HAEMODYNAMIC STABILITY OF CKD PATIENTS UNDERGOING DIALYSIS AT ISOTHERMIC DIALYSATE TEMPERATURE

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ABSTRACT

BACKGROUND

Chronic Kidney Disease patients undergo dialysis for their ailment, due to which they experience many complications and adverse effects. One of the most important complications is haemodynamic instability (hypotension/untoward events). Many studies have shown that cool dialysate improves cardiovascular tolerance among haemodialysis patient and reduces hypotensive episodes during haemodialysis.

METHODS

From January 2013 to December 2013, an observational, prospective cohort study was done to determine the basal body temperature in chronic kidney disease patients who are on maintenance dialysis, using mercury thermometer and tympanic membrane thermometry, to determine the effect of isothermic dialysis (patient's body temperature) on haemodynamic stability.

RESULTS

In this study, we randomly assigned 60 Stage V CKD patients attending Nephrology OPD to the study. Out of the total of 60 patients, 44 (73.3%) were males and 16 (26.66%) were females. The major cause of CKD was hypertension (44%) followed by diabetes mellitus (29%), both diabetes and hypertension (21%), obstructive uropathy (11%) and unknown (29%). The BMI ranges from 17.5 to 30.3. The age ranges from 23 to 75 years. The mean tympanic temperature calculated was 36.54±0.232. The mean axillary temperature calculated was 36.883±0.1416.

CONCLUSIONS

Haemodialysis done in isothermic dialysate temperature contributes more to haemodynamic stability than haemodialysis in normal temperature in terms of reduced fluctuations and maintaining stable blood pressure.

KEYWORDS

CKD, Haemodynamic Stability, Dialysis, Isothermic Dialysate Temperature.

HOW TO CITE THIS ARTICLE: Thiruvenkadam G, Gunaseelan P. Haemodynamic stability of CKD patients undergoing dialysis at isothermic dialysate temperature. J. Evid. Based Med. Healthc. 2019; 6(22), 1593-1597. DOI: 10.18410/jebmh/2019/322

BACKGROUND

Haemodialysis is one of the most preferred modality of renal replacement therapy since ancient days, since the very beginning of dialytic therapy, diffusion and convection have been combined in an attempt to replace renal functions.[1] Later the diffusive phenomenon from industrial chemistry and dialyser mechanism were employed for counter-current exchangers.[2]

Chronic Kidney Disease patient undergo dialysis for their ailment, due to which they experience many complications and adverse effects. One of the most important complication is haemodynamic instability (hypotension / untoward events). Many Studies have shown that Cool dialysate improves cardiovascular tolerance among haemodialysis patient and reduces hypotensive episodes during haemodialysis. During standard haemodialysis and ultrafiltration the combination of low blood volume and loss of peripheral vascular resistance causes hypotension. Blood cooling has been used to stabilize blood pressure during very high efficiency haemodialysis with high ultrafiltration rate and helps to maintain blood pressure without compromising the efficacy of haemodialysis. Use of cooler dialysate also improves left ventricular contractility, pre and after load, but there was less literature regarding the use of isothermic temperature on haemodialysis, which initiated this study on haemodynamic stability using isothermic dialysate temperature in CKD patients.

This study is to assess the haemodynamic stability (both hypo and hypertension) during haemodialysis with patients own body temperature. Isothermic dialysate temperature is maintenance of constant temperature throughout the dialysis. Energy transfer plays a major role in vascular stability, (which again depends on core body temperature) during haemodialysis.[3,4] Isothermic temperature improves the vascular stability by maintaining a constant blood pressure, decrease in fluctuation of blood pressure with constant heart rate and decrease the intra-dialytic hypotension (IDH). Patient tolerate isothermic dialysis better than thermoneutral or normal temperature dialysis.[5] Low

Financial or Other, Competing Interest: None.
Submission 13-05-2019, Peer Review 20-05-2019,
Acceptance 28-05-2019, Published 03-06-2019.
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DOI: 10.18410/jebmh/2019/322

mortality rate is observed in CKD patients with stable body temperature,[6] even a 0.3 to 0.8 ^{0}C reduction in body temperature prevent cardiovascular mortality.[4] This study was aimed to assess the haemodynamic stability of CKD patients undergoing dialysis at isothermic dialysate temperature.

