Original Paper

Effect of the Chronic Kidney Disease—Peritoneal Dialysis (CKD-PD) App on Improvement of Overhydration Treatment in Patients on Peritoneal Dialysis: Randomized Controlled Trial

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Abstract

Background: Overhydration is associated with increased morbidity and mortality in patients on peritoneal dialysis (PD). Early detection of overhydration is possible by monitoring hydration metrics, but the critical gap for treatment is obtaining timely and actionable data.

Objective: This study compares the detection of overhydration and clinical outcomes in patients on PD using the Chronic Kidney Disease—Peritoneal Dialysis (CKD-PD) smartphone app with standard monitoring and management.

Methods: An open-label randomized controlled trial was conducted at 3 hospitals in northeast Thailand. Enrolled participants from PD clinics were randomized into 2 equal groups: CKD-PD (App users) and usual management (No-App). Participants or their caregivers in the App group recorded hydration metrics in the CKD-PD app, which were uploaded to a central database monitored by nephrology staff. The No-App group used a handwritten logbook. Both groups had bimonthly clinic visits. The primary outcome was the incidence rate ratio (IRR) for clinical interventions for overhydration. Secondary outcomes included hospitalizations, technique failure, and death.

Results: A total of 208 participants were randomized into App (N=103) and No-App (N=105) groups with the median follow-up time of 11.2 months. Hydration metric upload compliance in the App group was 85.7% (IQR 71.4-95.6). The IRR of overall interventions for overhydration was 2.51 times higher in the App group (95% CI 2.18-2.89; *P*<.001). Types of clinical interventions for overhydration differed between groups with dietary change and prescription of antihypertensive drugs more frequent in App users and diuretics and change of dialysis prescription more frequent in the No-App group. Hospitalizations were significantly higher in the No-App group due to any cause (adjusted IRR 1.58) and volume overload (adjusted IRR 4.07). There was no significant difference in survival analysis and technique failure between the 2 groups.

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Conclusions: Use of the CKD-PD app improved early detection of overhydration and early treatment interventions, resulting in fewer all-cause and volume overload hospitalizations.

Trial Registration: ClinicalTrials.gov NCT04797195; https://clinicaltrials.gov/study/NCT04797195

(J Med Internet Res 2025;27:e70641) doi: 10.2196/70641

KEYWORDS

overhydration; peritoneal dialysis; smartphone app; mobile health; chronic kidney disease; hospitalization

Introduction

The global prevalence of chronic kidney disease (CKD) is 11%-13% [1] and increasing in low and middle-income countries paralleling the rising rates of diabetes and hypertension and lack of access to early CKD treatment [2-4]. The use of peritoneal dialysis (PD), a modality of home renal replacement therapy for patients with kidney failure (KF), is growing to meet this demand, especially in Asian countries with limited resources [5-7]. In 2008, Thailand adopted a "PD first" policy to offer this benefit in its Universal Health Coverage Scheme [8], resulting in an 11.3-fold increase in patients on PD from 2168 to 24,439 cases from 2008 to 2022 [9].

Overhydration (OH) is one of the most common complications in patients on PD. Clinical manifestations of OH include peripheral edema, dyspnea, and hypertension [10]. It is estimated that 50%-60% of patients on PD are overhydrated, with severe OH producing clinical symptoms in 25% [11,12]. OH is associated with increased morbidity and mortality due to infections, including peritonitis [13], and major adverse cardiovascular events such as myocardial infarction, pulmonary edema, stroke, and hypertensive crisis [10]. OH alone, independent of coexisting cardiovascular pathologies, is a risk factor for increased morbidity and mortality [14]. Early detection of OH is possible by monitoring patients' hydration metrics. In northeast Thailand, nephrologists and PD nurses routinely assess hydration status of patients on PD by reviewing hydration metrics—blood pressure (BP), body weight (BW), and ultrafiltration (UF) volume collected and recorded by patients in a handwritten logbook during scheduled bimonthly clinic visits. The critical gap for the treatment of OH lies in obtaining these hydration metrics in a timely and actionable format when early interventions can be made to improve quality of life, decrease health care costs, and reduce morbidity and mortality [15].

Our multidisciplinary team developed a smartphone app ("Chronic Kidney Disease—Peritoneal Dialysis" [CKD-PD] app) for Thai patients on PD [16]. Hydration metrics are recorded in the CKD-PD app and uploaded to a central health database merging patient-collected data with hospital and clinic records [17]. The objective of this study was to compare the detection of OH and clinical outcomes in patients on PD using the CKD-PD app with the standard monitoring and management of patients on PD.

Methods

Study Design and Participants

This study was an open-label randomized controlled trial (RCT) conducted between December 2021 and February 2023 at the three hospitals in northeast Thailand: (1) Srinagarind Hospital (academic tertiary), (2) Khon Kaen Hospital (urban provincial), and (3) Chaiyaphum Hospital (rural provincial). Patients with KF currently on PD at clinics of these hospitals were enrolled using the inclusion criteria: willingness to participate, aged 18 years and older, access to a smartphone, and the ability to use the CKD-PD app (independently or with a surrogate). Randomization codes for the 2 groups were generated by the statistician using computer software. Block randomization with varying block sizes of 2 and 4 was used to ensure allocation concealment and balance between the arms. The randomization sequence was created using a random number generator and was implemented without stratification. The allocation sequence was concealed from study personnel and participants until assignment when research nurses enrolled and allocated participants. After writing informed consent, all participants were randomized by software (Sealed Envelope Ltd, 2024. Create a Blocked Randomization List [available online]) into 2 equal groups at each hospital, 1 using the CKD-PD app ("App" group) and 1 receiving usual management ("No-App" group). A CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth; version 1.6.1) checklist was completed (Multimedia Appendix 1).

Ethical Considerations

The study protocol was approved by the Khon Kaen University ethics committee for human research (HE 621494) in accordance with the ethical principles of the Declaration of Helsinki, the Good Clinical Practice guidelines. It was registered in the Clinical Trials Registry (ClinicalTrials.gov ID#NCT04797195 with the first postdate March 15, 2021) prior to patient enrollment. Ethics approval was obtained from the Massachusetts General Brigham institutional review board (protocol 2019P002648). All participants were informed that their participation is voluntary, and they could drop out of the study at any time without impact on their treatment. The original informed consent allows the secondary data analysis without additional consent. Signed copies of the informed consent were stored with study records, and a copy was given to the participants. All study data were securely stored in password-protected computers and participant information was deidentified by using a unique identification code. Participants were provided with home hydration metric–monitoring

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