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The Effect of Weight Change on DXA Scans in a 2-Year Trial of Etidronate Therapy

R. Patel, G. M. Blake, R. J. M. Herd, I. Fogelman

Department of Nuclear Medicine, Guy's Hospital, St. Thomas Street, London SE1 9RT, United Kingdom

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Abstract. Variation in soft tissue composition is a potential cause of error in dual X-ray absorptiometry (DXA) measurements of bone mineral density (BMD). We investigated the effect of patients' change of weight on DXA scans in 152 women enrolled in a 2-year trial of cyclical etidronate therapy. Scans of the spine, hip, and total body were performed at baseline, 1 and 2 years on a Hologic QDR-2000. The study was completed by 135 subjects (64 on etidronate, 71 on placebo). Results were expressed as the percentage change in BMD (spine, femoral neck, total body) or bone mineral content (BMC) (total body only) at 2 years. Total body scans were analyzed using the manufacturer's 'standard' and 'enhanced' algorithms. Analysis was performed using multivariate regression with percentage change in BMD or BMC as the dependent variable, and treatment group and percentage change in weight as the independent variables. Weight change varied between −14.4% and +16.7%. All DXA variables showed a statistically significant treatment effect. Standard total body BMD and BMC and enhanced total body BMC all showed a significant dependence on weight change ($P < 0.01$, $P < 0.001$ and $P < 0.01$, respectively). No effect of weight change was seen on spine, femoral neck, or enhanced total body BMD. In order to investigate the effects of weight on long-term precision, patients were allocated to two groups according to baseline body mass index (BMI <25 and >25 kg/m^2, respectively). For femoral neck BMD the root mean square (RMS) residual percentage change was statistically significantly larger in the high BMI group ($P < 0.05$) but all other bone density variables showed no significant difference. With patients allocated to two groups according to their absolute percentage change in weight (<5% and >5%, respectively) the RMS residual percentage changes in the bone density variables were statistically significantly larger in the large weight change group for femoral neck BMD ($P < 0.05$) and for standard and enhanced total body BMC ($P < 0.01$ and $P < 0.05$, respectively). With the exception of the standard total body algorithm, weight change in a longitudinal study of postmenopausal women was not found to cause systematic errors in the results of DXA studies but may adversely affect precision.

Key words: Bone mineral measurements — Dual X-ray absorptiometry — Weight change — Clinical trials.

Correspondence to: R. Patel

Over the last 10 years, dual X-ray absorptiometry (DXA) has become established as the most widely used technique for assessing patients' skeletal status [1, 2]. When interpreted in conjunction with the World Health Organization (WHO) criteria for the diagnosis of osteoporosis [3, 4], DXA scans give a simple, safe, and precise method of identifying postmenopausal women at risk of fragility fracture. There is increasing evidence that such patients can benefit from preventive treatment that will reduce the risk of future fractures [5–8]. DXA can measure small changes in bone density because of its high precision and stable calibration, making it suitable for use in clinical trials of new therapies to prevent bone loss [5, 6, 9–11]. In many centers women recommended to start treatment for osteoporosis have follow-up scans after 1 or 2 years to monitor their response [12]. The ability of DXA to allow precision measurements of small changes in bone density is therefore an important factor in its widespread clinical application.

The basic physical principle behind DXA is the measurement of the transmission through the body of X-rays with high and low photon energies. Measurement of the transmission factors at two different energies enables the areal densities (i.e., mass per unit projected area) of two different types of tissue to be inferred because of the dependence of the X-ray attenuation coefficient on atomic number and photon energy [13]. In DXA scans these are taken to be bone mineral and soft tissue, respectively. However, the information on soft-tissue density is often not required and the conventional diagnostic result of DXA scanning is the measurement of mean bone mineral density (BMD, units: g/cm^2) at one or more skeletal sites.