METHODS

From January 2013 to December 2013, an Observational, prospective cohort study was done to determine the basal body temperature in CKD patient on maintenance dialysis using mercury thermometer and tympanic membrane thermometry and to determine the effect of isothermic dialysis (patient's body temperature) on haemodynamic stability. In this study, we randomly assigned 60 Stage V CKD patients attending Nephrology OPD to the group. The following patients were included: patient undergoing haemodialysis for more than 3 months, patients with twice or thrice weakly haemodialysis and patients undergoing haemodialysis with A-V fistula. Patients with reasonably controlled blood pressure (i.e. less than 180 mm hg systolic and less than 120 mm hg diastolic) were included.

Anti-hypertensive dose was kept constant 2 weeks prior to study. Room temperature was maintained at 25^{0}c. Care was taken to do all the four dialysis on the same time of the day to negate the changes due to circadian variation in body temperature. We considered Odd numbers as test temperature and even numbers as normal standard body temperature (37^{0}C). Blood pressure, pulse rate were measured before start of dialysis and monitored every 15 minutes for 4 hours using automated recordings from monitor. Axillary and Tympanic membrane temperature were measured during test haemodialysis before start of the dialysis. Temperature in dialysis machine was adjusted only during test measurements according to randomization process. Patients own body temperature was measured using both Tympanic and axillary methods, as tympanic thermometry was considered as good indicator for measuring core temperature next to rectal the dialysate temperature were adjusted accordingly. The tympanic temperature was measured by well calibrated Covidien Genius-2, which was imported from Mansfield United States for research purpose. Tympanic probe covers were changed for each measurement requiring 2covers for each patient (2 readings).

Two dialysis were done at standard (37^{0}c) temperature and two dialysis at isothermic (patient's body) temperature and haemodynamics were monitored. Axillary temperature was measured using axillary thermometer. If the value varies more than 25% the test were repeated. If patient has fever or acute illness haemodialysis recordings were not measured, during haemodialysis if patient develops any complications, hypotension or hypertension then dialysis was stopped and repeated using normal temperature. All patients were subjected to both standard and isothermic dialysis, twice each. The order in which each patient was subjected to the above two types of dialysis was decided using randomization process.

RESULTS

A total of 80 eligible patients underwent haemodialysis, out of which 76 patients were recruited who gave consent and 4 out of 80 patients rejected consent. These patients were analysed for their baseline haemodynamic status and complications associated with haemodialysis for 3 months, out of which 6 patients underwent transplant, 10 patients expired, the cause of death was septicemia for 6 patients and cardiovascular mortality for 4 patients and 5 patients lost follow up (shifted the dialysis unit near to their residence). So in order to obtain necessary sample size 5 new patients were re-recruited after obtaining consent and observed for 3 months for baseline haemodynamics, adverse events and complications. All recruited CKD patients were observed for 3 months and randomized.

Out of total 60 patients 44 (73.3%) were males and 16 (26.66%) were females. The major cause of CKD was hypertension (44%) followed by diabetes mellitus (29%), both diabetes and hypertension (21%), obstructive uropathy (11%) and unknown (29%). The BMI ranges from 17.5 to 30.3. The age ranges from 23 to 75 years. The basal body temperature of C.K.D patients are usually low. In our study we have calculated basal body temperature simultaneously using axillary and tympanic thermometry. The mean tympanic temperature calculated was 36.54±0.232. The mean axillary temperature calculated was 36.883±0.1416. The mean basal body temperature is 36.54+0.23 ^{0}C, which is low than normal individuals. The p value between mean axillary and tympanic temperature is less than 0.001 which is statistically significant, this is because even 0.3^{0}C change in temperature can alter haemodynamics significantly. So, the temperature difference is significant.

