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The Effect of Dialysate Temperature on Dialysis Adequacy and Hemodynamic Stability: An Experimental Study with Crossover Design

Articoli originali

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ABSTRACT

Cool dialysate has variable impact on hemodynamic stability and dialysis adequacy. Hemodynamic stability and dialysis adequacy are crucial indicators for better life expectancy and cardiovascular mortality. This research aims to evaluate the impact of cool dialysate temperature (35.5°C) compared to standard dialysate temperature (37°C) on blood pressures, pulse rate, and dialysis adequacy (Urea reduction ratio and online Kt/V) in a cross over design.

Material and Methods. Consenting ESRD patients on maintenance haemodialysis (HD) with minimum 3 months dialysis vintage and functioning permanent vascular access are included for the study. Each participant had two sessions of HD at 37°C followed by two sessions at 35.5° C on a Fresenius 4008S HD machine. Systolic blood pressure (SBP), diastolic blood pressure (DBP) and Pulse rate are measured pre-HD, every hourly and post dialysis. Pre-HD Blood urea nitrogen (BUN) and post-HD BUN are measured, and Urea reduction rate was calculated for each HD session. Kt/V was calculated by ionic conductance by HD machine for each session.

Results. 25 patients (5 females and 20 males) were enrolled. The mean age was 54 ± 9.58 years. Dialysis vintage was 21.48 ± 6.9 months for study participants 10 patients (40%) were diabetic nephropathy, 9 patients (36%) were presumed chronic glomerulonephritis, 2 patients (8%) were lupus nephritis and 4 patients (16%) were chronic interstitial nephritis. There was statistically no difference between pre-HD BUN ($p = 0.330$), post-HD BUN ($p = 0.776$), URR ($p = 0.718$) and Kt/V ($p = 0.534$) among the dialysis sessions done at 37°C and 35.5°C.

SBP variability in the low temperature (35.5°C) group at 4th hour and post dialysis assumed statistical significance with $p = 0.05$ and $p = 0.025$ respectively. DBP variability in the low temperature (35.5°C) group at 3rd hour, 4th hour and post-dialysis demonstrated statistical significance with $p = 0.027$, $p = 0.36$ and $p = 0.016$ respectively. Pulse rate variability was more in the low temperature (35.5°C) group at 3rd hour and 4th hour which showed statistical significance with $p = 0.037$ and $p = 0.05$ respectively.

Conclusion. Cool dialysate is non inferior to standard dialysate temperature in terms of dialysis adequacy and is associated with less variability in diastolic blood pressure, systolic blood pressure and more pulse rate variability thereby contributing to better hemodynamic stability.

KEYWORDS: Cool dialysate, Dialysis adequacy, Hemodynamic stability, Pulse rate variability

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Introduction

Hemodynamic stability and dialysis adequacy in hemodialysis translates to better quality of life and greater life expectancy [1]. One of the most adopted practices to enhance hemodynamic stability and prevent intradialytic hypotension is the use of cool dialysate [2]. Cardiovascular stability is improved due to increased peripheral resistance and tonicity of blood vessels along with secretion of catecholamine in the clinical context of cool dialysate [3]. Cool dialysate has not become popular due to patient perception of chills and shiver during haemodialysis and its theoretical risk of inferior dialysis adequacy due to entrapment of blood in peripheral blood vessels [4].

Hemodynamic stability is a well-established impact of cool dialysate; however, its influence on the clearance of uremic toxins is still debatable. Intercompartmental resistance is still a realistic concern in cool dialysate which may deter clearance and contribute to dialysis inadequacy [5]. Previous studies [6] have analysed the hemodynamic variability associated with a cool dialysate, but only few studies have conjointly analysed hemodynamics and dialysis adequacy in the same clinical setting. Our study aimed at evaluating the impact of cool dialysis (35.5°C) compared to standard dialysate temperature (37 °C) on blood pressures, pulse rate and dialysis adequacy (Urea reduction ratio (URR) and online Kt/V) in a crossover design study.

