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Changes in Nonosteoporotic Bone Density and Subsequent Fractures in Women

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Abstract

Objectives—Osteopenia is considerably more common than osteoporosis and accounts for most of the fracture burden in women older than 50 years. It is uncertain when to initiate treatment in osteopenia. We sought to determine in women with osteopenia what effect transitioning to lower categories had on subsequent fracturing.

Methods—We surveyed 1150 women from office-based practices who had initial normal or osteopenic bone mineral densities (BMDs) and who were retested after 5.75 years. We classified categories related to baseline T scores as follows: normal (> -1.0), mild osteopenia (-1.0 to -1.49), moderate osteopenia (-1.5 to -1.99), and severe osteopenia (-2.0 to -2.49). We determined during a 9.6-year follow-up period the fracture occurrence in those who maintained their initial category status or transitioned into lower categories.

Results—Transitioning to lower categories was not significantly different among baseline osteopenic categories but significantly more than normal baseline BMDs. Total fractures, individuals fracturing, and major fractures were significantly more, with baseline T scores of -1.5 (<0.001). Although only 10.2% transitioned to osteoporosis, 90.5% of these transitions occurred with baseline T scores -1.5 and accounted for significantly more fractures than baseline T scores of > -1.5 .

Conclusions—Most subsequent fractures and transitions to osteoporosis occurred with baseline T scores -1.5 . Clinical risk factors need to be used to determine at what T score threshold treatment would be cost effective.

Keywords

nonosteoporotic BMD; osteopenia; subsequent fractures; transition changes

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Bone mineral density (BMD) by dual x-ray absorptiometry (DXA) is a strong and highly reliable predictor of future fractures.^{1–3} Although an osteoporotic BMD (T score of -2.5) confers the highest risk for future fractures, more fractures occur in the range of osteopenia (T scores between -1.0 and -2.5).^{4,5} In fact, more than half of all women in the United

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States older than 50 years have osteopenia, with a prevalence of approximately 3.4 times more than osteoporosis.^{6,7}

Although routine BMD screening is recommended to identify fracture risk in women aged 65 years or older, the National Osteoporosis Foundation (NOF) has recommended guidelines for testing postmenopausal women younger than age 65 for osteoporosis based on clinical risk factors (CRFs) that would prevent unnecessary screening.^{8,9} Although several other formulas using CRFs have been developed to screen for osteoporosis, the NOF guidelines (either a low body weight, previous fracture, high-risk medication use, or disease or condition associated with bone loss) are simple to perform and display a high sensitivity in identifying osteoporosis.^{8–10} Application of these CRFs, however, will reveal a considerable proportion of patients with increased fracture risk in osteopenia. This can be challenging for physicians because treating women with osteopenia remains an unresolved issue.

Evidence to initiate treatment in women with osteopenia has relied primarily on clinical trials designed to treat osteoporosis. The Women's Health Initiative found that estrogen plus progestin had no significant effect on fracture reduction in those outside the range of osteoporosis.¹¹ A review of raloxifene (a selective estrogen-receptor modulator) trials, however, found a significant reduction in the risk of symptomatic and radiographic vertebral fractures in women.¹² Alendronate was reported to have no effect in the reduction of clinical fractures in osteopenic women, but a post hoc analysis found significant reductions in symptomatic and radiographic vertebral fractures.^{13,14} An additional post hoc analysis of four placebo-controlled trials reported risedronate significantly reduced fragility fractures in osteopenic women with T scores between -1.0 and -2.5 .¹⁵ Identifying osteopenic women who are at high fracture risk or likely to transition to osteoporosis may aid in making treatment decisions.

To determine the fracture occurrences related to transitions after a repeat BMD, we conducted a study in postmenopausal women from community office-based practices who previously had initial normal or osteopenic BMDs. Performing BMDs was based primarily on physicians' decisions before the wide-spread availability of CRF formulas.

Methods

Population Database

We retrieved data from electronic medical records from community practices of women aged 50 years or older who had an initial normal or osteopenic BMD followed by a subsequent BMD for subsequent fracture occurrence up to a 17.5-year period (January 1, 1996–July 1, 2013). Our regional population consisted of approximately 350,000 urban and rural individuals in central Appalachia, with one-third aged 50 years or older and more than 97% white. The study was approved by the Charleston Area Medical Center-West Virginia University institutional review board.

