Karacan & Gungormus, (2024)** stated that the most of patients in the clinical and Roy groups had fistulas.

Concerning type of dietary regimen, this study found the more than half of the study group and more than one third in the control group follow low salt diet regimen. This is because high salt is prevented for HD patients as salt raises blood pressure and causes edema.This result comes in agreement with **Li, et al., (2023)** who reported that, about 75% of patients adhere to a low- salt diet.

As regard to intradialytic blood pressure assessment, the result of the current study clarifies that, there was a highly statistically significant difference between mean score of intradialytic blood pressure of both groups post-intervention (2nd and 4th week) in the first, second, third, and fourth hour

of observation, with a statistically significant P-value of <0.001**. **From the researcher's point of view** this result may be due to using cool dialysate reduce IDH in patients on HD. Therefore, using this method to improve IDH in HD patients is recommended

This result was consistent with a study conducted by **Moustafa, et al., (2022).** stated that statistically significant difference in the occurrence of IDH was observed between pre and post intervention during every hour of hemodialysis ($p < 0.01$).

In relation to mean score of incidence of signs and symptoms of IDH of both groups, the results of this study reported that there were a highly statistically significant difference between mean score of incidence of signs and symptoms of IDH of both groups post-intervention in the 2nd week and 4th week, with a statistically significant P-value of <0.001**. **According to the researcher's viewpoint** this result may be due to using cool dialysate reduce incidence of signs and symptoms of IDH in patients on HD. Therefore, using this method to reduce incidence of signs and symptoms IDH in HD patients is recommended.

This finding is supported with a study conducted by **Moustafa, et al., (2022)**.whose found that over 50% of patients had IDH symptoms prior to intervention, and that these symptoms differed statistically significantly from those following intervention ($p = 0.001$).

Also, the outcomes were similar also to results of a study conducted by **Ghazanfari et al., (2022)** stated that interventions and education-based programs were successful in lowering HD patients' levels of fatigue.

As regard to total mean score of incidence of restless legs syndrome of both groups post-intervention, with a statistically significant P-value of less than 0.001, the current study's findings showed a very significant difference between the mean score of incidence of RLS of the two groups post-intervention in the second and fourth weeks.

According to the study, this outcome could be because cool dialysate, a non-pharmacological treatment, lessens the intensity of RLS in HD patients. Consequently, it is advised to use this technique to enhance RLS in HD patients**.**

carried out by **Zirak (2020)** stated that both techniques decreased the severity of RLS and could be used as safe, non-pharmaceutical ways to manage the condition. Also, this finding is consistent with **Chen (2022)** , declared that cool dialysate produced the largest RLS severity score.

Finally, regarding correlation between intradialytic systolic& diastolic blood pressure and RLS among patients of both groups, the result of the current study revealed that there was a negative correlation between intradialytic systolic& diastolic blood pressure and RLS among patients of both groups. As when blood pressure decreases, the possibility of RLS increases. The p-value was <0.001**. However, among patients in both groups, there was a highly statistically significant positive connection between the occurrence of IDH signs and symptoms and RLS. The p-value was less than 0.001.

Conclusion

Application of cool dialysate reduced IDH and RLS among HD patient in the study group compared to control group.

Recommendations

- The dialysate may be routinely cooled as a therapeutic routine to manage HD patients suffering from RLS& to avoid IDH in HD units.
- Similar studies should be replicated on a large sample size in different geographic areas in Egypt to generalize the findings.

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