

Integration of Bioelectrical Impedance Analysis (BIA) and Estimated Glomerular Filtration Rate (eGFR): A Novel Approach to Assessing Nutritional Status in Hemodialysis Patients

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Location of the research: Tartu University Hospital, Tartu, Estonia

2. RESEARCH AND RESEARCH CENTERS

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3. RESEARCH FUNDING

The only research to be conducted specifically for this study is the BIA analysis. This will be carried out by the researcher using equipment belonging to the University of Tartu (UT), for which no additional fee will be charged. The equipment used includes a bioelectrical impedance analysis device, which is already available and in use in the nephrology department. All other reviewed tests are those that have already been performed for clinical reasons and registered in the patients' hospital records in the eHL system.

The study (comparative analysis of bioelectrical impedance analysis (BIA) and estimated glomerular filtration rate (eGFR) for assessing nutritional status in hemodialysis patients) does not have an external funding source. This study will be conducted in compliance with ethical research standards. All aspects of the study, including data collection, analysis, and reporting, will be carried out without external financial support.

4. BRIEF OVERVIEW OF PREVIOUS RESEARCH ON THE SAME TOPIC

A critical review highlights how BIA helps measure body composition and hydration, particularly intracellular and extracellular water, in patients with chronic kidney disease (CKD) and heart failure. It emphasizes the potential of BIA in managing fluid overload but notes that standardization and further validation are needed for routine clinical use (1). A 2024 study presented at the ASN Kidney Week identified BIA markers, such as phase angle and hydration indices, as potential predictors of CKD progression. These findings suggest that BIA is a valuable tool for non-invasive monitoring alongside traditional methods like eGFR (2).

BIA and eGFR have complementary roles in managing the nutritional and hydration status of CKD patients. The integration of both tools allows for better monitoring and the application of individualized treatment plans, improving clinical outcomes (3).

The value of integrating bioelectrical impedance analysis (BIA) and estimated glomerular filtration rate (eGFR) in the treatment of CKD has been recognized. BIA provides detailed information on body composition, such as fat mass, fat-free mass, and hydration levels, enabling better nutritional and fluid management, particularly in patients with malnutrition or fluid overload. BIA-derived metrics, including phase angle and extracellular fluid volume, have proven useful in assessing CKD progression and dialysis adequacy, complementing eGFR in evaluating the patient's overall health status (2) (3).

5. OBJECTIVE, SUMMARY, AND RATIONALE OF THE PROPOSED RESEARCH

The primary objective of the study is to assess the correlation between BIA-derived body composition parameters (e.g., fat mass, fat-free mass, total body water, phase angle) and eGFR in hemodialysis patients.

The study will investigate how BIA and eGFR can be used together to more effectively monitor nutritional interventions in hemodialysis patients. The study will also assess the prevalence of malnutrition and protein-energy wasting (PEW) in the study population using BIA and eGFR data.

Hemodialysis patients often suffer from complex nutritional problems due to the interplay between kidney function, protein-energy wasting, and fluid management. Current nutritional assessments in hemodialysis patients are limited, with most relying on clinical observations or basic biochemical tests. A more comprehensive, non-invasive approach is needed to assess both nutritional status and fluid balance. The study will determine whether comparing BIA metrics with eGFR provides a better picture of the patient's nutritional and kidney health, which could improve patient outcomes and dialysis management.

Malnutrition, fluid balance disorders, and protein-energy wasting (PEW) are common in hemodialysis patients due to the effects of chronic kidney disease (CKD) and dialysis therapy. Nutritional status is a critical factor influencing patient outcomes but is often under-monitored.

Traditional methods of assessing kidney function, such as estimated glomerular filtration rate (eGFR), provide an overview of kidney health but do not directly measure body composition or nutritional value. In contrast, bioelectrical impedance analysis (BIA) provides detailed information on body composition, including fat mass, fat-free mass, total body water, and phase angle. The aim

of this study is to investigate the relationship between BIA-derived nutritional markers and eGFR to assess their combined utility in evaluating the nutritional status of hemodialysis patients.

6. RESEARCH TIMELINE

Data collection: February – March 2025

Data analysis: April 2025

Report writing, completion, and presentation: April – June 2025

7. INCLUSION AND EXCLUSION CRITERIA

Sample size: 25-30 adult hemodialysis patients will be recruited.

Inclusion criteria:

- Patients must be 18 years or older.
- Patients must have been receiving regular hemodialysis for at least the last 6 months.

Exclusion criteria:

- Patients with a pacemaker or implanted defibrillator will not be included, as these are contraindications for BIA.
- Pregnant women will not be included due to changes in body composition and safety concerns.
- Patients who have recently had an acute illness or surgery that affected their hydration or nutritional status, as this could provide inaccurate body composition results.

8. RESEARCH METHODOLOGY DESCRIPTION

Study type: Observational, cross-sectional study

Data collection:

Patient data will be collected from the hemodialysis department of Tartu University Hospital. All participating patients will undergo BIA. BIA analysis will be performed using dialysis-related measurement instruments, as described in the methodology section. This will be done before routine dialysis and does not require a separate visit. The patient does not need to come in specifically for this purpose.