Despite the extensive use of DXA scanning for diagnostic and longitudinal studies, it is widely recognized that a significant limitation of the technique is that soft tissue is composed of separate lean and fat constituents. Adipose tissue has a different X-ray attenuation coefficient to lean tissue because of its higher hydrogen content and differences in the composition of soft tissue in the path of the X-ray beam through bone compared with the adjacent soft tissue reference area will cause errors in the BMD measurements [13–16]. These errors can have a significant influence on the interpretation of BMD measurements based on the WHO criteria [3, 14–16]. Similarly, in patients participating in clinical trials or having follow-up scans after commencing therapy, changes of body weight might influence the observed changes in BMD [17].

Many previous studies have examined the magnitude of the BMD measurement errors caused by adipose tissue in either DXA or the earlier technology of dual photon absorptiometry (DPA) based on the use of a ^{153}Gd radionuclide source. These include theoretical studies based on the mass attenuation coefficients of hydroxyapatite, lean tissue and

Table 1. Baseline demographic and bone densitometry data by treatment group

Parameter	Treatment group: Placebo mean (and SD) (n = 69)	Treatment group: Etidronate mean (and SD) (n = 64)	Statistical significance
Age (years)	54.9 (4.3)	54.7 (5.3)	NS
Height (cm)	161.6 (6.3)	161.2 (6.1)	NS
Weight by scales (kg)	62.8 (8.3)	60.6 (9.4)	NS
Weight by DXA (kg)	62.9 (8.3)	60.6 (9.4)	NS
Years since menopause	5.3 (2.8)	5.5 (2.8)	NS
PA spine BMD (g/cm^2)	0.826 (0.07)	0.844 (0.08)	NS
Femoral neck BMD (g/cm^2)	0.705 (0.081)	0.702 (0.090)	NS
Total body BMD (s) (g/cm^2)	1.028 (0.057)	1.018 (0.068)	NS
Total body BMC (s) (g/cm^2)	1983 (233)	1936 (267)	NS
Total body BMD (e) (g/cm^2)	0.994 (0.059)	0.999 (0.073)	NS
Total body BMC (e) (g/cm^2)	1853 (202)	1839 (225)	NS

s = standard total body algorithm; e = enhanced total body algorithm

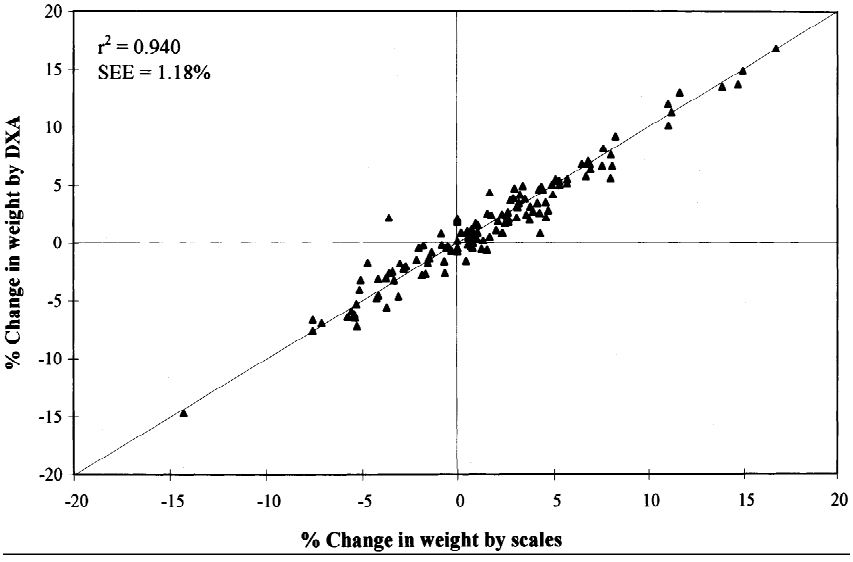


Fig. 1. Correlation between the percentage change in weight measured with DXA and percentage change in weight measured with scales. The diagonal line is the line of identity.

fat [13], and studies using phantoms [18, 19] and cadavers [15]. In a series of elegant studies, Tothill et al. [14, 17, 20, 21] used computed tomography (CT) images to delineate the distribution of lean and fat tissue in transaxial scans through the lumbar vertebrae and hence estimate the effect on posteroanterior (PA) and lateral projection BMD measurements of the spine. In a small group of patients they were able to use CT studies to estimate the effect of weight change on longitudinal BMD measurements [17].

