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Effect of Cooler Dialysate Temperature on Haemodynamic Stability in Hypotensive Patients on Maintenance Haemodialysis

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ABSTRACT

Objective: To assess the impact of lowering the dialysate temperature on the haemodynamic status of patients on maintenance haemodialysis.

Study Design: Randomised Controlled Trial (IRCT trial ID 81745).

Place and Duration of Study: Haemodialysis Unit, Pak Emirates Military Hospital, Rawalpindi, from September 2024 to January 2025.

Methodology: Patients from both genders between 18 and 60 years old who were on twice-weeklyhemodialysis and had hypotension were included. Patients with thyroid disease, anaemia, and taking anti-hypertensive medications were excluded. The participants were randomized into two groups using an online randomization tool. The cooler dialysate group underwent cooler dialysate hemodialysis sessions, while the thermoneutral group underwent thermoneutral dialysate (37ºC) hemodialysis sessions. During the hemodialysis session, intradialytic blood pressure and pulse rate changes were documented every hour and at the end of the session.

Results: In this interventional trial, seventy (n=70) patients with 35 individuals in each group were enrolled. The median age of the participants was 54.50(46.00 -60.25) years, with 36(51.43%) males and 34(48.57%) females. The dialysis vintage was 21.00 (16.00 – 39.25) months. No significant statistical difference was observed between the cooler dialysate and thermoneutral groups regarding baseline demographic and clinical features. The systolic blood pressure increased in the intervention group at 1-hour (p=0.112) till 4-hour (p<0.001). The pulse rate showed a significant change in the intervention group in the third hour of the hemodialysis sessions (p=0.048).

Conclusion: The cooler dialysate improved the hemodynamic stability in hypotensive hemodialysis-dependent patients by either maintaining or increasing blood pressure.

Keywords: Dialysis adequacy, End-stage renal disease, Hypotension, Renal replacement therapy.

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INTRODUCTION

Dialysis either peritoneal or haemodialysis (HD) is a lifesaving renal replacement therapy for end-stage renal disease patients especially in those who are not ableto undergo renal transplant.[1] Haemodialysis is done either via arteriovenous fistula or catheters inserted for venous access. It is a dynamic process involving rapid but sustained replacement of electrolytes and removal of toxins and excess fluid from the body in a relatively shorter duration.[2] This exposes the human body to an increased risk of haemodynamic instability, such as variation in blood pressure, pulse rate, pulse pressure and mean arterial pressure (MAP) during HD sessions. One of the few reasons that HD sessions are associated with an increased risk of mortality (80%) in the initial months of therapy.[3] However, this stability is associated with better quality of life and contributes to an increase in life expectancy.[4]

Despite recent advancements, few inherent complications of hemodialysis persist, which are either avoidable or, to some extent, controllable. Like hypotension and its associated complications, hemodynamic instability is among those intrinsic factors. Intradialytic hypotension (IDH) is one of the few factors which cause increased mortality, and at times, patients refuse to undergo hemodialysis therapy due to IDH-induced tachycardia and apprehension. To cater to IDH, the cool dialysate, compared to thermoneutral dialysate, was found to be associated with improved cardiac function and health.[5] On the contrary, a review on cold dialysate found no benefit with cold dialysate.[6] However, the underlying postulated mechanism for this might be cold-induced peripheral vasoconstriction which

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improves hemodynamic stability but at the cost of decreased toxin removal due to entrapment in constricted capillary/peripheral vascular beds.

Hemodynamic stability is essential for completing HD sessions, as it is one of the causes of early termination of HD sessions. However, the variability in the literature on this subject limits the use of cooler dialysate temperatures in maintaining stable hemodynamic status. This research was planned to see the impact of cooler dialysate temperature on the hemodynamic status of HD-dependent end-stage renal disease patients. This research will help to improve renal replacement therapies in hemodynamically unstable patients.

METHODOLOGY

This randomized controlled trial enrolled 70 patients at the Dialysis Unit, Pak Emirates Military Hospital Rawalpindi. The trial was started after approval of the institute's ethical review board (ERC#A/28/ERC/178/24) following the guidelines and moral principles of the Declaration of Helsinki. The trial was registered with IRCT trial ID 81745. The sample size of 35 individuals in each group was calculated by OpenEpi sample size calculator using a confidence intervalof 95%, Type-I errorof 0.05, Type-II errorof 0.10, 10% dropout, the difference in population means of hypotensive events 0.6; standard deviation for normal (37ºC) temperature dialysate 0.9 and standard deviation for cooler dialysate 0.6 given by Hussain *et al.*[7] It was hypothesized that the cooler dialysate temperature would affect hemodynamic stability. The randomization was done using an online tool (random.org), and sampling was done using randomization sequence. The informed written consent was obtained from participants after explaining the purpose and procedure of the study.

