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Development and Validation of Bioimpedance Analysis Prediction Equations for Dry Weight in Hemodialysis Patients

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Background: Accurate assessment of hydration status and specification of dry weight (DW) are major problems in the clinical treatment of hemodialysis (HD) patients. Bioelectrical impedance analysis (BIA) has been recognized as a noninvasive and simple technique for the determination of DW in HD patients.

Design, setting, participants, and measurements: This study was designed to develop and validate BIA prediction equations for DW in HD patients. It included white adults (1540 disease-free adults with normal body mass index [BMI] and 456 prevalent and 27 incident HD patients). All participants underwent at least one single-frequency BIA measurement (800 μ A and 50 kHz alternating sinusoidal current with a standard tetrapolar technique). The BIA variable measured was resistance (R). Data of 1463 (95% of the cohort) disease-free individuals with normal BMI (prediction sample) were used to establish best-fitting BIA prediction equations of body weight. The latter were cross-validated in the residual 5% subset (77 individuals) of the same cohort (validation sample).

Results: Multiple regression analysis showed a significant relationship among body weight, R, age, and height in 739 men ($R^2 = 0.82$, $P < 0.0001$) and among body weight, R, and height in 724 women ($R^2 = 0.68$, $P < 0.0001$) in the prediction sample. The Bland Altman analysis showed a mean difference between predicted and measured body weight of 0.3 ± 1.0 kg (95% confidence interval ± 2.0 kg) in the validation sample. The BIA prediction equations that were obtained in disease-free individuals with normal BMI were applied to a cohort of 456 prevalent HD patients: The mean difference between achieved and estimated DW was 0.1 ± 1.0 kg ($P = 0.53$) in men and -0.3 ± 1.0 ($P = 0.76$) in women. Finally, BIA prediction equations were tested in a cohort of 27 incident HD patients. The mean difference between predicted and achieved DW was -0.6 ± 1.0 kg ($P = 0.76$) in men and 0.6 ± 1.0 ($P = 0.50$) in women.

Conclusions: This study was able to develop and validate BIA prediction equations for DW in HD patients. They seem to be a promising tool; however, they still need external validation.

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Accurate assessment of hydration status and specification of dry weight (DW) are major problems in the clinical treatment of hemodialysis (HD) patients. DW may be defined as the target post-HD weight at which the patient is as close as possible to a normal hydration state without experiencing symptoms that are indicative of over- or underhydration at or after the end of HD treatment (1). In the clinical practice of HD, postdialysis DW is estimated by trial and error, and the degree of imprecision is reflected in the development of intradialytic symptoms or chronic volume overload with poor control of BP (1). Traditionally, euolemia in dialysis patients is achieved by the application of clinical criteria such as absence of symptomatic dialysis-associated hy-

potension, by arterial normotension in the dialysis interval without the need for antihypertensive medications, or by absence of any signs or symptoms of hypotension or hypertension (2). To assess the hydration status more quantitatively, Wizemann and Schilling (3) developed a clinical score of volume state. This practice of fluid management requires a well-educated and dedicated staff and is relatively time-consuming and thereby expensive (2). However, the reality for many dialysis centers is that their patients have an enormous range in the prevalence of arterial hypertension and incidence of dialysis hypotension (4,5). To address these shortcomings, much research effort has been expended on the search for an objective measurement of fluid status that provides a common standard against which patients may be compared (1,2,6). Blood volume monitoring (2,7), ultrasound assessment of inferior vena cava diameter (2,8), and several biochemical parameters, such as brain or atrial natriuretic peptide (9), have been shown not to give an accurate estimate of DW (1,2). For more than 20 yr,

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bioelectrical impedance analysis (BIA) has been recognized as a noninvasive and simple technique to measure body hydration status of patients and has gained much attention for the determination of DW in HD patients (10–13). Several approaches to DW determination using BIA have been developed, such as the resistance reactance graph (11), the normovolemia/hypervolemia slope method (12), and the continuous calf bioimpedance (13). The first method offers a combined rapid assessment of hydration status and nutritional status within one graph (11). It does not, however, provide an absolute number for DW. The second method predicts an absolute DW from one multifrequency bioimpedance spectroscopy measure (12). It does, however, await further refinements (1). The third method records intradialytic continuous regional bioimpedance spectroscopy for assessment of DW in HD patients (13). This new method still needs external validation but seems to be a promising tool for determination of DW in HD patients (1).