Bone Density Measurements

DXA scans were performed by two Hologic devices (Hologic Inc, Bedford, MA) and one GE Lunar device (GE Healthcare, Little Chalfont, UK) located on three campus sites at the

Charleston Area Medical Center. The longitudinal coefficient of variation measured daily by a phantom spine averaged 0.36% to 0.44% for Hologic devices and 0.44% for GE Lunar. Before the availability of fan-beamed screening devices in 2002, a pencil-beamed DXA was available at only one site. Because 26.6% of women had initial BMDs performed by a pencil-beamed device, we attempted to make corrections when necessary on subsequent BMDs performed by fan-beamed devices.¹⁶ We classified women using the lowest available T score at either the femoral neck, total hip, or lumbar spine into the following categories: normal (T scores > -1.0), mild osteopenia (T scores -1.0 to -1.49), moderate osteopenia (T scores -1.5 to -1.99), and severe osteopenia (T scores -2.0 to -2.49). Because all three sites were not always reported, the most frequent sites available for review were the spine plus total hip (54.6%), spine plus total hip and femoral neck (37.8%), and spine plus femoral neck (4.74%). Only 2.9% relied on a single site. We then compared the lowest available T score site on repeat DXAs, with the identical site available on the initial DXA to determine whether any transitional changes had occurred. The final sites that determined transitional changes were the spine (39.7%), total hip (37.3%), and femoral neck (23.0%)

Data Analysis

We investigated the relation of fracture occurrence with the following data: age at the initial BMD, changes in category status from initial to repeat DXA values, time intervals between initial and repeat DXAs, and follow-up years for fracture occurrence from initial DXA to the last available medical information recorded. Follow-up information was obtained from data on laboratory reports, hospitalizations, emergency department visits, or radiographs. We compared women with baseline mild, moderate, or severe osteopenia with those with normal BMDs. We considered fractures as major (hip, femur, humerus, pelvis, and vertebral), intermediate (wrist, ankle, patella, shoulder, and elbow), and minor (hand, foot, ribs, clavicle, and others). We excluded women receiving bone remedial therapy (bisphosphonates, raloxifene, teriparatide, or current estrogen therapy); those with metastatic bone disease; those undergoing cancer chemotherapy; and patients with insufficient data concerning medications, untreated illness associated with bone loss, and DXA scans performed outside campus sites. Women with prior estrogen therapy were included if this was discontinued at least 2 years previously. Although 1384 women met eligibility for review, 234 were excluded because of insufficient data from DXA reports.

Statistical Analysis

Statistical analysis was performed using SAS 9.3 (SAS Institute, Cary, NC). Data were described as number and percentage of the population and mean $\pm$ standard deviation. Categorical variables were compared using χ^2 and Fisher exact tests where appropriate. A *t* test or the general linear model was used for testing between groups with continuous variables. A *P* value of <0.05 was considered significant.

Results

Baseline Characteristics

Three-fourths of 1150 women surveyed were younger than age 70 (Table 1). Women with baseline normal BMDs were significantly younger than those with osteopenia and had

significantly more follow-up years than those with severe osteopenia. Repeat BMDs were performed significantly earlier in women with severe osteopenia than other categories.

Table 2 lists the variables associated with individuals subsequently fracturing. Longer follow-up periods and lower DXA T scores both at baseline and retesting were significantly related to women fracturing with baseline normal BMDs. Women with mild osteopenia, however, had significantly more changes in T score after retesting associated with subsequent fractures.

Transitional Changes and Fractures

After an average 5.75-year period of BMD retesting, all women with baseline osteopenia transitioned significantly into lower categories and osteoporosis when compared with those with normal BMDs (Table 3). Women with baseline osteopenia had significantly more fracturing, total fractures, and intermediate fractures than those with baseline normal BMDs during an average 9.6-year follow-up period. Fractures at the hip, spine, minor sites, and all major sites, however, were only significantly higher in women with moderate and severe osteopenia.

Fig. 1 shows that significantly more fractures occurred in women who transitioned into lower categories with normal BMDs and moderate osteopenia than those with baseline moderate and severe osteopenia. The significant decline in T scores on BMD retesting in those with normal BMDs and mild osteopenia accounted for this finding.

