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The Beauty of Individualize Peritoneal Dialysis Prescription by Using Incremental Peritoneal Dialysis during Ramadan Fasting

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Abstract

Fasting, which mandates abstinence from food and water from dawn to sunset, can sometimes be challenging for patients, particularly in countries with a high-temperature climate. Several Muslim patients with ESRD are maintained on peritoneal dialysis worldwide, with the vast majority of them wishing to fast during the month of Ramadan. Although such patients are not obliged to fast from the religious point of view, they still wish to fast to fulfill their spiritual needs and social pressure despite the advice of contrary, and here comes Shared decision -making as a cornerstone of a patient-centered approach, based on patient preferences, values, and benefits versus harms of different treatment modalities. Data in this matter is scarce, with a considerable gap in the literature. The aim of this prospective cohort study to evaluate the safety and outcomes of Ramadan fasting by using incremental automated peritoneal dialysis (APD) and compare it to full-dose APD in a single PD center. The study included 56 adult PD patients who fasted for 30 days between April 12th and May 12th, 2021. The primary outcomes were hospitalization rate, all-cause mortality, and reduction of residual renal function, whereas the secondary outcomes included other important variables such as fluctuation in dry weight, episodes of hypoglycemia and hyperglycemia, hyperkalemia, serum albumin, peritonitis, and exit site infection.

Results: There were only significant differences in Serum albumin (95% CI -0.337, -0.081; p 0.002) and CO2 (95% CI 0.88, 2.84; p 0.001) before and after Ramadan fasting. The body weight after Fasting Ramadan (79.31±14.88) was lower than the body weight before Fasting Ramadan (80.78±15.23), but it was not statistically significant (p 0.090). The average daily urine output (an estimate of residual renal function) was 1044.3 ± 764 mL before Ramadan and 1155 ± 797.1 mL after 4 weeks of fasting. The average weight gain was 1.67 ± 1.347 kg. The total weekly Kt/V was 2.3228 ± 0.80160 initially and 2.3033 ± 0.83 after Ramadan fasting.

Conclusion: By using incremental PD in a selected group of patients with end stage renal failure in peritoneal dialysis who had a good residual renal function and stable clinical condition, Ramadan fasting can be safe and beneficial, providing that patient strictly adhere to diet, medications, and dialysis prescription.

Keywords: ESRD; Peritoneal Dialysis; Fasting; Ramadan; Peritonitis; Renal Residual Function.

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Introduction

Muslims are considered the second-largest religious group with a population of 1.907 billion (24.9%) after Christianity, with a population of 2.382 billion (31.11%). Islam is based on tenets that are known as 5 pillars to, which all Muslims should adhere to & fasting is considered the 4th pillar, which state that all adult Muslims who are physically and mentally well should fast from dawn to dusk (daylight hours varies from continent to another with roughly range from 10-21 hrs at most) and refrain from eating and drinking except for elderly, sick, and special conditions in pregnancy. But even with this merciful exemption, some people with background medical conditions still insist on fasting due to what the holy month of Ramadan carries in Muslims hearts from the spiritual, religious, and social aspects, and fasting the holy months will undoubtedly reinforce the sense of equality and limit of their isolation within their families and community and enhances their overall wellbeing [1-3].

The word fasting does not carry a religious essence; only it's a way of living since the concept of Intermittent fasting has gained a lot of popularity in recent years, with many health care providers advocating for it [4]. Ramadan fasting is a religious obligation for Muslims. In contrast, intermittent fasting is a lifestyle choice for non-Muslims, but both concepts are almost the same in terms of caloric deprivation during certain hours of the day. Still, slight differences lie in the duration of intermittent fasting that can extend for months while Ramadan fasting is obligated once a year for one lunar month, and the accessibility to calories-free drinks and beverages in intermittent faster [3,4,5].