Methodology

This was a prospective crossover study which enrolled 25 consenting End Stage renal disease (ESRD) patients who were aged between 18-60 years on maintenance hemodialysis (HD) with a well-functioning AV fistula/Central tunnelled dialysis catheter and with a minimum dialysis vintage of 3 months.

All study participants were on twice weekly haemodialysis and were on same dialyzer membrane with same surface area during the study period.

Institutional ethics clearance was obtained (No: 2368/IEC/2020) and the sample size was deduced to be 25 to retain a statistical power of 80%. Patients with acute kidney injury requiring HD, temporary dialysis catheters as vascular access, critically ill patients and non-consenting individuals were excluded.

After enrolment, study participants underwent 2 sessions of bicarbonate-based standard haemodialysis of 4 hours duration at 37 °C with blood flow of 200 ml/min and dialysate flow of 500 ml/minute on a Fresenius Medical care 4008 S Haemodialysis (HD) machine with a dialysate sodium-138 followed by another two sessions of haemodialysis at 35.5°C with same blood flow, dialysate flow, dialysate sodium and duration.

The 37 °C dialysis is referred as standard temperature dialysis and 35.5°C is termed as cool dialysate haemodialysis for the purpose of this study. Kt/V is a measure of urea removal which indicates the volume of plasma cleared of urea in unit time (Kt) (K-dialyser urea clearance, t-dialysis session length) divided by the urea distribution Volume. It is a dimensionless ratio with values greater than 1.2 indicative of dialysis adequacy. The Kt/V was calculated by the online conductance monitoring software based on ionic conductance (largely sodium based) incorporated in the Fresenius 4008 S HD machines. Bicarbonate based dialysate with same electrolyte composition was used for all dialysis sessions. Pre-dialysis blood urea nitrogen (BUN) value was estimated prior to the start of the dialysis session and post-dialysis BUN value was done after 30 minutes of culmination of the HD session at each dialysis session for calculation of URR. URR was calculated by the formula “(Pre-dialysis BUN – Post-dialysis BUN)/Pre dialysis BUN” and expressed as a percentage. Pre-dialysis

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blood pressure (pre-BP), BP at every hour and post dialysis BP were recorded manually by using automatic sphygmomanometer by the assigned dialysis technician. Pulse rate at every hour inclusive of pre-dialysis and post-dialysis were recorded by the dialysis technician. Any untoward clinical event like chills, shivers, and hemodynamic instability (Intradialytic Hypotension SBP< 90 mmHg) and ultrafiltration during each HD session were documented.

Mean, standard deviation or median were used for expressing continuous variables and for significant difference between the bivariate samples in paired groups, the paired sample t-test was used. Mann Whitney U test was used to evaluate non normally distributed variables.

Fishers' test/Chi square tests were used to evaluate categorical variables. Pearson's correlation coefficient was used to indicate association between bivariate variables. SPSS version 23.0 was used for data analysis, MS Excel spread sheet was used for data entry and a p value £ 0.05 was considered significant.

Results

Clinical and Demographic Parameters

This is a prospective crossover study involving 25 maintenance haemodialysis patients conducted at a South Indian tertiary care dialysis unit. There were 20 male patients and 5 female patients enrolled in the study. There were 10 diabetic patients (40%) and 21 hypertensives (84%) and 6 (24%) were both diabetic and hypertensives with 1 hypothyroid patient. Only 4 patients (16%) were normotensive. The mean age group was 54.48 ± 9.58 years. In terms of native kidney disease, 10 patients (40%) had diabetic nephropathy, 9 patients (36%) were presumed to have chronic glomerulonephritis, 2 patients (8%) had lupus nephritis, and 4 patients (16%) were presumed to have chronic interstitial nephritis. The ultrafiltration rate of any patient didn't exceed 13 ml/kg/hour. The demographic and clinical details of the study participants are outlined in the Table 1. There was no statistical difference between pre-HD BUN (p = 0.330), post-HD BUN (p = 0.776), URR (p = 0.718) and Kt/V (p = 0.534) among the dialysis sessions done at 37 °C and 35.5 °C.

