Static and Mobile DXA Scanner In-Vivo Cross-Calibration Study.

Keywords: DXA, cross calibration, bone mineral density, QA, Quality assurance, clinical practice, osteoporosis

Abstract

Cross calibration of DXA scanning equipment with phantom subjects has been recommended for assessing agreement between devices co-located within DXA scanning services.

This study evaluated in-vivo and in-vitro cross calibration of a static and a mobile DXA scanner within the same service in their individual clinical settings.

50 individuals from a volunteer group were recruited to take part in this study and had DXA measurements made on two GE Lunar Prodigy Advance (GE Lunar, Bedford, UK) scanners.

Results in this study showed that the scanners agreed, with no statistically significant differences in BMD measurements made at the same site on the individual devices used in this study. The in-vivo cross calibration of the instruments was a useful experience, which demonstrated closely calibrated systems and raised the profile of the bone densitometry service within the hospital.

Introduction

Central dual energy x-ray absorptiometry (DXA) of the spine and hip is the current preferred method for the diagnosis of osteoporosis [1]. DXA scanners have good long term precision due to stable calibration and effective instrument quality control procedures to detect long term drift [1]. However, the results from DXA scanners produced by different manufacturers and even the same make of scanner made by the same manufacturer cannot be directly compared due to potential differences in calibration [2]. When introducing additional or replacing DXA scanners it is therefore recommended to perform cross calibration whether the new machine is from the same manufacturer or not [3]. While cross calibration between two machines of the same manufacturer and using the same manufacture's phantom has been reported to have good agreement of 0.2%, in vivo measurements may differ by more than 2% [4] The increased errors in-vivo can be partly attributed to the increased precision errors introduced by virtue of scanning an individual who has in-homogeneity within their tissue, meaning that the x-ray photons may not pass though the same structures on both scans. Precision errors within DXA are also important for the characterisation of it's ability to assess bone mineral density and detect longitudinal change. Monitoring measurement errors within a service is also dependant on QA systems to detect scanner changes [5]. When introducing a new scanner, it is recommended to undertake a cross-calibration of the scanners within a service. The optimum technique for undertaking a cross-calibration study of DXA scanners is to use in-vivo measurements since this is how DXA scanners are used in clinical practice [4,6].

In 2009, a GE Lunar Prodigy DXA scanner (GE Healthcare, Bedford, UK) was purchased and commissioned to operate in a mobile vehicle, alongside the existing static GE Lunar Prodigy within the Healthy Bones Service at Derriford Hospital (Plymouth UK). While it is not good practice to make longitudinal measurements of

individual patients using different scanners, a wider understanding of the agreement and the long term stability between the scanners was sought, in the event of scanner breakdown, replacement or change in individual patient pathway in accessing the service.

Cross-calibration with phantoms may be misleading, and in vivo measurements could differ by more than 2% [4] which is a statistically significant difference effecting or limiting clinical practice and patient pathway developments.

Binkley et al in their study comparing in-vivo and in-vitro cross calibration concluded that in-vitro phantom cross calibration studies alone are not sufficient in assessing the agreement between two DXA scanners. The poster also suggested that in-vivo cross calibration should become a routine aspect of quality bone densitometry: where two or more scanners form part of a centres inventory [6].

Since the two scanners are operating side by side, it was felt to be an important exercise to cross-calibrate them, evaluate any potential differences and understand any relationship between the two scanners. This information was intended to assist in the formation of local pathway policy about which patients are scanned on which scanner and to determine whether in practice it made any difference. Since precision errors vary between subjects due to differences in body habitus, bone mass, soft tissue ratio and adipose tissue distribution it is important to measure a set of subjects representative of a centre's workload [7] [8].

Materials and Methodology

The introduction of variables in the form of 'volunteers' leads to an increased precision error: In in-vitro studies the subject (phantom), scanner and operator are all

constant and the introduction of many different subjects will increase the precision error, but will more accurately reflect the subjects in clinical practice.

The study was designed to replicate, where possible, a true patient cohort by enlisting volunteers with risk factors for low bone mass and osteoporosis from within the hospitals staff population.

Participants

50 volunteers were recruited and screened for clinical risk factors for osteoporosis. To be eligible for the study volunteers had to fulfil at least one of the hospital trusts referral criteria for DXA scanning. A group of 50 patients were also selected, at random, for comparison with the volunteer group.

The study was over subscribed with 120 volunteers applying for the study. Those with clinical risk factors for osteoporosis were prioritised in order of clinical 'need' and 50 individuals with one or more clinically significant risk factors were invited to participate in the study.

