Introduction

Of the various methods of assessing human body composition, bioelectrical impedance analysis (BIA) has emerged as a promising technique because of its simplicity, low cost, high reproducibility, and patient acceptability. It has been demonstrated to quantify fat-free mass, body fat, and total body water reliably, as validated by densitometry,[1] deuterium isotope dilution[2,3] and dual energy X-ray absorptiometry (DXA)[4,5] in normal and obese individuals. Few studies have been done in special populations (e.g. diabetes, renal failure, etc.). Studies in insulin-dependent (Type 1) diabetic patients have recently been published, confirming the validity of BIA in this group.[6] However, the vast majority of diabetic patients have Type 2 non-insulin-dependent diabetes (NIDDM), which is associated with obesity in 85% of individuals. As a consequence, the use of BIA for the measurement of body composition in Type 2 diabetes would be of interest both for clinical and investigative purposes.

A new device (TBF 105, Tanita Corporation, Tokyo, Japan) utilizes a single frequency 50 kHz leg-to-leg bioimpedance analysis (BIA) system for standing impedance and body weight measurement. The use of this system in the determination of body composition has been validated against $3H_2O$ dilution volume, underwater weighing, and DXA methods in healthy adults.[7] The aim of our study was to determine the validity of BIA as assessed with this new device for the measurement of body composition in Type 2 diabetes mellitus. DXA was employed as the established reference method.[8,9]

Patients and Methods

The protocol was approved by the Human Subjects Review Committee of the University of Toronto and informed written consent was obtained from all subjects. Ninety-eight subjects (50 male, 48 female) aged 40-70 years were recruited consecutively from the diabetes clinic outpatient population of Mt. Sinai Hospital. All subjects met the diagnostic criteria of Type 2 diabetes established by the National Diabetes Data Group.[10] Subjects with a history of lower limb amputation, oedema or current pregnancy were excluded.

During a single study visit, history, physical examination (height, weight, skinfold thickness and waist:hip ratio), blood sampling, BIA measurement, and DXA measurement were performed. All subjects were instructed to refrain from ingesting alcohol and from strenuous physical activity for 24 h prior to the study visit.

Height

Height was measured without shoes to the nearest 0.1 cm, using a wall-mounted stadiometer (Accustat, Genetech, Inc. San Francisco, CA, USA)

Bioelectrical Impedance Analysis and Weight

BIA and weight were measured using a new BIA system (TBF 105, Tanita Corporation, Tokyo, Japan) in which two foot-pad electrodes are incorporated into a precision electronic scale. The measurements were performed in a standing position, with electrodes in contact with soles and heels of both feet. Biological impedance was measured with 4 terminals; a sine wave current with frequency 50 Hz and 0.8 mA was applied via source electrodes on both feet, and the voltage drop was compared with the heel electrodes. TBF 105 automatically measured weight and impedance. The computer software in the machine then used the measured resistance (R), the programmed subject's gender and height (Ht), and the measured weight (W) to calculate the body density (BD), based on previously derived equations obtained from regression analysis with underwater weighing:

$$\text{Male BD} = 1.1008 - 0.1129\ WR/Ht^2 + 0.000178R$$

$$\text{Female BD} = 1.0907 - 0.1120\ WR/Ht^2 + 0.000134R$$

This was then applied automatically to a standard densitometric formula according to Brozek to calculate the % fat which was provided in the final printout.

$$\%\ \text{fat} = \{(4.57/BD) - 4.142\} \times 100$$

The coefficient of variations for within-day impedance measurement was 0.9% and the between-day CVs for impedance was 2.1%.[7]

Table 1. Baseline characteristics of study population.

