DETECT-PD -- Dialysis Efficiency and Transporter Evaluation Computational Tool in Peritoneal Dialysis

To develop and investigate possibility and performance of artificial intelligence in predicting peritoneum transporter status and dialysis efficiency

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Glossary of Abbreviations

PD Peritoneal Dialysis

ESKD End-Stage Kidney Disease

PET Peritoneal Equilibration Test

AI Artificial Intelligence

TMH Tuen Mun Hospital

RRT Renal Replacement Therapy

Keywords

Peritoneal dialysis

Artificial intelligence

Dialysis adequacy

Peritoneum transporter status

Renal replacement therapy

Study Summary

TITLE DETECT-PD -- Dialysis Efficiency and Transporter Evaluation Computational Tool in Peritoneal Dialysis

DESIGN Prospective and diagnostic test (correlation) study

AIMS To develop and investigate possibility and performance of artificial intelligence in predicting peritoneum transporter status and dialysis efficiency

OUTCOME MEASURES Peritoneum transporter status measured with peritoneum equilibrium test and dialysis adequacy measured as Kt/V

POPULATION Patients treated with peritoneal dialysis

ELIGIBILITY All adult patients both incident and prevalent to peritoneal dialysis

DURATION Twelve months following study enrolment

Introduction

Background

Peritoneal dialysis (PD) is a widely utilized renal replacement therapy (RRT) for patients with end-stage kidney disease (ESKD), accounting for approximately 9% of such therapies worldwide(1). PD offers several advantages over hemodialysis, including lower cost, ease of learning at home, and reduced need for intensive nursing support. These factors make it a viable alternative to hemodialysis, particularly in regions with limited healthcare resources.

A key aspect of PD management is the regular assessment of dialysis adequacy and peritoneal membrane transporter status. These measurements are crucial for optimizing dialysis regimens, preserving residual renal function, and improving patient outcomes and quality of life(2–5). Traditionally, the peritoneal equilibration test (PET) and the assessment of dialysis adequacy, often require patients to store drained peritoneal fluid or undergo standardized dwell studies (e.g., a 4-hour dwell), which are both labor- and time-intensive(6,7). As continuous peritoneal monitoring becomes increasingly important, these conventional methods pose challenges for both patients and healthcare providers.

Multiple attempts have tried to reduce the time and manpower burden of the tests(8). The recent development of artificial intelligence (AI) makes the prediction of dialysis adequacy and transporter status become possible(9).

However, there is still a lack of a model that can help renal physicians and patients to monitor dialysis adequacy and peritoneum transportation with simple measurements.

This study aims to develop and evaluate the possibility and performance of models in assessing the dialysis adequacy and peritoneum transporter status in peritoneal dialysis patients.

Rationale for the current study

Current methods for assessing PD adequacy and transporter status are time-consuming and inconvenient for both patients and healthcare providers.

Artificial intelligence offers a potential solution to simplify these assessments, reducing the burden on patients and clinicians.

Study Objectives

The primary objective of this research protocol is to develop an AI model and evaluate its performance in predicting peritoneal dialysis adequacy and peritoneal transporter status of PD patients.

Study Design

This double-blind diagnostic test (correlation) study will examine a prospective cohort of patients treated with PD for their ESKD.

Patients recruited for this study will be randomized into two arms: a training/validation arm and a test arm in the ratio of 4:1. Around 350 participants will be recruited, with 280 patients allocated to the training/validation arm and 70 patients to the test arm. Randomization will be performed using a computer-generated randomization sequence to ensure an unbiased and equitable allocation of participants. The Principal Investigator and participants will not know the allocation details. The assessor will not know whether the samples are originated from participants of this study.

All participants in the study will receive the same standard investigations and

care as part of their routine PD management, including clinical evaluations, biochemical testing, and measurements of peritoneal transporter status via the Peritoneal Equilibrium Test (PET) and dialysis adequacy (Kt/V). There will be no change to the clinical care of patients participating in this study. All medication and renal replacement therapy (RRT) prescription changes will be made solely by the clinical team caring for the patient, without reference to the predictions of AI models.

Participants randomized to the training/validation arm will have their data used for model development, including the training and validation phases. Those randomized to the test arm will also undergo the same investigations and care but will have their data isolated and reserved exclusively for evaluating the performance of the final AI model. This ensures a robust and unbiased assessment of the model while maintaining equity in clinical care across all participants.

This study will involve an additional collection of peritoneal dialysate and spot urine samples. These samples are essential for developing and testing the AI model but do not impact the patients' standard treatment or care protocols.

Study Outline

The outline of the study will be presented in this session.

Patient consent will be obtained during their routine dialysis adequacy and peritoneal transporter status assessments at Tuen Mun Hospital (TMH). After consent, patients will be randomly assigned to either the training/validation arm or the test arm. Both investigators and patients will remain blinded to the group assignments.

An extra sample of peritoneal dialysate from the patient’s latest pre-exchange outflow dwell and an extra sample of urine will be collected. If the patient is anuric, the anuric condition will also be recorded as one of the features. The patient will then undergo the routine dialysis adequacy and peritoneum equilibrium test.

The latest blood investigation data will be collected in the coming renal specialty

clinic follow-up, and no extra blood test will be performed.