The most dreadful complications in this context are fluid overload, dehydration, electrolyte imbalance, hypo, and hyperglycaemia, and the negative effect on residual renal function all these fears had been addressed in several previous studies [6-8]. There is no consensus in the literature about Ramadan fasting for patients with chronic renal failure CRF. Various guidelines have been published which clearly stated that prior to the holy month of Ramadan, patients need to stratify according to their risk of potential adverse events and clearly stated that patients with stage III -V CRF are considered at high risk for adverse events and not allowed to fast [6,7]. Most published studies address patients pre-dialysis or hemodialysis, and only one study addresses peritoneal dialysis patients [1]. Mogahed et al. conducted a multi-center observational study on the Status of fasting Ramadan in chronic hemodialysis patients all over Egypt and found 47% of the patients can fast without significant adverse events [11]. All trustworthy Islamic references came into an agreement that the presence of glucose in PD fluid invalidate Muslim fasting [5], and to achieve a result that does not contradict these rules and considerations for patients who insisted on fasting despite the advice of contrary, a shared decision -making has been adopted as a cornerstone of patient-centered approach which is a process of an agreement between health care providers and patients based on patient preferences, values, and benefits versus harms of different treatment modalities [14]. It also allows physicians to learn more about patients' values, goals, and preferences and, at the same time, it also give the patients a chance to learn more about their the consequences of available therapies [14-15]. And this in turn help us to provide a high quality of patient-centered care that is respect patients desire, value, ensuring that patient values guide all clinical decisions. We have engaged all patients, their families, and their caregivers in shared decision -making prior to starting of Ramadan. We proportionally adjusted their treatment strategies to address what matters most in terms of their diets, fluid intakes, and PD prescription according to everyone by using incremental PD during the holy month of Ramadan. Incremental PD can be tolerated in 50% of PD patients at any point in time particularly, patients with preserved residual renal function [16]. It has myriad of potential advantages such as less burden to patient, family, and caregiver, allows more free time to join social and religious activities during the holy month of Ramadan, which matters most to Muslims during Ramadan [16-18].

This prospective observational cohort study addressing safety and the clinical outcomes pre and post Ramadan fasting in ESRD peritoneal dialysis patients by comparing the full dose of APD prescription to incremental PD prescription on hospitalization, all-cause mortality, and reduction of residual renal function, whereas the secondary outcomes included the rest of the other important variables such as fluctuation in dry weight, fluid overload, dehydration, episodes of hypo and hyperglycaemia, Hyperkalemia, serum albumin, peritonitis, and exit site infection.

Methodology

This study is a prospective cohort study of 56 ESRD patients on peritoneal dialysis, conducted between April 12th and May 12th, 2021, in the peritoneal dialysis unit at King Fahad hospital of the University of Imam Abdulrahman bin Faisal in Saudi Arabia. The unit is one of the biggest units of peritoneal dialysis in the Kingdom of Saudi Arabia and a leading PD center in the eastern province that provide peritoneal dialysis services to many ESRD patients. All participants were end-stage renal disease patients aged 18 years or older who are maintained on regular APD by (Claria, Baxter Machines), with full dialysis prescription 10 litre APD over 9 hours each fill vary from 2-3 litre and last fill icodextrin 2 litre as needed and had a good urine output and clinically stable who insisted on fasting during the holy month of Ramadan, and after thorough clinical and laboratory evaluation, all patients started on incremental PD 8 liter over 6 hours each fill 2-3 litre and last fill 1-2 litre of icodextrin as needed daily. The participating patients fasted for 30 days,

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and the average fasting hours were about 14 hours, with an average temperature of 38 to 40 degrees Celsius. All the participants in this study had been provided with written and informed consent for participation in the study according to the declaration of Helsinki and the ethical committee of the Institutional Review Board at King Fahd hospital of university. The Exclusions criteria are patients with active peritonitis, coronary artery disease with severe heart failure, frequent episodes of pulmonary edema that require frequent changes of PD prescriptions, chronic liver disease, frequent episodes of hypo and hyperglycemia, malignancy, and frail patients.

The patients enrolled in the study were clearly instructed about the fluid intake not to exceed more than 1 liter daily, to avoid food and drinks rich in potassium, and regular monitoring of Blood pressure at home and random blood glucose three to four-time during fasting in diabetic patients as well as seeking medical help and breakfasting when feeling unwell. They were informed and explained about symptoms of hypotension like dizziness and weakness, Symptoms of hypoglycemia such as palpitation and excessive sweating, symptoms of overload like Lower limb edema, dyspnea or orthopnea, and uremic symptoms such as loss of appetite, lethargy, nausea, vomiting, and abdominal pain as well as symptoms and signs of peritonitis. Every participating patient was evaluated by a dietician before fasting, and each patient was given a dietary plan according to their nutritional status. All medications were taken and divided between dusk to dawn.