Approximately 10.2% of patients transitioned to osteoporosis, with 90.5% having moderate or severe osteopenia at baseline. Fig. 2 shows the number of women transitioning to osteoporosis in each category during various time intervals. A repeat BMD was performed in 70.5% of women with baseline moderate or severe osteoporosis during this time span. We speculate that this resulted from physicians being more aware of repeating BMD in women with lower T scores.

Table 4 compares fracture occurrences when combining baseline normal and mild osteopenia categories (T scores > -1.5) to moderate and severe categories (T scores ≤ -1.5). A T score cutoff threshold of ≤ -1.5 identified significantly more total fractures and individuals fracturing. Of individuals fracturing in the ≤ -1.5 cutoff T score threshold group, 22.8% transitioned to osteoporosis, whereas only 2.4% of individuals fracturing in the > -1.5 cutoff T score threshold group transitioned to osteoporosis. Hip fractures, which consume considerably higher costs and loss of quality-adjusted life-years, were 2.5 times more likely to occur at the ≤ -1.5 cutoff threshold.

Discussion

In this retrospective study of postmenopausal women with normal BMDs or various categories of osteopenia, most transitions to osteoporosis occurred in those with moderate to severe osteopenia (T scores ≤ -1.5) and were identified within a 6-year period when compared with those with normal or mild osteopenic BMDs (T scores > -1.5). These findings confirm a previous report that women with moderate or severe osteopenia should

undergo repeat BMD testing 5 years or earlier depending on the severity of low T scores to detect osteoporosis.¹⁷ In comparison, Hillier and associates found that a repeated BMD after 8 years provided little additional value for fracture prediction.¹⁸ Their report, however, differs from ours because the population surveyed was considerably older, included asymptomatic vertebral fractures, and relied on total hip T scores. In addition, the Framingham Osteoporosis Study conducted in older men and women with osteopenia or osteoporosis concluded that a repeat BMD after a mean of 3.7 years did not meaningfully improve the prediction of the hip or other major fractures.¹⁹ Considering these conflicting results, the NOF simple guidelines should be considered in determining when to repeat a BMD in younger postmenopausal women.^{8,9}

The proportion of women with baseline T scores > -1.5 who subsequently fractured was significantly greater when transitioning to lower categories than those with baseline T scores < -1.5 . The rapid bone loss observed on BMD retesting with baseline T scores > -1.5 played a role in this fracture susceptibility and has been reported independent of baseline BMDs as a substantial risk factor in women with osteopenia.^{18,20} Bone fragility also can vary among individuals of similar ages and T scores because other factors are involved. Cortical bone resorption in women profoundly increases during the 10 years after menopause and then shows a gradual decline; this results in expansion of the medullary areas.²¹ The use of high-resolution quantitative computed tomography and microscopic magnetic resonance imaging has improved identification of bone micro-structure and mechanical competence. Lower trabecular volume, cortical porosity, and higher trabecular erosion indices have been shown to be associated with increased risk for fracture in non-osteoporotic women independent of BMD.^{22–25} The widespread application of such technology for fracture risk determination and preventive intervention in nonosteoporotic women requires further study.

Individuals fracturing, total fractures, and major fractures were significantly higher in women with baseline moderate and severe osteogenic categories (T scores of < -1.5). Furthermore, women in these categories contributed to the majority of those who transitioned to osteoporosis and accounted for 22.8% of individuals fracturing, whereas $<3\%$ was noted in the women with baseline T scores > -1.5 . This has implications as to whether the current recommended T score threshold for treatment should be lowered to -2.0 or even -1.5 for treating osteopenia. Evidence from prospective trials for treating osteopenia at certain T score thresholds is weak; however, chronic glucocorticoid therapy and asymptomatic vertebral fractures appear to warrant intervention.^{26–28}

Overtreatment of osteopenia remains a concern. In addition to benefits, harms and costs need to be considered. Schousboe and colleagues, using nongeneric alendronate costs without CRFs, could not validate cost-effectiveness in treating women with osteopenia.²⁹ A study performed in Japanese women found that cost-effectiveness was limited to age 70 years, with BMD values 70% below the young adult mean and at least three CRFs.³⁰ The implications of this report, however, are limited because prior fractures were not included, and only hip and symptomatic vertebral fractures were evaluated in the model simulation. The authors acknowledged that hip fracture incident rates were lower in Japan than in countries with white populations. Declining costs of bisphosphonates and BMD

examinations in the United States in recent years support reevaluating a cost-analysis. Meanwhile, the 10-year absolute fracture risk by FRAX formula CRFs needs to be used in treatment decisions to determine what T score threshold in osteopenic women would be cost effective.³¹