Materials and Methods

Design of the Study

This study was designed by C.B. and L.V. to develop and validate BIA prediction equations for DW in HD patients. It was conceived as a four-step, multicenter study in which white adult, including normal individuals and prevalent and incident HD patients were enrolled. Weight was measured to the nearest 0.1 kg and height to the nearest 0.5 cm. Body mass index (BMI) was subsequently calculated as the ratio weight/height² (kg/m²). All participants underwent at least one single-frequency BIA assessment (average of two measurements). It was determined on the nondominant side of the body, injecting 800 μ A and 50 kHz alternating sinusoidal current with a standard tetrapolar technique (BIA 101 Impedance Analyzer; Akern, Florence, Italy). Specifically, it was performed 30 min after the end of the HD session in both prevalent and incident HD patients. The BIA variable measured was resistance (R). R is the opposition to flow of an alternating current through intra- and extracellular ionic solutions (11).

The four steps of the study were as follows:

Step 1: To enroll disease-free individuals of both genders with normal BMI (women 19 to 24 and men 20 to 25 kg/m²).

Step 2: To use 95% of the participants enrolled in step 1 to establish best-fitting BIA prediction equations of body weight, then to cross-validate the resulting final BIA prediction equations by separate reapplication to the residual 5% subset of disease-free individuals with normal BMI. These subpopulations were selected to match age, gender, weight, height, and BMI in both groups.

Step 3: To apply BIA prediction equations to a cohort of prevalent stable HD patients (treated for at least 6 mo) to verify the correspondence between their actual and estimated postdialysis DW.

Step 4: To test BIA prediction equations in a cohort of incident HD patients to confirm their accuracy in targeting the optimal DW.

Study Population

The study population consisted of white adults who were subdivided into three categories:

- Disease-free individuals ($n = 2294$; 1152 men and 1142 women): They were present in a unique database under the responsibility of one single unit (B.D.I.). Worth noting, all of the BIA measurements of these individuals were performed by the same operator using the same device (14). When the inclusion criteria were restricted to disease-free individuals of both genders with normal BMI (women 19 to 24 and men 20 to 25 kg/m²), the final number of disease-free individuals with normal BMI enrolled in the study was 1540 (778 men and 762 women).
- Prevalent patients who were on long-term HD for at least 6 mo and in a stable state of hydration at the time of assessment without overt edema ($n = 456$; 308 men and 148 women): They were treated in two dialysis units (B.D.I. and N.D.). Worth noting, all of the BIA measurements of these individuals were performed by only two operators (one per unit). Furthermore, their postdialysis DW used to be determined under strict clinical surveillance (3) associated with the monthly use of the resistance reactance graph (targeted to be as close as possible to the 95% confidence ellipse for the healthy population) (11).
- Incident HD patients ($n = 27$; 14 men and 13 women): They were enrolled by the four dialysis units involved in the study. They underwent a baseline BIA measurement before starting the first HD session, then their postdialysis DW was searched in a stepwise manner under strict clinical surveillance (3); when, after a variable number of HD runs, the attending physicians, completely blinded to the BIA measurement, deemed that their DW had been attained, the comparison between the achieved DW and the same parameters that were predicted by means of prediction equations before the first HD session was performed.

The study protocol was designed according to the Declaration of Helsinki and approved by the local ethical committees. Moreover all of the participants gave their informed consent to the study.

