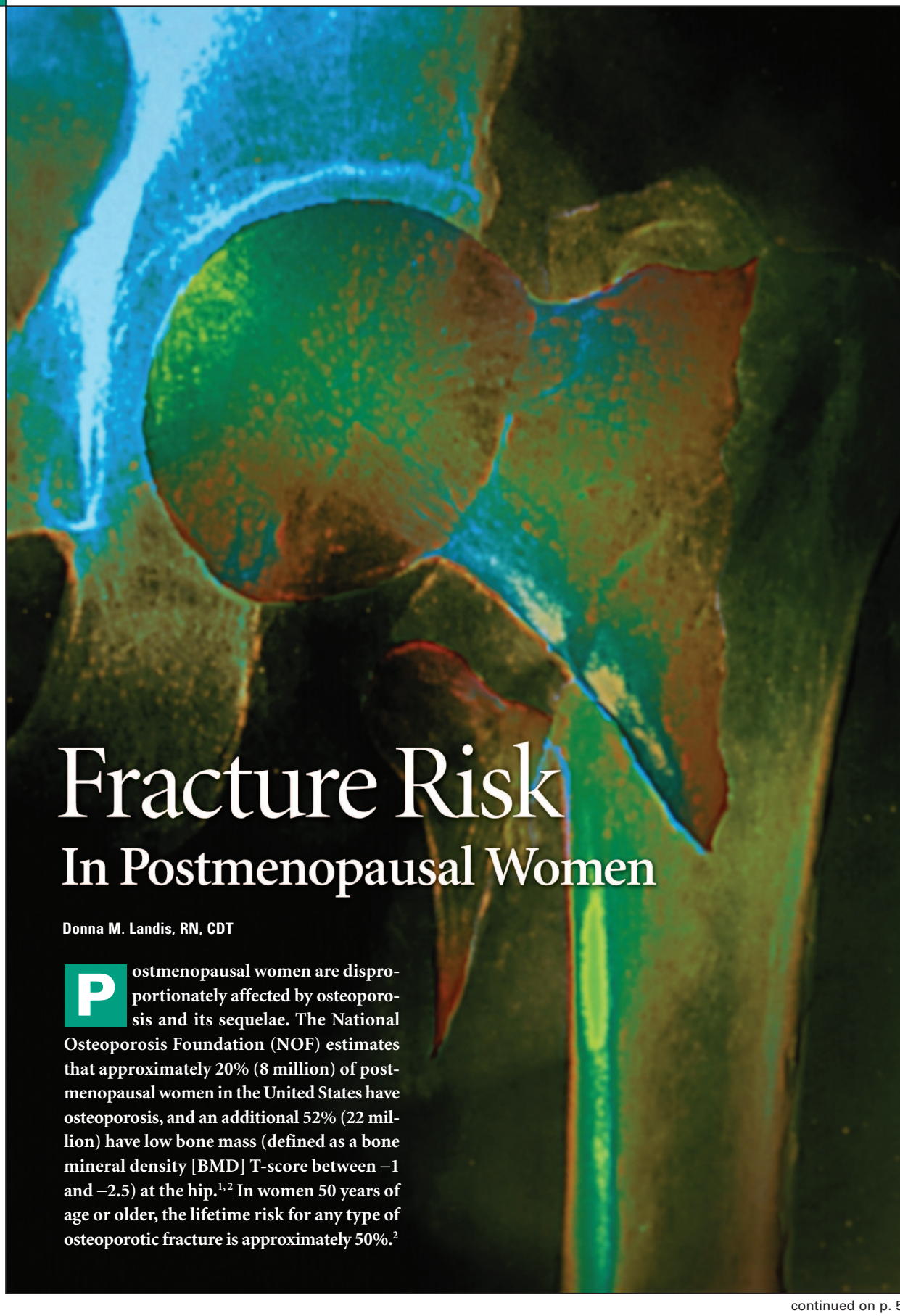

Fracture Risk
In Postmenopausal Women

Donna M. Landis, RN, CDT

Postmenopausal women are disproportionately affected by osteoporosis and its sequelae. The National Osteoporosis Foundation (NOF) estimates that approximately 20% (8 million) of postmenopausal women in the United States have osteoporosis, and an additional 52% (22 million) have low bone mass (defined as a bone mineral density [BMD] T-score between –1 and –2.5) at the hip.[1,2] In women 50 years of age or older, the lifetime risk for any type of osteoporotic fracture is approximately 50%.[2]

