A NOVEL ULTRASOUND PARAMETER TO ASSESS SKELETAL FRAGILITY AND FRACTURE RISK FROM AN ECHOGRAPHIC SCAN OF LUMBAR SPINE

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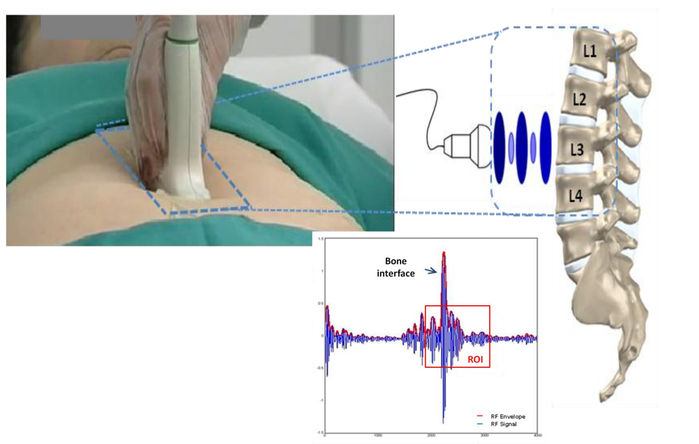
Abstract

Osteoporotic fractures are a recognized major health problem, leading to increased mortality and morbidity affecting more than 200 million people worldwide, causing over 8 million of new fractures each year and 43,000 deaths, accounting for a direct cost of about €40 billion. It has been demonstrated that bone mineral density (BMD) measurement, standardly evaluated by dual-energy X-ray absorptiometry (DXA) examinations, is an integral part of the prediction of the general risk of osteoporotic fractures but, unfortunately, is affected by accessibility issues and technical limitations. On the other hand currently available US techniques, which show a number of intrinsic advantages, have the major drawback of not being employable on the reference anatomical sites for Osteoporosis diagnosis (lumbar spine and proximal femur). In the present work, we evaluated the performance of a new ultrasound (US)-based method for the prediction of osteoporotic fractures. We enrolled 50 women with recent non-vertebral osteoporotic fractures (frail subjects) and 50 controls without fracture history (non-frail subjects). From abdominal US scans performed on each patient employing the ECHOS echographic device (Echolight s.r.l., Lecce, Italy), we defined and quantified a new US diagnostic parameter named Fragility Score (FS), which estimates bone fragility. The discriminatory power of the novel US methodology applied on spine was compared with lumbar DXA by building the corresponding Receiver Operating Characteristics (ROC) curves. The Area Under the Curve (AUC) values resulted equal to 0.75 for both DXA-BMD and US-FS. Therefore, the new proposed US parameter FS showing the potential to become an innovative tool for the estimation of osteoporotic fracture risk through early identification of "frail" patients by a safe US spinal scan.

Objectives

To evaluate the effectiveness of a **novel (US) parameter** in the identification of patients with a skeletal structure prone to fragility fractures.



Methods

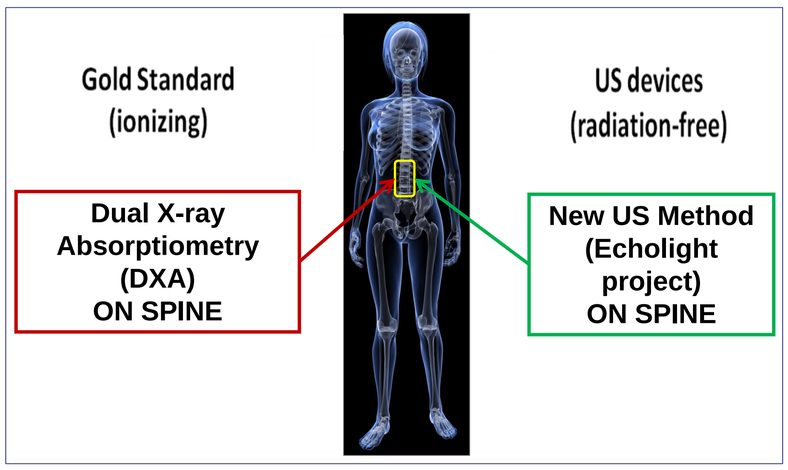
PATIENTS

A cohort of 100 female patients was recruited according to the following criteria:

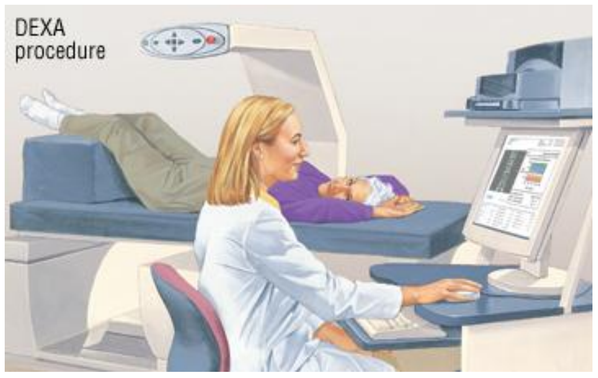
- 40-80 years of age
- BMI (body mass index) ≤ 30 kg/m^2,
- 50 women with recent non-vertebral osteoporotic fractures
- 50 controls without fracture history
- medical prescription for a SPINAL DXA
- signed informed consent