Data collection:

Demographic and clinical characteristics had been collected from the patients and their medical records and the PD unit database registry. These included age, gender, number of years on Peritoneal dialysis, PD prescriptions, diabetic status, hypertension status, weight before and after fasting the holy month. The biochemical parameters included serum levels of Sodium, potassium, phosphorus, albumin, calcium, blood urea nitrogen (BUN), creatinine, hemoglobin, FBS, HbA1C, Lipid profile, Uric acid, Urine output, Kt/V, CRP, and ESR. The biochemical serum samples were collected one month before Ramadan fasting and at the end of Ramadan. All biochemical parameters were collected before the start of the peritoneal dialysis. All blood samples were sent to the laboratory for analysis immediately after collection and were analyzed on the same day. The primary outcomes were the residual renal function, rate of hospitalization, and all-cause mortality, and the secondary outcomes were the rate of Peritonitis, Exit site infection, symptoms of hypoglycemia, hypotension, and dehydration

Statistical analysis

The biochemical and demographic characteristics of the participants were summarized using descriptive statistics. Means with standard deviation (SD) were used to summarize continuous variables and frequencies. The percentages were used for the categorical variables. The t-test was utilized to examine the statistically significant differences between the biochemical parameters before and after Ramadan fasting. P-value less than 0.05 is considered to be statistically significant, and all analyses were conducted using the SPSS computer software version 26.0 (IBM Corp).

Results

Fifty-six ESRD fasting patients on APD during the month of Ramadan have completed the study by fasting for thirty days. All patients had completed the study without changing their original PD prescription before and after Ramadan fasting. The mean age of participants was 60.48 years (SD = 14.26), and 27 patients (48.2 %) were males. About 66.1% (n = 37) and 78.6 % (n = 44) had diabetes and hypertension, respectively. The mean duration on peritoneal dialysis was 4.82 years (SD = 3.96), 17 patients (30.4 %) were on PD prescription glucose 2.27% alternating with 1.36% while the rest were only on glucose 2.27% 10 liters. The baseline demographic and clinical characteristics of patients are summarized in table 1, and the outcomes of Ramadan fasting on the biochemical parameters are shown in table 2. Among the fasting patients, 2 were admitted after fasting of Ramadan because of peritonitis, 1 patient developed cerebrovascular stroke. None of the patients experienced any symptoms of hypotension, hypoglycemia, abdominal pain, fever, or uremic symptoms during the month of Ramadan. After adjusting for diabetes and hypertension status and other statistically significant demographic variables, there were only significant changes in serum albumin (95% CI -0.337, -0.081; p 0.002) and HCO3 (95% CI 0.88, 2.84; p 0.001) before and after Ramadan fasting. The body weight after fasting Ramadan

Table 1: Baseline demographic and biomedical characteristics of PD patients

Variable	Mean± SD
Age (mean + SD)	60.48±14.26
Gender	
Female (n, %)	29 (51.8%)
Male (n, %)	27 (48.2%)
Duration on PD (mean + SD)	4.82±3.96
Diabetes Mellitus status	
No (n, %)	19 (33.9%)
Yes (n, %)	37 (66.1%)
Hypertension status	
No (n, %)	12 (21.4%)
Yes (n, %)	44 (78.6%)

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(79.31±14.88) was lower than the bodyweight before Fasting Ramadan (80.78±15.23), but it was not statistically significant (p 0.090). The average daily urine output (an estimate of residual renal function) was 1044.3 ± 764 mL before Ramadan and 1155 ± 797.1 mL after 4 weeks of fasting. The average weight gain was 1.67 ± 1.347 kg. The total weekly Kt/V was 2.3228 ± 0.80160 initially and 2.3033 ± 0.83after Fasting Ramadan. None of those differences was statistically significant. There were no statistically significant differences before and after Fasting Ramadan regarding the rest of the other biochemical parameters.