The present study was based on a group of 152 women enrolled in a prospective clinical trial for the prevention of early postmenopausal bone loss by cyclical etidronate therapy. During data analysis it was apparent that many subjects experienced significant weight gain or loss during the 2-year period of the study and we therefore examined the clinical trial data for evidence of the effect of weight change on longitudinal DXA scanning. We have examined the data for both evidence of the effect of weight change on the observed changes in BMD and the effect of weight at baseline and change of weight during the study on the long-term precision of the DXA measurements.

Subjects and Methods

The effect of patients' change of weight on the results of DXA scanning was investigated in a group of 152 postmenopausal women recruited into a randomized, single center, double-blind, placebo-controlled clinical trial of cyclical etidronate therapy. All were Caucasian, ambulatory, and at least 1 year but not more than 10 postmenopausal. None had a history of vertebral, wrist, or hip fracture, none had ever previously taken bisphosphonate treatment, and none had taken estrogen therapy within the last 6 months. Either spine or femoral neck BMD were 0 to −2 SD of normal values for age-matched, healthy women in the local population [22]. Subjects were randomly allocated to one of two treatment groups: oral etidronate (400 mg/day) for 14 days followed by 76 days of calcium supplements (500 mg/day) or placebo etidronate for 14 days followed by 76 days of calcium. Each 90-day cycle was repeated eight times for a total duration of 2 years.

PA lumbar spine (L1–L4), left hip, and total body DXA were performed on a Hologic QDR-2000 (Hologic Inc., Waltham, MA) at baseline, 12 months, and 24 months. The spine and hip scans were acquired using the medium array mode and analyzed using software version 4.52. Total body scans were performed in pencil beam mode and analyzed using software version 5.54. Follow-up

Table 2. Results for multivariate regression analysis with percentage change in baseline BMD as the dependent variable and treatment group and percentage change in weight as independent variables

Measurement parameter	Treatment coefficient (%)	Statistical significance (*t*-value)	Δ Weight coefficient (%/% wt)	Statistical significance (*t*-value)
BMD_{LS}	3.873	6.185^{c}	0.026	0.399^{NS}
BMD_{FN}	1.956	2.901^{b}	0.132	1.902^{NS}
Standard BMD_{TB}	0.963	3.319^{b}	0.082	2.745^{b}
Standard BMC_{TB}	1.134	2.710^{b}	0.452	10.455^{c}
Enhanced BMD_{TB}	0.849	2.322^{a}	−0.053	-1.371^{NS}
Enhanced BMC_{TB}	1.660	4.295^{c}	0.117	2.924^{b}

NS = not significant
[a] $P < 0.05$; [b] $P < 0.01$; [c] $P < 0.001$

scans were analyzed using the manufacturer's scan comparison software. Daily scans of an anthropomorphic spine phantom were performed throughout the study to ensure consistency of calibration. Along with other safety checks, subjects' weight was measured on electronic scales at each visit. The scales used were calibrated by the Weights and Measures Inspectorate of Southwark Trading Standards Department. Body mass index (BMI) was calculated from weight (kg)/height^2 (m^2) for all subjects using weight measured on scales.

A second measure of patients' weight was available from the body composition analysis provided by the total body DXA scans [23]. Two versions of software were available for the analysis of pencil beam mode total body scans [24]. 'Standard' analysis used a global calibration in which the BMD result for each bone pixel was calculated from calibration data derived from the QDR-2000 internal reference wheel [18] averaged over all soft tissue pixels across the whole scan. In the alternative 'enhanced' analysis, BMD results were derived from calibration data restricted to separate subregions of the body, for example, the trunk, pelvis, legs, and arms. Enhanced software rather than standard software [24] is used to give bone densitometry data that are more sensitive to the effects of large changes in patients' weight.

