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The Management of Osteoporosis among Home Health and Long Term Care Patients with a Prior Fracture

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Abstract

Osteoporosis is a growing health concern as the number of senior adults continues to increase worldwide. Falls and fractures are very common among frail older adults requiring home health and long-term care. Preventative strategies for reducing falls have been identified and many therapies (both prescription and non-prescription) with proven efficacy for reducing fracture risk are available. However, many practitioners overlook the fact that a fragility fracture is diagnostic for osteoporosis even without knowledge of bone mineral density testing. As a result, osteoporosis is infrequently diagnosed and treated in the elderly after a fracture. Based on existing literature, we have developed an algorithm for the assessment and treatment of osteoporosis among persons with known prior fracture(s) living in long-term care facilities or receiving home health care.

Introduction

Osteoporosis is a significant problem among older adults, with up to a 90% prevalence among nursing home residents [1–3]. Fractures are the main burden associated with osteoporosis, with more than 2 million fractures occurring in the US in 2005 [4]. Of those who sustain a hip fracture, up to 75% require nursing home placement for rehabilitation or long-term care [5]. Many of the remainder receive home health care, resulting in over 2 million home health care visits for post-hospitalization fracture care annually [6].

Although the risk for fracture among nursing home and home health patients is already high [7,8], history of a prior fracture in this population makes intervention even more compelling given the exceedingly high risk for a second fracture[9]. In the presence of a fragility fracture, osteoporosis can be assumed, negating the need for bone densitometry for diagnosis[10]. Thus, current guidelines call for treatment for osteoporosis for all persons with a history of a prior hip or vertebral fracture [11]. Despite these recommendations, osteoporosis is underdiagnosed and undertreated in nursing home residents and community-dwelling senior adults [10,12, 13]. Osteoporosis medications have been found to reduce the risk of fracture in senior adults [14–16], but the use of antiresorptive therapy occurs in only 10–20% of nursing home residents with osteoporosis or a recent fracture [10,17]. The use of calcium and vitamin D in this population is higher, but the doses provided may not be sufficient based on current recommendations [10,17].

In light of the gap between treatment guidelines and current quality of care, we have developed an algorithm for the assessment and care of nursing home and home health care patients with a prior fracture. The purpose of this report is to further discuss the literature supporting these recommendations.

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Overview of Management Algorithm for Osteoporosis Care for Home Health and Long Term Care Patients with Prior Fracture

As shown in Figure 1, an initial laboratory evaluation of renal function, serum calcium, and alkaline phosphatase levels is a reasonable first step in evaluating a person with a prior fracture for possible osteoporosis treatment. These tests both screen for possible secondary causes of low bone mass or fracture and also provide baseline information useful for deciding on a treatment option. Other lab tests may be helpful in certain settings and are listed under Supplemental lab tests. Serum 25-hydroxy vitamin D should be assessed, although if not feasible, empiric treatment could be offered given a high expected prevalence of vitamin D insufficiency in this population. Additional lab tests (e.g. serum albumin, to correct serum calcium) should be ordered as clinically indicated. Thereafter, initiation of calcium and vitamin D therapy, fall risk assessment, and weight bearing exercise is recommended. Bone mineral density evaluation with a DXA scan provides further information, but the inability to obtain a DXA scan for some nursing home or home health care patients should not hinder management. Once osteoporosis therapy is started, adherence and tolerance of the therapy should be monitored regularly and treatment should be adjusted if indicated.

Recurrent fractures

In community-dwelling senior adults, prior fracture is a well-described risk factor for future fracture. Two meta-analyses have shown that the relative risk (RR) of developing a second or subsequent fracture at any site is approximately 2-fold higher than the risk of developing an initial fracture (RR = 1.86; 95% CI 1.75–1.98) [8,18]. For certain fracture sites (e.g. spine), the RR of developing a second vertebral fracture is nearly 4-fold higher (RR = 4.4, 95% CI 3.6–5.4) [8,18].

Risk factors for a second hip fracture differ from those associated with initial fractures and include cognitive impairment, prior falls, institutionalization, Parkinson's disease, weight loss, and poor perceived health [19,20]. Age and functional status were found to be the most important predictors of a second hip fracture among community-dwelling older adults, with higher functioning persons at the greatest risk [19]. This difference was likely seen in part due to higher activity levels in the more functional persons, resulting in increased opportunities for falls and fractures. In nursing home residents, functional status is also an important predictor of future fractures. A prospective study of U.S. nursing home residents found independence in transfers to be an independent risk factor for fracture (hazard ratio 1.6, 95% CI 1.2–2.2) when compared to those who required assistance with transfers [21].