Our study has limitations. Previous fractures before 1996 or height and weight could not be retrieved from electronic records to calculate the FRAX formula. Because all BMD T score sites were not always reported, we had to rely on the lowest available T score values. Moreover, precision can vary among different sites.³² Although the total hip and femoral neck are somewhat better predictors of fracture, the spine in younger postmenopausal women may define a lower bone mass earlier.^{33,34} Our results may not apply to other US races and US regions because virtually all of our population was white and has one of the highest rates of osteoporosis in the country.³⁵ The strength of our study is that the population surveyed had a younger mean age and represented real-world, office-based patients rather than a structured protocol.

Conclusions

Increased fracturing occurred in women with moderate and severe osteopenia when transitioning to osteoporosis. Women with baseline normal BMDs and mild osteopenia were more likely to transition into lower categories associated with fracturing. Individuals fracturing, total fractures, and major fractures were significantly higher at T scores of -1.5 than those with T scores of > -1.5 . A cost analysis using CRFs would identify what T score threshold would be cost effective for treating osteopenia.

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Key Points

- Approximately 60% of women with osteopenia transition to lower categories after an average of 5.75 years of bone mineral density retesting.
- Only 10.5% of women transitioned to osteoporosis; 90.5% of these transitions occurred with T scores ≥ -1.5 .
- When compared with baseline T scores > -1.5 , women with baseline T scores ≤ -1.5 had significantly more individuals fracturing, total fractures, and major fractures.
- Transitioning to osteoporosis accounted for more than one-fifth of individuals fracturing having T scores ≤ -1.5 .

Fig. 1.

The effect of transitioning into lower categories from baseline or maintaining baseline bone mineral density on subsequent fracturing during a 9.6-year follow-up period.

Fig. 2.
Interval years of transitioning to osteoporosis from initial to subsequent bone mineral density examinations.

Table 1

Characteristics of women with initial normal or osteopenic bone mineral densities

Population no.	1150
Age, y, mean (SD)	63.00 (7.99)
BMD follow-up, y, mean (SD)	5.90 (3.08)
Total follow-up, y, mean (SD)	9.65 (3.24)
Baseline T scores, y, mean (SD)	−0.99 (0.99)
Age groups, y	
50–59, n (%)	440 (38.26)
60–69, n (%)	438 (38.09)
70–79, n (%)	240 (20.87)
80, n (%)	32 (2.78)

Baseline BMD categories	Normal ^a	Mild	Moderate	Severe
n (%)	396 (34.4)	277 (24.1)	281 (24.4)	196 (17.0)
Age, y, mean (SD)	61.1 (7.47)	63.5 (7.92)	64.3 (8.10)	64.4 (8.28)
BMD follow-up, y, mean (SD), y ^b	6.28 (3.2)	6.18 (3.20)	5.74 (2.85)	4.94 (2.73)
Total follow-up, mean (SD), y ^c	9.96 (3.18)	9.62 (3.31)	9.56 (3.24)	9.18 (3.20)
Initial BMD T score	.055 (0.80)	−1.08 (0.39)	−1.58 (0.34)	−2.12 (0.26)

^aNormal significantly ($P < 0.0001$) from mild, moderate, and severe.^bSevere significantly different from moderate ($P = 0.003$), mild, and normal ($P < 0.0001$).^cNormal significantly different ($P = 0.01$) from severe.

BMD, bone mineral density; SD, standard deviation.

Table 2

Variables in each category associated with individuals fracturing after an average of 9.6 years of follow-up