Changes in patients' weight and in the bone densitometry variables were expressed as the percentage change from baseline. Six bone densitometry variables were studied: PA spine BMD (BMD_{LS}), femoral neck BMD (BMD_{FN}), 'standard' and 'enhanced' total body BMD (BMD_{TB}), and standard and enhanced total body bone mineral content (BMC_{TB}). For each of these variables, multivariate regression analysis was performed on the percentage change from baseline. The independent variables were treatment group and percentage change in weight. The statistical model gave values for two coefficients: (1) the treatment coefficient giving the difference between the etidronate and placebo groups corrected to zero change in weight; (2) the change of weight coefficient giving the percentage change in bone densitometry variable for a 1% change in weight. The statistical significance of each coefficient was expressed in terms of the value for the Students *t*-test. Results were taken to be statistically significant if $P < 0.05$.

The effect of weight at baseline on the long-term precision of DXA measurements was investigated by allocating the patients to two groups according to BMI (<25 and >25 kg/m^2, respectively). For each bone densitometry variable the root mean square (RMS) residual after performing the multivariate regression analysis was calculated for each of the two BMI groups. Results for BMI <25 and >25 kg/m^2 were compared using the F-test. A similar study of the effect of weight change on the precision of the DXA measurements was performed by allocating patients to two groups according to the absolute percentage change in weight (<5% and >5%, respectively).

Results

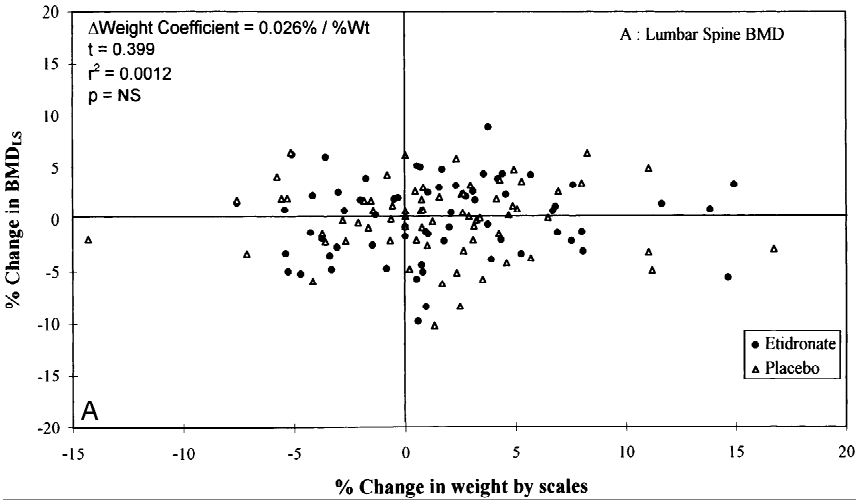
One hundred and thirty-five subjects completed the clinical trial at 2 years, 64 of whom were given etidronate and 71 placebo. Data for two patients in the placebo group were disregarded. One subject had an exceptionally high BMI (50 kg/m^2) and the second subject did not have the 2-year hip and total body scans performed because of scanner failure. A preliminary report of the effect of cyclical etidronate therapy in preventing early postmenopausal bone loss is presented elsewhere [25]. In this report we examine the effect of patients' weight change during the study on the bone densitometry data and discuss the implications for longitudinal DXA studies.