	Male (n=48)		Female (n=48)	
	Mean ± SD	Range	Mean ± SD	Range
Age (yr)	54.6±7.85	40-69	54±8.7	40-70
Age of onset (yr)	45.9±8.58	24-62	47.6±8.27	33-65
Duration of known diabetes (yr)	8.77±7.49	0.2-35	6.81±4.9	1-20
Treatment Group				
Diet	11		11	
Oral Agent	23		27	
Insulin	14		10	
Height (cm)	172.6±7.2	147-188	160.1±6.6	149.5-178
Weight (kg)	85.7±15.17	56.2-115	78.6±16.4	49.3-118.5
Body mass index	28.8±4.19	20.6-38.4	30.9±5.6	19-43
Waist:hip ratio	1.01±0.06	0.89-1.18	0.93±0.09	0.72-1.2
Haemoglobin A_{1c} (%)	7.63±1.90	3.7-11.1	7.90±1.80	4.1-12.4

DXA

Whole body DXA was performed using Hologic QDR Model #1000/w (Hologic Co., Waltham, MA, USA). The scan image was analysed for bone and soft tissue composition using enhanced whole body software, version 5.62 (Hologic Co., Waltham, MA USA). Subjects were scanned wearing hospital gowns, having removed all jewelry and other metal objects. The coefficients of variation for measurement of % fat and fat free mass were 1.04% and 0.4% respectively.[11]

Statistical Analysis

Data were analysed using Version 6.09 of the SAS statistical software.[12] Results were expressed as mean ± SD and the significance level set at $p<0.05$. Linear regression analysis and Pearson correlation coefficients were used to evaluate the relationship between predictions of percentage body fat by BIA and DXA. Agreement between % BF DXA and % BF BIA was further assessed by using the procedure suggested by Bland and Altman.[13]

Results

Population Characteristics of Study Cohort

Ninety-eight patients were recruited and underwent the study protocol. Two men were over 120 kg and measurement from DXA was not possible. They were excluded from the analysis. Table 1 summarizes the relevant characteristics of the remaining 96 subjects.

Comparison of BIA with DXA

There was a high correlation between % BF BIA and % BF DXA (r=0.89, $p<0.0001$, 95% confidence interval of r was 0.84 - 0.93), as shown in Figure 1. The correlation between % BF BIA and % BF DXA (lower limbs and trunk), and % BF DXA (lower limb) was 0.88 and 0.83 respectively. Figure 2 demonstrated the plots of the difference against the mean for the log-transformed measurements, as well as the 95% limits of difference for our sample.

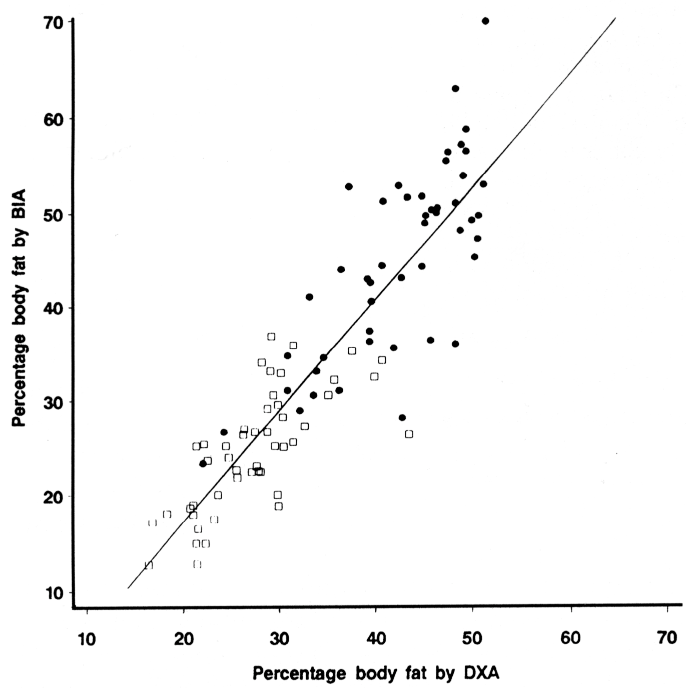

Figure 1. Regression of percentage body fat by DXA (dual-X-ray absorptiometry) against percentage body fat by BIA (Bioelectrical Impedance Analysis); r-0.89, p<0.0001; ❐ males, ● females.