continued on p. 53

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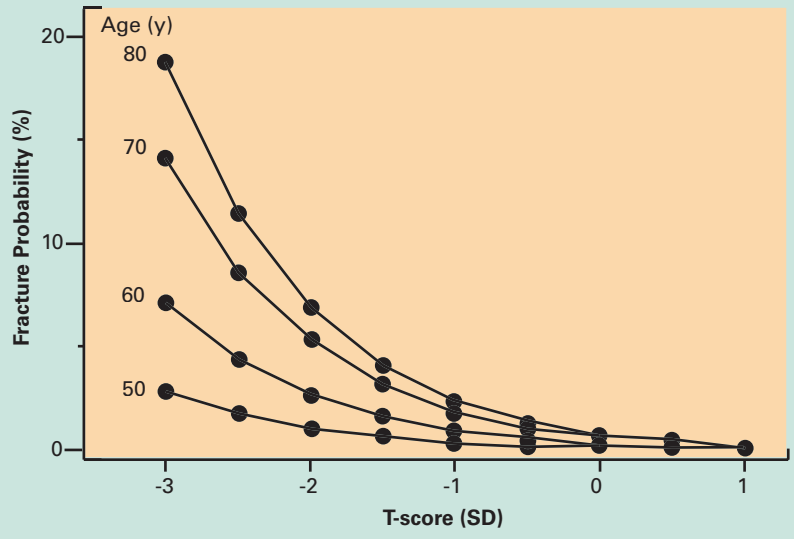
The Problem

The societal costs of osteoporotic fractures are considerable. Hip and vertebral fractures in particular have long-term adverse effects on health-related quality of life[3-5] and cause significant increases in morbidity and mortality. Hip fracture is associated with an increase in mortality of up to 20% within 1 year following the fracture.[1] Approximately 60% of hip fracture patients are unable to fully regain their premorbid levels of independence, and up to one-quarter may require long-term nursing home care.[1] The occurrence of an osteoporotic fracture at any site approximately doubles a woman's overall risk for future fractures.[6] This increased risk is particularly striking for women with prevalent vertebral fractures, which are associated with an increased risk of subsequent vertebral and hip fractures.[7,8] Research has also demonstrated that after sustaining a vertebral fracture, postmenopausal women have a one in five chance of experiencing another vertebral fracture within 1 year.[8]

The resultant risk increase following a fracture indicates that early identification of at-risk patients followed by effective therapy is warranted; and yet, this often does not occur. A 2002 survey of 1,004 female members (40 to 69 years of age) of a managed care network found that more than 50% of respondents had never discussed osteoporosis with their healthcare provider.[9] Furthermore, three out of four vertebral fractures are asymptomatic.[8,10] Therefore, many fractures remain undiagnosed.[11-13] Even when fractures are identified, as many as three-quarters of patients do not receive appropriate subsequent pharmacologic therapy.[14,15]