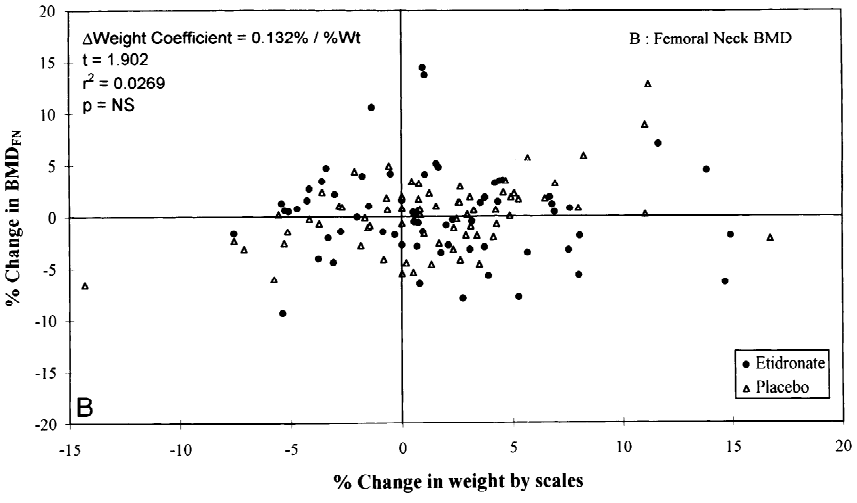
Baseline demographic data for age, weight, height, and number of years since menopause were not statistically significantly different between the treated and placebo groups (Table 1). Neither was there any significant difference at baseline for any of the bone densitometry variables studied (Table 1). Subjects' weight at baseline, measured using the total body DXA body composition software, correlated closely with weight measured on scales ($r^2 = 0.996$, SEE = 0.56 kg). Similarly, subjects' percentage change in weight over the 2 years of the study, measured using total body DXA and scales, also correlated well [$r^2 = 0.940$, standard errors of estimate (SEE) = 1.18%] (Fig. 1).

The results of the multivariate regression analysis on the effect of treatment group and percentage change of weight on the six bone densitometry variables studied are listed in Table 2. Each DXA variable showed a statistically significant treatment effect (Table 2, column 3).

A graphical representation of the effect of weight change on BMD and BMC was obtained by adding the treatment coefficient (Table 2, column 2) to the percentage change in DXA variables for all subjects in the placebo group before pooling data for the two groups and plotting against the percentage change in weight measured by scales. The intercept obtained from linear regression analysis was then subtracted from each data point and the scatter graphs were replotted (Fig. 2A–F). The slopes of the regression lines and their statistical significance were identical to the results of the multivariate regression analysis (Table 2, columns 4 and 5). The analysis showed that for BMD_{LS}, BMD_{FN}, and enhanced BMD_{TB} the effect of weight change was not statistically significant. In contrast, the trend for standard BMC_{TB} was highly significant (Fig. 2D, $r^2 = 0.4550$, $P < 0.001$), whereas standard BMD_{TB} ($r^2 = 0.050$, $P < 0.01$) and enhanced BMC_{TB} ($r^2 = 0.061$, $P < 0.01$) showed evidence of small but statistically significant trends. For standard BMC_{TB} a change in weight of 1 kg would result in a change of 0.7%.