Inclusion Criteria: Patients from both genders between 18 to 60 years on twice weekly HD and having systolic blood pressure (SBP) below 90mmHg or diastolic blood pressure (DBP) below 60mmHg or both. Moreover, patients with SBP above 90mmHg or mean arterial pressure ≥ 65 on pharmacological support were included.

Exclusion Criteria: Patients having thyroid disease, anaemia, taking anti-hypertensive medications, recent heart attack, not willing to participate and pregnant females were excluded.

Allthe participants enrolled in the study were interviewed for basic demographic details and clinical information. They were randomized into two groups, cooler dialysate (CD) and thermoneutral (TN) group, using an online randomization tool (random.org). The Group-CD underwent cooler dialysate HD sessions, while the Group-TN underwent thermoneutral dialysate HD sessions. The dialysate was labelled as thermoneutral for standard 37ºC temperature while it was labelled as cooler dialysate at 35.5ºC temperature. The temperature was maintained by in-built thermoregulatory module of HD machines. The patient flow diagram has been shared as Figure. The temperature was monitored every hour during HD sessions. All participants underwent HD as per their group. The pre-dialysis blood pressure was noted along with the pulse rate, serum creatinine, haemoglobin, serum urea and dependence on cardiac inotropic support. HD was done for 4 hours with a 300 – 350 ml/min blood flow rate and a 500 ml/min dialysate flow rate using standard dialysate filters. During the HD session, intradialytic blood pressure and pulse rate changes were documented every hour and at the end of the session. The blood pressure (BP) and pulse rate was measured with the built-in measuring mechanism. Moreover, intradialytic symptoms like rigors and chills, cramps, dizziness, and other patient-reported symptoms were also noted. The primary variable was the change in systolic and diastolic blood pressure. It was measured at the start, every hour during dialysis and at the end of the hemodialysis session. The secondary variable was pulse rate, which was measured at the same intervals.

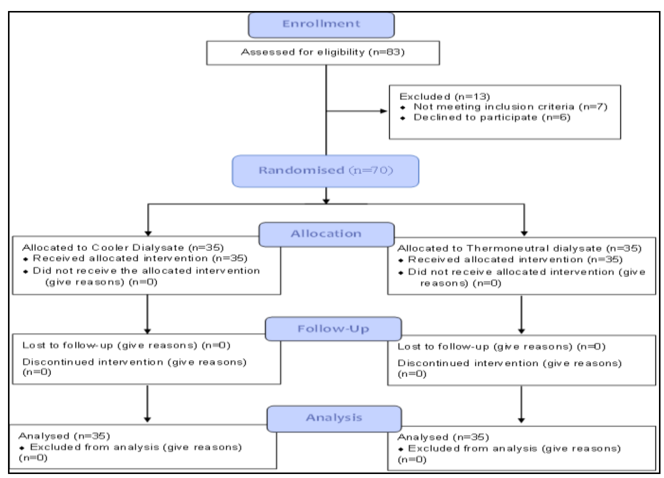

Figure: Patient Flow Diagram(n=83)

The mean, standard deviation or median was used for numerical variables while frequency and percentages for categorical variables were used. The

Chi-square test, independent sample t-test and Mann-Whitney U test were used to assess for statistical significance. The comparison was made between intra- and post-dialytic blood pressure and pulse rate changes. The *p*-value ≤0.05 was taken as significant. The Statistical Package for Social Sciences Ver. 25.0 was used for data entry and analysis.

RESULTS

In this interventional trial, seventy (n=70) patients with 35 individuals in each group were enrolled. The median age of the participants was 54.50 (46.00-60.25) years with 36(51.43%) males and 34(48.57%) females. The dialysis vintage was 21.00 (16.00 – 39.25) months. The median creatinine and haemoglobin levels were 457.35 (394.91 – 600.75) µmol/L and 11.67 (10.96 – 13.60)g/dl. Group-wise details are shared in Table-I. No significant difference was observed statistically between Group-CD and Group-TN about baseline demographic and clinical features.