Data Collection

The following data will be collected throughout the study from the training of AI model:

Demographic Data

- Age
- Gender
- Body Height
- Body Weight

Past Medical History

- History of hypertension
- History of diabetes
- History of cardiovascular events(10)
- Cause of ESKD
- Date of Tenckhoff Catheter insertion

PD related data

- Latest outflow volume
- Latest dwell bag dextrose/icodextrin concentration
- Latest dwell time

Biochemical Data

- Blood
- Serum Creatinine
- Serum Urea
- Serum Glucose

- Glycosylated Haemoglobin (Hba1c)
- Urine
- Anuric or not
- Spot urine protein-creatinine ratio
- Peritoneal dialysate
- Dialysate Creatinine
- Dialysate Urea
- Dialysate Glucose

Study Outcomes

Primary Outcome: Peritoneal Equilibration Test (PET) Parameters

AI-predicted vs. actual 2-hour and 4-hour dialysate-to-plasma creatinine ratio (D/P Cr)

AI-predicted vs. actual dialysate-to-baseline dialysate glucose concentration ratio (D/D0 Glu)

Performance Metrics:

Mean Absolute Error (MAE)

Mean Squared Error (MSE)

Coefficient of Determination (R^2)

Intraclass Correlation Coefficient (ICC)

Time Frame: Baseline (measured at study enrollment)

Secondary Outcome:

Dialysis Adequacy (Kt/V) Parameters

AI-predicted vs. actual total weekly Kt/V

Performance Metrics:

MAE, MSE, R^2, ICC

Time Frame: Baseline (measured at study enrollment)

Discriminative Ability of AI Model

Classification of peritoneal transporter type (low, low-average, high-average, high) based on PET

Performance Metrics:

Area Under the Receiver Operating Characteristic Curve (AUC-ROC)

Area Under the Precision-Recall Curve (AUC-PR)

Sensitivity, Specificity, F1-score, and Accuracy

Time Frame: Baseline (measured at study enrollment)

Calibration Performance of AI Model

Model-predicted vs. actual transporter status and dialysis adequacy (Kt/V)

Performance Metrics:

Calibration Slope

Calibration-in-the-large (Mean Calibration Error)

Brier Score

Time Frame: Baseline (measured at study enrollment)

Statistics and Data Analysis

The local data showed that the mean and standard deviation of the 4-hour dialysate to plasma creatinine ratio is 0.747 ± 0.115 with Kt/V 1.99 ± 0.52(11). Assuming a zero dropout rate, 15 features are used in the model to make predictions, a 0.5 R-square value and a 0.9 level of shrinkage. A minimum of 280 samples are required for model training and validation(12). Considering 20% of the total sample will be required for model testing, a total of 350 patients will be recruited.

Data Analysis

Descriptive statistics will be used in assessing outcome measures. Python version 3.11 and Pytorch 2.41 will be used for model development and evaluation.

Data Storage

Data and all appropriate documentation will be stored for 7 years after the completion of the study, including the follow-up period. To protect participants' privacy, all research and personal data would be handled in line with HA / Hospital's policy in handling / storage / destruction of patients' medical records. Hard copies will be locked in cabinet during the course of the study while the soft copy would be encrypted/ password-protected. The Principal Investigator and HA Central Institutional Review Board (Central IRB) to access the personal data and study data for monitoring purpose issue. All research and personal data will be destroyed and discarded within 7 years after the study is completed using data destruction software. Hard copies will be discarded as confidential waste while the soft copy would be deleted and unrecoverable after completion of the study.

Participant entry

Pre-registration evaluations

No pre-registration evaluations are required. All patients with kidney failure treated with peritoneal dialysis are eligible.

Inclusion criteria

- Age 18 years or older
- Diagnosis of end-stage renal failure requiring peritoneal dialysis as renal replacement therapy
- Ability to give informed consent and comply with study procedures.

Exclusion criteria

- History of hernia or peritoneal leak, including pleuroperitoneal fistula (PPF), patent processus vaginalis (PPV) and retroperitoneal leak
- Ongoing PD peritonitis with or without antibiotic therapy
- Just finished PD peritonitis antibiotic treatment within recent 4 weeks
- Pregnancy
- Patient refusal.

Assessment and Follow-up

All candidates will be followed up for 12 months following initial PD fluid and urine sampling. The formal end of this study will be 12 months after the PD fluid and urine sampling of the 350th patient. Incidental findings will not be recorded and reported in this study. Only the outcomes mentioned in previous sessions will be recorded and analysed. Participants will be advised to report incidental findings to their General Practitioners and clinical care team as per local guidelines or standards of care.

Regulatory issues

Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time without giving reasons and without prejudicing present and further treatment.

Confidentiality

The Principal Investigator will preserve the confidentiality of participants taking part in the study. Information will be pseudonymised when possible. Only the

pseudonymized form of data will be shared with the study management team statistician.

All participants' information will be stored securely and analysed using a password-protected local computer with strict arrangements for access and use, ensuring that the information is used only for health and care research or to contact participants about future research opportunities. No cloud service will be involved. All identifiable personal data will be anonymised and will follow the HA policy on handling of patient data privacy. Subjects will be voluntary and they can withdraw at any time without providing any reason. This will not affect their present or future medical care and the legal rights.

Study Management

The day-to-day management of the study will be co-ordinated through Dr Ka Chun Leung with contact details listed above.

Publication Policy

- The study results will be disseminated through publication in peer-reviewed scientific journals, presentation at scientific conferences, and other appropriate channels.

- The study team will develop a summary of the findings in plain language to be made available to study participants, as well as to healthcare professionals and patient groups.

- All publications and presentations will acknowledge the contribution of study participants and comply with ethical standards for authorship.

- The study team will ensure that the results are communicated in a timely manner to stakeholders, including healthcare providers, policymakers, and patient groups.

- The study team will encourage and support the uptake of the study findings

into clinical practice, where appropriate.

- The study team will comply with all relevant laws and regulations governing the dissemination of research findings.

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