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Original Article

Validation of Bioelectrical Impedance Analysis for Assessing Dry Weight of Dialysis Patients in Pakistan

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ABSTRACT. Accurate dry weight estimation (DW) to achieve euvolemia is one of the key objectives of hemodialysis (HD). While conventionally DW is estimated by clinical examination, bioelectrical impedance analysis (BIA) has been proposed as an objective method to determine DW and has been tested extensively in the Western population. We aim to validate BIA for determining DW in a Pakistani population against the conventional clinician's method. This is a single-center validation study conducted at two outpatient HD units of Aga Khan Hospital, Karachi. One hundred and forty-eight DW readings of patients who were on maintenance HD were taken both by BIA technology and by clinical assessment. The clinician was blinded to readings obtained by BIA. Data analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 19. Median age of patients was 63 years (range 12–89). Nearly 54.1% of the samples were female (n = 80). Spearman's correlation between the clinician's estimate and BIA-derived DW showed a correlation coefficient of 0.982, which was statistically significant (P <0.001). This association remained significant when stratified analysis was carried out by dividing the sample into subgroups according to age, gender, body mass index, and total body water content. Inter-rater reliability analysis using the kappa statistics showed almost perfect agreement between the two methods, κ = 0.929 (95% confidence interval, 0.878–0.980, P <0.001). BIA has been validated as a tool for DW assessment of HD patients in Pakistan in comparison to clinical method.

Introduction

Ultrafiltration to achieve preset dry weight (DW) is one of the prime aspects of hemodialysis (HD) prescription.[1,2] Defined as the lowest weight that a patient can tolerate without developing symptoms of fluid imbalance; DW is the target weight that a patient should reach at the end of each dialysis session.[3]

Establishment of accurate DW is pivotal in maintaining quality of life of patients receiving HD treatment.[4] Achieving "normohydration" or appropriate DW is associated with longer survival of dialysis patients.[5] Both under- and

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over-hydration have deleterious consequences. Chronic volume overload is directly associated with hypertension, increased arterial stiffness, left ventricular hypertrophy, heart failure, and subsequently higher mortality.[2] Almost 80% of all hypertension in dialysis patients are related to chronic hypervolemia.[2] Dehydration, on the other hand, results in hypotension, tinnitus, dizziness, and cramps and increases the chance of cardiac or neurological ischemic events, vascular access thrombosis, and dysrhythmias.[2,6-8]

Traditional DW estimation is done by clinical examination, especially blood pressure monitoring and is based on a trial and error method until euvolemia is achieved.[9] Clinical assessment is a feasible method for determining and achieving DW.[9] However, this requires expertise of a skilled onsite nephrologist. Moreover, clinical decision-making is complicated by factors such as heart failure, third-spaced fluid, and presence of renin-mediated blood pressure surges which are common in dialysis population. The conventional method of DW assessment may also fall short to account for ongoing changes in nutritional status effecting lean body mass.[1,10]

As there is a significant relationship between the correct estimation of DW and outcomes and clinical difficulty in fluid management of dialysis patients, the natural inclination is to turn to technology.[11] Therefore, various objective methods have been proposed, including biochemical indicators, bioelectrical impedance technique, and online real-time blood volume monitoring.[12]

The basic principles of bioelectrical impedance were initially described by Thomassett in 1963.[13] These measurements are based on the basic principle that the electrical impedance of a cylinder is directly proportional to its length and inversely proportional to its cross-sectional area multiplied by its specific resistivity. Assuming that the human body is a sum of homogeneous cylinders and that current would pass only through ion- and water-containing media; in 1969, Hoffer was the first to attempt to measure total body water by this method.[14]

Bioelectrical impedance analysis (BIA) is a noninvasive method to determine body composition and DW in HD patients with interobserver and intraobserver error of <2%, making it a reliable tool for fluid management in HD patients.[1] In recent years, BIA devices have been extensively tested in the Western population to aid clinical decision-making of DW estimation in HD patients. There is emerging evidence of its usefulness in tailoring the dialysis prescription based on individual patient needs.[1,15] The reproducibility of this method permits a long-term follow-up of changes in the hydration status of dialysis patients which is particularly useful in case of occurrence of acute or chronic comorbid conditions.[16]