	No fractures	Individuals fracturing	<i>P</i>
Normal, n = 396	358	38	
Age, y, mean (SD)	60.99 (7.57)	61.58 (6.48)	0.65
Initial BMD T score	0.094 (0.79)	−0.31 (0.71)	0.003
Follow-up BMD T score	−0.25 (0.88)	−0.74 (0.75)	0.001
Total follow-up, y	9.83 (3.12)	11.16 (3.59)	0.014
T score changes	−0.35 (0.62)	−0.43 (0.45)	0.29
Mild, n = 277	230	47	
Age, y, mean (SD)	63.52 (7.86)	63.26 (8.26)	0.84
Initial BMD T score	−1.07 (0.36)	−1.11 (0.49)	0.62
Follow-up BMD T score	−1.29 (0.58)	−1.53 (0.58)	0.009
Total follow-up, y	9.53 (3.36)	10.08 (3.08)	0.29
T score changes	−0.21 (0.51)	−0.42 (0.71)	0.06
Moderate, n = 281	222	59	
Age, y, mean (SD)	63.85 (7.71)	66.07 (9.22)	0.09
Initial BMD T score	−1.58 (0.34)	−1.59 (0.34)	0.78
Follow-up BMD T score	−1.86 (0.47)	−1.88 (0.43)	0.66
Total follow-up, y	9.43 (3.21)	10.03 (3.36)	0.21
T score changes	−0.27 (0.45)	−0.30 (0.37)	0.81
Severe, n = 196	141	55	
Age, y, mean (SD)	63.94 (8.24)	65.45 (8.34)	0.25
Initial BMD T score	−2.12 (0.27)	−2.11 (0.23)	0.85
Follow-up BMD T score	−2.30 (0.42)	−2.32 (0.41)	0.77
Total follow-up, y	8.95 (3.09)	9.78 (3.41)	0.10
T score changes	−0.18 (0.47)	−0.21 (0.45)	0.71

BMD, bone mineral density; SD, standard deviation.

Table 3

Changes related to transition in women with osteopenia compared with those with normal BMDs at baseline and subsequent fracture occurrence

Initial DXA score	Normal N = 396	Mild N = 277	Moderate N = 281	Severe N = 196
Transition to lower categories, n = 399	101 (25.5)	104 (37.5)	117 (41.6)	77 (39.3)
<i>P</i>	—	0.001	<0.001	0.001
Transition to osteoporosis, n = 116	1 (0.01)	10 (3.6)	28 (9.9)	77 (39.3)
<i>P</i> ^a	—	<0.001	<0.001	<0.001
Individuals fracturing, n = 199	38 (9.6)	47 (17.0)	59 (21.0)	55 (28.1)
<i>P</i>	—	0.005	<0.001	<0.001
Total fractures, n = 239	43 (10.9)	55 (19.5)	74 (26.3)	67 (34.2)
<i>P</i>	—	0.001	<0.001	<0.001
Major fractures, n = 64	12 (3.0)	10 (3.6)	22 (7.83)	20 (10.2)
<i>P</i>	—	0.68	0.005	<0.001
Hip fractures, n = 22	2 (0.5)	4 (1.44)	7 (2.49)	9 (4.59)
<i>P</i>	—	0.24 ^F	0.04	0.001
Vertebral fractures, n = 31	7 (1.77)	4 (1.44)	12 (4.27)	8 (4.08)
<i>P</i>	—	1.00 ^F	0.052	0.092
Intermediate fractures, n = 127	24 (6.06)	34 (12.3)	38 (13.9)	30 (15.3)
<i>P</i>	—	0.005	0.001	<0.001
Minor fractures, n = 48	7 (1.76)	11 (3.97)	13 (4.63)	17 (8.67)
<i>P</i>	—	0.081	0.030	<0.001

Values in parentheses represent the percentage of the total population in each category.

BMD, bone mineral density; DXA, dual x-ray absorptiometry.

^aFisher exact test.

Table 4 Comparison of categories in women with vaseline T scores of > -1.5 and -1.5

	> -1.5 n (%) n = 673	-1.5 n (%) n = 477	<i>P</i>
Transitions to lower categories, n = 399	205 (30.5)	194 (40.7)	<0.001
Individuals fracturing, n = 199	85 (12.6)	114 (23.9)	<0.001
Total fractures, n = 239	98 (14.6)	141 (29.6)	<0.001
Transitioning to osteoporosis, n = 116	11 (1.63)	105 (22.0)	<0.001
Individuals fracturing by transitioning, n = 2	2 (0.3)	26 (5.45)	<0.001
Total fractures by transitioning, n = 37	2 (0.3)	35 (7.34)	<0.001
Major fractures, n = 64	22 (3.29)	42 (8.81)	<0.001
Hip, n = 21	6 (0.89)	15 (3.14)	0.005
Vertebral, n = 26	6 (0.89)	20 (4.19)	<0.001
Intermediate fractures, n = 127	58 (8.62)	69 (14.5)	0.002
Minor fractures, n = 48	18 (2.67)	30 (6.29)	0.003