When patients were allocated to two groups according to





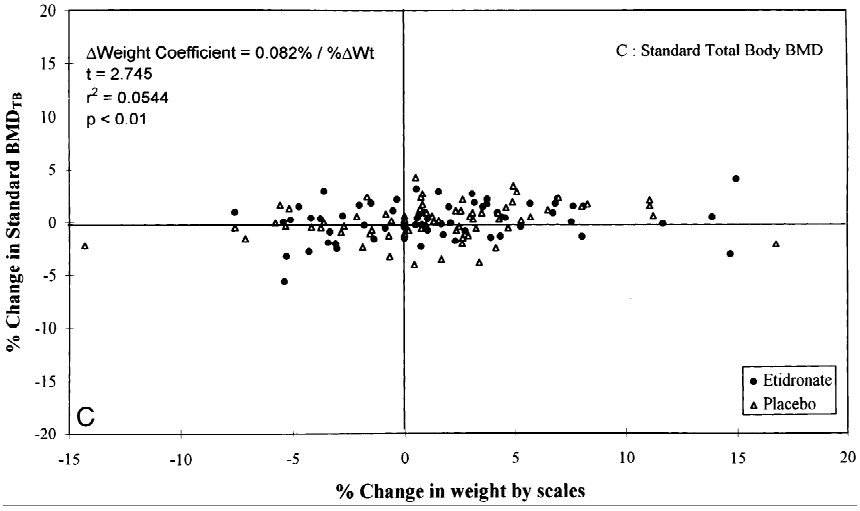
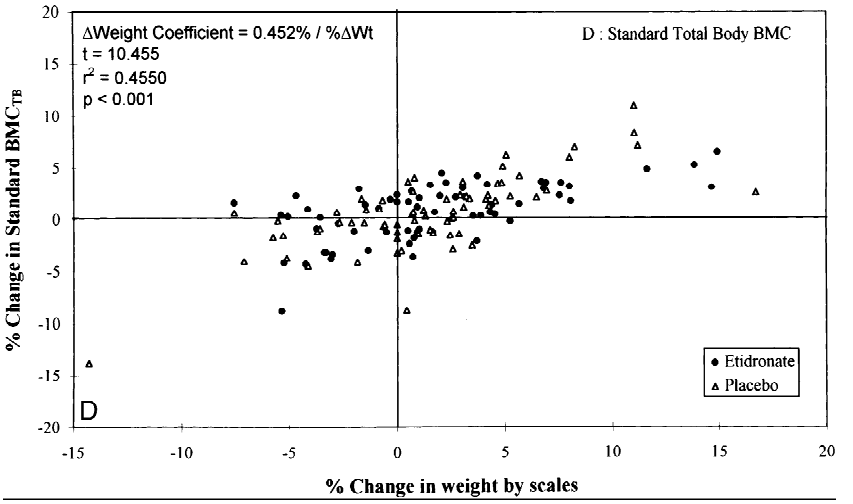
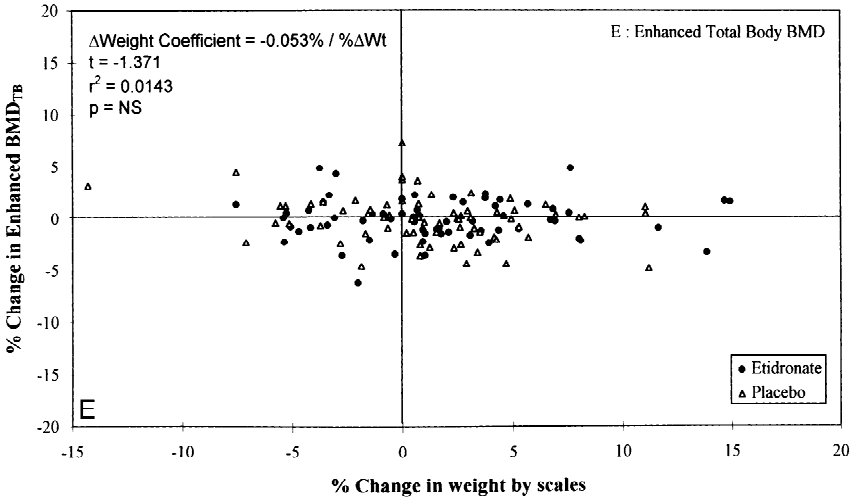


Fig. 2. The effect of weight change on the change in DXA variables. **(A)** PA spine BMD; **(B)** femoral neck BMD; **(C)** total body BMC analyzed using standard software algorithm; **(D)** total body BMD analyzed using standard software algorithm; **(E)** total body BMD analyzed using enhanced software algorithm; **(F)** total body BMC analyzed using enhanced software algorithm.

baseline BMI there were 96 subjects with BMI <25 kg/m^2 (mean BMI: 22.27; range 18.00–24.99 kg/m^2) and 37 with BMI >25 kg/m^2 (mean BMI: 26.96; range 25.00–32.40 kg/m^2). The RMS residual percentage changes in the DXA variables following the multivariate regression analysis were larger in the high BMI group for three of the six variables (BMD_{LS}, BMD_{FN} and enhanced BMC_{TB}) (Table 3). However, for only one variable (BMD_{FN}) was the difference statistically significant ($P < 0.05$).