Furthermore, while BIA has been validated in Caucasian adults, it is not known whether the prediction equations on which it functions are applicable to all HD patients worldwide.[17] The body composition of Asians is quite different from that of Caucasians in terms of fat content and lean mass.[18,19] Previously, BIA data on end-stage renal disease (ESRD) patients available from South Asia has been provided by one study conducted in India; however, a large proportion of that population is vegetarian, which makes their body composition different and limits the applicability of previous studies on Pakistani population.[20] Body composition affects the electrical impedance and therefore the BIA derived DW of the patient, necessitating the validation of BIA in Pakistan. In addition, previous studies have identified a discrepancy between BIA and clinically derived DW at extremes of body mass index (BMI) and recommend the validation of BIA in such scenarios.[21] Our objective in this study was to validate DW estimation by BIA in patients with ESRD undergoing HD against DW estimation by conventional (clinical) method, which is considered the gold standard.

Subjects and Methods

This is a single-center validation study in which we validated the use of BIA for DW determination in comparison to the gold standard - clinician's method (CM).

This study was conducted in two outpatient HD units of Aga Khan University Hospital (AKUH), Karachi, Pakistan, from November 2014 to February 2015. Data collection was commenced after receiving approval from the Ethical Review Committee of AKUH. Informed consent was taken from each participating individual in line with the ethical norms. The purpose and procedure of the study was explained to the participants, and consent forms were made available to them in English as well as in local language "Urdu."

One hundred and forty-eight DW readings of patients who were on maintenance HD were taken both by the BIA technology using Maltron BioScan 915, 916 S and by simultaneous clinical assessment by trained/trainee nephrologists. Each patient was included to the maximum of 3 times in the study. For those patients who were included more than once in the study, the readings were taken at least one month apart. Those patients who developed intradialytic hypotension during their dialysis session were excluded from the study.

The inclusion criteria were patients with ESRD who were on maintenance HD for more than three months and were stable, with no hospitalization history during the last one month. Participants were excluded if they were pregnant, had a pacemaker, had ascites, or were known cases of nephrotic syndrome.

DW of each patient was assessed first by the clinician and then by BIA before the start of each HD session. Thus, the nephrologist was blinded to the DW reading obtained by BIA.

Before the dialysis session, patients were clinically assessed by the nephrologist for edema and effusion (crackles on chest examination, ankle edema, ascites, jugular venous pressure, and blood pressure were checked). The weight at which patient had no abnormal findings suggestive of volume overload and further dialysis may lead to hemodynamic disturbance was considered as clinical DW (CDW). DW in all patients was also measured by a single-frequency bioelectric impedance analyses device (BioScan 915, 916 S). The device has four electrodes. Two electrodes are attached to the upper extremity which do not have arterio-venous fistula (wrist and dorsum of 3rd metacarpi), and two electrodes are attached to the ankle and dorsum of the third metatarsal. Basic information including height, weight, age, and sex was recorded, and then, the BioScan calculates the DW along with other body composition parameters. DW measurement was performed before beginning the dialysis session. To standardize the procedure, BIA measurements were taken with the patients in fasting condition, supine position with the limbs spread apart, and after voiding urine. Room temperature was maintained in the dialysis units where these readings were taken.

In addition, blood pressure readings were checked before the start, during, and after the completion of HD along with the heart rate and oxygen saturation. Patients were assessed by the nephrologist before, during the session, and at the end of HD for signs and symptoms of over- and under-hydration.

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 19.0, IBM Corp., Armonk, NY, USA. Median and interquartile ranges were reported for continuous variables. Continuous variables were also divided on the basis of gender and then their median and interquartile ranges were generated and compared using Mann–Whitney U-test. Percentages were obtained for categorical variables.

Kolmogorov–Smirnov test showed that the values of DW by both methods were not normally distributed; hence, Spearman's correlation was applied to find the strength of association between the two methods of DW determination.

Bland–Altman analysis was used to assess agreement and bias. Inter-rater reliability analysis was performed to determine agreement between values of DW determined by BIA and CM. This was done by computing intraclass correlation coefficient (ICC) and kappa statistics. For kappa statistic, the values of DW were ranked in ascending order and divided into tertiles. The observed level of agreement was determined by cross-tabulating the values of DW by both methods, and expected level of agreement was determined by