Table-I: Clinical and Baseline features of Hypotensive Hemodialysis (n=70)

Values	Total Population (n=70)	Groups		*p*-Value
		Group-Cooler Dialysate (n=35)	Group-Thermoneutral Dialysate (n=35)	
Age, years	54.50 (46.00 - 60.25)	52.00 (45.00–57.00)	58.00 (46.00–62.00)	0.131
Gender				
Male Female	36(51.43%) 34(48.57%)	20(57.15%) 15(42.86%)	16(45.71%) 19(54.29%)	0.339
Diabetes Mellitus	19(27.14%)	11(31.43%)	8(22.86%)	0.420
Ischemic Heart Disease	14(20.00%)	7(20.00%)	7(20.00%)	1.000
Hypertension	24(34.29%)	15(42.86%)	9(25.71%)	0.131
Vascular Access				
AVF TDL DLC	40(57.14%) 23(32.86%) 7(10.00%)	22(62.86%) 10(28.57%) 3(8.57%)	18(51.41%) 13(37.14%) 4(11.43%)	0.627
Inotropic Support	22(31.43%)	12(34.29%)	10 (28.57%)	0.607
Dialysis Vintage, months	21.00 (16.00 – 39.25)	18.00 (16.00–38.00)	30.00 (14.00–43.00)	0.728
Haemoglobin, g/dL	11.67 (10.96 – 13.60)	11.60 (10.81-13.00)	12.08 (11.00–14.10)	0.215
Serum Urea,mmol/L	16.21 (12.70–20.04)	17.42 (12.90–20.17)	15.23 (12.32–19.73)	0.327
Serum Creatinine, µmol/L	457.35 (394.91–600.75)	439.90 (395.31–598.50)	478.60 (391.41–607.50)	0.765

AVF: Arteriovenous fistula; TDL: Tunnelled double lumen catheter; DLC: Double lumen catheter

The intra-dialytic SBP and DBP progressively increased over time in both groups with better and greater increments in the Group-CD (Table-II). The pre-SBP was 100.00 (95.00 – 106.00) mmHg and at the end of the 4-hour HD session, it was 126.00 (120.00 – 130.00) mmHg in the Group-CD. Similarly, in the Group-TN pre-SBP was 100.00 (96.00 – 110.00) mmHg and at the end of the 4-hour HD session, it was 110.00 (120.00 – 122.00)mmHg. The pre-DBP was 59.00 (56.00 – 61.00) mmHg and at the end of the 4-hour HD session, it was 64.00 (63.00–68.00)mmHg in the Group-CD compared to the Group-TNin which pre-DBP was 60.00 (56.00 – 63.00)mmHg and at the end of 4-hour HD session it was 65.00 (62.00 – 68.00)mmHg. The intra-dialytic BP increment was statistically significant in the Group-CD as compared to the Group-TN (Table-II). The pulse rate increased in Group-CD from 79.00 (73.00 – 88.00) bpm to 81.00 (76.00 – 84.00) bpm at the end of 4 hours HD session while it dropped from 80.00 (70.00 – 91.00) bpm to 72.00 (64.00 – 85.00) bpm in Group-TN. There was statistically insignificant difference at the end of 4-hour HD session (*p*=0.052) among the groups as shown in Table-II.

The leg cramps and shivering were reported by 2(5.71%) and 5(14.29%) patients in Group-CD while 2(5.71%) patients reported leg cramps and 1(2.86%) reported apprehension in Group-TN.

Table-II: Comparison of Pre-Intervention and Intra-Dialytic Haemodynamic Parameters Between Cooler and Thermoneutral Dialysate Groups (n=70)