Less is known about the risk of subsequent fracture among nursing home residents; however, a retrospective cohort study of nursing home residents found a 3-fold increased risk of subsequent fracture among residents with a history of hip fracture [19,22,23]. The increased risk of subsequent fracture likely reflects the high prevalence of risk factors for fracture in the nursing home setting, including high fall rate, low bone mineral density (BMD), multiple comorbidities, polypharmacy, and low use of osteoporosis treatments, including calcium and vitamin D [1,2,21]. In a prospective study of 18,855 nursing home residents, a history of falls was the strongest predictor of future falls (OR 3.59, 95% CI 3.36–3.82) [24]. In another study, there was a direct correlation between the number of medications a patient was taking and the risk of falls [25]. Nursing home residents may also be at increased risk because of sensory impairment (hearing/sight), impaired balance, decreased strength, depression, and urinary/ fecal urgency [26].

Fracture Risk Prediction

To better predict the absolute fracture risk, WHO has introduced a fracture prediction algorithm (FRAX) [27]. Using the FRAX calculator, ten-year probabilities of major osteoporotic fractures (e.g., hip, clinical vertebral, proximal humerus, distal forearm) can be estimated. This is especially useful when BMD testing is not feasible, as FRAX can compute fracture risk using body mass index (BMI) as a proxy for BMD. Table 1 illustrates fracture probabilities among patients with a prior fracture and normal body mass index when no BMD data is available.

Vitamin D: Fractures and Falls

Vitamin D is important in bone health due to its ability to counter-regulate parathyroid hormone (PTH) (a promoter of bone loss) and stimulate intestinal and renal calcium absorption. With a vitamin D deficiency or inadequate calcium intake, PTH levels typically rise, resulting in secondary hyperparathyroidism and bone loss.

With normal aging, there is decreased ability of the skin to synthesize vitamin D, resulting in vitamin D deficiency in as many as 90% of older adults [28,29], yet optimizing vitamin D status is often overlooked. In one study of 147 elderly patients with hip fracture, no patients had vitamin D levels checked and only 14% were given vitamin D supplementation [30].

Prior prospective studies have shown that the combination of calcium plus vitamin D improved BMD and reduced risk of fracture [14,31,32]. These improvements were greatest in older adults with low body weight, low dietary calcium intake, increased baseline risk of fracture, and the institutionalized [33]. A Cochrane database systematic review of the topic reported a reduction of hip and non-vertebral fractures when vitamin D and calcium were taken together [34]. A subgroup analysis found that the benefit was most significant in institutionalized persons [34]. In a meta-analysis, daily vitamin D supplementation of at least 700–800 IU led to a 23% fracture risk reduction [35]. However, with vitamin D doses of only 400 IU daily, fracture risk reduction was not seen [35]. The inconsistency in vitamin D dosing likely explains some of the heterogeneity seen in some other studies, including the Women's Health Initiative [35–39]. The reason for the variation in benefit observed across studies is likely multifactorial, but variations in compliance and baseline vitamin D levels are likely to be important factors as well.

In addition to improving bone health, low vitamin D appears to be an independent predictor of fall risk [40] and supplementation has been found to reduce this risk, likely through improved musculoskeletal function [41–43]. Two randomized clinical trials of vitamin D supplementation confirmed this hypothesis [44,45]. The effect was found to persist even in persons with adequate 25(OH)-Vitamin D {25(OH)D} levels at the start of the study [44,45] and was more prominent in the less active women [44]. In a recent study of nursing home residents treated with varying doses of vitamin D, those treated with 800 IU of cholecalciferol had a significant reduction in fall risk (RR 0.28; 95% CI, 0.11–0.75) compared to placebo [43]. No significant benefit was seen with lower doses of vitamin D, again emphasizing the importance of dose [43].

Vitamin D: Supplementation

The optimal level of serum 25(OH)D remains unclear, as do the optimal doses of vitamin D for replacement and maintenance. Most agree that vitamin D deficiency can be defined as a 25 (OH)D level of less than 20ng/ml [46]. Because a 25(OH)D level below 30ng/ml is sometimes associated with PTH elevation, a serum 25(OH)D level of 30ng/ml has been recommended [47,48]. Vitamin D intoxication, leading to hypercalcemia, generally does not occur until 25

(OH)vitamin D levels reach 150ng/ml or higher, except in patients with primary hyperparathyroidism [46,49,50].