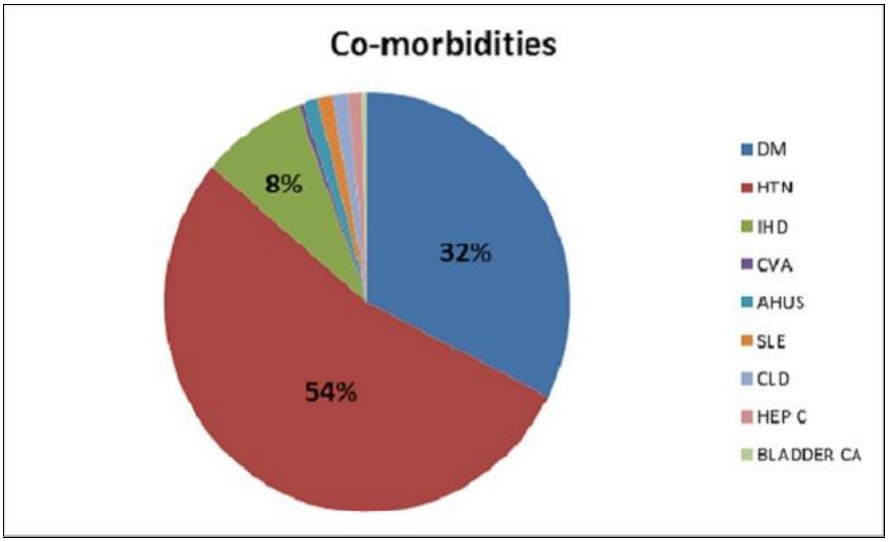

Figure 1. Distribution of comorbid conditions among the study population.
DM: Diabetes mellitus, HTN: Hypertension, HD: Ischemic heart disease, CVA: Cerebrovascular accident, AHUS: Atypical hemolytic uremic syndrome, SLE: Systemic lupus erythematosus, CLD: Chronic liver disease, Hep C: Hepatitis C, Bladder CA: Urinary bladder carcinoma.

marginal frequencies. 95% confidence interval (CI) was used for both measures.

Results

In this study, 148 readings were taken to assess the DW of HD patients in AKUH using bioimpedance analysis and compared it to the CDW. Among 148 readings, 80 readings of DW were of female dialysis patients and 68 were of males. A total of 82 (55.4%) out of 148 readings were of patients with diabetes mellitus while 99 (66.8%) had a history of hypertension. Figure 1 shows the distribution of comorbidities in our study population.

Median age of patients was 63 years (range 12–89 years), with median age of male patients being 62 years and of females being 64 years. Median BMI was 24.20 (range 12.20–47.20) for the combined sample population. Thirteen (8.7%) of these patients were underweight (BMI <18.5) while 71 (47.9%) were of normal weight (BMI 18.5–24.99), 46 (31%) were overweight (BMI 25–29.9), and 18 (12.1%) were obese (BMI ≥30).

Paired sample *t*-test showed a significant reduction in blood pressure was achieved at the end of HF. Cardiovascular parameters of the study population have been summarized in Table 1.

Spearman's correlation showed that there was a significant association between values of DW obtained by BIA and clinical method (P <0.001). In addition, stratified analysis done by dividing the sample into subgroups according to age, gender, BMI, total body water content, and presence or absence of diabetes as comorbidity showed that the association remained a significant regardless of these factors. Figure 2 shows the graphical representation of DW measured by both methods.

An inter-rater reliability analysis using the kappa statistic was performed to determine consistency between DW determined by BIA

Table 1. Mean ± standard deviation of hemodynamic parameters of study population.

Hemodynamic parameters	Predialysis	Postdialysis	*P*
Heart rate (bpm)	80±13	81±16	0.398
Systolic blood pressure (mm Hg)	154±21	144±21	0.006
Diastolic blood pressure (mm Hg)	77±16	74±15	<0.001

