Kidney and Blood Pressure Research

Kidney Blood Press Res , DOI: 10.1159/000524140
Received: July 24, 2021
Accepted: March 15, 2022
Published online: June 7, 2022

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ISSN: 1420-4096 (Print), eISSN: 1423-0143 (Online)
https://www.karger.com/KBR
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Bioelectrical impedance vector analysis and brain natriuretic peptide in the evaluation of patients with chronic kidney disease in hemodialitic treatment

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Short title: BIVA and BNP in HD patients

Abstract
Introduction: Setting dry weight (DW) in haemodialysis (HD) patients is still an hard issue. Several clinical, haematochimical and instrumental parameters have been considered. In the last years bioelectrical impedance vector analysis (BIVA) became the main method to evaluate body composition and water body percentage. However it is still difficult to assess the nutritional status and identify a correct DW in HD patients.
Aim: to set DW and nutritional status, combining BIVA with phase angle (PhA) and serum brain natriuretic peptide (BNP) in HD patients.
Methods: we evaluated PhA and BNP modifications before (T0), after HD section (T1) and after 60 days (T2), in all patients treated in our HD centre.
Results: A total of 50 patients (36 males) with a mean age of 70.1 ± 8.85 years, were recruited. We did not report significant changes in BNP and PhA between T0 and T1, while they were significantly different between T0 and T2. We also reported a significant difference between T0 and T2 in ECW / TBW, while we did not show significant variations in ECM / BMC between T0, T1 and T2 indicating a stability of the nutritional status. PhA, BNP and ECW / TBW, returned to a normal value in patients in which we reached a DW, also considering clinical parameters such as blood pressure and antihypertensive therapy. The weight loss obtained with the evaluation of the BIVA and the BNP was 1.2-5.7 kg, greater than that calculated empirically which stood at around 0.9-4.3 Kg.

Conclusion: We suggest to carry out BIVA with PhA combined with BNP to assess an adequate DW and evaluate a correct nutritional status in HD patients.

Keywords: brain natriuretic peptide, phase angle, dry weight, bioelectrical impedance vector analysis, haemodialysis.

INTRODUCTION

The population of patients receiving dialysis grow rapidly, worldwide, approximately 89% of patients on dialysis receive haemodialysis (HD) and cardiovascular diseases (CVD) are the main cause of death in HD patients. Fluid balance is an integral component of HD treatments to prevent under- or overhydration, both of which have been demonstrated to have significant effects on intradialytic morbidity and long-term cardiovascular complications [1]. The definition of dry weight (DW) in patients on three-weekly HD treatment is still a debated topic since Thomson's first definition in 1967. DW is currently defined as the lowest weight a patient can tolerate without the development of symptoms or hypotension [2]. In 2009, Sinha and Agarwal first proposed the use of objective measures in the definition of DW [3]. DW estimation and nutrition assessment are vital procedures for HD patients because they affect the patient's prognosis and quality of life. Bioelectrical impedance vector analysis (BIVA) has been widely used to analyze the volume, body composition and nutritional status of dialysis patients [4-5]. BIVA estimates body composition, including intracellular water (ICW), extracellular water (ECW), total body water (TBW), Body Cell Mass (BCM), protein mass, mineral mass, skeletal muscle mass, and visceral fat area, based on measurements of resistance (Rz), reactance (Xc), and phase angle (PhA) [6-7]. Segmental multi-frequency BIVA has recently been developed and utilized in clinical practice, allowing measurement of not only the total body composition but also the segmental body composition. Dialysis, particularly HD, is amenable to BIVA because of the need for fluid removal and post-dialytic fluid retention. Routine evaluation of hydration includes monitoring of body weight and blood pressure changes that are not reliably determined by fluid volume. Edema is not usually detectable until interstitial fluid volume increases 30% over normal levels (4–5 kg gain in body weight) and severe dehydration can occur before appearance of clinical signs. Thus, traditional indicators of over- and under-hydration in patients with renal disease are insensitive and inadequate [8-9]. Serum brain natriuretic peptide (BNP), is produced by the left ventricle, following an overload of pressure and / or volume, is involved in the regulation of blood pressure and volume and of the hydroelectrolytic balance. In recent years, this molecule has been proposed as a marker for hypervolemia in HD patients. BNP levels, which reflect the degree of volume overload and serve as an independent predictor of mortality in CKD patients [10], have been positively correlated with hypervolemia measured by bioimpedance in HD patients [11].

The aim of this study was to set DW and nutritional status, combining BIVA with PhA and BNP in HD patients.

