# Heel ultrasound scan in detecting osteoporosis in low trauma fracture patients

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## Abstract

Osteoporosis is the most common metabolic disease with significant impact on the morbidity and mortality of affected patients. Osteoporosis has a significant impact on the economy worldwide. The aim of this study was to find out whether heel ultrasound is as good as central bone densitometry scanning in diagnosing osteoporosis in patients who are at high risk of osteoporosis. This was a prospective study of patients comparing heel ultrasound to central bone densitometry scanning (dual X-ray absorptiometry, DEXA) in patients. The recruited patients attended for a DEXA scan of the left hip and lumbar spine. All subjects had an ultrasound of the left heel using the quantitative heel ultrasound machine. The results of DEXA scan were blinded from the results of ultrasound and vice versa. There were 59 patients who took part in the study, 12 men and 47 women. The mean age was 66 years (SD 11.9) and mean weight was 62.5 kg (SD 10.7). The sensitivity and specificity of the ultrasound heel test to predict osteoporosis were 53% (95%CI: 29-77) and 86% (95%CI: 75-96) respectively. Specificity for predicting bone mineral density (BMD)-defined osteoporosis was high (86%), but sensitivity was low (53%). A heel ultrasound result in the osteoporotic range was highly predictive of BMD-defined osteoporosis. A positive ultrasound heel test in high risk patients is more useful in ruling in osteoporosis than a negative test to rule out osteoporosis.

# Introduction

Osteoporosis is the most common metabolic disease with significant impact on the morbidity and mortality of affected patients.<sup>1</sup> Osteoporosis defined by the World Health Organization is a condition in which bone mineral density is less than 2.5 standard deviation below the average density in gender matched young adults.<sup>2</sup> It affects both men and women at different stages of life, as a consequence of interaction of lifetime behavioural and genetic factors. Osteoporosis has a significant impact on the economy worldwide. In the UK, it is estimated that osteoporosis is costing the Government about five million pounds daily.<sup>3</sup> In the United States, the spending on osteoporosis is about seventeen billion dollars annually.<sup>4</sup>

#### Objective

The aim of this study was to find out whether heel ultrasound is as good as central bone densitometry scanning in diagnosing osteoporosis in patients who are at high risk of osteoporosis. Previous studies mainly compared heel ultrasound and central bone densitometry scanning (DEXA) in screening purposes, and inclusion of high risk patients for osteoporosis to our knowledge, has not been done previously.

#### Materials and Methods

This was a prospective study of patients comparing heel ultrasound to central bone DEXA in patients who presented to the Accident & Emergency Department of Birmingham Heartlands Hospital NHS Trust (now called the Heart Of England NHS Foundation Trust), with a low trauma fracture.

Patients were recruited from the Accident and Emergency Department of Birmingham Heartlands Hospital, who presented with low trauma fractures over an eight month period. The recruited patients attended for a DEXA scan of the left hip and lumbar spine at Solihull Hospital. The test results are computer generated and analyzed using WHO criteria for the diagnosis of osteoporosis. All subjects had an ultrasound of the left heel using the Quantitative Heel Ultrasound machine (QUS-2). The results of DEXA scan were blinded from the results of ultrasound and vice versa. The accuracy was presented as sensitivity, specificity, predictive value and likelihood ratio. I have also estimated post-test probability of having osteoporosis for the study population depending on whether the test result was positive or negative.

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Key words: Osteoporosis; central bone density; quantitative ultrasound; bone mineral density.

Contributions: FRH, acquisition of data, conception, study design, drafting the article; KOE acquisition of data, conception, analysis of data, drafting the article.

Conflict of interest: the authors declare no potential conflict of interest.

Received for publication: 9 December 2015. Accepted for publication: 16 May 2016.

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and negative predictive values were 60% (95%CI: 35-85) and 82% (95%CI: 70-93). The likelihood ratios for positive and negative test results were 3.7 (95%CI: 1.6-8.8) and 0.55 (95%CI: 0.33-0.92) respectively (Tables 2 and 3). A positive ultrasound heel test raised the pre-test probability of 28% to a post-test probability of 60%. A negative ultrasound heel test lowered the pre-test probability from 28% to a post-test probability of 18%.

Specificity for predicting BMD-defined osteoporosis was high (86%), but sensitivity was low (53%). A Heel Ultrasound result in the osteoporotic range was highly predictive of BMD-defined osteoporosis. On the other hand a Heel Ultrasound result in the normal range (*i.e.* no osteoporosis) lowered the per-test probability from 28% to a post-test probability of 18%. A positive ultrasound heel test in high risk patients is more useful in ruling in osteoporosis than a negative test to rule out osteoporosis.

## Results

There were 59 patients who took part in the study, 12 men and 47 women. The mean age was 66 years (SD 11.9) and mean weight was 62.5 kg (SD 10.7). Of the 59 patients, 17 (28%) had osteoporosis (Table 1). The sensitivity and specificity of the ultrasound heel test to predict osteoporosis were 53% (95%CI: 29-77) and 86% (95%CI: 75-96) respectively. The positive

## **Discussion and Conclusions**

Osteoporosis prevalence in developed countries is very high and is increasing especially with increasing age and decrease physical activity.

In the UK, NICE guideline recommend prophylactic use of antiosteoporotic medication in high risk patients especially with low impact fractures. The cast and unnecessary intake of



medication in normal population has increased the financial burden on NHS which is already struggling.

The use of Quantitative ultrasound in this high risk group will detect patients with osteoporosis who can start medication and the remaining patients can be discharged safely.