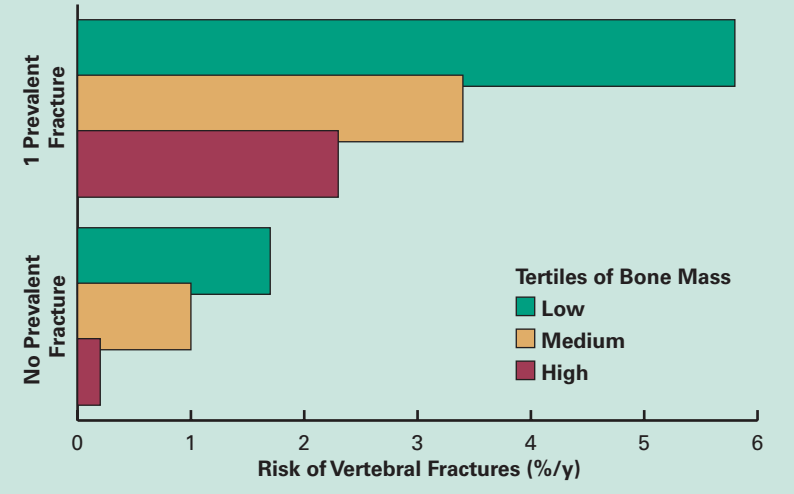
As important gatekeepers in the healthcare system, nurse practitioners (NPs) are in a key position to identify and counsel patients at risk for osteoporotic fracture and to initiate medical intervention. Lifestyle choices that may have a favorable effect on bone mass and fracture incidence reduction should be discussed with all patients regardless of age, gender, or disease status. The availability of an easy-to-use risk assessment tool can be a helpful adjunct in quantifying this risk and identifying patients in need of further evaluation.

Ten-Year Probability of Hip Fracture in Women (by Age and T-score)



SD=standard deviation.
Reproduced with permission from Kanis JA, Johnell O, Oden A, et al: Ten-year probabilities of osteoporotic fractures according to BMD and diagnostic thresholds. Osteoporos Int 2001;12:989-995.

History of Fracture and Bone Mass



Source: Ross PD, Davis JW, Epstein RS, et al: Pre-existing fractures and bone mass predict vertebral fracture incidence in women. Ann Intern Med. 1991;114:919-923.

Fracture Risk Assessment

Although the BMD measurement was traditionally used to diagnose osteoporosis, relying on BMD assessment alone may not adequately identify all women at risk for fracture. Recent data from two large-scale longitudinal observational

FRACTURE Index for Predicting Fracture Risk in Postmenopausal Women[24]

What is your current age?
- ❑ < 65 — 0
- ❑ 65–69 — 1
- ❑ 70–74 — 2
- ❑ 75–79 — 3
- ❑ 80–84 — 4
- ❑ ≥ 85 — 5

Have you broken any bones after age 50?
- ❑ Yes — 1
- ❑ No/don't know — 0

Has your mother had a hip fracture after age 50?
- ❑ Yes — 1
- ❑ No/don't know — 0

Do you weigh 125 pounds or less?
- ❑ Yes — 1
- ❑ No — 0

Are you currently a smoker?
- ❑ Yes — 1
- ❑ No — 0

Do you usually need to use your arms to assist yourself in standing up from a chair?
- ❑ Yes — 2
- ❑ No/don't know — 0

If you have a current BMD assessment, what was your total hip T-score?
- ❑ ≥ –1 — 0
- ❑ –1 to –2 — 2
- ❑ –2 to –2.5 — 3
- ❑ < –2.5 — 4

Total

BMD=bone mineral density.
*Women without current BMD assessment and a total score of ≥ 4 should receive further evaluation, including bone density testing. Women with current BMD and total score of ≥ 6 should receive further evaluation and intervention. Adapted with permission.

Risk Factors for Osteoporosis-Related Fractures in Postmenopausal Women[1,25,26]

Major Risk Factors
- Caucasian or Asian race
- Personal history of fracture as an adult
- History of fragility fracture in a first-degree relative
- Family history of osteoporosis
- Low body weight and body mass index
- Current smoking
- Height loss (≥ 1.5 in)

Additional Risk Factors
- Visual impairment
- Sedentary lifestyle (inadequate exercise)
- Recent history of falls
- Excessive alcohol intake (> 2 drinks daily)
- Early estrogen deficiency (menopause younger than 45 years, bilateral oophorectomy, > 1 y premenopausal amenorrhea)
- Dementia
- Low calcium intake (lifelong)
- Poor health