MATERIALS AND METHODS

The study protocol was approved by the local Clinical Research Ethics Committee. The study conforms to the principles outlined in the Declaration of Helsinki and we obtained a written consent by each patient enrolled.

Study design and subjects

We performed a prospective, longitudinal, single-centre study, on 50 patients (36 males) in three-weekly HD treatment, enrolled from September 2020 to January 2021 at the Dialysis centre of Diaverum of Latina. We performed clinical examinations, BIVA and laboratory measurements during the middle of the week, before HD (T0), after treatment (T1) and after 60 days (T2). Statins, antihypertensive, antiplatelet therapies, and/or therapies with calcium, calcitriol and phosphate binders were continued in all patients included in the study. We recorded the anamnesis and excluded patients affected by severe heart disease, ongoing infections, neoplastic disease in progress as well as chronic liver impairments and cerebro-vascular disease. We did not enroll patients with missing data and without consent.

Laboratory Measurements

Blood was drawn in the morning after an overnight fast of at least 12 h, before patients started HD, after treatment and after 60 days. In all patients, BNP (pg/dL) was measured using automated analyzer Elecsys® 2010 (Roche Elecsys 2010 chemistry analyzer, Cobas Integra 400 Plus Analyzer, Geislingen, Germany).

Anthropometric assessments

Body weight was determined to the nearest 0.1 kg using a calibrated digital scale. Body mass index was calculated from a person's weight and height (weight (kg)/[height (m)]^2).

BP Measurements

Blood pressure (BP) measurements were made in the dominant arm after 10 minutes of rest in the sitting position using a standard automatic sphygmomanometer. The mean of the three measurements was recorded. Hypertension was defined according to International guidelines [12], as SBP ≥140 mmHg or DBP ≥ 90 mmHg on repeated measurements.

X-Ray Measurements

Chest X-ray was used to evaluate the cardio-thoracic index (CTR), and it was performed before the HD session. We used technically adequate posterior-anterior chest X-ray, with defined borders and a defined heart aortic arch. Three adjudicators independently assessed technical adequacy, with disagreements resolved by consensus. Standard chest radiographs were taken in a standing position in the anterior-posterior view and the CTR was measured based on these radiographs [13]. The CTR was calculated as the ratio of the maximum transverse cardiac diameter in millimeters to the maximum thoracic diameter in millimeters. We defined a normal CTR value as less than 0.5.

Echocardiography

Transthoracic echocardiography was performed before the HD session. M-mode 2D echocardiographic examinations were completed by a single experienced sonographer in the echocardiography laboratory using a standard institutional protocol. Commercially available instruments (Toshiba Aplio xV, Toshiba American Medical Systems, Inc., Tustin, Calif., USA) equipped with 2.25- to 7.5-MHz imaging transducers were used; the subjects were in the left decubitus position, and the sonographer was blinded to all clinical details of the patients. All echocardiographic data were recorded according to the guidelines of the European Society of Echocardiography (ASE) [14]. The end-diastolic and end-systolic LV internal diameter, interventricular septum thickness, posterior wall thickness and ejection fraction (EF) were measured. The LV mass (LVM) was estimated by Devereux's formula normalized by body surface area and height.

Body Composition Analysis

BIVA was performed in all HD patients to assess body composition overtime (BIA 101 BIVA Akern, Florence, Italy). We preferred to use BIVA with respect to BIA, because it uses vector models and is based on the electrical properties of tissues without the use of constants, equations and body weight. This therefore allows an evaluation of the state of hydration and nutrition of the subject, independent weight and without a mathematical calculation of the data on the basis of the resistance / reactance measured, therefore without the postulate of the constant hydration factor. It is therefore more useful in the clinical and nutritional field. Blinded research staff performed BIVA to the second HD session of the week, to avoid the long dialysis interval. The patient maintained a supine position during this period [15]. The pairs of electrodes were placed on the non-access side of the body on the hand to the foot for injecting current and on the wrist to the ankle for measuring voltage. Total body water (TBW) was estimated using the Rz extrapolated to frequency and parameters, including intracellular water (ICW), extra cellular water (ECM), metabolically inactive tissues, and Body Cell Mass (BCM), as the metabolically active component of lean tissue mass, were calculated using a program provided by the producer. The derived BIVA variables that were considered were

PhA, the ECM / BCM and ECW / TBW ratio. ECM / BCM is a very sensitive index of malnutrition and its eventual increase can represent a warning sign of worsening nutritional status. Its normal value is between 0.9 and 1, while the normal value of ECW / TBW ratio is between 36-42%. The Rz / Xc expresses the PhA, that is related to BCM and soft tissue composition. In fact PhA is a prognostic index of numerous diseases and a PhA < 5 indicates an accumulation of extracellular fluids, conversely a PhA > 8 indicates dehydration [16].

