Original Article

Broadband Ultrasound Attenuation Reference Database for Southeast Asian Males and Females

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Abstract

   Introduction: The objective of this study was to establish the broadband ultrasound attenuation (BUA) measurements of the calcaneum for Southeast Asian males and females. A database was used to draw the reference curve for the Southeast Asian male and female population. **Materials and Methods:** The database included 366 healthy females and 236 healthy males. We measured the BUA values of the left heel using the Contact Ultrasound Bone Analyser (CUBA) clinical system. **Results:** The mean difference between Southeast Asian males and Caucasian males was 9.3 dB MHz^{-1} and that for females was 5.0 dB MHz^{-1}. The standard deviations (SDs) for Southeast Asian female and male normative values were 17.43 and 20.10, respectively. This is comparable with the SD for the McCue Caucasian female and male normative data of 16.54 and 17.45 respectively. **Conclusion:** The study shows that the Southeast Asian population has a significantly lower normative value than the Caucasian population. This BUA reference database obtained will allow for more accurate determination of Southeast Asian patients at risk of osteoporosis.

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   Key words: Calcaneus, Osteoporosis

Introduction

   Quantitative ultrasound (QUS) systems measuring the calcaneus are currently approved for the assessment of osteoporotic risks in Europe, Canada and the USA. A QUS bone sonometer basically measures, in ms^{-1}, how quickly sound travels through the bone, i.e., the velocity of sound (VOS) and, in dB MHz^{-1}, how much sound is absorbed by the bone, i.e., broadband ultrasound attenuation (BUA). An osteoporotic bone absorbs less ultrasound compared to a denser bone with a different microstructure. Hence, measurement by QUS is an evaluation of bone status relating to its density as well as microstructure. Unlike QUS, bone mineral density (BMD) tests measure only density. Cancellous bone is 8 times more metabolically active than cortical bone. Age and disease related to bone loss is more readily apparent at sites where there is a high percentage of cancellous bone i.e., the hip. Calcaneum is a bone that is 75% to 90% cancellous, similar to the hip. There is little soft tissue surrounding the bone, making it an excellent site for BUA measurement. It has also been established that BUA is a more significant predictor of fracture risks compared to VOS.[1]

   According to the United States' Food and Drug

Administration (FDA) Bone Sonometer PMA applications, final guidance for industry and FDA, dated 21 June 2001, Caucasian female normative reference databases cannot be used as a reference database for different ethnic group and genders. However, there are currently no Southeast Asian normative values available for the use in the Contact Ultrasound Bone Analyser (CUBA) clinical system for this purpose. It is imperative that Southeast Asians have their own normative reference databases for both males and females to allow for more accurate interpretation of BUA. This study was carried out with the aim of establishing such databases, using the US FDA guidelines.

Materials and Methods

   Volunteers were recruited from the clinical and non-clinical staff of the institution as well as from the relatives of patients in the specialist outpatient clinic. Three hundred and sixty-seven females and 241 males from various ethnic groups including Chinese, Malay, Indian and Filipino were recruited for the study. This is representative of the population in Southeast Asia. The BUA values of their left heels were measured using the CUBA clinical system from McCue. These patients were screened and found to have no

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clinical risk factors for osteoporosis and no pre-existing medical ailments. The screening exclusion criteria were based on FDA guidelines:

1. Current or recent use of bone active drugs;
2. Presence of metabolic bone disease;
3. Gastrointestinal malabsorption;
4. Liver disorders;
5. Chronic renal disease;
6. Unstabilised hyper- or hypothyroidism;
7. Hyper- or hypoadrenocorticism;
8. Use of corticosteroids;
9. Stroke; and
10. Previous fracture.

The ultrasound system consists of 2 transducers (emitting and receiving) faced with silicone rubber coupling pads. These are placed in direct contact on either side of the heel using a coupling gel. All but 1 female and 5 males had their left feet measured. For consistency, we excluded the data of the 6 people whose right feet had been measured.

Using the same method of calculating normative data used in Caucasian data as described in the manufacturer's FDA submission, we plotted all the female BUA values versus age and put a best fit regression line through these. This produced a $y = mx + c$ graph. This was repeated for the male data (Figs. 1 and 2).

Results

At every age group and for both genders, the BUA values for Caucasians were consistently higher than those for Southeast Asians (Table 1). This difference was accentuated with an increase in age. The mean difference between Southeast Asian males and Caucasian males was 9.3 dB MHz^{-1} (range, 2.45 dB MHz^{-1} to 16.12 dB MHz^{-1}). The mean difference between Southeast Asian females and Caucasian females was 5.0 dB MHz^{-1} (range, 3.82 dB

MHz^{-1} to 6.13 dB MHz^{-1}). There was a larger difference in the BUA values for males than females. The standard deviations (SDs) for Southeast Asian female and male normative BUA values were 17.43 and 20.10, respectively. These SDs are comparable with those of the McCue Caucasian female and male normative data of 16.54 and 17.45, respectively (Tables 2 and 3).

Discussion

In 1993, the World Health Organization defined osteoporosis as a "progressive systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture." The approximate prevalence of women having osteoporosis has been estimated to be 4% of women aged 50 to 59 years, 8% of women aged 60 to 69 years, 25% of women aged 70 to 79 years and 48% of women aged 80 years and above.[2] In Singapore, as in the rest of Asia, osteoporosis will become an increasingly important public health problem. It has been projected that, over the next 50 years, more than half of all hip fractures will occur in Asia. Our age-adjusted rates of hip fracture among women over the age of 50 years are currently among the highest in Asia and are approaching those of the West. The burden of osteoporosis lies not only in hospitalisation but also in the morbidity that arises from a reduction in independence and increased disability.