DATA ACQUISITION

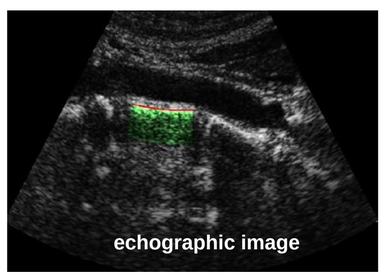
All patients recruited for the study underwent two examinations:



1. Conventional spinal DXA (Hologic Discovery)



2. Novel US-based investigation for fracture risk estimation from an echographic spinal scan



DATA ANALYSIS

US DATA ANALISYS BY A NOVEL ALGORITHM THAT:

1. processes both echographic images and "raw" radiofrequency (RF) signals by selection of the target bone interface and automatic detection of the region of interest (ROI)

2. compares spectral characteristics of the acquired RFsignals with the appropriate "frail" and "non - frail" bone models

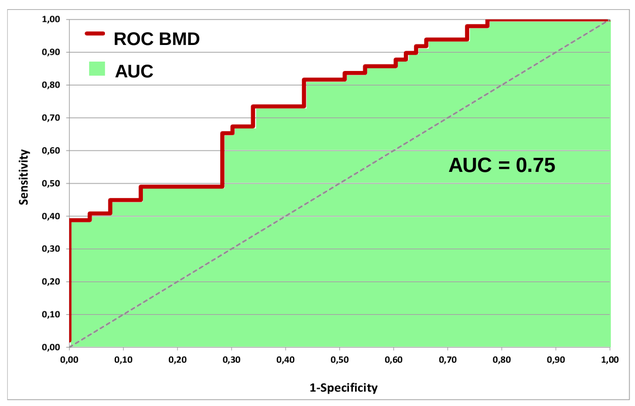
3. provides as final output a new US diagnostic parameter named **Fragility Score (FS)**, which represents an estimation of skeletal fragility and, consequently, of fracture risk.

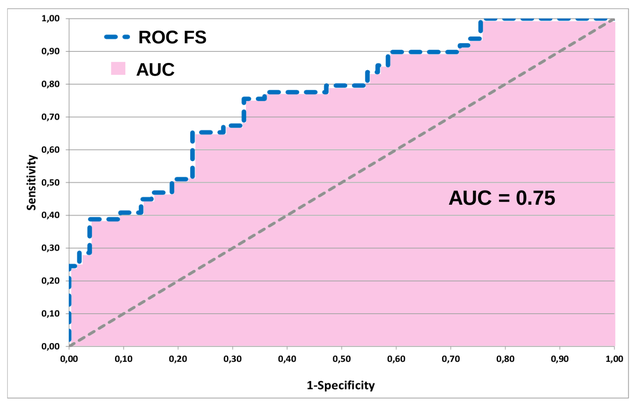
Results

Frail subjects were significantly discriminated from non-frail ones (see Table below) by both FS (58.0±12.1 *vs* 43.8±10.0, $p<0.001$) and spinal BMD (0.832±0.129 g/cm^2 *vs* 0.983±0.154 g/cm^2, $p<0.001$), although the two groups did not show significant differences in age (64.2±11.4 y *vs* 63.9±9.5 y, *p* n.s.) nor in BMI values (24.22±2.90 kg/m^2 *vs* 24.58±2.76 kg/m^2, *p* n.s.).

	Fracture Group	*Control group*	*p*
	Mean ± SD	**Mean ± SD**	
Age (years)	64.2 ± 11.4	63.9 ± 9.5	*n.s.*
BMI (kg/m^2)	24.22 ± 2.90	24.58 ± 2.76	*n.s.*
BMD (g/cm^2)	0.832 ± 0.129	0.983 ± 0.154	*p<0.001*
FS	58.0 ± 12.1	43.8 ± 10.0	*p<0.001*

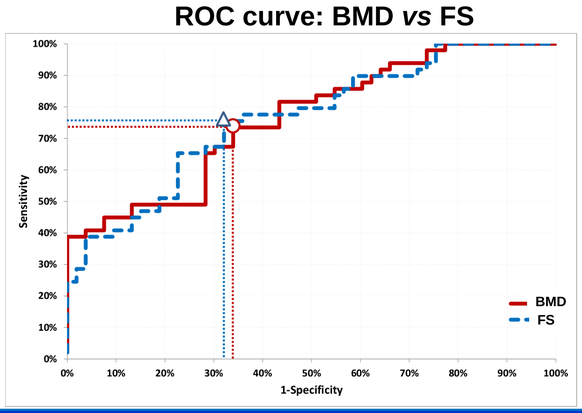
As shown in the following Figures, AUC values confirmed that discrimination powers of the two methods were comparable (AUC=0.75 for both).





However, sensitivity value associated to the "best cut-off" (Youden's index) for FS was higher than the corresponding one for BMD (76% vs 73%), implicating that our approach is more suitable for population screening purposes (see Figure below).

ROC curve: BMD *vs* FS



Conclusions

Fragility Score identified patients prone to fragility fractures with an accuracy similar to spinal BMD, showing the potential for osteoporotic fracture prevention through extended population screenings.

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