Repeated Measures-Pulse Rate

The mean pulse rate of test temperature varies from 72-82 beats/minute, while the mean pulse rate of control varies from 81-91 beats/ min. The p- value is 0.09 not statistically significant. Even though the p value is not statistically, the figure in 1 shows significant difference between test and control temperature towards the end of dialysis. Clinically there was significant pulse rate difference observed. Figure 1 shows the comparison pulse rates for every 15 minutes in both test and control population. The pulse rate (fluctuations) within both control and test population (shown in figure 8b and c respectively) has significant variation, the p value calculated for both populations is 0.00 statistically significant which indicates both are similar and no difference is observed in test and control temperature. Figure 2- shows the trends (fluctuations) of pulse rate every 15 minutes in test temperature (patient's own body temperature) calculated via repeated measures. Figure 3: shows the trends (fluctuations) of pulse rate every 15 minutes in control temperature (normal temperature) calculated via repeated measures.

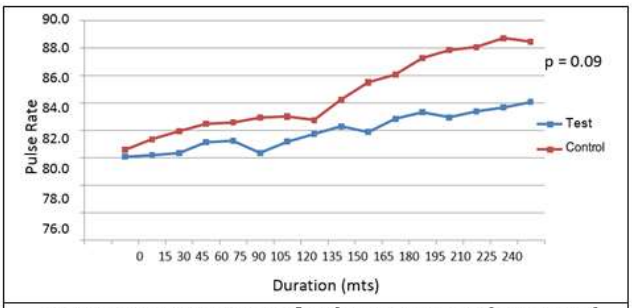

Figure 1. Comparison of Pulse Rate in Both Test and Control Temperature Every 15 Minutes

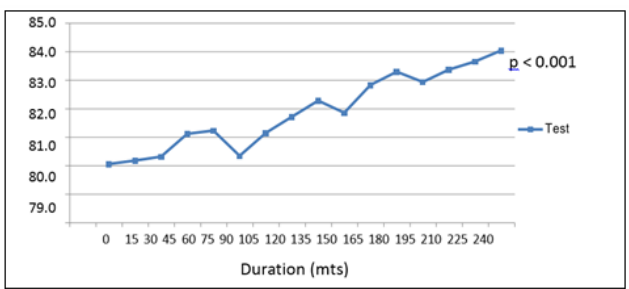

Figure 2. Shows the Trends (Fluctuations) of Pulse Rate Every 15 Minutes in Test Temperature (Patients's Own Body Temperature)

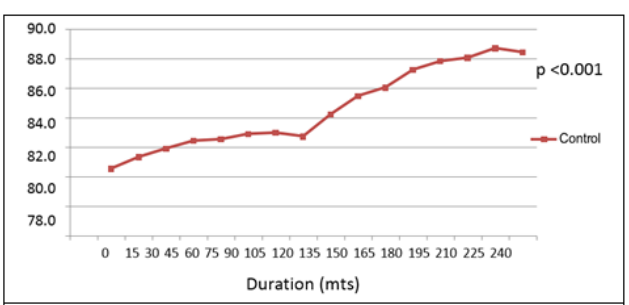

Figure 3. Shows the Trends (Fluctuations) of Pulse Rate Every 15 Minutes in Control Temperature (Normal Temperature)