Volunteers with risk factors who were not selected to participate in the study were offered advice including osteoporosis risk assessment and nutritional and exercise guidance, based on National Osteoporosis Society literature [9] [10] and were advised to discuss their risks with their own GP. The volunteers without any clinical risk factors for osteoporosis were reassured that they were currently at a low risk of osteoporosis.

The exclusion criteria for participation in the study included: pregnancy, DXA scan in previous 24 months, and bilateral hip replacement.

The study was approved by the Clinical Lead and IR(ME)R Practitioner for the Bone densitometry service who was responsible for justifying exposures made during the study.

An ethical opinion was sought from the National Research Ethics Service, and the Research and Development department at the hospital trust and both agreed that ethical approval was not required. The Clinical Audit department at the hospital trust approved the study as an audit.

Methods

All participants were consented using written informed consent and were weighed and measured, using SECA 701 scales & SECA 220 stadiometer (SECA Medical Scales and Measuring Systems, Birmingham UK) The scan mode was selected automatically by the scanners' software using an estimated tissue thickness based on the participants weight and height (BMI).

Each participant was scanned on both the static and the mobile scanner. The lumbar spine and same proximal femur were scanned on all participants on both scanners in line current clinical practice. [11] All participants had both scans performed on the same day in order to minimise errors resulting from weight changes or real changes in bone mass [12] and by the same Radiographer in order to reduce inter-operator precision error. A total of two radiographers took part in the data collection and analysis.

Data Analysis

Descriptive statistics were used to display the group characteristics.

The agreement between the scanners and 95% confidence intervals were calculated and the results were plotted using Bland-Altman plots with 95% confidence intervals

added. The diagnostic agreement was calculated by identifying how many participants reached the same diagnosis on both scanners. A two-tailed paired t-test was used to test for any statistically significant differences between the two scanners. The percentage agreement and intraclass correlations were calculated. All statistics were performed using SPSS version 19 (IBM).

Results

The presenting clinical risk factors for osteoporosis were recorded in all individuals participating in the study. The largest risk factor presented by the volunteer group with 27% was a family history of osteoporosis, also reported was a parental history of hip fracture in 11% and 16% presented with early untreated natural or surgical menopause. The largest risk group presented by the patient comparison group was fragility fracture (26%), glucocorticoid use (22%) and a family history of osteoporosis was reported by 16%.

The participant characteristics in comparison to the patient comparison group are outlined in table 1. The patient group were more than 12 years older than the volunteer group and were on average shorter and slightly heavier than the volunteer group. The mix of male and female was similar with 10% of the patient group and 8% in the volunteer group being male. The prevalence of osteoporosis and osteopenia diagnosed, based on the 1994 WHO classification of osteoporosis [13] [14], in the volunteer and patient populations was noted.

The cross-calibration results were analysed using Bland-Altman plots and 95% confidence intervals. The scanner mean bone mineral densities (BMD) are outlined in table 1, along with their 95% confidence intervals, which indicate that the BMD measured on the Mobile scanner, was slightly higher than that measured on the static scanner. When the means were compared using a paired t-test, there was a

statistically significant difference between the two scanners. The Bland-Altman plots for the spine and hip are presented in figures 1 and 2 respectively, with the 95% confidence intervals plotted on the graphs. Intra-class correlations are presented in figure 3, with both the lumbar spine and total hip yielding intra-class correlations of r=0.99. Percentage differences for the lumbar spine and total hip between the static and mobile scanners were 0.9 and 0.7% respectively, with the mobile scanner reading higher than the static scanner.

The percentage of diagnostic agreement between the static, and mobile scanners, was 88% for the spine and 100% for the hip.

Discussion

The results of this study provide an evidence base for practice within the service. The Bland-Altman plots demonstrate a virtually random distribution of variance between the two scanners, which falls within the expected statistical limits. Since there are no clinically significant systematic differences, with one scanner consistently measuring lower than the other, no correction factor can be applied to these data for research datasets. It would be inappropriate to use a correction factor for normal clinical scans, even if there was a difference between the scanners. However, the clinicians using the service would benefit from being aware of any differences. The intraclass correlations demonstrate a good correlation between the scanners with r=0.99 for both sites. While the paired t-test yielded p-values demonstrating a statistically significant difference between the scanners, the percentage agreement of 0.9% and 0.7% for the lumbar spine and total hip respectively suggests that these differences are unlikely to be clinically significant and fall within the reported precision errors of DXA scanners [7].