Statistical Analyses

The database was subdivided into development and validation data sets: A cohort that included 95% of the disease-free individuals with normal BMI ($n = 1463$) was used to establish the principal multivariate relationships among height, age, R, and body weight. These parameters were chosen on the basis of their significant relationships with body weight in the gender-specific univariate analysis. The need for constructing gender-specific equations derived from the examination of the best-fitting single-term equation for remaining systematic effects by anthropometric variables or gender. The precision of the prediction equations was expressed by the root mean square error (RMSE; *i.e.*, the square root of the sum of squared differences between the observed and the predicted values divided by the number of individuals studied). The smaller the RMSE, the greater the accuracy of the equation. There is no absolute criterion value for an RMSE that is useful for indicating successful validation. Moreover, the RMSE was expressed by the coefficient of variation (*i.e.*, RMSE divided by the mean value of the dependent variable). The resulting final prediction equations were internally cross-validated by separate reapplication to the residual 5% of disease-free individuals with normal BMI ($n = 77$) and by using the Bland Altman plots to assess the significance of the mean difference between predicted and measured body weight values. Data regarding prevalent and incident HD patients underwent the Kolmogorov-Smirnov test to assess the feature of their distributions. Then, non-normally distributed data were log-transformed. Last, unpaired *t* test was used when appropriate.

Data are reported as means $\pm$ SD. Statistical analysis was performed by using SPSS 10.0 software (SPSS, Chicago, IL), and $P < 0.05$ was considered for the statistical significance.

Results

Step 1: Body Weight in Disease-Free Individuals of Both Genders with Normal BMI

Demographic and anthropometric characteristics of 1540 disease-free individuals with normal BMI are described in Table 1.

Table 1. Demographic and anthropometric characteristics of 1540 disease-free individuals with normal BMI^a

Characteristic	Men	Women
<i>n</i>	778	762
Age (yr)	47.9 ± 22.3	40.3 ± 20.8
Height (cm)	171.5 ± 9.4	159.6 ± 7.7
Body weight (kg)	68.2 ± 8.8	55.4 ± 6.2
BMI (kg/m ²)	23.1 ± 1.3	21.7 ± 1.4

^aData are means ± SD. BMI, body mass index.

The age ranged from 18 to 104 yr in women and from 18 to 100 yr in men.

Step 2: Development of BIA Prediction Equations of Body Weight in Disease-Free Individuals of Both Genders with Normal BMI

The enrollment of 95% of the individuals of step 1 allowed us to establish best-fitting BIA prediction equations of body weight by means of two multiple regression analysis models (Table 2):

Body weight in men = $(0.008995 \times \text{age}) - (0.01116 \times R) + (0.871078 \times \text{height}) - 75.55197$ (equation 1)

Body weight in females = $-(0.01389 \times R) + (0.62956 \times \text{height}) - 36.31924$ (equation 2)

where age is in years, height is in centimeters, and R is in Ω . Parameters that were input into equations 1 and 2 were chosen on the basis of their significant relationships with body weight in the gender-specific univariate analysis. Thus, age was present in equation 1 (men) but not in equation 2 (women).

A random cohort of 77 (however, equally distributed between genders: 39 men and 38 women) disease-free individuals with normal BMI (5% of total) were used for validation of prediction equations. Demographic and anthropometric characteristics of the 1463 individuals who were included in the prediction sample and of the 77 individuals who were included

Table 2. Output of the multiple regression analysis in determining the BIA prediction equations (equations 1 and 2) for body weight^a

Parameter	Age	Height	Resistance
Men (<i>n</i> = 739)^b			
coefficient	0.008995	0.871078	-0.01116
SE	0.009	0.021	0.002
<i>P</i>	<0.0001	<0.0001	<0.0001
Women (<i>n</i> = 724)^c			
coefficient		0.62956	-0.01389
SE		0.02	0.002
<i>P</i>		<0.0001	<0.0001

^aBIA, bioelectrical impedance.

^b $R^2 = 0.82$; constant = -75.55197; $P < 0.0001$.

^c $R^2 = 0.68$; constant = -36.31924; $P < 0.0001$.

in the validation sample of the BIA prediction equations for body weight are shown in Table 3. In the validation sample, mean measured body weights were 67.8 ± 10.0 kg in men and 56.4 ± 9.8 in women, whereas mean predicted body weights were 67.6 ± 5.2 and 56.3 ± 5.2 kg, respectively ($P = 0.13$). The cumulative RMSE of the estimates on the basis of equations 1 and 2 was 1.19 relative to the measured data (coefficient of variation 2.0%). The Bland Altman analysis of the residual variation in the relationship between measured and predicted body weight disclosed significant results, with a mean difference between predicted and measured body weight of 0.3 ± 1.0 kg ($P = 0.03$; Figure 1).