Discussion

The safety and outcome of fasting Ramadan during different seasons have been addressed in multiple studies of which an article from Saudi Arabia confirmed the safety of fasting of renal transplant patients in milder weather months, but the concern had been raised toward the outcome of fasting in the warmer months [8] since lunar months starts with astronomical moon each month, so Islamic calendar is not corresponding with the Georgian calendar in means that Ramadan occurs around 11 days earlier every year thereby changing seasons every few years. This concern was

Table 2: Comparison between different variable before and after Ramadan fasting

Variable	Pre	Post	P Value
BW, Kg (mean ± SD)	80.79 ± 15.23	79.32 ± 14.89	> 0.05
Hgb, gm/dl (mean ± SD)	11.05 ± 1.23	11.06 ± 1.45	> 0.05
BUN, mg/dl (mean ± SD)	48.46 ± 13.47	50.20 ± 17.31	> 0.05
Serum Cr, mg/dl (mean ± SD)	7.99 ± 7.48	7.54 ± 6.18	> 0.05
Serum Na, mEq/L (mean ± SD)	137.23 ± 3.53	137.0 ± 3.25	> 0.05
Serum K, mEq/L (mean ± SD)	4.40 ± 0.57	4.39 + 0.71	> 0.05
Serum HCO3, mEq/L (mean ± SD)	26.31 ± 4.39	24.45 ± 5.10	0.001
Serum Calcium, mg/dl (mean ± SD)	8.14 ± 0.66	8.15 ± 0.88	> 0.05
Serum P, mg/dl (mean ± SD)	5.11 ± 1.37	4.84 ± 1.37	> 0.05
Serum albumin, gm/dl (mean ± SD)	3.03 ± 0.66	3.24 ± 0.68	0.002
FBS, mg/dl (mean ± SD)	151.16 ± 68.20	140.94 ± 63.09	> 0.05
Hgb A1-C, % (mean ± SD)	7.95 ± 3.48	7.59 ± 2.91	> 0.05
Serum Cholesterol, mg/dl (mean ± SD)	172.06 ± 34.47	170.78 ± 38.39	> 0.05
LDL	96.21 ± 26.70	97.62 ± 36.04	
HDL	42.03 ± 16.64	39.98 ± 13.40	
Triglycerides, mg/dl (mean ± SD)	177.28 ± 82.86	177.38 ± 90.08	> 0.05
Serum uric acid, mg/dl (mean ± SD)	6.15 ± 0.96	6.37 ± 1.44	> 0.05
Vitamin D level, ng/ml (mean ± SD)	11.78 ± 5.16	13.75 ± 8.96	> 0.05
PTH, pg/ml (mean ± SD)	70.97 ± 38.65	72.84 ± 48.87	> 0.05
CRP, mg/L (mean ± SD)	1.38 ± 1.57	1.07 ± 1.10	> 0.05
ESR, mm/hr (mean ± SD)	67.84 ± 29.35	62.29 ± 26.36	> 0.05
Urine volume, ml/24h (mean ± SD)	1044.39 ± 764.05	1155.0 ± 797.17	> 0.05
Kt/V (mean ± SD)	2.32 ± 0.80	2.30 ± 0.83	> 0.05
CrCl, ml/minute (mean ± SD)	10.42 ± 12.58	10.30 ± 14.08	> 0.05

BW: body weight, Hgb: hemoglobin, BUN: blood urea nitrogen, Cr: creatinine, Na: sodium, K: potassium, HCO3: bicarbonate, P: phosphorous, FBS: fasting blood sugar, PTH: parathormone, CRP: C reactive protein, ESR: erythrocyte sedimentation rate, CrCl: creatinine clearance