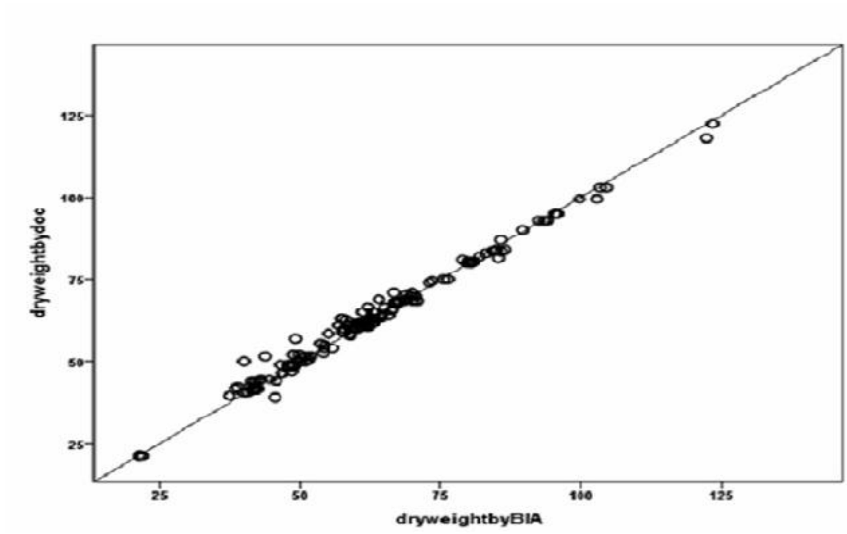

Figure 2. Scattered graph: Association of dry weight measured by BIA versus clinical method.

and CM. There was almost perfect agreement between the two methods, κ = 0.929 (95% CI, 0.878–0.980), P <0.001. These results were corroborated by computing the ICC, a second measure of reliability. The value of ICC was 0.996 (95% CI, 0.995–0.997), P <0.001, again indicating almost perfect agreement between the two methods.

Discussion

This study demonstrates the utility of BIA in the determination of DW in a South Asian population. DW measured by BIA was compared with the conventional method of estimation by clinical judgment and symptomatology. Clinical assessment remains the foundation for DW determination with several methods currently being investigated to aid this process.[16]

We found a significant association between the values of DW determined by both methods. These results are corroborated by similar studies done in Western populations.[17] BIA appears to have significant potential in the assessment of hydration status and measurement of DW.[11] A study done in 2000 by Cooper et al concluded that the values of total body water varied significantly depending on the method of calculation and that BIA was the most accurate method of determining patients' body composition.[22] Another study done in Iran concluded that an accurate estimate of the DW can be made by combining the conventional method of measurement and BIA and determining the correlation between values from the two methods even though the conventional method is time consuming and dependent on the attributes of the professional performing the measurements.[10]

Body composition, fat/mineral content, and volume distribution are significantly different in South Asian/Asian Indian populations compared to Caucasians. These differences can potentially effect DW assessment by devices that were initially tested in Caucasian population and not validated in the South Asian/ Indian population.[18,19] Therefore, we compared the DW assessed by clinical method with the DW assessment by BIA technique in a South Asian population. Our study showed a significant association as depicted by the linear scattered graph for overall population. This association held true in all subgroup analyses according to age, gender, BMI, and total body water and in the diabetic and nondiabetic population. This was an important finding in our study as previous studies have recommended the validation of BIA in patients at extremes of BMI ranges.[21] BMI of the participants in the present study ranged from 12.20–47.20, providing a fairly representative sample.

We used a single-frequency BIA device in this study. The use of multiple frequencies, usually termed as bioimpedance spectroscopy, enables calculation of theoretical resistance values at zero and infinite frequencies by fitting a polynomial curve termed as Cole-Cole plot and thus improving the accuracy of equations that are used to determine intracellular and extracellular fluid compartments.[23] Some studies show that single-frequency bioimpedance and multiple-frequency spectroscopy are both equally accurate in measuring total body water and intracellular fluid.[24,25]

This study was the first of its kind in Pakistan. DW estimation using BIA is a relatively uninvestigated entity in our part of the world, specifically in South Asia. Furthermore, several possible sources of bias have been identified in the literature when using BIA which include body position, food intake, environmental conditions, temperature of the skin, and bladder content.[21] These were eliminated in our study by following standardized conditions.

Limitations of the current study were that it was a single-center study with a small patient population. In addition, we used a single-frequency BIA device which is simpler and easier to use than multifrequency BIA; however, while certain studies claim that both types of devices are equally accurate, other studies report that the inability to make an accurate distinction between extracellular and intracellular volume with a single-frequency device is a possible limitation.[2]

Each individual technique of DW estimation has its limitations. According to Purcell et al, DW cannot be determined in any patient by a single parameter.[26] Whatever new technologies we apply, attention to careful clinical examination and history would continue to play an important role in optimizing fluid management. Therefore, combination of BIA technique with the clinical method for the correct DW estimation should be used and tested.

It is obvious that our study is only an initial step toward the process of accurate estimation of DW, and hopefully, it will result in further investigation in this field in our population. We feel that BIA has been validated as a tool for DW assessment of HD patients in Pakistan in comparison to clinical method.

Conflict of interest: None declared.

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