

## ACCURACY OF A NEW ULTRASONIC METHOD FOR OSTEOPOROSIS DIAGNOSIS ON LUMBAR SPINE

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**Background:** Osteoporosis is a 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. Fractures associated with osteoporosis represent a major cause of public health burden in terms of mortality, disability and health care costs emphasizing the need of more effective diagnostic methods. Currently, osteoporosis is mainly diagnosed through dual-energy X-ray absorptiometry (DXA) which provides quantitative measurements of bone mineral density (BMD). Spinal DXA, in particular, is the preferred technique for temporal monitoring of BMD variations, since it has been demonstrated that BMD measurement on this site is the most reliable to predict the global fracture risk. However, DXA cannot be used for early diagnoses through population mass screenings because of issues related to ionizing radiation employment.

**Objectives:** Aim of this work is to test the diagnostic accuracy of a novel ultrasound (US)-based method to perform spinal densitometry without employing X-rays.

**Methods:** A cohort of 358 female patients was recruited according to the following criteria: 45-65 years, body mass index (BMI) < 25 kg/m<sup>2</sup>, absence of significant severe deambulation impairments, medical prescription for a spinal DXA, signed informed consent. All the enrolled patients underwent two examinations: a conventional spinal DXA (Hologic Discovery) and an US scan of lumbar spine. US data were analyzed by a novel algorithm that processed both echographic images and "raw" radiofrequency signals and, performing a series of spectral and statistical analyses, calculated the same diagnostic parameters provided by DXA (bone mineral density (BMD), T-score, Z-score). Diagnostic accuracy of obtained results was evaluated through a direct comparison with DXA output as a function of patient age.

**Results:** For 83.0% of the patients US diagnosis (osteoporotic, osteopenic, healthy) was the same of the corresponding DXA one. In particular, diagnostic accuracy showed the following trend as a function of patient age range: accuracy was 86.4% in 45-50 y, 85.6% in 50-55 y, 87.1% in 55-60 y and 72.4% in 60-65 y. For patients in the same age range, Pearson correlation coefficient (r) between DXA and US measurements was also evaluated for each diagnostic parameter (BMD, T-score, Z-score): all the obtained values of r were within the interval 0.52-0.78 (p<0.001) and their trends against age qualitatively resembled the observed diagnostic accuracy profile. The lower diagnostic agreement and correlation values found in correspondence of the oldest analyzed patients can be at least partially due to spinal degenerations affecting the accuracy of DXA measurements.

**Conclusions:** The proposed method for US evaluation of BMD directly on the spine showed a very good and significant agreement with DXA diagnoses. This innovative non-ionizing approach has the potential to anticipate osteoporosis diagnosis by several years through extended screenings in younger populations and to become a useful tool for therapeutic outcome monitoring.

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