Statistical analysis

Data management and analysis were performed using IBM® SPSS® Statistics 22 software for Windows® (IBM Corporation, Armonk, NY). The normality of the variables was tested using the Kolmogorov–Smirnov test for normal distributions. All continuous variables following a normal distribution were expressed as mean ± standard deviation. Categorical variables were expressed as number (percentage). Pearson's or Spearman's correlation was used to determine the relation and strength of the association between the variables. Student's t test, Mann-Whitney U test, and Fisher's exact test were performed to determine differences between groups, as appropriate. The binomial test or $\chi 2$ test was used for comparison of categorical data. A probability value of $p < 0.05$ was considered statistically significant.

RESULTS

Patients' characteristics are shown in Table 1. A total of 50 patients (36 males) with a mean age of 70.1 ± 8.85 years, in three-weekly HD treatment, were recruited. Evaluation of EF and CTR did not show significant differences between T0 and T2 (data non showed). We did not report significant changes in BNP and PhA between T0 and T1, while they were significantly different between T0 and T2 (Table 2, Figure 1). We also reported a significant difference between T0 and T2 in ECW / TBW (Table 1), while we did not show significant variations between ECM / BMC between T0, T1 and T2 indicating a stability of the nutritional status. PhA, BNP and ECW / TBW, returned to a normal value in patients in which we reached the DW, also considering clinical parameters such as BP and antihypertensive therapy. The weight loss obtained with the evaluation of the BIVA and the BNP was 1.2-5.7 kg, greater than that calculated empirically which stood at around 0.9-4.3 Kg. We excluded from the study 5 patients who had elevated BNP values, not correlated to hyper-hydration, with elevated BNP values and instrumental data that gave evidence of heart failure (ultrasound data (FE <60%), chest x-ray (cardio- thoracic ratio> 0.5).

DISCUSSION

Fluid status abnormalities were common among HD patients and can lead to increased morbidity and mortality. Currently, Computed Tomography and Magnetic Resonance Imaging are the gold standard for the assessment of body composition, but they are expensive, technically complex, not practical and nor always available in clinical practice [17]. DW estimation and nutrition assessment in HD patients remains a difficult although essential target for dialysis adequacy. However BIVA is a noninvasive, safe and quick methods, and permit a validated assessment of hydration status and body composition [18]. The clinical use of BIVA in HD patients is currently increasingly used in DW and nutritional status management. PhA measured by BIVA has been studied as indicator of nutritional status or muscle function in HD patients. It is the most clinically relevant impedance parameter, an index of cell membrane integrity and vitality and is a direct measure of BIVA and therefore not influenced by assumptions that can affect body composition or hydration assessments. Moreover, PhA has been recently used as a tool for assessing disease progression as well as for predicting clinical outcome in many clinical situations [19]. Alongside this tool, which is also indispensable for a precise evaluation of the nutritional status and DW, some authors consider the dosage of BNP to be extremely useful, as a marker of a state of hyperhydration, allowing together with the BIVA values improved the determination of the DW in HD. In our study PhA and BNP have been found to be extremely useful for the assessment and achievement of DW in HD patients, in fact they were significantly different and returned to normal values only when the DW was reached. Furthermore, the DW achieved was decidedly different from that obtained empirically based only on clinical data. Different types of fluid status distinguished by BIVA combined with serum BNP measurements could correspond to different clinical conditions and treatment, which implies a value of this method for evaluation of fluid status among HD patients. In the past, it has been suggested that in HD patients, BNP levels may be falsely elevated because of decreased renal clearance, instead, the predictive value of BNP for cardiovascular events has been shown to be maintained in these patients and reflect the subclinical cardiac damage [20]. In fact BNP is secreted by cardiomyocytes under stretch condition, and high blood levels are associated with decreased patient survival also in HD patients, even if in this population it is difficult to know whether BNP increase is related to the cardiac condition, fluid excess, or both [21]. However some authors showed that BNP is a marker of fluid overload in