When patients were allocated to two groups according to their absolute percentage change in weight there were 98 subjects with weight change <5% (mean absolute weight change = 2.21%; range = 0.00–4.92%) and 35 with weight change >5% (mean absolute weight change = 8.14%; range





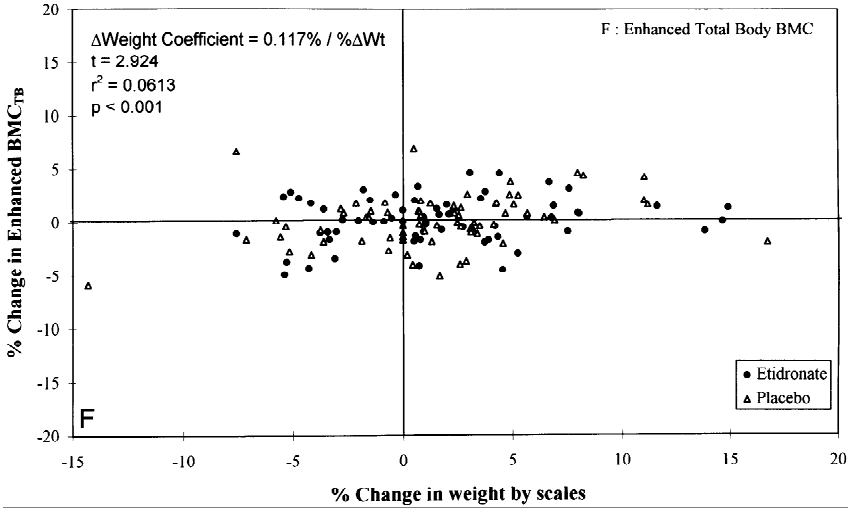


Fig. 2. *Continued.*

= 5.07–16.73%). The RMS residual percentage changes in the bone densitometry variables were larger in the group with the greatest weight change for four of the six variables (BMD_{FN}, standard BMD_{TB}, standard BMC_{TB}, and enhanced BMC_{TB}) (Table 4). For three out of four (BMD_{FN}, standard BMC_{TB}, and enhanced BMC_{TB}) the F-test showed that the difference was statistically significant ($P < 0.01$– $P < 0.05$).

Discussion

Although previous studies have estimated the magnitude of the BMD measurement errors in DXA scanning caused by adipose tissue [13–16, 18–21], apart from the report of Tothill and Avenell [17] the effect on longitudinal studies has generally been ignored. The present study included pa-

Table 3. Precision expressed as the RMS residual percentage changes in bone density parameter in subjects with BMI less than and greater than 25 kg/m^2

Measurement site	RMS residual (%) BMI < 25 kg/m^2 (n = 96)	BMI > 25 kg/m^2 (n = 37)	Statistical significance
PA spine BMD	2.44	2.61	NS
Femoral neck BMD	2.42	3.10	$P < 0.05$
Total body BMD (s)	1.22	1.04	NS
Total body BMC (s)	1.74	1.59	NS
Total body BMD (e)	1.52	1.34	NS
Total body BMC (e)	1.50	1.74	NS

Residuals were measured as the percentage change over 2 years after correction for treatment effect and weight change (Table 2).
s = standard total body algorithm, e = enhanced total body algorithm

Table 4. Precision expressed as the RMS residual percentage in bone density parameter in subjects with absolute percentage weight change less than and greater than 5%.