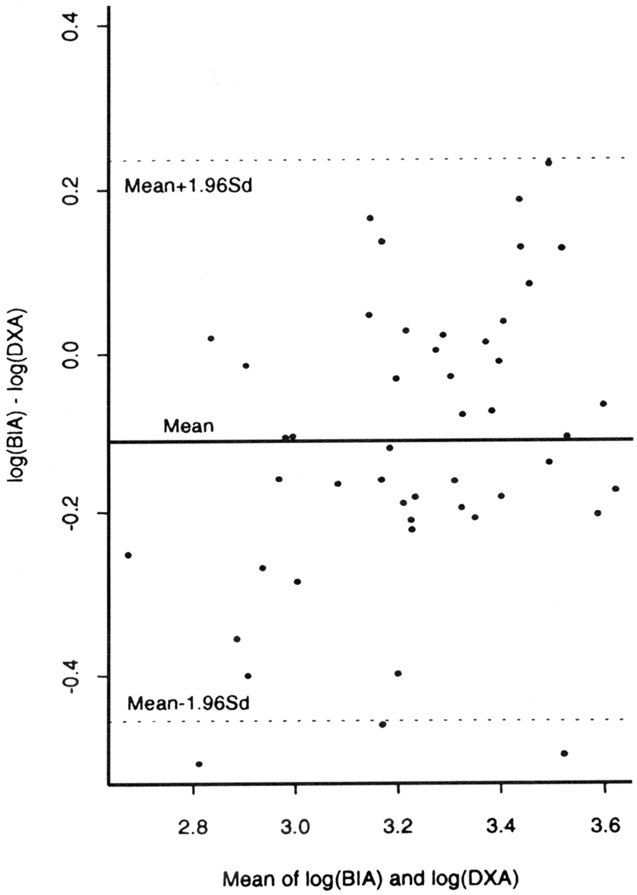

Figure 2. The difference in logarithmic transformation of the percentage body fat by BIA and DXA plotted against the mean of the logarithmic transformation of two percentage body fat for (a) males and (b) females.

On average, %BF BIA was 89.6% of the value determined by DXA for men and 105.4% for females. These differences were statistically significant ($p<0.0001$, *t*-test). The 95% limits of agreement between % BF BIA and % BF DXA for our sample were (63.3%, 126.7%) for males, and (78.3%, 140.8%) for females.

Discussion

This study shows that % BF BIA correlates well with an established method of determining body fat (DXA) in a population of patients with Type 2 diabetes mellitus, similar to data previously shown in healthy individuals. Agreement analysis however showed that there is a consistent bias in the percentage of fat determined by BIA across the entire group, independent of their body fat content. (Figure 2). This bias is different for males and females: in men % fat is underestimated with BIA by approximately 10% while in women, % fat by BIA is overestimated by approximately 5%. As an example, for a Type 2 diabetic subject with % BF DXA of 30%, the average % BF determined by BIA would be 27% if the subject is a man, while it would be 31.5% if the subject is a woman. This bias, though statistically significant, is small and probably of no clinical significance. This gender difference has also been observed in a recently published study examining the use of this machine for body composition measurement in healthy adults.[7] Specifically why these gender differences occur is not entirely clear but presumably relates to the substantial differences in fat distribution in men and women.

BIA is based on measurement of impedance which is then applied to a gender specific equation to calculate body density (BD). This is in turn used to calculate % fat according to standard densitometric formula which assumes constant density of fat and fat free mass.[14,15]

Variables which might be different in people with diabetes include changes in bone mass which had been reported to be increased,[16,17] similar[18,19] or decreased[20,21] as compared to non diabetic individuals; and hydration status might be disturbed depending on the severity of hyperglycaemia, leading to perturbation of the relationship between impedance and fat free mass. All these could have made the equations previously derived from the general population not directly applicable to our diabetic population, resulting in discrepancy seen in the agreement analysis. Further studies specifically designed to evaluate the above questions will have to be performed. This could result in the development of a diabetes-specific equation for TBF 105, to minimize the bias and improve the accuracy of this BIA method in the diabetes population.

In summary, BIA using bipolar foot electrodes provides a valid estimate of % body fat in subjects with Type 2 diabetes mellitus. It does not require examiner skill, is rapid, portable, and free from discomfort, and is a reliable technique for determination of body composition in Type 2 diabetic subjects in clinical and investigative studies, provided that the gender-specific bias is recognized.

Acknowledgements

We thank S.S. Krishnan at the Toronto Hospital, General Division for performing the body composition measurement by DXA and Tanita Corporation, Tokyo, Japan for making the TBF 105 body composition analyser available and providing a research grant to support these studies.

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