Parameter	Value
Age (years)	54 ± 9.58 years
Dialysis vintage (months)	21.48 ± 6.9 months
Average Weight gain (in all sessions) (kilograms)	3.64 ± 2.75 kilograms
Episodes of hypotension	1 episode in 37 °C, 0 episodes in 35.5 °C
Vascular access	24 AV fistula and 1 Internal Jugular dialysis tunnelled catheter
Pre-HD BUN at 37 °C (mg/dl)	121.88 ± 27.16
Post-HD BUN at 37 °C (mg/dl)	118.64 ± 28.46
Pre-HD BUN at 35.5 °C (mg/dl)	33.52 ± 10.50
Post-HD BUN at 35.5 °C (mg/dl)	33 ± 10.95
URR at 37 °C (%)	72.62 ± 5.31
URR at 35.5 °C (%)	71.7 ± 8.16
Online Kt/V at 37 °C	1.69 ± 0.30
Online Kt/V at 35.5 °C	1.67 ± 0.27

Table 1. Clinical, lab, and dialysis parameters for the study participants.

Systolic blood pressure variability at 37 °C and 35.5 °C

The systolic blood pressure (SBP) at various time intervals — pre-dialysis (pre-SBP), 1 hour (SBP1), 2 hours (SBP2), 3 hour (SBP3), 4 hour (SBP4), and post-dialysis SBP at 37 °C (T37) and 35.5 °C (T35.5) — along with the standard deviation (SD) and p value are tabulated in Table 2. The relevant findings include lower SBP variability in the low-temperature (35.5 °C) group at 4th hour and-post dialysis,

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which were statistically significant with p = 0.05 and p = 0.025 respectively, indicating better hemodynamic stability.

Parameter	SBP	SD	P value
PRE-SBP T37 (mm Hg) PRE-SBP T35.5 (mm Hg)	151.7 152.4	13.2 13.0	0.805
SBP 1 T37 (mm Hg) SBP 1 T35.5 (mm Hg)	154.2 157.6	12.8 13.3	0.211
SBP 2 T37 (mm Hg) SBP 2 T35.5 (mm Hg)	153.4 155.1	17.4 18.9	0.725
SBP 3 T37 (mm Hg) SBP 3 T35.5 (mm Hg)	154.8 160.7	13.4 12.4	0.08
SBP4 T37(mm Hg) SBP4 T35.5(mm Hg)	154.5 160.8	14.4 18.4	0.043
POST-SBP T37(mm Hg) POST-SBP T35.5(mm Hg)	153.9 160.8	15.5 15.2	0.025

Table 2. Systolic blood pressure variability at 37 °C and 35.5 °C during the dialysis and post dialysis period.

Diastolic blood pressure variability at 37 °C and 35.5 °C

The Diastolic Blood Pressure (DBP) at various time intervals — pre-dialysis (pre-DBP),1 hour (DBP1), 2 hours (DBP2), 3 hours (DBP3), 4 hours (DBP4) and post-dialysis DBP at 37 °C (T37) and 35.5 °C (T35.5) — along with the standard deviation and p value are tabulated in Table 3.

The relevant findings include lower DBP variability in the low-temperature (35.5 °C) group at 3rd hour, 4th hour and post-dialysis, with statistical significance at p = 0.027, p = 0.36, and p = 0.016, respectively, indicative better hemodynamic stability.

Parameter	SBP	SD	P value
PRE-DBP T37(mm Hg) PRE-DBP T35.5(mm Hg)	91.3 93.5	7.1 6	0.476
DBP 1 T37(mm Hg) DBP 1 T35.5(mm Hg)	91 92.2	8.7 6.3	0.503
DBP 2 T37(mm Hg) DBP 2 T35.5(mm Hg)	91.9 91.5	8.6 6.2	0.779
DBP 3 T37(mm Hg) DBP 3 T35.5(mm Hg)	89.8 94.3	7.6 5.8	0.027
DBP4 T37(mm Hg) DBP4 T35.5(mm Hg)	91.3 94.1	7.7 6.6	0.036
POST-DBP T37(mm Hg) POST-DBP T35.5(mm Hg)	90.6 94.5	7.9 6.5	0.016

Table 3. Diastolic blood pressure variability at 37 °C and 35.5 °C during the dialysis and post dialysis period.