Step 3: Application of BIA Equations for Estimation of DW in Prevalent HD Patients

The application of the two BIA equations for the estimation of DW in 456 prevalent stable HD patients led to a large difference between the estimated and the actual DW (men 2.9 ± 7.4 kg; women 4.7 ± 7.3). However, this finding was not unexpected for the following reason: BIA prediction equations of body weight derive from disease-free individuals of both genders with normal BMI; on the contrary, the prevalent HD cohort consists in patients with both normal and abnormal BMI (either low or high). The estimated DW, to reflect the reference population, must be corrected for the mean BMI of the disease-free men and women with normal BMI (23.1 and 21.7, respectively; Table 1). Therefore, the postdialysis DW that is obtained by applying equations 1 and 2 must be corrected by a normalization factor (in men: postdialysis BMI/23.1; in women: postdialysis BMI/21.7). Therefore, equations 1 and 2 must be reformulated in the following way:

DW in men = $[(0.008995 \times \text{age}) - (0.01116 \times R) + (0.871078 \times \text{height}) - 75.55197] \times \text{postdialysis BMI}/23.1$ (equation 1a)

DW in women = $[-(0.01389 \times R) + (0.62956 \times \text{height}) - 36.31924] \times \text{postdialysis BMI}/21.7$ (equation 2a)

where age is in years, height is in centimeters, and R is in Ω .

Table 4 reports data pertaining to the application of equations 1a and 2a to the cohort of 456 prevalent stable HD patients. The mean difference between the log-transformed actual and estimated DW was 0.0013 ± 0.0072 kg ($P = 0.53$) in men and -0.0020 ± 0.0076 kg ($P = 0.76$) in women.

Step 4: Application of BIA Equations for Prediction of DW in Incident HD Patients

The accuracy of prediction equations in targeting the optimal DW was tested in 27 incident HD patients whose clinical and anthropometric characteristics are shown in Table 5. We predicted DW by inputting data that were recorded before the first HD session into equations 1a and 2a. Then, DW was increased or reduced in a stepwise manner according to the usual clinical criteria of trial and error. When the clinical DW was deemed to have been achieved on a clinical basis (after 22.7 ± 6.2 HD sessions performed during 8.2 ± 2.3 wk), we performed the comparison between the achieved DW and the same parameters that were predicted by means of our prediction equations before the first HD session. Table 5 shows that the mean difference between log-transformed achieved and predicted DW

Table 3. Demographic and anthropometric characteristics of the 1463 disease-free individuals with normal BMI included in the prediction sample and of the 77 disease-free individuals with normal BMI included in the validation sample of the BIA prediction equations (equations 1 and 2) for body weight, subdivided according to the gender^a

Parameter	Prediction Sample	Validation Sample	P
Men			
n	739	39	
age (yr)	49.9 ± 22.6	49.2 ± 20.6	0.82
height (cm)	171.1 ± 9.4	172.0 ± 8.6	0.48
BMI (kg/m ²)	23.2 ± 1.3	22.9 ± 1.4	0.78
actual body weight (kg)	68.1 ± 8.9	67.8 ± 10.0	0.34
Women			
n	724	38	
age (yr)	42.0 ± 21.8	37.4 ± 22.6	0.09
height (cm)	159.0 ± 7.9	160.2 ± 12.2	0.28
BMI (kg/m ²)	21.7 ± 1.5	21.7 ± 1.8	0.89
actual body weight (kg)	55.1 ± 6.3	56.4 ± 9.8	0.21

^aData are means ± SD. The *t* test for unpaired data was used for the statistical analysis.