Repeated Measures-Systolic Blood Pressure

The repeated measures of systolic blood pressure for test temperature varies from 151.9-157.1 mmHg while that of control varies 154.4-158.7 mmHg and the p value is 0.22 which is not statistically significant. Even though clinically the blood pressure difference was significant, statistical significance could not be achieved. Their comparison is plotted in figure 4. Figure 5 shows the trend (fluctuations) of systolic blood pressure within test temperature (patient's own body temperature) every 15 minutes calculated via repeated measures. Figure 6 shows the trends (fluctuations) of systolic blood pressure within control temperature (normal temperature) every 15 minutes calculated via repeated measures. Figure 5 and 6 shows trends (fluctuations) within test and control temperature, from the figure we can see after 3 hours there is a drop in systolic blood pressure in control temperature while in test temperature there is no drop in systolic blood pressure and from the initiation of HD in test temperature (figure 5) the graph sticks to the baseline and there is a constant and steady increase in blood pressure with less fluctuations while in control temperature the graph is more fluctuating from the initiation of HD and moreover there is a drop in systolic blood pressure after 3 hours (fig-6). From the above two figures (4 and 5) it is clear that fluctuations are less in test temperature when compared to control temperature, the p value of test temperature is 0.21 while that of control is 0.32 which is much greater than that of test. It clearly signifies that test temperature is better and has less fluctuations than control.

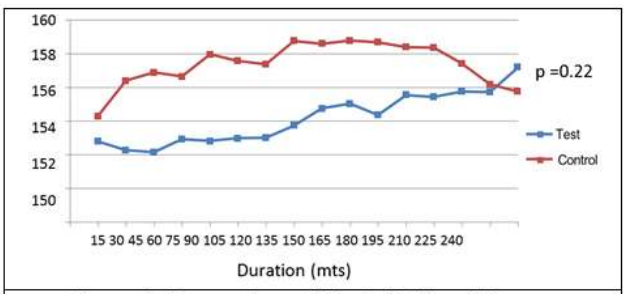

Figure 4. Comparison of Systolic Blood Pressure Between Test and Control Temperature Every 15 Minutes

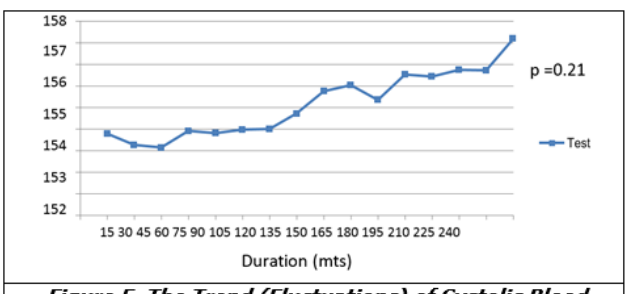

Figure 5. The Trend (Fluctuations) of Systolic Blood Pressure Within Test Temperature (Patient's Own Body Temperature) Every 15 Minutes

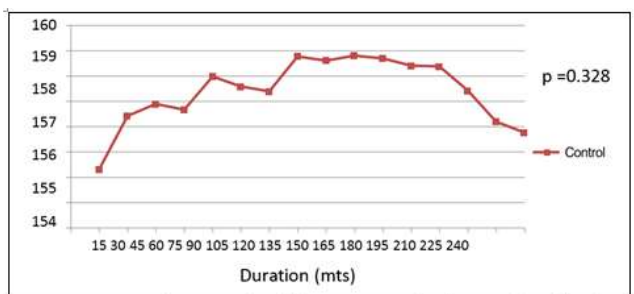

Figure 6. The Trends (Fluctuations) of Systolic Blood Pressure Within Control Temperature (Normal Temperature) Every 15 Minutes

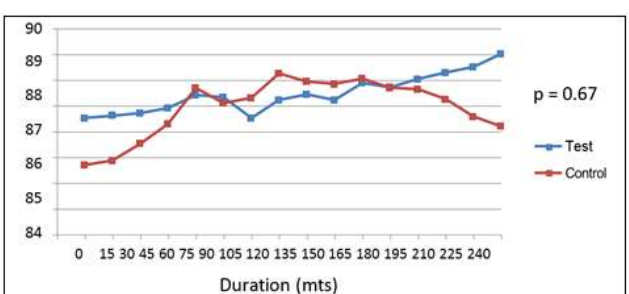

Figure 7. Comparison of Diastolic Blood Pressure in Test and Control Group Every 15 Minutes

Repeated Measures-Diastolic Blood Pressure

The repeated measures of diastolic blood pressure for test population varies from 86.5-89 mmHg while that of control varies 84.6-88 mmHg and the p value is 0.67 which is not statistically significant. Clinically the blood pressure difference is small, and their comparison is plotted in figure 7.