The following data will be collected from participating patients:

Demographic data:

- Age
- Gender
- Height
- Weight
- Body mass index (BMI)
- Duration of dialysis (months/years)

Bioelectrical impedance analysis (BIA):

- Fat mass
- Fat-free mass

- Total body water
- Extracellular water
- Phase angle

Laboratory parameters:

- eGFR

Bioelectrical impedance measures body fat, muscle, and water using a low-voltage electric current that is harmless and imperceptible to the patient. Two electrodes are placed on the wrist and two on the ankle, similar to an EKG but faster (approximately 5 minutes). Although the procedure is safe, it requires minimal patient preparation. Measurements will only be taken from patients who consent. Measurements include fat mass, fat-free mass, total body water, extracellular water, and phase angle. To minimize fluid shifts, measurements will be taken before dialysis. eGFR will be taken from the patient's recent blood test. eGFR data will be collected routinely and will use measurements from the last 6 months. Clinical data such as dialysis duration and comorbidities will also be considered.

Data analysis will be performed using statistical software (SPSS).

The analysis will include several steps to thoroughly evaluate the relationship between bioelectrical impedance analysis (BIA) parameters and estimated glomerular filtration rate (eGFR) in hemodialysis patients. Descriptive statistics will summarize the main characteristics, such as age, gender, dialysis duration, eGFR, and BIA parameters. Pearson or Spearman correlation tests will be used to assess relationships between BIA measurements (e.g., fat mass, lean body mass, phase angle) and eGFR. Multivariate regression analysis will identify significant predictors of malnutrition and clinical outcomes, focusing on factors such as phase angle, lean body mass, and fluid status.

Data will be collected from the hemodialysis department of Tartu University Hospital.

9. ANALYSIS OF ETHICAL ASPECTS OF THE RESEARCH

Confidentiality and data protection are paramount in this study. To ensure privacy, the consent form will not include contact details, birthdates, or personal identification codes. Personal data will be processed in accordance with the University of Tartu Hospital's established procedures, following the requirements of the Personal Data Protection Act.

Collected personal data will be coded, and only coded data will be processed and analyzed. All personal data will be securely stored in a folder on the University of Tartu's OneDrive server, accessible only to authorized researchers. This folder is protected by the University of Tartu's secure password system and can only be accessed by authorized users. The link between the data collected during the study and the patient's identity will only be known to the researcher conducting the analysis and those with access to the code key.

The code key will contain the following information: patient name, study ID, personal identification code, phone number, and data collection date. This code key will be deleted one year after the study's follow-up period, at which point the data will be fully anonymized. Anonymization is planned for April 2026, and anonymized data will be stored in a password-protected folder on the University of Tartu's OneDrive server.

Pseudonymized data (i.e., coded study data) will remain accessible only to the researchers involved in the study until the code key is deleted. Copies of consent forms will be securely stored in a locked cabinet in the University of Tartu Hospital's locked office, located in room L6027 on the 6th floor of building L. These consent forms will be stored until June 2032.

This study uses patient data collected from the hemodialysis department of Tartu University Hospital, which will later be anonymized to ensure compliance with ethical standards. Patients will be informed about the study and asked to sign a consent form. Participants may withdraw from the study at any time. All data will be treated with strict confidentiality, and all identifying information (names, contact details) will be removed to protect patient privacy. Ethical approval for the study will be sought from the University of Tartu Research Ethics Committee to ensure compliance with local regulations and ethical guidelines. Transparency will be maintained in presenting the methodology, data analysis, and limitations, and data collection will be conducted in accordance with institutional policies. All data will be securely stored and fully compliant with GDPR. By adhering to these measures, the study will uphold the principles of integrity, respect, and responsibility in research.

10. PRIVACY AND CONFIDENTIALITY

- Data will be anonymized and coded before analysis.
- Electronic data will be stored on the University of Tartu's OneDrive server.
- Electronic data will be saved in password-protected files.
- Only the researcher will have access to identifiable data.

11. PREVIOUS OR SIMULTANEOUS EVALUATIONS OR APPROVALS OF THE SAME PROJECT ELSEWHERE

The integration of bioelectrical impedance analysis (BIA) and estimated glomerular filtration rate (eGFR) for assessing nutritional status in hemodialysis patients is an active area of research. Although several studies have explored the use of BIA for assessing body composition and nutritional health in this patient population, the integration of BIA with eGFR for this specific

purpose remains an emerging field. Further studies are needed to validate combined assessment models and establish standardized protocols for their use in clinical practice.

A comprehensive review highlighted the use of BIA in managing the nutrition of CKD patients, including those on hemodialysis. The review emphasized the role of BIA in measuring body composition parameters such as fat-free mass, fat mass, phase angle, and body water, which are crucial for assessing nutritional status and guiding interventions (4).

Another study examined changes in body composition during the transition to hemodialysis using BIA to assess nutritional value (phase angle) and hydration (vector length). The findings showed that starting dialysis is associated with changes in body composition, reflecting changes in cellular integrity and fluid volume control (5).

Another study investigated the performance of BIA and anthropometric measurements in assessing body composition in CKD patients in stages 3–5, including those on dialysis. The study found that BIA can assess body composition across different stages of CKD, with eGFR calculated using the CKD-EPI equation. This highlights the potential of combining BIA and eGFR for monitoring nutritional status and disease progression (6).

Direct studies linking BIA and eGFR for assessing nutritional status in hemodialysis patients are limited, but existing studies suggest that both metrics are valuable. Their combined application allows for a more comprehensive assessment of patient health, warranting further research in this area.

12. REFERENCES

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