Medical Conditions
- Eating disorders (eg, anorexia nervosa)
- Hyperparathyroidism
- Diabetes mellitus type 1
- Malabsorption syndromes
- Thyrotoxicosis

Medications
- Oral corticosteroid treatment ≥ 3 mo
- Nonthiazide diuretics
- Anticonvulsants (phenobarbital, phenytoin)
- Tamoxifen (premenopausal use)
- Gonadotropin-releasing hormone agonists

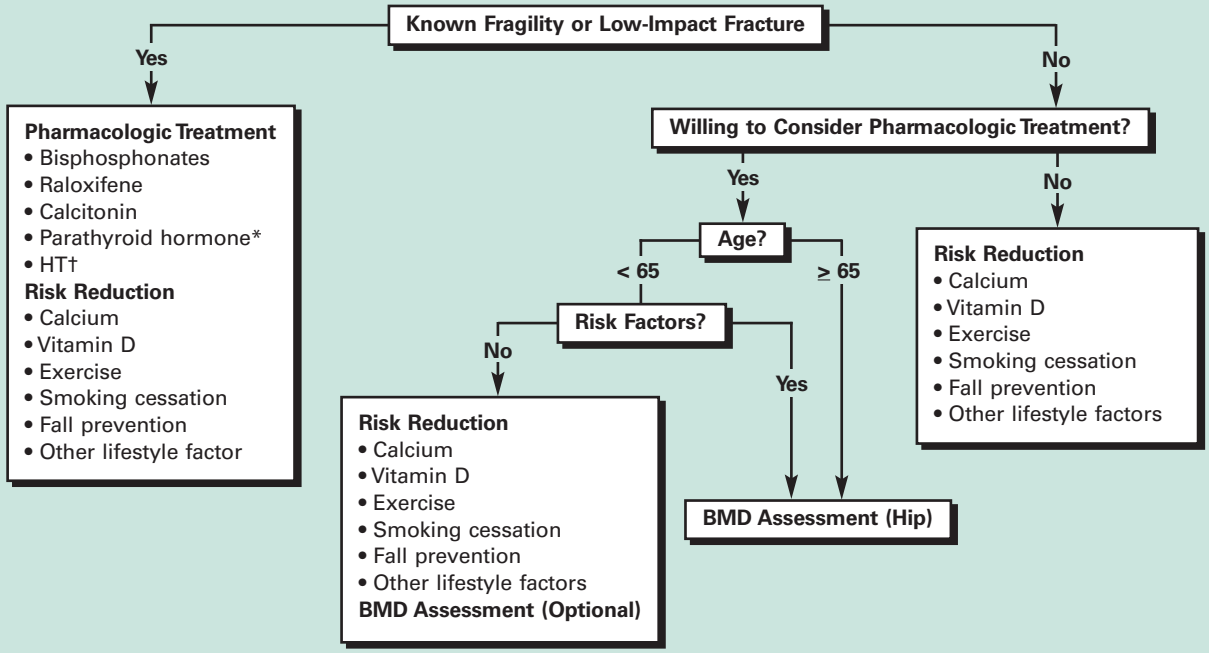
studies—the Study of Osteoporotic Fractures (SOF) and the National Osteoporosis Risk Assessment (NORA)— highlight discrepancies between the World Health Organization's diagnostic threshold (T-score of ≤ –2.5), and T-score levels at which fractures actually occur. Using central dual-energy x-ray absorptiometry in the SOF population, 32% of patients with hip fracture and 54% of those with any nonvertebral fracture had baseline hip T-scores of > –2.[16] Evidence of fractures occurring in patients with BMD T-scores above the diagnostic threshold has also been substantiated in a much larger database, using peripheral bone density testing.[17,18] The NORA study found that 52% of the women who experienced an osteoporotic fracture in the first year of follow-up had T-scores between –1 and –2.5.[18]

Strategies combining BMD and clinical risk factors for osteoporotic fracture may allow for more effective identification of women who are at increased risk for fracture. Several demographic factors impact fracture risk independent of BMD, notably age, Caucasian or Asian race, and previous fragility fracture (see Figures: "Ten-Year Probability of Hip Fracture in Women" and "History of Fracture and Bone Mass"). In addition, a wide range of medical conditions, medications, and lifestyle factors impair bone strength and increase fracture risk (see Table: "Risk Factors for Osteoporosis-Related Fractures in Postmenopausal Women"). Because it may not be possible to screen all women with bone density testing, assessment of these clinical risk factors is an important step in identifying patients who require further evaluation and/or medical intervention.