The economic burden on society is also formidable. As our society greys, prevention of the disease seems to be the best way to counter this social and economic burden. Although dual-energy x-ray absorptiometry (DEXA) is the gold standard in the diagnosis of osteoporosis, using it as a screening tool is not feasible due to limited resources and costs. Traditionally, clinical risk factors have been used to screen patients but they have proven to be very poor
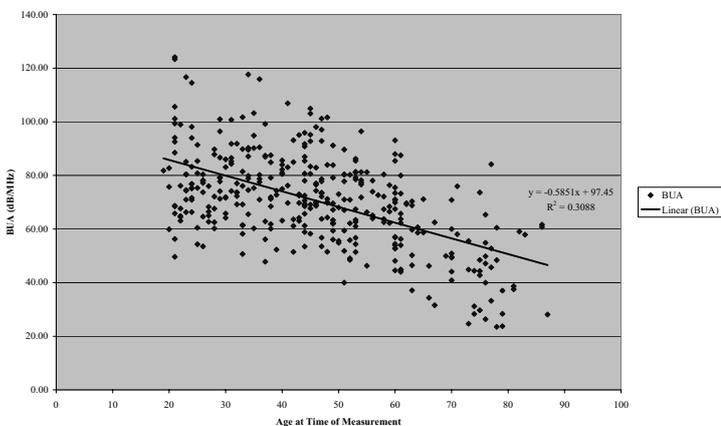

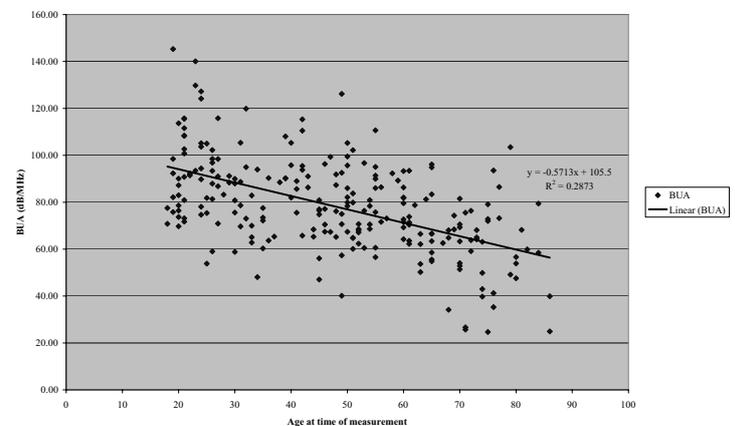Fig. 1. Normative BUA values of Southeast Asian females.

Fig. 2. Normative BUA values of Southeast Asian males.

Table 1. Mean BUA Values for Southeast Asians and Caucasians

Age (y)	Female		Male	
	Southeast Asian BUA values (dB MHz^{-1})	Caucasian BUA values (dB MHz^{-1})	Southeast Asian BUA values (dB MHz^{-1})	Caucasian BUA values (dB MHz^{-1})
20-29	85.75	89.57	94.07	96.52
30-39	79.90	84.10	88.36	93.09
40-49	74.05	78.64	82.65	89.65
50-59	68.20	73.17	76.94	86.22
60-69	62.34	67.70	71.22	82.79
70-79	56.49	62.24	65.51	79.36
>80	50.64	56.77	59.80	75.92

Table 2. Mean BUA Values and Standard Deviations for Southeast Asians for the Age Group 20-29 Years and >80 Years

Southeast Asian Female Data	Southeast Asian Male Data
Mean BUA value for age 20-29 years = 85.74762	Mean BUA values for age 20-29 years = 94.07287
Mean BUA value for age >80 years = 50.6404	Mean BUA value for age >80 years = 59.79529
Standard deviation = 17.4376	Standard deviation = 20.10357

Table 3. Mean BUA Values and Standard Deviations for Caucasians for the Age Group 20-29 Years and >80 Years

McCue Caucasian Female Data	McCue Caucasian Male Data
V4-2-2 Normative Data-Female Data	V4-2-2 Normative Data-Male Data
Mean BUA value for age 20-29 years = 89.57	Mean BUA value for age 20-29 years = 96.52
Mean BUA value for age >80 years = 56.77	Mean BUA value for age >80 years = 75.92
Standard deviation = 16.54	Standard deviation = 17.45

Note: The McCue Caucasian data only contains subjects between the ages of 20 and 80 years. The Singapore data include has subjects aged 18 to 87 years.

discriminators of low BMD of the hip and spine.[3] Hence, patients often develop osteoporotic fractures before any prevention strategy can be put forth.

QUS seems to be able to provide the answer. It is relatively inexpensive, free of ionising radiation, simple to apply and portable. The amount of training required to operate the machine is minimal. It takes about 1 minute to perform the test and the result is instantaneous as well. Several studies, including 4 prospective studies,[1,4-6] have demonstrated that BUA is a good predictor of low BMD. Furthermore, BUA is also an independent predictor of hip fracture.[4,5] These studies have also shown that there is a twofold increase in the relative risk of hip fracture for each SD reduction in BUA value.

The mean BUA value of males is higher than that of females and BUA values decrease with increasing age. The SDs in our study are comparable to those of Caucasian studies. Our study also shows that the normative BUA value for Southeast Asians is indeed significantly lower than that for Caucasians, especially for males.

Conclusion

This study has established a normative reference database for Southeast Asian males and females based on FDA guidelines. This set of data will allow for more accurate determination of BUA. It acts as an impetus to encourage the use of QUS in the primary settings, thereby allowing more postmenopausal women to be screened for osteoporosis.

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