There is no significant p value. Clinically also there was only little difference in diastolic blood pressure. There is no much difference in diastolic pressure between two temperatures.

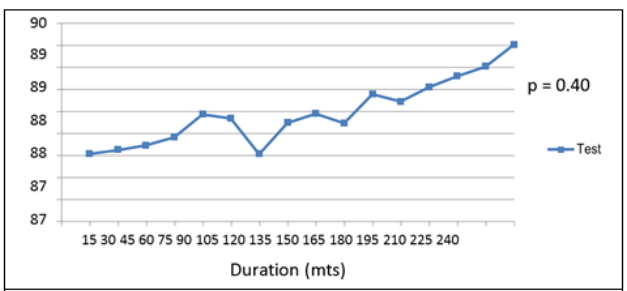

Figure 8. Shows the Trend (Fluctuations) of Diastolic Blood Pressure Every 15 Minutes in Test Temperature (Patient's Own Body Temperature) Via Repeated Measures

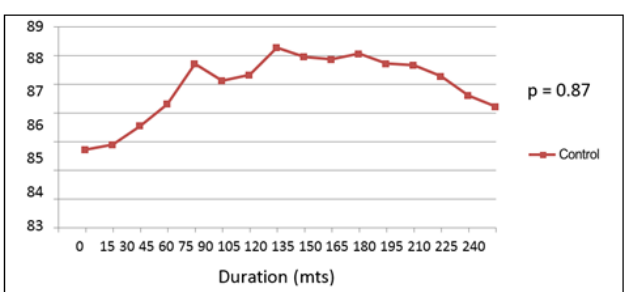

Figure 9. Shows the Trend (Fluctuations) of Diastolic Blood Pressure Every 15 Minutes in Control Temperature (Normal Temperature) Via Repeated Measures

Comparison of Diastolic blood pressure in both test and control temperature is almost similar, the p-value of 0.67 is also not significant, but if we take and analyse diastolic blood pressure separately within test temperature plotted every 15 minutes shown in fig 10-b has less fluctuation and there is no drop in blood pressure the graph steadily increases and no hypotension or drop in blood pressure after 3 hours. Whereas in control shown in fig 10-c there is a drop in blood pressure after 3 hours and fluctuations are definitely more when compared to test temperature, which is also evident by p value of 0.40 and 0.87 in test and control temperature respectively. There is no other significant cardiac event or vascular events. From the above results the basal body temperature of C.K.D. patients is determined and there is no statistically significant difference in haemodynamic stability in test population when compared to control population temperature. There was significant reduction in adverse effects observed in test temperature.

DISCUSSION

Pérgola PE et al[5] in 2004 in their study in Body temperature regulation during haemodialysis in long-term patients: is it time to change dialysate temperature prescription? Stated that even 0.3 to 0.8^{0}C reduction in temperature prevents cardiovascular mortality.

So, this relatively low temperature difference is important, the mean body temperature calculated was 36.54±0.232 assuming tympanic temperature will be more accurate than axillary temperature. Maggiore Q et al studied the effects of control of thermal balance on vascular stability in haemodialysis patients results of the European randomized clinical trial in 2002[7] shows incidence of IDH can be reduced by isothermic dialysate temperature dialysis they calculated energy flow rates which is more stable in isothermic temperature, they also stated stable haemodynamics in terms of systolic, diastolic and pulse rate.

In our study also we clinically found significant difference in pulse rate, systolic blood pressure, however diastolic blood pressure was not contributory. The p value between test and control pulse rate was 0.009, again the repeated measures (fluctuations) within test and control temperature appears to be less in both temperature with p value of <0.001, the figure in 8a, b, c illustrates the pulse rate repeated measures. These figures clearly states that even the statistical significance was not enough and the p value is not contributory which could have been achieved if the sample is large.