Obtaining a thorough history, including family and personal history of fracture, is important in evaluating risk factors for fracture. Easily administered risk assessment tools for predicting osteoporosis/fracture risk based on risk factors are available.[19-22] These questionnaires have shown good specificities and are valuable when performing an initial risk assessment or when counseling a patient about her fracture risk.[19-23]

The FRACTURE Index is a quantitative tool that assesses age, fracture history (personal and maternal), weight, smoking status, use of arms to stand up from a chair, and T-score (when available) to identify patients at high risk for fracture (see Table: "FRACTURE Index for Predicting Fracture Risk in Postmenopausal Women").[24] These factors are consistent with those published by the NOF.[1] This tool is strongly predictive of both vertebral and nonvertebral fracture risk, and is also useful for identifying patients who need further as-

Algorithm for Assessment and Management of Fracture Risk[1]



*Only to be considered for patients at high risk for osteoporotic fracture. †Only after consideration of nonestrogen treatment options.
BMD=bone mineral density; HT=hormone therapy. Adapted with permission.

sessment (including BMD testing).[24] It may be useful in patient counseling as well. Furthermore, taking accurate height measurements at each visit can help identify those who may have new vertebral fractures.[25]

Insurance reimbursement, as well as clinical guidelines for bone density assessment, frequently specify that testing should be limited to older women 65 years of age or older), women with prevalent fracture, or younger postmenopausal women (younger than 65 years of age) with risk factors. However, many guidelines—including those provided by the American College of Obstetricians and Gynecologists, the NOF, and the American Association of Clinical Endocrinologists—do not quantify the relative "weight" to be given to any individual risk factor.[1,26,27] High scores on a risk assessment tool, such as the FRACTURE Index, suggest further evaluation. This tool can be used alongside current guidelines for BMD testing and osteoporosis treatment (see Figure: "Algorithm for Assessment and Management of Fracture Risk"). Risk factors may help explain the contributing causes of osteoporosis and guide therapeutic considerations.

Prevention and Treatment Therapies

Postmenopausal women can have fractures well before their BMD has declined to the diagnostic threshold level for osteoporosis (T-score ≤ –2.5).[16,18] Thus, early and effective intervention is needed to reduce the risk of future fractures (see Table: "Nonestrogen Therapies for the Treatment and/or Prevention of Osteoporosis"). As a result of the Women's Health Initiative safety findings, hormone therapy (HT) is

Nonestrogen Therapies for the Treatment and/or Prevention of Osteoporosis

Medication	Administration	Indications for Postmenopausal Osteoporosis
Alendronate	Oral tablet Oral liquid*	Prevention and treatment
Ibandronate	Oral tablet	Prevention and treatment
Risedronate	Oral tablet	Prevention and treatment
Raloxifene	Oral tablet	Prevention and treatment
Calcitonin	Intranasal injection	Treatment
Teriparatide	Injection	Treatment

* Approved for treatment.

no longer recommended as first-line therapy for the prevention of osteoporosis.[28, 29]

Alendronate

In clinical trials, alendronate (Fosamax), a bisphosphonate, produced significant reductions in the risk of clinical (symptomatic) vertebral and nonvertebral fracture at 1 year in post hoc analyses.[30, 31] Vertebral fracture risk was also reduced by 47% and 44% at 3 and 4 years of therapy, respectively.[32,33] Data from a 3-year placebo-controlled trial, in addition to subsequent extension studies, indicate that BMD increases were sustained over a 10-year period.[34]

