

The Impact of Personalized Dialysis Prescription on Clinical Outcomes in Maintenance Hemodialysis Patients: A Randomized Controlled Trial

Dr. Rajesh Kumar Padhi¹, Dr Ashim kumar Mahali², Dr Soumya Mishra³, Dr A. C. Mahakur^{*4}

¹Associate Professor, Department of Nephrology, Kims Bhubaneswar

²Associate Professor, Department of Nephrology, KIMS,Bhubaneswar

³Associate professor, Dept of Physiology, KIMS,Bhubaneswar

^{4*}Consultant Nephrologist, Department of Nephrology, Kalinga Hospital,Bhubaneswar

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ABSTRACT

Background: The research evaluates if individualized dialysis prescriptions can boost clinical results for people who require maintenance hemodialysis while examining their effects on survival rates and arrhythmogenic events and blood pressure regulation alongside electrolyte balance.

Methods: A randomized controlled trial involving 120 patients under maintenance hemodialysis included them. Two separate dialysis groupings with sixty participants were formed which included standard dialysis and personalized dialysis. Each patient received individualized dialysis prescriptions which took into account their electrolyte concentrations and health conditions in the personalized group. Research measured mortality and arrhythmia events and blood pressure and electrolyte changes before and after six months of the study period.

Results: Results showed that the personalized dialysis treatment performance surpassed those of standard dialysis. The personalized dialysis group recorded better health results with fewer mortalities combined with fewer arrhythmia events and improved blood pressure control and more stable potassium and magnesium serum levels. Fluid balance in the personalized dialysis approach was better while the number of fluid overload cases remained lower.

Conclusions: Medical care for patients under hemodialysis treatment substantially improved through customized dialysis prescriptions. In patients with haemodialysis, personalized therapy, based upon individual needs is increasingly effective while minimizing complications with the general patient's well-being. Such discoveries help to adopt personalization procedures into routine medical practice for achieving optimized dialysis treatment.

Keywords: *Personalized dialysis, hemodialysis, clinical outcomes, electrolyte balance, blood pressure control, arrhythmias.*

1. INTRODUCTION

Personalized prescription of dialysis is the turning point by which clinical outcomes for maintenance hemodialysis are dramatically improved. Generally, the treatment is individualized according to the needs of every patient. During the past decades management approaches for hemodialysis stepped away from standardized techniques toward individual patient-centered care strategies which incorporate specific clinical needs as well as electrolyte imbalances and additional important variables. The patient's clinical results advance substantially when providers individualize dialysis treatment choices for electrolytes potassium sodium and magnesium.

Scientific research has proven that the composition of dialysis fluids with particular attention to electrolyte amounts plays a crucial role in managing patient fluid status and linked complications in those receiving renal replacement therapy.

Dilaver and Ikizler (2023) [1] demonstrated how personalized electrolyte control provides various tolerance levels among patients and improved dialysis treatment prescriptions lead to enhanced clinical results for MHD patients during short and long-term periods (Dilaver & Ikizler, 2023) [1]. Scientific research has investigated in detail how dialysate potassium levels affect patient mortality statistics and arrhythmic complications rates. A study based on DOPPS data led Karaboyas et al. (2017) [2] to discover an obvious survival connection between rising dialysate potassium values and diminished mortality risks (Karaboyas et al., 2017) [2].

Research also focused on magnesium electrolytes since they affect the risks connected to hemodialysis treatment. According to Pun and Middleton (2017) dialysate magnesium affects cardiovascular stability and modifies the danger level of adverse outcomes which occur during hemodialysis (Pun & Middleton, 2017) [3]. The specific approach remains essential because electrolyte disorder treatment failures can lead to dangerous hypotension conditions along with arrhythmias that might end in death.

Recent research in the Monitoring in Dialysis study attempted to uncover if modifications in electrolyte balance during hemodialysis resulted in the same healthcare outcomes. According to Correa et al. 2021 in their subanalysis of the MiD ongoing practice methods for electrolyte management in haemodialysis remain vital for achieving better patient outcomes and cardiovascular stability along with electrolyte homeostasis [4].

Hecking et al. (2014) studied dialysate sodium adjustment effects on blood pressure management in people undergoing hemodialysis which showed this method enables effective blood pressure control to lower hypertension risks for dialysis patients (Hecking et al., 2014) [5]. The requirement exists to optimize dialysis therapy alongside multi-risk factor treatment for achieving optimal patient wellness [6].