Pulse rate variability at 37 °C and 35.5°C

The Pulse rate (PR) at various time intervals — pre-dialysis PR, 1 hour (PR1), 2 hours (PR2), 3 hours (PR3), 4 hours (PR4) and post-dialysis PR at 37 °C (T37) and 35.5 °C (T35.5) — along with the standard deviation and p value are tabulated in Table 4.

The relevant findings include greater pulse rate variability in the low-temperature (35.5°C) group at 3rd hour and 4th hour, with statistical significance at p = 0.037 and p = 0.05, respectively.

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Parameter	PR	SD	P value
PRE-PR T37 (beats/min) PRE-PR T35.5 (beats/min)	83.6 83.7	5.6 6	0.833
PR1 T37 (beats/min) PR1 T35.5 (beats/min)	84.1 84.8	5.8 7.5	0.376
PR2 T37 (beats/min) PR2 T35.5 (beats/min)	83.6 85.6	5.8 7.2	0.103
PR 3 T37 (beats/min) PR 3 T35.5 (beats/min)	85 84	6.7 5.5	0.037
PR 4 T37 (beats/min) PR 4 T35.5 (beats/min)	84.4 86	6.9 7.6	0.05
POST-PR T37 (beats/min) POST-PR T35.5 (beats/min)	84.4 85.9	6.2 6.9	0.172

Table 4. Pulse rate variability at 37 °C and 35.5°C during the dialysis and post dialysis period.

Discussion

This was a prospective crossover study involving twenty-five ESRD patients on maintenance hemodialysis twice weekly, of South Indian origin. Majority of the Western literature [3, 5, 7, 11] have included only patients on thrice weekly hemodialysis to study the impact of cool dialysate HD on hemodynamic stability. Our research is unique in that all our patients were on twice-weekly dialysis and achieved optimal URR and Kt/V in both the standard and cool dialysate crossover. This challenges the traditional notion of thrice-weekly HD and reignites the concept of incremental/personalized dialysis in the modern era [8, 9]. The practise of the incremental dialysis/twice weekly dialysis at our centre is in concordance with common dialysis practise pattern prevalent in India [10].

This study demonstrated a higher systolic blood pressure in the cool dialysate crossover arm (160.8 ± 15.2) compared to the standard dialysate which was statistically significant in the fourth hour and post-dialysis period. This vital finding was in concordance with the study done by Ahmadi F et al. [12]. However, other studies [6, 13] found no statistical difference in the systolic blood pressure in the cool dialysate arm compared to standard dialysate temperature arm. These differences in findings may be due to differences in the pre-defined set points of temperature, defined as standard temperature and cool dialysate temperature in the respective studies [12, 13]. It is a well-established fact that isothermic dialysis would lead to less hemodynamic variability and any lower set point temperature defined as cool dialysate temperature would not yield statistical benefit in terms of hemodynamic stability [14]. Our study is unique in the fact that it studied SBP variability along with the absolute values of SBP which demonstrated that SBP in the cooler dialysate crossover had less variability in the 4^{th} hour ($p = 0.043$) and post dialysis stage ($p = 0.025$). This reduced blood pressure variability is a pivotal factor to ensure hemodynamic stability and prevent myocardial stunning, which translates to greater life expectancy and reduced cardiovascular mortality [15].

Our study also analysed the impact of diastolic pressure and its variability in the standard dialysate temperature HD and cool dialysate temperature HD sessions which is also one of the merits of our research. Our study demonstrated that there is less diastolic blood pressure variability in the 3^{rd} hour ($p = 0.027$), 4^{th} hour ($p = 0.036$) and post-dialysis stage ($p = 0.016$) in the cool dialysate sessions. Diastolic blood pressure is an important parameter to ensure adequate coronary perfusion and any variability in DBP will compromise the viability of the heart [16]. A large metanalysis by Zhao et al. [17] emphasized the importance of diastolic blood pressure variability and wide pulse pressure as vital players in determining cardiovascular mortality in HD patients. Large randomized studies are required to validate our findings and to reassert the importance of cool dialysate in reducing DBP variability.