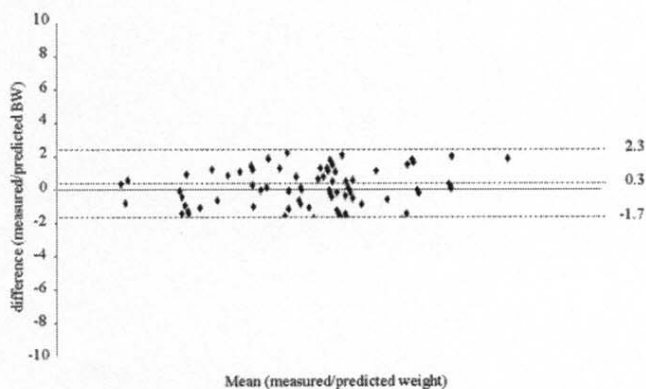


Figure 1. Bland Altman analysis of the residual variation in the relationship between measured and predicted body weight in 77 disease-free individuals who were included in the validation sample of the Bioelectrical impedance analysis prediction equations.

was -0.0041 ± 0.0040 kg ($P = 0.76$) in men and 0.0045 ± 0.0094 ($P = 0.50$) in women.

Discussion

Methods that use BIA are property-based methods (15). Impedance is a measurable property of electrical ionic conduction of soft tissue, because fat and bone are poor conductors (16). Whole-body impedance is a combination of R and reactance (XC) across tissues. R is the opposition to flow of an alternating current through intra- and extracellular ionic solutions, whereas XC represents the capacitance that is produced by tissue interfaces and cell membranes. For a constant signal frequency (at 50 kHz), the electrical impedance of a conductor is proportional to the specific impeditivity ($\text{ohm} \times \text{m}$) multiplied by the length and divided by the cross-sectional area of

Table 4. Demographic and anthropometric characteristics of 456 prevalent HD patients^a

Characteristic	Men	Women
n	308	148
Age (yr)	62.7 ± 13.6	63.8 ± 14.3
Height (cm)	163.2 ± 7.3	153.9 ± 7.0
BMI (kg/m ²)	23.9 ± 4.3	24.7 ± 4.9
Actual DW (kg)	64.3 ± 11.6	58.4 ± 12.6
Estimated DW (kg)	64.2 ± 11.8	58.7 ± 12.4

^aData are means ± SD. BIA equations (equations 1a and 2a) were applied for estimation of dry weight (DW).

Table 5. Demographic and anthropometric characteristics of 27 incident HD patients^a

Characteristic	Men	Women
n	14	13
Age (yr)	68.2 ± 13.7	68.3 ± 11.6
Height (cm)	164.3 ± 7.7	156.4 ± 6.4
BMI (kg/m ²) ^b	24.9 ± 4.4	26.3 ± 5.3
Body weight (kg) ^b	68.6 ± 7.2	64.8 ± 6.4
Achieved DW (kg)	66.8 ± 7.9	62.8 ± 6.7
Predicted DW (kg)	67.4 ± 7.2	62.2 ± 6.6

^aData are means ± SD. BIA equations (equations 1a and 2a) were applied for prediction of DW.

^bAt baseline.

the conductor (11,17). R determines total body water, whereas XC reflects intracellular body water. Thus, if, on the one hand, it is true that DW problems are essentially problems of extracellular water, then on the other hand, extracellular water is directly influenced by (and influences) intracellular water: Both

determine total body water. R remains constant and highly reproducible during the 120 min after the end of HD, that is, in the DW state of HD patients (17). Finally, BIA was performed in standardized conditions: A quiet environment, ambient temperature of 22 to 24°C, and after being 20 min at rest in the supine position (18). This is the way to restrict bias.