Long term precision of the QC data of both devices was investigated , which showed the mobile unit, in comparison to the static scanner, to have more variability. The CV for the mobile device being 0.44% and the static scanner being 0.29%. The mobile scanner QC measurements were shown to be stable with no long term drift over the lifetime of the scanner. The larger variation in measurements shown on the mobile instrument could be reflective of environmental variances in temperature and humidity. The mobile unit is temperature controlled via an air conditioning unit, however for periods of transit, where a power supply has been interrupted overnight or in extreme external temperatures and humid conditions maintaining a stable internal environment is difficult. Variations also might occur where it has not been possible to fully level the scanner via the unit's hydraulic legs, when the lorry is parked on a slope.

While the study was designed to have a comparable volunteer group to the patients seen in clinical practice there were limitations, since the patient-volunteer demographics were not a perfect match.

The mean age difference between the patient and volunteer population was 12.7 years raising the question of the younger volunteer population having less degeneration and subsequently more 'true' reflections of spinal measurements where the patient cohort may have artificially elevated spinal measurements. It is not surprising that there was a large age difference between the younger volunteer group with a range of 23-67 years and older patient group with a range of 26-83 years, since the volunteer group was restricted to working individuals and the patient group was not discriminate to those outside working ages. A future study might discriminate for age in the comparative patient population or select a volunteer patient population to better represent the characteristics of the clinical population.

It has been long understood that spinal BMD measurements in older people using DXA technology, are subject to variation due to both difficulties in interpreting images, and inherent additional bone mineral being present where the spine may be degenerate, have calcification of the aorta projected over it or anatomical variation with scoliosis in addition to other normal variants such as absent or additional vertebrae [15].

The influence of participant BMI was investigated, and incidence of obesity, with a BMI >30, was similar in both volunteer and patient populations at 30% and 36% respectively. The volunteer group showed greater differences between the two measurements for the femur with increased BMI, but not between the spinal measurements. This may be as a result of greater difficulty replicating hip positioning in larger patients [7]. The presence, in obese subjects of an overlying fat panniculus at the femur site when the subjects were supine may affect precision at this site by altering soft tissue densities in a non-uniform manner [16]. The fat panniculus was not retracted during scanning on this study.

In addition to the basic aim of the study being achieved, performing this study with volunteers from within hospital staff members had additional and un-anticipated outcomes. All the participating volunteers received copies of their scan results.

36% of the study participants had a low bone mass at either site measured or recorded on either scanner: 15 individuals were recorded as having Osteopenia and 3 with osteoporosis. Following diagnosis these volunteers with low bone mass received lifestyle advice, [9] [10] and were advised to discuss their bone mass and subsequent fracture risk with their GP. An additional benefit of the study was that the profile of the Bone densitometry service was raised within the hospital trust.

Conclusion

In conclusion, the small differences in the mean measurements between the two scanners for the spine and hip are clinically insignificant and the Bland-Altman plots demonstrate no systematic differences between the scanners, and the measurements obtained from both scanners are comparable. The spread of differences around the mean are within the expected statistical variation. It is good practice to always perform follow up scans on the same scanner as that which the baseline scan was performed using where possible the same software version and reference data. However, these results demonstrate that the measurements obtained from both scanners are comparable. The mobile service delivers the same standard and quality of scan as the static service, where the long term QC precision remains stable and robust mobile unit set up and lock down procedures are in place to preserve stability, maintain reliable QC acquisition and consistent scanning conditions in clinical practice.

In vivo measurements reflect more accurately populations served in clinical practice than phantom measurements alone. Conclusions drawn from this study might not apply to other centres with co-located, or static and mobile DXA scanners and individual centres should perform their own cross calibration studies as part of routine QA procedures. Table 1: Volunteer Participant Characteristics.

	Mobile scanner	Static scanner	Randomly
			selected patients
			for comparison
	Mean (SD)	Mean (SD)	Mean (SD)
Age	49.7 (8.63)		62.4(11.44)
Gender (m/f)	8% m		10% m
Height (m)	1.65 (0.07)		1.60 (0.09)
Weight (kg)	74.85 (15.07)		75.4 (17.4)
BMI (kg/m²)	27.48 (5.12)		29.3 (6.6)
BMD (g/cm²)			
Lumbar Spine	1.168 (0.148)	1.158 (0.149)*	1.048 (0.23)
Нір	0.980 (0.127)	0.972 (0.125)*	0.878 (0.16)
T-score			
Lumbar Spine	-0.12 (1.23)	-0.21 (1.23)*	-0.98 (1.69)
Hip	-0.24 (1.05)	-0.33 (0.98)*	-0.99 (1.29)

* p = <0.01 when compared to the mobile scanner

Figure 1: Bland-Altman plot for the spine.



Bland-Altman Spine

Figure 2: Bland-Altman plot for the hip



Bland-Altman Hip

Figure 3: Intraclass correlations.





Total Hip



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