In systolic blood pressure the p value between test and control is 0.22 which also statistically not significant. figure 9 illustrates the trends on systolic blood pressure comparison of both test and normal temperature, if we take a close look at the graph in test temperature the fluctuations are less when compared to control, moreover when the dialysis is initiated there is a sudden jet increase in blood pressure followed by up's and down and there is a curve and sudden drop in blood pressure after 3 hours of dialysis, whereas in test temperature the curve is more or less similar and less fluctuations when compared to control (normal) temperature and there is neither hypotension nor hypertension maintains within baseline, at the end we can notice there is a slow peaking of blood pressure returning to normal. The R-ANOVA calculated within test group was p value of 0.21 while that of control was 0.32 which clearly says that there is less fluctuations in test temperature.

In diastolic blood pressure the p value was 0.67 between test and control while within test was 0.40 within control was 0.87 shown in graph 10-a, b, c respectively. Here also there is no statistical significance the graph of test temperature in end was more stable than control, decreased fluctuations in test compared to that of control was noticed. We have achieved and proved our hypothesis of haemodynamic stability in terms of blood pressure and pulse rate, but we could not achieve statistical significance due to small size. One observation we found in our patients was significant hypertension about 60% of patient (36) who participated in the study had hypertension (high B.P.) during dialysis were in most of dialysis unit only 20% have

hypertension and about only 13% experienced hypotension, which contradictory to other study and dialysis unit. The incidence of hypertension in overall CKD patients was also high 73%, this may be related to adherence of anti-hypertensives, which could have contributed to blood pressure during HD.

We also found not only hypotension was reduced to 3% from 13% even hypertension was reduced to 13% from 60% which contributes significantly to reduce the cardiovascular mortality. In many studies like Tisler and Shji T et al mentioned that IDH is the main immediate cause of death in haemodialysis patient followed by cardiovascular mortality due to ischemic events in haemodialysis.[8,9]

Tisler et al[8] in his study the effect of frequent or occasional dialysis-associated hypotension on survival of patients on maintenance haemodialysis, 2003 and Shoji T et al[9] also stated the complications of dialysis and IDH mortality in CKD patients in his work on Haemodialysis-associated hypotension as an independent risk factor for two-year mortality in haemodialysis patients 2004. Selby NM et al[10] in 2006 in Occurrence of regional left ventricular dysfunction in patients undergoing standard and biofeedback dialysis, stated occurrence of transient myocardial ischemia will be responsible for reduced long term ejection fraction and impaired cardiovascular functions in CKD patients.

Braunwald E et al[11] have already named such transient ischemic myocardium as stunned myocardium. Later solution for this IDH was found to be cool haemodialysis Nicholas and Heng-Jung studied the effect of cool haemodialysis in CKD patients found improved cardiovascular response and decreased myocardial ischemia in CKD patients.

Nicholas M and Selby et al[12] in his study in 2006, Dialysis-Induced Regional Left Ventricular

CONCLUSIONS

Dysfunction is ameliorated by cooling the dialysate. Many studies have evaluated the use of cool haemodialysis. Even IDH and cardiovascular mortality is prevented by cool haemodialysis, this cool haemodialysis has its own adverse effects like shivering and hypothermia related sepsis and its long-term benefits are questionable to CKD patients. In our study, only one person developed CVA during last normal temperature dialysis, so HD was stopped. She recovered from that episode and is still under our follow-up. She is doing well. No CVA events seen in test temperature. Other variables and adverse effects were also significantly reduced. Cramps, shivering and headache were significantly reduced from 83% to 18%, 60% to 13% and 51% to 5% respectively. The incidence of body ache was also reduced. Variables like vomiting, fever were equivocal. Further studies are required to substantiate the findings from this study.

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