

Commentary

The Good and the Bad About the 2017 American College of Physicians Osteoporosis Guidelines



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ABSTRACT

Purpose: The American College of Physicians (ACP) published a set of guidelines on how to prevent fractures in men and women with low bone density or osteoporosis. As the population ages, the overall risk of fractures increases, thus burdening the health care system. These guidelines review current evidence for osteoporosis management, providing an update to the previous 2008 ACP's guidelines.

Methods: The ACP put forth 6 recommendations addressing the complexities in osteoporosis management based on evidence available through October 2016 with a focus on bisphosphonates, calcium, vitamin D, and estrogen. Evidence was graded according to recommended strength by using the ACP standard methods.

Findings: The ACP recommends anti-osteoporosis therapy with 1 of 3 bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab in patients with osteoporosis, while excluding anabolic therapies, and recommends against raloxifene. Although bisphosphonates are the mainstay of treatment, anabolic therapy and raloxifene may be used in specific situations. Pharmacologic therapy is recommended for 5 years, oversimplifying length of therapy and failing to promote an individualized patient-centered care approach. Moreover, abrupt discontinuation of denosumab is associated with a decline in bone mineral density (BMD), which must be addressed. Routine monitoring of BMD by dual x-ray absorptiometry is not endorsed during treatment, which leads to underrecognition of management issues. Pharmacologic treatment with bisphosphonates for male osteoporosis is recommended, although therapies such as denosumab and teriparatide are

excluded. Finally, the ACP recommends treatment for women aged ≥ 65 years at high risk for fracture with osteopenia after a discussion of patient preferences, fracture risk profile, and medications.

Implications: Osteoporosis management is complex. The 2017 ACP guidelines address challenges faced by clinicians but oversimplify more complex issues. These are among a number of guidelines that are available for osteoporosis management, which may be used in combination with other sources to assist clinicians with diagnostic and management strategies. (*Clin Ther.* 2018;40:168–176) Published by Elsevier HS Journals, Inc.

Key words: commentary, fracture, guidelines, osteoporosis.

PURPOSE

Recently, the American College of Physicians (ACP) published an updated set of guidelines on how to prevent fractures in men and women with low bone density or osteoporosis.¹ The ACP correctly recognized that osteoporotic fractures pose a significant public health problem. As the population ages, the overall risk of fractures increases, resulting in a considerable burden to the health care system. These guidelines review the most current available evidence for management of osteoporosis, providing an update to the previous 2008 ACP guidelines.² The ACP put

Accepted for publication November 14, 2017.

<https://doi.org/10.1016/j.clinthera.2017.11.008>

0149-2918/\$ - see front matter

Published by Elsevier HS Journals, Inc.

forth 6 recommendations addressing complex issues in the arena of osteoporosis management.

ACP METHODS

The guidelines committee reviewed evidence available through October 2016 with a focus on bisphosphonates, calcium, vitamin D, and estrogen. The evidence was graded according to recommended strength by using the ACP's standard methods.³ Of the 6 recommendations put forward by the ACP, 2 are based on high-quality evidence and graded as strong recommendations, and 4 are graded as weak due to low-quality evidence.

FINDINGS

The first recommendation from the ACP guideline committee is of great importance and highlights the need for primary care physicians to offer anti-osteoporosis therapy with 1 of 3 bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab in patients who have a known diagnosis of osteoporosis. This recommendation was graded as "strong" with "high-quality evidence."

The National Osteoporosis Foundation, the US Preventive Services Task Force, the International Society for Clinical Densitometry, and the American Association for Clinical Endocrinology recommend that women aged ≥ 65 years, young premenopausal women with risk factors, and all men aged ≥ 70 years should have a bone density test. A major hindrance to the treatment of osteoporosis is lack of recognition and appropriate screening. Currently, bone mineral density (BMD) testing by dual x-ray absorptiometry (DXA) is the international standard for the clinical assessment of skeletal health, for the diagnosis of osteoporosis, and for monitoring of BMD changes that occur over time.⁴ Overall, the number of bone density tests that are performed for screening of osteoporosis has declined, based on reviews of Medicare claims data.⁵

Pharmacologic treatment of patients with a diagnosis of osteoporosis is also declining, as shown by a decrease in the annual unadjusted probability of osteoporosis medications.⁶ Multiple randomized controlled trials have shown the effectiveness of bisphosphonates and denosumab in reducing fractures (vertebral, nonvertebral, and hip fractures) in postmenopausal women with osteoporosis, diagnosed by using a

T score of less than or equal to -2.5 or a fragility fracture.

Bisphosphonates inhibit bone resorption and target the osteoclast to exert their antifracture effects. They are the most widely prescribed medications for osteoporosis treatment. All oral bisphosphonates, along with calcium and vitamin D, have been shown in large randomized controlled trials to decrease fracture study end points.⁷ The FIT (The Fracture Intervention Trials) studies of alendronate involving postmenopausal women with BMD T scores of -1.6 or less at the femoral neck reported a reduction in the rate of vertebral fractures of $\sim 50\%$ compared with placebo.^{8,9} The first alendronate trial, which was performed in women with previous vertebral fractures, found that the rate of hip fractures decreased by 51% and the rate of nonvertebral fractures decreased by 20% with alendronate compared with placebo ($P = 0.06$).⁸ The second study, which did not include women with previous vertebral fractures, resulted in a reduction in nonvertebral (35%) and hip (56%) fractures in a subgroup of patients with a BMD T score of -2.5 or less at the hip.^{9,10} Trials of risedronate showed that rates of vertebral fractures and nonvertebral fractures were lowered by 41% to 49% and 33% to 40% over a period of 3 years compared with placebo.^{11,12} The ibandronate trial reported reductions in vertebral fractures (62%) but no reduction in the rate of nonvertebral fracture,¹³ with the exception of the subgroup of women with a T score less than -3.0 .¹⁴

IV bisphosphonates are convenient options for osteoporosis management in patients who cannot take these medications orally. In women with low BMD, previous vertebral fractures, or a history of both, an annual infusion of IV zoledronic acid yielded lower rates of vertebral fractures by 70%, hip fractures by 41%, and nonvertebral fractures by 25% compared with placebo.¹⁵ In patients who had sustained a hip fracture, administration of IV zoledronic acid resulted in lowered secondary clinical fractures by 35%.¹⁶

Denosumab was the first biologic therapy approved for the treatment of osteoporosis. Its mechanism of action is different from that of bisphosphonates because it inhibits bone resorption by targeting the receptor activator of nuclear factor- κ B ligand, thereby inhibiting the differentiation of preosteoclasts to mature osteoclasts. A benefit of denosumab is that it

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