Measurement site	RMS residual (%) % Δ Weight < 5% (n = 98)	% Δ Weight > 5% (n = 35)	Statistical significance
PA spine BMD	2.57	2.42	NS
Femoral neck BMD	2.54	3.28	$P < 0.05$
Total body BMD (s)	1.16	1.33	NS
Total body BMC (s)	1.71	3.39	$P < 0.01$
Total body BMD (e)	1.52	1.37	NS
Total body BMC (e)	1.49	1.93	$P < 0.05$

Residuals were measured as the percentage change over 2 years after correction for treatment effect and weight change (Table 2).
s = standard total body algorithm, e = enhanced total body algorithm.

tients who underwent a wide range of change in weight with a maximum increase of 10.0 kg (67.4 kg–77.4 kg) and a maximum decrease of 9.3 kg (64.4 kg–55.1 kg). No detectable effect of weight change was observed on BMD_{LS} or BMD_{FN} in the group of 133 postmenopausal women followed over a 2-year period. However, a substantial effect of weight change was found for BMC_{TB} derived using the standard algorithm. A smaller but statistically significant effect was found for standard BMD_{TB} and enhanced BMC_{TB}. BMD_{TB} derived using the enhanced algorithm, was found to be independent of weight change. Total body DXA scans in the present study were all acquired using the pencil beam scan mode. We are therefore unable to comment on the effect of weight change on fan beam total body scans [24]. The data in this study apply specifically to Hologic QDR densitometers, and differences in edge detection algorithms for other manufacturers' equipment might result in a different dependence on weight change [26].

When the effect of weight at baseline on the long-term precision of the DXA measurements was examined, the RMS standard deviation of the percentage change in bone density variable was larger in the high BMI group for three of six variables. However, only for BMD_{FN} was the difference statistically significant. We have previously examined the effect of BMI on the precision of spine and hip BMD measurements in a group of 151 women having DXA screening scans on a QDR-4500 bone densitometer [27]. In this latter study a noticeable trend for RMS standard deviation to increase with BMI was seen for both BMD_{LS} and BMD_{FN}, although the changes were statistically significant only in the spine. In the present study there were fewer patients with a BMI less than 20 kg/m^2 or greater than 30 kg/m^2 compared with the earlier study [27] and this probably explains the relative lack of evidence for the dependence of precision on BMI.

When the effect of weight change on the long-term precision of the DXA measurements was examined, the RMS standard deviation of the percentage change in bone density parameter was statistically significantly larger in the group showing an absolute percentage change of weight greater than 5% for three of six parameters (BMD_{FN}, standard BMC_{TB}, and enhanced BMC_{TB}). A weight change of 5% corresponded to 3 kg in a typical subject with a weight of 60 kg (Table 1). These results suggest that weight changes greater than 3 kg are likely to have an adverse effect on the precision of bone densitometry measurements even if they do not cause systematic errors in the measured BMD changes.

The results of this study show that the effect of weight change in generating systematic errors in the results of longitudinal DXA studies of the PA spine, femoral neck, and total body is negligible. For total body scans, the enhanced software algorithm should be used. It is reasonable to assume that the long-term precision of DXA measurements, which is important in determining the ability of longitudinal studies to detect statistically significant changes [10, 12], is a function of patients' body mass index [27]. This effect was difficult to detect in the present study, probably because

there were only two subjects with a BMI greater than 30 kg/m^2 and therefore classed as obese. It may prove more important in follow-up studies in the general population [12] where the careful weight selection criteria commonly applied to subjects in clinical trials do not apply. Change of weight during a longitudinal study, either an increase or a decrease, would also be expected to have an adverse effect on precision. This was confirmed by the present study, although it is notable that the largest effect in Table 4 was for BMC_{TB}.

In conclusion, weight change in a longitudinal study of postmenopausal women was not found to cause systematic errors in the results of DXA bone densitometry studies with the exception of the standard total body algorithm. However, obesity and change in weight may have an adverse effect on precision errors in individual patients and should be borne in mind when interpreting the results of follow-up scans.

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