Researchers have thoroughly studied the dialytic factors including sodium levels and potassium contents and their effects on arrhythmia development in individuals undergoing hemodialysis. Tumlin et al. (2019) indicate that a properly optimized dialytic treatment serves as an arrhythmia preventive measure while delivering individualized patient care (Tumlin et al., 2019) [7-8].

Considering the burgeoning evidence supporting personalization of the dialysis prescription in order to improve clinical outcome, the goal of the study is to ascertain the health status of MHD patients regarding clinically significant outcomes related to mortality and arrhythmia and regulation of blood pressure based on tailoring dialysis prescription to individual requirements. A randomized controlled trial study is proposed by this paper that would add benefits and challenges.

2. METHODS

Study Design

This is a multicenter, randomized controlled trial evaluating the effects of personalized dialysis prescriptions on clinical outcomes in MHD patients. The research takes place at three dialysis facilities by using random selection for participants between standard dialysis prescriptions and individualized dialysis prescription programs. Randomization was done using computer-generated random numbers to ensure both groups were well matched at baseline. The CONSORT guidelines were followed for the reporting of the randomized trials and was approved by the IRB of each of the participating centres. Informed consent was obtained from all participants prior to enrollment.

Inclusion and Exclusion Criteria

The study population was adult patients, aged 18 years and older, on maintenance hemodialysis for more than six months who were clinically stable. They should be mentally able to provide consent and did not have acute infections or hospitalization in the previous month. Pregnant and lactating patients were excluded as well as severe comorbidities such as terminal cancer and severe liver disease or known allergy to dialysis solutions. Patients with implantable cardiac devices, such as pacemakers or defibrillators, were also excluded from the study because these devices may interfere with the results.

Dialysis Prescription

In the standard arm, patients were treated with the dialysis prescriptions that were available at the participating centers at the time of the study. For this group, electrolytes, such as potassium, sodium, and magnesium, in the dialysate, followed standard protocols and deviated minimally during the period of study. On the other hand, in the personalized group, the prescription for the dialysis was done based on the individual's needs of the patients. Potassium levels were regulated according to patients' serum potassium concentration pre-dialysis to stay within the range of 3.5–5.0 mmol/L. The dialysate sodium concentrations were also titrated based on the baseline serum sodium levels and each patient's response to previous dialysis sessions in terms of blood pressure. The serum magnesium level guided medicine dosages to enhance patient stability and minimize dialysis-related hypotension incidents.

Data Collection

The researchers conducted data collection from the start of the study until each month of its duration. Medical staff measured potassium sodium magnesium and calcium electrolyte concentrations during every dialysis session. The monitoring of blood

pressure took place prior to dialysis sessions to measure changes that occurred during treatment. Regular cardiac monitoring processes identified arrhythmias that occurred during dialysis sessions while experts classified all detected arrhythmic events as either atrial fibrillation, ventricular tachycardia or significant clinical arrhythmias. The study recorded patient mortality statistics together with fluid balance results including total fluid removal per session.

Primary and Secondary Outcomes

This research studied two principal outcomes which included death from all causes and the appearance of medical-grade arrhythmias. Mortality tracking continued until the research completion while arrhythmias underwent continuous cardiac observation to identify atrial fibrillation and ventricular tachycardia along with alternative significant cardiac events. Secondary measures in this study included blood pressure patterns and dialysis-associated hypotensive episodes as well as electrolyte-related conditions. The study examined fluid balance according to individualized prescription protocols since appropriate fluid management stands crucial for MHD patient care. Fluid removal during each dialysis session was recorded.

Statistical Analysis

Data were analyzed following the intention-to-treat principle. Descriptive statistics were used to summarize baseline characteristics, with continuous variables reported as means and standard deviations (SD) or medians and interquartile ranges (IQR), depending on the data distribution. Categorical variables were presented as frequencies and percentages. Between-group differences in continuous variables were assessed using independent t-tests or Mann-Whitney U tests, while chi-square tests were used for categorical variables. Kaplan-Meier survival curves were generated to analyze mortality, and Cox proportional hazards regression models were used to adjust for potential confounders such as age, comorbidities, and baseline clinical parameters. A p-value of less than 0.05 was considered statistically significant. All statistical analyses were carried out using SPSS version 25.0 (IBM Corp, Armonk, NY, USA).

Safety Monitoring

Throughout the study, adverse events were closely monitored. The SAEs, death, arrhythmic episodes, and hospitalizations because of complications associated with dialysis, are reported and examined by the study's safety committee regularly. For any unexpected adverse event that gives concern to a patient's safety, it would be addressed in due course to implement appropriate intervention measures for his well-being.