The emblematic title of a recent editorial comment was "Can Technology Solve the Clinical Problem of Dry Weight?" (19). Actually, several approaches to DW prediction and to optimization of fluid removal during HD using BIA have been shown to be successful (2,11-13); furthermore, very recently, an equivalence of information in fluid monitoring during HD, using measurements at 50 KHz, conventional series circuit, *versus* bioimpedance spectroscopy with Cole and Hanai model was demonstrated (20). Therefore, the answer to the question of whether technology (BIA) can solve the clinical problem of DW is definitely yes, as outlined by Schneditz in a very recent editorial comment (21): "... when appropriately used, bioimpedance can provide measures of body hydration characterized by a small error, a high sensitivity to changes in water volume, and, above all, a linear relationship over a wide range of volume changes. These features make it very useful to measure body hydration in hemodialysis patients" (21). However, as outlined by Schneditz (21), the crucial point is that the method in BIA application must be appropriate. We believe that our approach was correct and appropriate for two main reasons: (1) The high quality and standardization of the procedures; for example, all of the BIA measurements of the reference population (disease-free individuals with normal BMI) were performed by the same operator using the same device; and (2) the crucial choice of introducing a normalization factor in applying BIA prediction equations of DW in HD patients; the simple reason is that these patients do not have normal levels of body composition (22,23).

A point that deserves comment is related to the data that pertain to the application of equations 1a and 2a to the cohort of 456 prevalent stable HD patients and to the cohort of 27 incident HD patients. The mean difference between the actual and estimated DW was 0.1 ± 1.0 kg ($P = 0.53$) in men and -0.3 ± 1.0 ($P = 0.76$) in women (cohort of prevalent patients). The explanation for these good results may lie once again in the high quality and the standardization of the procedures: All of the BIA measurements were performed by only one operator in each of the two dialysis units in which the patients were treated. Furthermore, their postdialysis DW used to be determined under strict clinical surveillance (3) associated with the monthly use of the resistance reactance graph (11). Therefore, our conclusion is that these data constitute a reciprocal validation of the resistance reactance graph (11) and of our equations—much more so of our equations, which still need, evidently, external validations.

Also the results that we obtained in the cohort of incident patients are good: The mean difference between the achieved and predicted DW was -0.6 ± 1.0 kg ($P = 0.76$) in men and 0.6 ± 1.0 ($P = 0.50$) in women. This seems to be more true when it is realized that the change in body weight is not necessarily caused by a change in overhydration alone. Usually it takes some weeks

to get the patient to his or her DW. Within this time, the lean tissue mass and the fat mass of the patient also may change considerably. These changes may be even more pronounced in the phase of starting HD therapy, when major changes in appetite, metabolism, and physical activity are probable. Therefore, the change in overhydration cannot easily be derived from the observed weight changes of a patient (2). Worth noting, a very recent article that aimed to compare in parallel in a cohort of 16 incident patients the measurement of vena cava diameter, vena cava collapsibility index, the blood volume drop during an ultrafiltration bolus, the rebound after the ultrafiltration bolus, and the extracellular fluid volume determined with whole-body bioimpedance spectroscopy showed this interesting result: The bioimpedance spectroscopy seemed to be the most promising method for a practical fluid management system in HD because the detection limits of bioimpedance spectroscopy for changes in fluid status (*i.e.*, the sensitivity in detecting clinically relevant changes in fluid status) was the lowest among them, 0.87 ± 0.64 kg (2).

Another point that deserves comment is that age as a variable in our equations played a role only in men but not in women; this might raise a question about age distribution in both genders. Actually, age distribution was similar both in men and women with similar SD. A final question could be raised: Are these prediction equations that are validated in adult white HD patients generally applicable to all HD patients worldwide? The answer is probably not; however, we think that our four-step model could be applied successfully in other ethnic groups and/or races.

As a practical approach to the hot issue of DW in HD patients, we suggest integration of routine monitoring of BIA measurements with a strict clinical surveillance (3); we are not able to suggest any monitoring schedule because the study was not aimed for such a purpose; therefore, we can only suggest performance of periodic BIA measurements (two times a year could be a good compromise). Long-term studies are needed to establish whether routine monitoring of hydration and the maintenance of the patient at normal hydration using this approach translate to improved cardiovascular status and improved treatment outcome (19). As a future technological approach, the recognition from the scientific community that BIA measurements are a useful tool for the prediction of DW in HD patients might lead to their incorporation into the next generation of HD equipment, possibly with feedback architecture (19).

Conclusion

This study was able to develop and validate BIA prediction equations for DW in HD patients. They seem to be a promising tool for prediction of DW in HD patients. This new method still needs external validation.

Disclosures

None.

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