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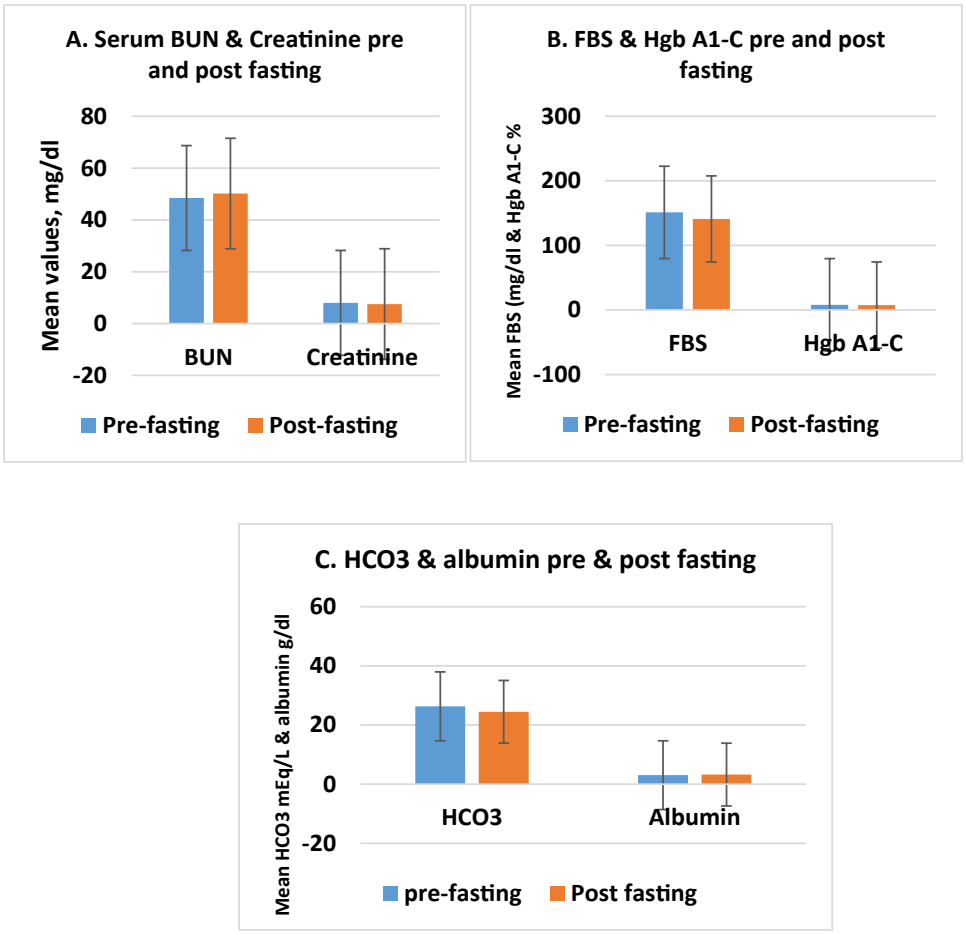

Figure1: Pre and post fasting of some variables: A ($p > o.05$), B ($p > 0.05$), C ($p = 0.001$ & $p = 0.002$ respectively).

confirmed by means of worsening renal function in CKD when fasting in Ramadan in the summer months [9]. Dogan et al. reported that there is no significant harm to the kidney while fasting evident by a non-significant reduction in GFR & rise in Creatine provided a careful selection of fasting patients [10] The safety of fasting Ramadan was supported in the CKD population in different studies [11.12.13] and hemodialysis patients with proven tolerability may have no potential clinical complications [11]. There is inconsistency in the literature about Ramadan fasting for a patient with ESRD on PD. Various guidelines have been published which clearly stated that prior to the holy month of Ramadan, patients need to stratified according to their risk of potential adverse events during Ramadan and indicated that patients with stage III -V chronic renal failure are considered at high risk and not allowed to fast [6,7]. Most published studies address patient pre-dialysis or hemodialysis. Only one study addresses peritoneal dialysis patients, which concluded that stable PD patients could fast during the holy month of Ramadan, providing that they strictly adhered to their medication and dialysis prescriptions in addition to their dietary restrictions [1].

Since the inception of incremental PD in 1990 as it was referred to as strategy of starting PD with prescription less than the full dose of usual PD prescription in a stable patient with good residual renal function and the combination of renal and peritoneal dialysis to achieve the desired target of dialysis adequacy [16], it needs frequent assessment as the dialysis prescription will be gradually increased if residual renal function deteriorates [17]. Incremental PD can be afforded to 50% of the PD population at any point in time particularly, in patients with preserved residual renal function [18]. It has myriad of potential advantages such as less burden to patient, family, and caregiver, allows more free time to join social and religious activities during the holy month of Ramadan which matters most to Muslim people during Ramadan, it may require less PD solution and cost, it may lead to slower loss of residual renal function[16-18]. Incremental PD is a person-centered approach that individualizes PD prescription leading to less workload and dialysis-related complications [16-17]. There is no consensus in the literature about the full dose of APD prescription, but it is usually defined as 8 litre over 9 hour during night and 2 litre day dwell [18]. Recently, ample evidence suggests a clear, consistent association