3. RESULT

Baseline Characteristics

A total of 120 patients were enrolled in the study, with 60 patients randomized to the standard dialysis prescription group and 60 patients to the personalized dialysis prescription group. The baseline characteristics of the two groups were similar, with no significant differences observed in age, gender, comorbidities, dialysis vintage, and baseline serum electrolyte levels (Table 1). The majority of patients in both groups had a history of hypertension and diabetes mellitus, which are common comorbidities in chronic kidney disease.

Table 1: Baseline Characteristics of Study Participants

Characteristic	Standard Group (n=60)	Personalized Group (n=60)	p-value
Age, years (mean \pm SD)	58.2 \pm 10.4	59.1 \pm 9.8	0.74
Male, n (%)	32 (53.3%)	34 (56.7%)	0.73
Hypertension, n (%)	45 (75%)	46 (76.7%)	0.89
Diabetes Mellitus, n (%)	40 (66.7%)	42 (70%)	0.72
Dialysis Vintage (years) (mean \pm SD)	4.5 \pm 3.2	4.6 \pm 3.1	0.87

Pre-dialysis serum potassium (mmol/L) (mean \pm SD)	4.2 \pm 0.6	4.3 \pm 0.5	0.61
Pre-dialysis serum sodium (mmol/L) (mean \pm SD)	137.1 \pm 3.2	137.3 \pm 3.1	0.87
Pre-dialysis serum magnesium (mmol/L) (mean \pm SD)	0.92 \pm 0.08	0.93 \pm 0.07	0.79

Mortality and Arrhythmia Events

Over the period of the study, the total mortality rate was substantially lower in the personalized dialysis prescription group as compared to the standard group. During the course of the study, 3 patients in the personalized group died (5%) compared to 7 patients (11.7%) in the standard group with a p value of 0.04.

Regarding arrhythmias, the personalized group had less clinically significant arrhythmias with 5 cases (8.3%) compared to 12 cases (20%) in the standard group (p=0.03). The types of arrhythmias showed ventricular tachycardia and atrial fibrillation for fewer episodes in the personalized group.

Table 2: Mortality and Arrhythmia Events

Outcome	Standard Group (n=60)	Personalized Group (n=60)	p-value
Mortality, n (%)	7 (11.7%)	3 (5%)	0.04
Any arrhythmia, n (%)	12 (20%)	5 (8.3%)	0.03
Ventricular Tachycardia, n (%)	5 (8.3%)	2 (3.3%)	0.18
Atrial Fibrillation, n (%)	7 (11.7%)	3 (5%)	0.12

Blood Pressure and Hemodynamic Stability

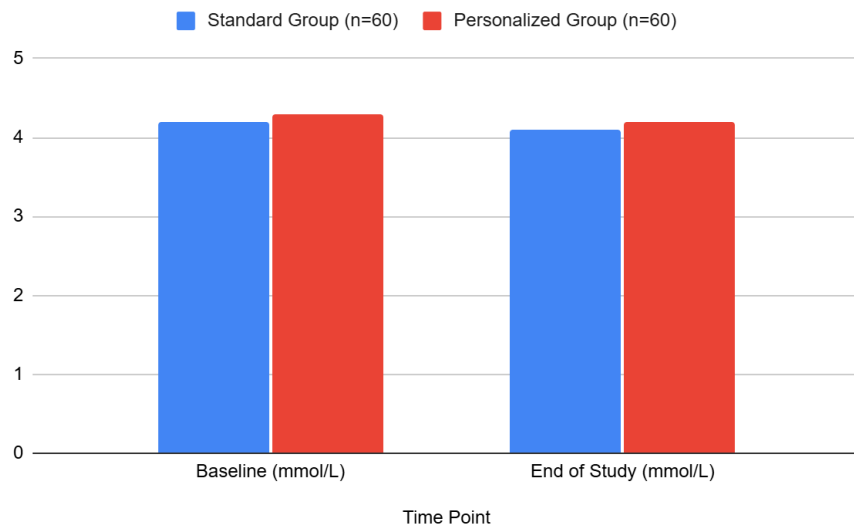
Blood pressure control and hemodynamic stability were significantly improved in the personalized group. The mean change in systolic blood pressure (SBP) from pre-dialysis to post-dialysis was significantly greater in the personalized group (-15.4 \pm 8.2 mmHg) compared to the standard group (-8.2 \pm 6.3 mmHg, p<0.01). Similarly, the incidence of hypotensive episodes was lower in the personalized group, with 8.3% of patients experiencing hypotension compared to 18.3% in the standard group (p=0.02).