HD patients, with a significant reduction associated with fluid removal, as in our study. The high BNP levels at dialysis start underline the deleterious effect of fluid excess on the heart, in fact BNP is a marker of cardiac stretch under the effect of fluid overload [22]. Some authors showed that direct measurement of fluid excess using BIVA clearly found an association of fluid excess and BNP increase, as in our study. Tapolyai et al [23] reported an exponential relationship between the BNP level and the fluid excess assessed using BIVA. Moreover, Ohashi et al [24] showed the critical role in BCM decrease HD patients, reflected by extracellular and intracellular fluid imbalance, and its relationship with BNP increase, confirming the results of our study. In fact, BIVA vector analysis allows the use of other parameters in addition to PhA, which are related to it, and which can better characterize complicated HD patients, as BCM, ICW, ECW and TBW, or better the ratio, showing an association with hydration and nutritional status. PhA seems to reflect BCM, or cell membrane function [25]. Increased ECW is associated with poor nutritional status, and reduced TBW, an indicator of lower BCM. Therefore, an increase in the ECW/TBW may be explained by malnutrition or skeletal muscle mass loss, as well as by fluid overload status [18]. Our study also demonstrated that lower PhA tended to have a higher ECW/TBW ratio among HD patients, and the estimated normal hydrated weight using ECW/TBW can be a good marker for determining DW, in fact HD subjects had higher ECW/TBW and could be useful to predict UF volume differences. HD patients had more ECW than the normal population and the relative overhydration of HD patients showed the highest correlation with the CTR and moderate correlation with leg edema and EF. Moreover it is important to perform a BIVA in HD patients, because some studies have evaluated the association between PhA and mortality or CV event in HD patients, and Bansal et al [26] and Segall et al [27] demonstrated that PhA was significantly associated with mortality in CKD patients and HD patients. Varan et al [28] reported a significant increase in the risk of death among HD patients with reduced PhA, even after adjustment of several nutritional indicators.

Study limitations

Several limitations of our present study should be noted, our findings are limited to a relatively small number of patients at a single HD center. Future research needs to evaluate the diagnostic, prognostic, and predictive accuracy of PhA and BNP on evaluation of DW in HD patients through a larger sample and longer follow-up

CONCLUSIONS

This study showed the importance of BIVA and serum BNP in the clinical assessment of the DW in HD patients. Moreover PhA could be a useful, simple indicator to evaluate DW and cardiovascular event risk among HD patients, in fact lower PhA was associated with a greater cardiovascular risk. Thus, we propose that regular screening would be essential to monitor HD patients and could help in the early identification of patients with high risk of overhydration and cardiovascular morbidity and mortality. BIVA is a noninvasive, safe and quick methods, and permit a validated assessment of hydration status and body composition, and BIVA measurements are gaining interest to assess and monitor hydration status in dialytic treatment, moreover it is highly reproducible and has the advantage of low interobserver error.

Statement of Ethics: The study protocol was approved by the local Clinical Research Ethics Committee (ethics committee Diaverum center) with reference number 03.21. The study conforms to the principles outlined in the Declaration of Helsinki and we obtained a written informed consent by each patient enrolled.

Conflict of Interest Statement: The authors report no conflicts of interest. The manuscript is not under consideration for publication elsewhere.

Funding Sources: This study was not funded.

Author Contributions:

Study design: Liliana Kristuli, Emanuela Capasso, Silvia Lai, Adolfo Marco Perrotta
Data collection: Giuseppe Pietro Zizzo, Claudio Riccardi, Emanuela Capasso
Statistical analysis: Alessandro Galani
Data interpretation: Liliana Kristuli, Silvia Lai, Adolfo Marco Perrotta, Elios Gaspare Russo
Final revision of the manuscript: Liliana Kristuli, Silvia Lai, Elios Gaspare Russo
The manuscript has been seen and approved by all authors.