Risedronate

Risedronate (Actonel), a bisphosphonate, has been shown to produce a rapid reduction in fracture risk in postmenopausal patients. Prospective analyses showed significant reductions in vertebral fracture risk after 1 year.[35, 36] Post hoc analyses demonstrated significant clinical vertebral and nonvertebral fracture risk reductions within 6 months of treatment initiation.[37, 38] Results from a 5-year, placebo-controlled study indicate that risedronate therapy over 5 years reduced vertebral and nonvertebral fracture risk by 50% and 37%, respectively.[39] A 2-year, open-label extension of this study demonstrated that the antifracture effect was maintained over 7 years.[40]

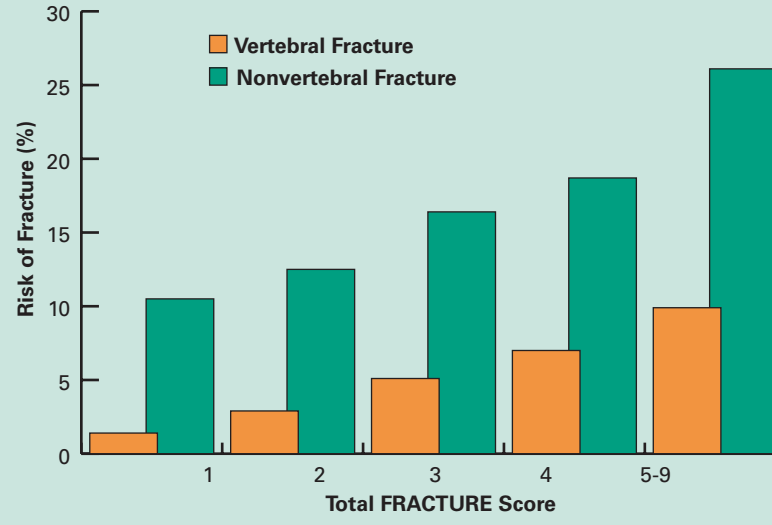
Ibandronate

Ibandronate (Boniva) is the most recent bisphosphonate to enter the market. The major benefit of this drug is that it is only taken once a month. In a 3-year placebo-controlled trial in postmenopausal women, new vertebral fractures were reduced by 62% and 50% in patients receiving daily and intermittent ibandronate, respectively, compared with placebo.[41] Nonvertebral fracture incidence was similar between the ibandronate and placebo groups.

Raloxifene

Raloxifene (Evista) is the first selective estrogen receptor modulator approved for the prevention and treatment of postmenopausal osteoporosis. The Multiple Outcomes of Raloxifene Evaluation trial documented a significant 30% decrease in the risk of new vertebral fractures in raloxifene-treated patients at 3 years, but did not show a benefit for nonvertebral or hip fracture risk when compared to placebo.[42] A post hoc analysis of this data showed that clinical vertebral fracture risk was reduced after 1 year of therapy.[43]

Five-Year Risk of Vertebral and Nonvertebral Fractures by FRACTURE Index Score Without BMD Assessment[24]



BMD = bone mineral density
Adapted with permission

Calcitonin

Calcitonin (Miacalcin) significantly reduced the 5-year risk of new vertebral fractures among treated patients in the Prevent Recurrence of Osteoporotic Fractures trial, but did not reduce the risk of nonvertebral or hip fractures. Women treated with intranasal calcitonin (200 international unit/d), were one-third less likely to sustain new vertebral fractures than those treated with placebo.[44] Calcitonin is approved for the treatment of osteoporosis in women 5 or more years after menopause.[45]

Teriparatide

Parathyroid hormone (1-34) (teriparatide [Forteo]) significantly reduced vertebral (65%) and nonvertebral (35%) fracture risk after 21 months.[46] The safety and efficacy of teriparatide have not been evaluated beyond 2 years of treatment. Teriparatide should be prescribed for no more than 2 years, and only to patients at high risk for fracture, or who have failed with or are intolerant of previous osteoporosis therapies.[47]

Educating, Counseling, and Monitoring

Adequate education, counseling, and follow-up are important for patients with (or at risk for) osteoporosis. After an

assessment, the NP should discuss the findings with the patient, detailing the risks for fracture and explaining the risks and benefits of intervention, including risk factor modification and pharmacologic therapy. Charts or graphics illustrating fracture risk by various factors may be used to educate the patient about her condition. The NP should then discuss why the prescribed therapeutic regimen is most appropriate and clearly explain the dosing regimen as well as the necessity of compliance for treatment success (fracture risk reduction).