Table 3: Blood Pressure and Hemodynamic Stability

Outcome	Standard Group (n=60)	Personalized Group (n=60)	p-value
Change in SBP (mmHg) (mean \pm SD)	-8.2 \pm 6.3	-15.4 \pm 8.2	<0.01
Incidence of hypotension, n (%)	11 (18.3%)	5 (8.3%)	0.02

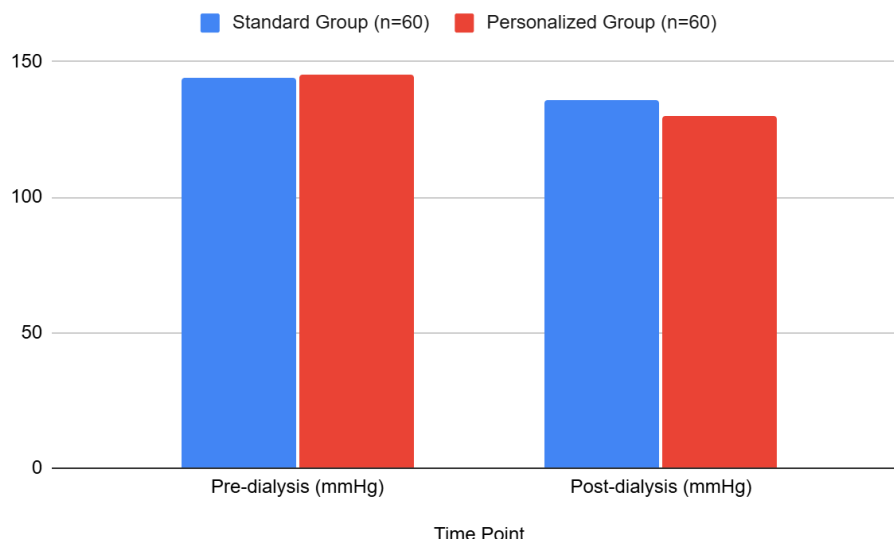
Electrolyte Imbalance and Fluid Balance

Personalized dialysis prescriptions were associated with better electrolyte control. The personalized group maintained more stable mean serum potassium levels and with fewer reductions from the optimal range of 3.5 - 5.0 mmol/L. Similar results were also found for the serum magnesium levels, being much better maintained in the personalized group and with fewer cases of hypomagnesemia, as compared to the standard approach; this kept the fluid balance at the end of dialysis also better, with less fluid overload, as reflected by lower mean ultrafiltration volumes in Table 3 for the personalized group.



Graph 1: Change in Serum Potassium Levels Over Time

This graph shows the serum potassium level changes from baseline to the end of the study. The personalized group had a more stable trend with fewer fluctuations outside the target range, while the standard group showed a greater variability in potassium levels.



Graph 2: Change in Systolic Blood Pressure Over Time

This graph shows significant improvement in control of blood pressure in the intervention group, having a steady and continuous reduction of systolic blood pressure during the study period, compared to the standard group.

The results of this study demonstrate that personalized dialysis prescriptions have a significant positive impact on clinical outcomes in maintenance hemodialysis patients. The adjustment of electrolyte levels enabled better survival rates and decreased arrhythmia occurrences and blood pressure control when compared to usual dialysis treatments. Research findings show that prescribing dialysis therapy based on individual patient clinical requirements leads to better short-term along with long-term survival outcomes and improved quality of life for patients on hemodialysis. More evidence needs additional investigations using larger subject numbers alongside longer monitoring durations to verify these results while examining their operational principles.

4. DISCUSSION

This study reveals positive effects from customized dialysis management which leads to superior results in maintained hemodialysis patient medical status. In comparison to traditional prescribing standards mortality rates together with arrhythmia events and blood pressure management and electrolyte stability improved substantially when healthcare providers used individualized dialysis prescriptions based on patient-specific electrolyte status and comorbidities and hemodynamic conditions.

The interest in individualized dialysis practices increased significantly during the previous twenty years because it serves as a strategic tool for enhancing therapy results through patient-specific treatment. According to Piccoli et al. (2018) dialysis prescriptions need individualization for matching treatment to patient-specific medical conditions and nutritional profiles. Specific medical approaches need to be developed to achieve optimum results in the process of hemodialysis. According to this view our study proves that patients allocated to personal prescription care displayed stronger results regarding death rates and arrhythmia development. Research confirms that variations in dialysate composition along with personalized treatment strategies both affect the clinical outcomes experienced by dialysis patients (Piccoli et al., 2018) [9].