Data Availability Statement: All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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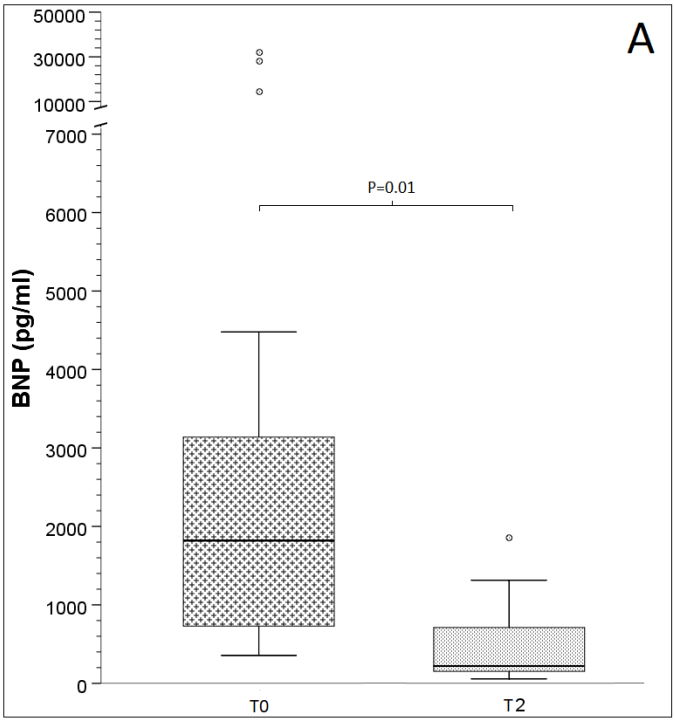
Figure 1. A: Box-and-whisker plot. There is a statistically significant different of median value of BNP at T0 versus T2 (1820.0 vs 220.5, p=0.01). B: Box-and-whisker plot. There is a statistically significant different of median value of PhA at T0 versus T1 (3.9 vs 3.6, p<0.001). ° Outliers.



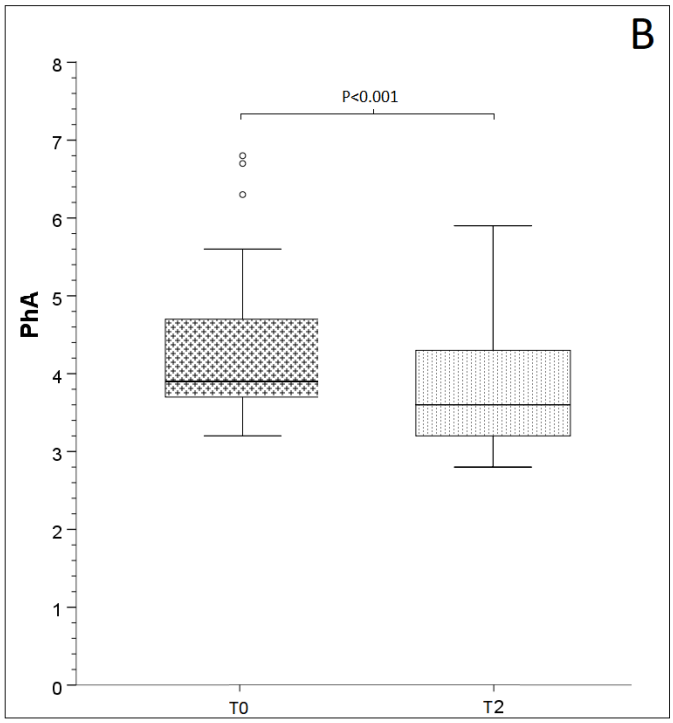


Table 1: Patients' characteristics. The parameters are expressed as media and deviation standard.
Abbreviations: BMI, Body Mass Index; CRP, C Reactive Protein.

Parameters	***Total*** ***N 50 patients***
Gender; n (%)	Female Male 36 (72)
Age (years)	70.1 ± 8.85
Time of dialytic treatment (years)	3.75 ± 4.31
Kt/V	3.34 ± 2.85
Type of filters	ELISIO Nipro
duration of the dialysis session (minuts)	240.0
Hemoglobin (g/dL)	8.29 ± 3.67
Albumin (g/dL)	4.35 ± 2.05
Mean arterial pressure (mmHg)	87.17 ± 13.90
Serum Sodium (mg/dL)	137.47± 2.57
Serum Potassium (mg/dL)	4.72 ± 1.94
Serum calcium (mg/dL)	7.01 ±2.48
Serum phosphorus (mg/dL)	4.52 ± 2.17
CRP (mg/dL)	20.70 ± 33.46
BMI (kg/m^2)	25.9 ± 8.2

Parameters	***T0***	***T2***	***p value***
Weight	69.75 ± 16.30	67.19 ± 17.04	***<0.001***
BNP	4451.65 ± 8026.97	465.88 ± 481.18	***0.013***
PhA	4.36 ± 0.97	3.77 ± 0.72	***<0.001***
ECW/TBW	61.80 ± 16.34	54.80 ± 9.83	***0.010***

Table 2**:** Patient's characteristics of the study. Difference between before hemodialysis section (T0) and after 60 days (T2). ***Abbreviations:*** BNP, Brain natriuretic peptides; PhA, phase angle; ECW/TBW, Extra Cellular Water/Total Body Water.