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Original Article

Impact of the NOGG and NOF Guidelines on the Indication of Bone Mineral Density in Routine Clinical Practice

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Abstract

The universal screening for osteoporosis by bone mineral density (BMD) is not feasible because of its unfavorable cost-benefit due to its low sensitivity. The aim of the present study was to estimate the population and economic impact of the diagnostic criteria of the National Osteoporosis Guideline Group (NOGG) and the National Osteoporosis Foundation (NOF) and assess the appropriateness of the BMD tests performed in routine clinical practice. A cross-sectional study was conducted in individuals referred for BMD testing who were not receiving antiresorptive therapy. The absolute risk of major and hip fracture was calculated using the British formula of the Fracture Risk Assessment Tool. NOGG and NOF guidelines diagnostic thresholds interventions were used. A total of 640 individuals were included, of which 95% were women, with a median age of 59.4 years (interquartile range = 14). When applying the NOGG criteria, BMD testing was recommended in 32.3% of the individuals, whereas this percentage increased to 75.6% with the NOF guidelines ($p < 0.05$). Regarding the appropriateness of the BMD tests performed, 31.9% were deemed appropriate according to both the NOGG and NOF guidelines, whereas 23.9% were considered inappropriate. In conclusion, the application of the NOGG and NOF guidelines led to a decrease in BMD indications, reducing costs and improving efficiency in the diagnostic management of osteoporosis, although variability exists between the guidelines.

Key Words: Bone density; FRAX; NOF; NOGG; osteoporosis.

Introduction

Osteoporosis is a public health problem characterized by low bone mass and skeletal fragility, resulting in an increased susceptibility to low-trauma fractures. Worldwide, about 200 million people experience osteoporosis, and each year 1.7 million hip fractures are caused by osteoporosis. In Spain, it is estimated that over the next 10 years 714,000 osteoporotic fractures will occur, mostly in women older than 70 years *(1)*. However, many cases of osteoporosis are undiagnosed and untreated, even when there has been a previous fracture *(2,3)*. Osteoporosis-related fractures entail a substantial burden of disability, costs, and mortality on postmenopausal women and older men *(4)*. Thus, osteoporosis prevention efforts in such groups should be of primary concern. However, the overvaluation of bone mineral density (BMD) test due to its close relationship with fracture risk has been such that some guidelines recommend performing densitometry in all women older than 65 years and males older than 70 years *(5,6)*. According to data from the Spanish Statistical Office, this would mean performing densitometries on nearly 7 million people (6,854,977) in Spain, which obviously is impracticable *(7)*.

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The overuse of BMD testing is definitely a concern (8,9). Some individuals who do not meet screening criteria are tested, and densitometric results are obtained in the range of osteopenia or osteoporosis. This can lead to unnecessary medical examinations, laboratory tests, and treatment of conditions that may not require therapy, resulting in a further economic burden on health care systems (10). Moreover, unnecessary testing may also cause needless anxiety in the subjects tested. The application of clinical guidelines using algorithms such as the Fracture Risk Assessment Tool (FRAX), which can differentiate individuals with increased fracture risk who will benefit from drug therapy, can help in streamlining the resources available and provide a better management of osteoporosis (11).

Thus, the aim of this study was to estimate the population and economic impact of the diagnostic criteria of NOGG and NOF guidelines and assess the appropriateness of the BMD tests performed in routine clinical practice.

Materials and Methods

Design and Population

A cross-sectional study was performed with a sample of individuals referred from different care settings (primary care and specialist) for conducting an axial dual-energy X-ray absorptiometry BMD test at the densitometric unit of the University Hospital of León, Spain. The sample study belonged to an area of 320,000 inhabitants in which the University Hospital of León is the reference health care center.

Inclusion and Exclusion Criteria

Individuals between 40 and 90 years who had received no previous treatment with bisphosphonates (alendronate, ibandronate, risedronate, or zoledronic acid), calcitonin, hormone replacement therapy, strontium ranelate, denosumab, teriparatide, raloxifene, or bazedoxifene were included. Furthermore, individuals referred for BMD testing after bariatric surgery or those who had been diagnosed with a metabolic bone disease other than osteoporosis (e.g., osteomalacia, Paget's disease), myeloma, or cancer with bone metastasis were also excluded.

Assessment of Fracture Risk

The fracture risk assessment tool available on the FRAX website (http://www.shef.ac.uk/FRAX/) was used to enter the data manually and calculate the risk of 10-year probability of hip fracture and major fracture. Although a Spanish calibration of the FRAX tool is available, the British one was used to correctly apply the NOGG diagnostic thresholds, and because of the limitations that the former presented in previous studies (12–14). The FRAX tool includes 11 variables that were collected using a structured questionnaire. In the case of uncertain data, the medical record was reviewed.

Selection of Guidelines

The most recent versions of 2 clinical practice guidelines were selected for inclusion in the study: the NOGG and NOF guidelines (5,15). They are considered by most experts in osteoporosis as the most important and influential in clinical practice.

The British NOGG guidelines propose the use of the FRAX tool for population screening and establish 3 categories based on the absolute risk of fracture after 10 years: high, intermediate, and low risk (15). Based on these results and an analysis of cost-effectiveness, the NOGG proposes a diagnostic decision algorithm in which evaluation of BMD by dual-energy X-ray absorptiometry is considered only for those with an intermediate risk probability of fracture.

The NOF guidelines, based on cost-effectiveness studies for the American population, propose another decision algorithm (5). BMD remains the basis for deciding whether or not to start treatment, and its realization is based on the following criteria: all women older than 65 years and men older than 70 years. In younger individuals, conducting a BMD test is indicated if they have experienced a fracture after the age of 50 or with pathologies or medications associated with bone loss.

Calculation of Cost-Effectiveness

The cost value imputed to each BMD test was taken from the rate that applies the health care system of Castilla y León, €58.6 (BOCYL January 31, 2011, available at: http://bocyl.jcyl.es/boletin.do?fechaBoletin=31/01/2011). In 2013, 3163 BMD tests were performed in the University Hospital of León, so the annual expenditure on this technique in the health area of León amounted to €185,352.

Statistical Analysis

A sample size of 639 individuals was calculated to detect a 25% avoidable BMD assessment with a confidence level of 95% and an error of 3%, based on preliminary data of the study. All collected variables (qualitative and quantitative) were introduced into a database (Microsoft Access) and subsequently analyzed using a statistical package (SPSS Inc., version 15.0, Chicago, IL, USA). The normality of the quantitative data was confirmed with the Kolmogorov–Smirnov test. If the data adjusted to a normal distribution, they were presented as means (standard deviation). In other cases, they were presented as medians (interquartile range). Categorical data were summarized with percentages. The differences among groups classified using the NOGG and/or NOF diagnostic criteria and actual clinicians' attitudes were determined using a Venn diagram to reveal the number of cases in each subset (16). The level of statistical significance was set at $p < 0.05$.

Ethical Aspects

All study subjects signed an informed consent granting the researchers access to the information contained in their