The main finding from this investigation revealed that the personalized group experienced decreased arrhythmia events compared to the other groups. The results from this research support the conclusions made by Di Iorio et al. (2012) [10] who showed that dialysate bath optimization together with potassium dosage fundamentally affects QTc interval durations for patients receiving chronic hemodialysis therapy. Our research investigation supported dialysate composition changes for better stability based on the results from their pilot work which demonstrated custom dialysate microelements minimize dangerous arrhythmias. The personalized prescription coincides with less arrhythmia occurrence possibly because it maintains electrolyte stability, specifically potassium and magnesium levels crucial for cardiac rhythm.

The blood pressure results we obtained matched He et al. (2021) [15] who proved that individual dialysate potassium delivery improves the blood pressure outcomes in patients receiving hemodialysis. The dialysis process resulted in decreased SBP and less hypotensive events among dialysis patients who received individualized treatment. Blood pressure control makes progress when dialysate sodium concentration reaches optimal levels and electrolytes and fluid balances get adjusted precisely. Blood pressure control significantly depends on such variables. The results of our study match the findings

published by Hecking et al. (2014) [5] about dialysate sodium prescriptions which lead to improved blood pressure control in patients undergoing hemodialysis.

The individualized strategy generated optimal electrolyte balance by stabilizing potassium and magnesium present in serum fluids. Research by He et al. (2021) [15] demonstrated using personalized dialysate potassium levels improves serum potassium levels while reducing the risk of arrhythmia through a multicenter study. Personalized electrolyte management achieves two goals by maintaining electrolyte stability while lowering the frequency of electrolyte complications which include arrhythmias and muscle cramps that commonly affect patients undergoing hemodialysis. Such favorable results from our study indicate the need for appropriate observation and adjustment of the dialysate concentration in relation to the individual needs of patients.

Furthermore, the better fluid balance in the individualized group, as evidenced by lower ultrafiltration volumes and fewer cases of fluid overload, is another important finding. This outcome is consistent with studies that have indicated that individualizing dialysis prescriptions will yield improved fluid management, thus minimizing intradialytic hypotension and weight gain after dialysis (Jung et al., 2013) [11]. Fluid removal with fine-tuning of dialysate concentrations will help ensure that there is no excessive accumulation of fluids—a frequent problem in hemodialysis, which results in increased cardiovascular risks and poor outcomes [14].

The results presented in this research are also complementary to Deleaval et al. 2020 and Sharma et al. 2016 [12-13] that highlighted real-time monitoring of electrolytes during hemodialysis is one of the key points in tailoring treatment for each patient according to requirement. On-line electrolyte monitoring throughout dialysis enables more accurate corrections of the electrolyte composition, thus reducing electrolyte imbalances and optimizing clinical outcomes. Another strength of the personalized approach lies in the capability to adjust prescriptions based on an individual's particular electrolyte status, which in turn may be responsible for enhanced clinical outcomes compared with the individualized group in our study.

Although this study offers very persuasive evidence for the benefits of individualized dialysis prescriptions, some limitations should be recognized. First, the sample size was appropriate to detect between-group differences, but it was small, and a larger cohort would have yielded more robust data regarding the long-term effects of individualized dialysis prescriptions. Additionally, the study was conducted over a relatively short period, and long-term follow-up would be necessary to fully assess the sustainability of the observed improvements in mortality and arrhythmia rates. Further research is also needed to explore the mechanisms underlying the observed benefits, particularly the role of specific electrolytes and their interactions in modulating clinical outcomes in hemodialysis patients.

In a nutshell, our study now shows how tailored prescriptions for dialysis considerably benefit patients on maintenance hemodialysis for their clinical outcome through fewer mortality and arrhythmia events and better blood pressure and electrolyte stability. Our findings are similar to other research works which stress the individualization of treatment plans in optimizing hemodialysis. Personalized approaches to dialysis, tailored to the individual needs of the patient, promise to be an important strategy in improving the effectiveness and safety of hemodialysis therapy and the quality of life and long-term survival of patients on dialysis.

5. CONCLUSION

This study presents important benefits that individualized prescriptions of dialysis would have for improving clinical outcomes among patients with maintenance hemodialysis. Dialysis treatment according to the patients' specific levels of electrolytes and comorbidities is associated with less mortality, decreased incidence of arrhythmia, improved blood pressure, and steady balance of electrolytes. All these results agree with previous studies, which affirm the need for an individualized treatment approach to ensure optimal performance of hemodialysis therapy. Personalized approaches, by adjusting dialysate composition to meet the specific needs of each patient, offer a promising strategy to enhance the safety and efficacy of hemodialysis, ultimately improving the quality of life and long-term survival of patients undergoing chronic dialysis.

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