Variables	Groups		*p*-value
	Group- Cooler Dialysate (n=35)	Group-Thermoneutral Dialysate (n=35)	
Pre-SBP, mmHg	100.00 (95.00 – 106.00)	100.00 (96.00 – 110.00)	0.471
SBP-1Hr, mmHg	105.00 (102.00 – 110.00)	104.00 (98.00–110.00)	0.112
SBP-2Hr, mmHg	114.46±9.24	109.77±11.17	0.060
SBP-3Hr, mmHg	120.00 (116.00–127.00)	116.00 (102.00–121.00)	0.008
SBP-4Hr, mmHg	126.00 (120.00–130.00)	110.00 (120.00–122.00)	<0.001
Pre-DBP, mmHg	59.00 (56.00–61.00)	60.00 (56.00–63.00)	0.460
DBP-1Hr, mmHg	62.00 (59.00–64.00)	59.00 (55.00–62.00)	0.003
DBP-2Hr, mmHg	64.00 (62.00–66.00)	64.00 (62.00–66.00)	0.925
DBP-3Hr, mmHg	66.00 (6300–68.00)	66.00 (63.00–69.00)	0.822
DBP-4Hr, mmHg	64.00 (63.00–68.00)	65.00 (62.00–68.00)	0.790
Pre-Pulse Rate, beats/min	79.00 (73.00–88.00)	80.00 (70.00–91.00)	0.837
Pulse Rate-1Hr, beats/min	76.69±8.32	76.63±10.23	0.980
Pulse Rate-2Hr, beats/min	76.00 (69.00–81.00)	75.00 (66.00–90.00)	0.441
Pulse Rate-3Hr, beats/min	78.97±7.56	74.63±10.26	0.048
Pulse Rate-4Hr, beats/min	81.00 (76.00–84.00)	72.00 (64.00–85.00)	0.052

SBP: Systolic blood pressure; DBP: Diastolic blood pressure; Hr: hour

DISCUSSION

The hemodialysis sessions are sometimes stopped for various reasons, among which hypotension or a significant drop in blood pressure is one factor. In this study, the effect of cooler dialysate (35.5ºC) on the haemodynamic stability in haemodialysis-dependent patients compared to the use of standard temperature (37ºC). This is the first study in our knowledge to see the effect of cooler dialysate in a hypotensive end-stage renal disease in Pakistani population. There was no statistically significant difference in the baseline characteristics of the two groups. Similarly, the pre-dialysis blood pressure was statistically the same in both groups (p=0.471 and 0.460). The systolic blood pressure gradually improved as the dialysis sessions progressed in both groups but the improvement in the Group-CD was better than the Group-TN. This improvement in SBP in the Group-TNcan be attributed to the removal of toxins and uremic end-products from the body via HD. On the other hand, improvement in the Group-CD can be due to an increase in the total peripheral resistance due to vasoconstriction in addition to the removal of toxins. No statistically significant change or difference was observed in DBP. However, the pulse pressure showed increment and significant change in the Group-CD in the third hour of the HD sessions (p=0.048). The renal replacement therapy like HD is a life-saving procedure that, if not adequately done or managed, increases the already augmented morbidity and mortality which is associated with end-stage renal disease.[8]

Different studies reported different effects of cold dialysate on haemodynamic stability, some favoured its use while others found a higher degree of hypotension with standard temperature haemodialysis.[9,10] A cross-over experimental trial conducted by Mathew *et al*. on 25 individuals showed that the cooler dialysate had better haemodynamic stability.[11] Similar findings were reported by another study but few other studies found no superiority of CD over thermo-neutral/ standard temperature.[12,13] This difference in responses might be due to differences in the study population, temperature differences and differences in inclusion/ exclusion criteria. Moreover, in this study, hypotensive patients were taken which was not the case in other studies.

Similarly, the cooler dialysate had an improving effect on DBP similar to the findings of Mathew *et al*.[11] The DBP is important for cardiac perfusion and viability.[14] These studies show that by improving DBP, cardiac health can be improved. In another research by Khalk *et al*., the cooler dialysate had a positive impact on SBP, DBP and mean arterial pressure.[15] All three parameters improved significantly compared to the control group. The cooler dialysate was associated with a decreased frequency of intra-dialytic hypotension.[16] A recent review of dialysate temperature on haemodynamic stability concluded that CD might help with addressing the problem of intra-dialytic hypotension but the long-term effects are still uncertain as studies have not probed into the lasting effects of CD.[17] The frequency of side effects like shivering and cramps with the Group-CD was higher as compared to the Group-TN. Similar findings were reported by another research.[18]

LIMITATIONS OF STUDY

Certain limitations associated with this study are the small sample size and short duration of study thus limiting the generalizability of the study. Moreover, the long-term effects of cooler dialysate are not studied in this study. Therefore, we recommend a clinical trial with a larger sample size and longer duration should done with special emphasis on cardiac functions, dialysis adequacy and haemodynamic stability in the long term.

CONCLUSION

The cooler dialysate improved the haemodynamic stability of the cohort in comparison to thermoneutral dialysate by increasing systolic blood pressure and maintaining diastolic blood pressure in the hypotensive population.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MUY & MNAK: Data acquisition, data analysis, critical review, approval of the final version to be published.

MI & QUAA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MHL & IQ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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