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We also studied the pulse rate variability in the cool dialysate sessions and standard temperature dialysate sessions. It was found that there was more pulse rate variability in the cool dialysate sessions in the 3rd hour (p = 0.037) and 4th hour (p = 0.05). In a seminal study done by Park S et al. [18], pulse rate variability and heart rate variability in the middle of the haemodialysis session was associated with better hemodynamic stability and less incidence of intradialytic hypotension. Pulse rate variability defines the integrity of the autonomic nervous system, and more pulse rate variability is a marker of an intact autonomic system. Since the majority of the patients in this study group is diabetic (and the most notable cause of chronic kidney disease in the world is diabetic kidney disease [19]) the importance of autonomic dysfunction cannot be underscored in haemodialysis. This finding emphasizes that cool dialysate may play a role in preserving the pulse rate variability by increasing baroreflex variability as a response to reduction in cardiac output [20]. This increase in baroreflex variability observed in cool dialysate HD sessions translates to less intradialytic hypotensive episodes [18, 20].

There was only one hypotensive episode in one dialysis session at 37 °C and none in the cool dialysate HD sessions. However, the sample size and the session numbers were insufficient to detect any significant differences in relation to intradialytic hypotension in both types of HD sessions. There were no chills, shivers or discontinuation of HD session due to any discomfort in both standard and cool dialysate sessions. Lack of discomfort from cool dialysate is a pertinent finding in an Indian context, as our study population is already exposed to a tropical climate, and it might have been particularly sensitive to low temperatures during haemodialysis.

This study didn't find any difference in dialysis adequacy in the standard temperature HD and cool dialysate HD sessions. The Kt/V (p = 0.534) and the URR (p = 0.718) were not statistically different in the cool dialysate and standard temperature HD sessions. This finding is similar to previous studies [12, 21] which didn't show any reduction in dialysis adequacy with cool dialysate. Cool dialysate has a theoretical risk of reducing dialysis adequacy by entrapment of blood in periphery due to increased vasoconstriction of the larger vessels [5, 12]. Clinicians should be wary of this theoretical risk and should try to set appropriate temperature retaining the benefits of cool dialysate.

This study emphasises the incorporation of cool dialysate in select patients especially for individuals who are prone to intradialytic hypotension. This study paves the way for large scale randomised clinical trials to evaluate the hemodynamic impact of cool dialysate and its clinical benefits in terms of long-term cardiovascular mortality and life expectancy.

Conclusion

Cool dialysate is not inferior to standard dialysate temperature in terms of dialysis adequacy and it is associated with less variability in diastolic blood pressure, systolic blood pressure and increased pulse rate variability, which translates to better hemodynamic stability.

Limitations

This study had a small sample size although it was statistically adequate. A small sample size has an important influence while assessing a clinical parameter like hemodynamic stability, and lack of large sample for this study is definitely a major drawback. We didn't use a scientific questionnaire to assess discomfort, like chills or post-dialysis fatigue, for this study; instead, it was based on subjective perception of the patient. This study did not report the values of patients' body temperature or the external temperature and assess its impact on the energy balance and calories within the extracorporeal circuit, which are crucial factors for hemodynamic stability in

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haemodialysis [22]. Our study didn't assess the impact of clinical variables like sodium profiling, ultrafiltration rate and different modalities of dialysis like hemodiafiltration on hemodynamic stability [23, 24] which have a long-term impact on morbidity and mortality.

Implication for health policy

This study paves the way for large scale future randomized controlled trials for evaluating the impact of cool dialysate on various factors influencing hemodynamic stability and its impact on various inflammatory, cardiovascular and nutritional markers in hemodialysis.

Ethical issues

This research was approved by institutional ethics committee (No:2368/IEC/2020) and informed consent of participants and appropriate laws including revised Declaration of Helsinki (2008) were observed in the research.

Data availability statement

The data for substantiating the findings of this manuscript are available with corresponding author and can be made available on request.

Abbreviations

ESRD: End Stage Renal Desease;
HD: Hemodialysis;
DBP: Diastolic Blood Pressure;
URR: Urea Reduction Ratio

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