In the light of the pilot Heel Ultrasound study, how can one interpret Heel Ultrasound results? If a Heel Ultrasound result is normal or negative for osteoporosis, it becomes more useful in ruling out osteoporosis as it has a predictive value of 82% and LR of 0.55 (95%CI: 0.33-0.92). Therefore, if Heel Ultrasound scans were performed on a population similar to the pilot study population (28% prevalence of osteoporosis) as all of them are high risk patients having presented with low trauma fractures. Then 15.2% would have a Heel Ultrasound result in the osteoporotic range (likely to have osteoporosis) and 61% would have results in the normal range (osteoporosis could fairly confidently be ruled out, with a post-test probability 18%). However, there would be a degree of uncertainty about the remaining 13.5%, who would then need a DEXA scan to identify those with osteoporosis.

Previous studies of Heel Ultrasound as a predictor of BMD have generally used conventional sensitivity and specificity analyses only. not LRs, and have not used the WHO BMD definitions. For example, two community-based cross-sectional studies on 700 postmenopausal,<sup>5</sup> and 1000 peri-menopausal women respectively,6 found that there was a 40-50% overlap in the number of women in the lowest quartile of both DEXA and Heel Ultrasound measurements. Two other studies found Heel Ultrasound parameters to have a sensitivity of 65-70% for BMD in the lowest guartile.<sup>7</sup> Only one study other than this pilot Heel Ultrasound has evaluated OUS in terms

Table 1. Description of demographic characteristic of patients by test results (heel ultrasound, HS); 17 patients were positive for osteoporosis defined by dual X-ray absorptiometry scans.

| Characteristic             | HS positive | HS negative     | P value          |
|----------------------------|-------------|-----------------|------------------|
| DEXA positive              | 9           | 8               | ≤l               |
| Age (years), mean $\pm$ SD | 70.7±12.1   | $63.1 \pm 14.6$ | 0.076            |
| Gender<br>Male<br>Female   | 0<br>15     | 12<br>32        | ≤0.001<br>≤0.001 |
| Ethnicity<br>Caucasian     | 7           | 44              | ≤0.001           |
| Asian                      | 2           | 6               | ≤0.05            |

Table 2. Association between quantitative heel ultrasound (QUS) results and bone mineral density by dual X-ray absorptiometry in 59 patients.

| QUS result |              | Bone mineral density | Total (n=59) |
|------------|--------------|----------------------|--------------|
|            | Osteoporosis | No osteoporosis      |              |
| Positive   | 9            | 6                    | 15 (25.4%)   |
| Negative   | 8            | 36                   | 44 (74.6%)   |

Table 3. Sensitivity and specificity of heel ultrasounds in diagnosing bone mineral density defined osteoporosis or ruling it out.

|  | 95% CI    |
|--|-----------|
| Sensitivity a / (a+c) 53%                                | 29-77     |
| Specificity d / (b+d) 86%                                | 75-96     |
| Pre-test Probability (Prevalence): (a+c) / (a+b+c+d) 29% | 17-40     |
| Positive Predictive Value: a / (a+b) 60%                 | 35-85     |
| Negative Predictive Value: d / (c+d) 82%                 | 70-93     |
| Likelihood Ratio + sens / (1-spec) 3.71                  | 1.56-8.81 |
| Likelihood Ratio - (1-sens) / spec 0.55                  | 0.33-0.92 |
|  |           |

CI, confidence interval. a, 9 (positive, osteoporosis); b, 6 (positive, no osteoporosis); c, 8 (negative, osteoporosis); d, 36 (negative, no osteoporosis).

of WHO BMD definitions. It found BUA (Broad band ultrasound attenuation) and VOS (Velocity of sound) to have higher sensitivities of 77% and 69%, respectively for diagnosing osteoporosis in 100 women aged 60-69 years.<sup>8</sup> These higher sensitivities may have been due to use of higher BUA and VOS cut-off values. As expected, specificities were lower than in the above pilot study.

There is no consensus on what cut-off values to use with QUS to diagnose osteoporosis. It was found that changing the cut-off could achieve higher sensitivity, but only by accepting higher rates of false positives (lower specificity) and less discriminating likelihood ratios.

Ouantitative ultrasound has proven to be a good predictor of fracture risk in several studies.9 In a large prospective study of 6189 postmenopausal women over age 65, quantitative ultrasonography of the calcaneus predicted hip fracture as accurately as bone densitometry.10 In a larger study of 14,824 patients that included younger women as well as men ages 42 to 82 years, quantitative calcaneal ultrasound also was a good predictor of total and hip fracture risk.11 A third study of 2837 women (463 ages 20 to 39 years and 2374 ages 55 to 79 years) found that quantitative ultrasound of the calcaneus worked as well as central DEXA for identification of women at high risk for osteoporotic vertebral fractures.12 In addition to predicting fracture risk, other studies have found that quantitative ultrasound is at least as good as and possibly better than clinical risk factors for predicting women at risk for osteoporosis.13,14

A major limitation to using quantitative ultrasound as a screening tool is that the criteria for diagnosing osteoporosis and recommending treatment based upon ultrasound are not yet well established.<sup>15</sup> Furthermore, ultrasound cannot reliably be used to follow women who are treated for osteoporosis because of limited precision and a slow rate of change of bone mass at peripheral sites. Thus, most women with a high risk ultrasound finding will need a confirmatory DEXA both to determine the need for treatment based upon well established guidelines, and as a baseline for monitoring therapy.

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