between better preservation of residual renal function and survival in the peritoneal dialysis population [19-20]. Still, no substantial body of evidence indicating that the full dose of PD prescription in patients with preserved residual renal function had a survival benefit compared to the incremental dialysis approach. So all PD patients with good urine output and clinically stable who desired to fast during the holy month of Ramadan after thorough clinical and laboratory evaluation were started on incremental PD 8 litre over 6 hours each fill 2-3 litre and last fill 1-2 litre of icodextrin as needed daily. There were no significant statistical differences between full dose PD and incremental PD pre and post-Ramadan fasting. Blood sugar monitoring and fluctuation is of great concern during the holy month due to the nature of dietary habits adopted by all Muslim communities, particularly in this month, which is dependent on traditional sweats, a ritual adapted since the ottoman and Mamluk era. Alawadi et al. reported that diabetic (CKD-3) fasting with proper monitoring wasn't associated with worsening HBA1c and renal function, but they had significantly more frequent and prolonged hypoglycaemic episodes during Ramadan [21]. Another study contradicts this result where they found that the blood sugar was high during fasting with an increment in the Hb A1c [22]. The beneficial effects of fasting Ramadan in terms of weight reduction, better blood pressure control, improvement in GFR, and better lipid profile (CKD) between stages 3-5 have been observed, not only in CKD patients but in hemodialysis patients where they observed in one study by Adanan NH, Significant improvement in serum phosphate levels, serum albumin, urea, creatinine [23]. Reduction in pre-and post-dialysis weight and the amount of ultrafiltration during Ramadan fasting [24].

On the contrary, some other articles found that fasting increases AKI incidence [25]. Mbarki et al. found that AKI was significantly higher for patients with baseline creatinine clearance of <60 mL/min/1.73 m 2 [26]. The renal tubular injury was significantly higher in the CKD patients than in the control group [25]. while Alshamsi et al. compared dialysis fasting and none fasting the only significant difference observed higher phosphorus in the fasting group for which he blames the younger age of fasting group and more likely to be working and to miss dialysis sessions [27].

The mortality and major cardiovascular events during Ramadhan had been addressed in limited studies, Imtiazet al; found that death rates in dialysis patients were higher in Ramadan than in all twelve Islamic months, but fasting status is not definite among this death, so death related to fasting and its complications is not sure [28]. Furthermore, Alwakeel et al. reported Fourteen-hour fasting for one month was tolerated by CKD and hemodialysis patients, with no serious adverse events occurring, and the only determinant of major adverse cardiovascular events occurring among fasting CKD patients was a pre-existing cardiovascular disease which again reinforces careful selection of fasting for CRF population [29]. This study evaluated the safety and outcomes of fasting in automated peritoneal dialysis patients who fasted for one month during the holy month of Ramadan 2021. The study showed that the mortality rate during fasting among the cohort of patients was zero, the hospitalization rate was 3.5 %, and there was no loss of residual renal function. In terms of the secondary outcomes, there were no statistically significant differences between almost all the studied parameters (table 2). Two patients were admitted with peritonitis which is not necessarily related to fasting, and one patient was admitted with a cerebrovascular stroke. The limitation of the current study was a single-center experience with a limited number of patients and short follow-up; therefore, the results cannot be generalized to the entire peritoneal dialysis population. Geographical variations may also play an essential role because fasting duration varies between geographical locations. However, to the best of our knowledge, the present study is the first one that is designed to assess the role of incremental APD during Ramadan fasting in clinically stable patients with good residual renal function and compare it to full dose of PD prescription prior to the month of Ramadan

Conclusion

By using incremental PD in a selected group of patients with end-stage renal failure in peritoneal dialysis who had a good residual renal function and stable clinical condition, Ramadan fasting can be safe and beneficial, providing that patient strictly adhere to diet, medications, and dialysis prescription. The favorable outcomes are due to proper education, counseling, shared decision making, prior selection and regular follow-up during and after fasting. Further studies are needed to assess the role of incremental PD during Ramadan fasting.

Declarations

Ethics approval and consent to participate and to publish:

After obtaining study-related approvals from the Ethics committee of King Fahd Hospital of the University, written informed consents to participate in and to publish the study was also obtained from all patients or their legal guardians.

Study protocols conformed to the ethical principles of medical research involving human subjects based on the Helsinki Declaration.

The authors also declare their consent to publication of this manuscript in "BMC Nephrology"

Availability of data and materials:

All data and materials are presented in detail within the manuscript.

Declaration of conflicting (competing) interests

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Alhwiesh AK, et al., Arch Nephrol Urol 2024
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