Clinical data, such as 5-year fracture risk reduction with risedronate (50% vertebral and 37% nonvertebral fracture risk reduction), or calcitonin (33% vertebral fracture risk reduction), can be compared with a patient's current 5-year fracture risk when deciding whether or not to initiate pharmacologic treatment (see Figure: "Five-Year Risk of Vertebral and Nonvertebral Fractures by FRACTURE Index Score Without BMD Assessment").

Nonpharmacologic Options

In addition to medical intervention, it is important to provide guidance, information, and support for nonpharmacologic measures. The surgeon general's first report on bone health provides recommendations for lifestyle changes to decrease the likelihood of developing osteoporosis.[48] For instance, most women do not receive enough calcium in their diets, even if they take supplements.[49] Discussing daily recommendations with patients can increase their daily dietary intake, along with the use of supplements.[50]

Patients should modify their lifestyles in the following areas:

- Adequate calcium intake, with supplements as needed: 1,200 to 1,500 mg/day; more than 600 mg per dose will not be effectively absorbed; split dosing into two or three times per day
- Adequate vitamin D intake: 400 to 800 international units/day
- Adequate diet with adequate protein
- Fall prevention strategies (see Table: "Fall Prevention Measures")
- Regular weight-bearing exercise and strength training
- Smoking cessation
- Moderate alcohol intake (≤ 1 drink/day)

Once a treatment plan is established, regular follow-up visits are essential to monitor the patient's progress and adherence to the treatment regimen. Follow-up BMD measurements, in addition to other clinical assessments such as bone turnover marker assays, can be used to reinforce compliance with therapy. These visits can also be used to monitor patient satisfaction with the treatment regimen and assess any adverse events that may affect compliance.

Fall Prevention Measures[26]

Intervention	Example
Gait training and assistive devices	• Canes, walkers, bed alarms, hip devices
Medication change	• Avoidance of medications that reduce strength/impair balance • Treatment of postural hypotension
Exercise programs	• Yoga, tai chi, strength training
Modification of environmental hazards	• Facilitated environmental home assessment • Removal of safety hazards and obstacles • Installation of handrails • Improved lighting

Adapted from Panel on Falls Prevention. Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. J Am Geriatr Soc 2001;49:664-672.

When To Consider Osteoporosis Therapy

A management strategy focused on lifestyle approaches may be all that is needed for women who are at low risk for osteoporotic fracture. The North American Menopause Society (NAMS) recommends considering osteoporosis therapy in the following populations (these recommendations represent a change from previous NAMS recommendations based on additional published data regarding fracture efficacy):

- All postmenopausal women with total hip or spine T-scores worse than -2.5.
- All postmenopausal women with total hip or spine T-scores from -2.0 to -2.5 and at least one additional risk factor for fracture.
- All postmenopausal women with an osteoporotic, vertebral fracture (no bone mineral density is needed).

Source: Management of postmenopausal osteoporosis: position statement of the North American Menopause Society. Menopause 2002 Mar-Apr;9(2):84-101.

Improving Patient Awareness

Osteoporosis is a significant and growing public health problem that affects millions of American women. Despite a growing awareness of the risks associated with osteoporosis, along with the importance of early diagnosis and care, many women are not diagnosed until they have sustained one or more osteoporotic fractures. Nurse practitioners have a unique opportunity to improve both patient awareness and medical management of osteoporosis through risk assessment, patient education including health promotion and disease prevention techniques, and by initiating and monitoring medical and lifestyle interventions. NP

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