In home health and nursing home patients, it may not always be feasible to measure 25(OH) D. Nevertheless, vitamin D supplementation should not be ignored, and empiric treatment can be offered if serum calcium levels are not elevated. When serum calcium levels are elevated, further evaluation into the cause should be considered prior to vitamin D supplementation due to the potential risk of worsening hypercalcemia and hypercalciuria. In a study of 2686 community dwelling persons aged 65-85, empiric treatment with 100,000IU oral cholecalciferol every four months for five years, regardless of baseline 25(OH)D levels, resulted in a 22% reduction of any first fracture and a 33% reduction of first hip, wrist or forearm, or vertebral fractures [51]. A dose of 100,000IU oral cholecalciferol is approximately equivalent to four months of 800 IU of daily cholecalciferol and led to mean 25(OH)D levels in the treatment group of approximately 30ng/ml, whereas the placebo group had average 25 (OH)D levels of 9.4ng/ml [51]. Because this dose was adequate to achieve sufficiency for only approximately half of the population, higher doses will be required to normalize vitamin D levels for high risk populations such as home health or nursing home patients. Empiric supplementation with a higher dose such as 50,000IU of ergocalciferol once or twice weekly for 12 weeks is likely needed [52-54]. After achieving vitamin D sufficiency with prescription vitamin D, maintenance doses of vitamin D (50,000-100,000IU of ergocalciferol once monthly, or 800-1000IU of cholecalciferol once daily) should be provided to maintain serum 25(OH)D levels at normal levels [55,56].

Non-pharmacologic fracture risk reduction

Approximately 90% of hip fractures are due to falls [57]. Several modifiable factors that may mitigate fall risk include a home safety assessment, alcohol cessation, evaluation of vision, review of medications (specifically psychoactive medications), and orthostatic blood pressure assessment. Studies of community dwellers have shown significant reduction of falls and fractures following exercise intervention, with the benefit increasing with escalating intensity of the exercise [58–64]. Studies that included even the frailest elderly had good participation, especially when the exercise consisted of resistance training [63,65]. The benefit of exercise does not seem to be as robust in nursing home residents when compared to community-dwelling persons [66–68].

Fall direction is an important predictor of hip fracture, [69] lending support to the use of hip protectors. Hip protectors have been found to significantly reduce the force to the hip during a fall [70]. Evidence from a meta-analysis showed a slight reduction in the risk of hip fracture among nursing home or residential care patients randomized to a hip protector (RR 0.77, 95% CI 0.62–0.97) but no significant benefit amongst community-dwellers (RR 1.16, 95% CI 0.85–1.59). Long-term adherence with hip protectors in both patient groups was poor, which may explain the differences [71]. These results should be interpreted cautiously given that individual studies used cluster randomization (i.e. nursing home ward), which may not have fully resolved potential imbalances between intervention, control patients and nursing home staff. A more recent trial that randomized individual nursing home residents to a one sided hip protector found no benefit of reducing hip fractures in the unprotected versus protected hip despite good adherence [72]. Also, hip protector brands vary in their force attenuating ability which may explain some variability in results from randomized trials. Despite these inconsistent results, hip protectors may be a reasonable option for high risk nursing home residents who are willing to wear them.

Pharmacologic Therapy

In 1994, the WHO published diagnostic criteria for osteoporosis based on BMD [73] and current guidelines recommend BMD evaluation of women over the age of 65 every two years [74]. As a result, traditional diagnostic criteria for osteoporosis rely heavily on the results of bone mineral density (BMD) testing. However, over 50% of fractures occur in the presence of only somewhat low BMD (i.e. osteopenia) [73]. As a result of the increased risk of recurrent fracture, it is recommended that persons with a prior fracture be started on medication for osteoporosis, in addition to calcium and vitamin D [18].

Bisphosphonates

Alendronate and risedronate were the first bisphosphonates approved for treatment and prevention of osteoporosis in postmenopausal women, with approval for the treatment of men coming more recently. Both can be taken either daily or weekly; risedronate can be taken monthly. There is increasing evidence that these medications are not only effective in the primary prevention of osteoporotic fractures, but in secondary prevention [75–77]. Alendronate and risedronate have been shown to have good cost-effectiveness for fracture reduction [78–81].

Ibandronate is approved for oral use daily or once-monthly, or intravenously every 3 months. Initial studies of these 3 formulations have shown significant improvement of BMD at the total hip, femoral neck, trochanter, and lumbar spine. Daily oral therapy has been shown to reduce the risk of vertebral fracture [82–85]. However, no effect on nonvertebral fractures was seen with this dose [82].

Zoledronic acid is the newest bisphosphonate available and adds a once yearly intravenous option. Initial studies showed significant reductions in spine, hip, and nonvertebral fractures [86]. It has also been shown to be effective in the prevention of subsequent fractures in persons with a recent hip fracture [9]. However, the mean age of these study participants was still 10 years younger than the average nursing home resident [87]. Table 2 illustrates the efficacy of the available bisphosphonates for secondary fracture prevention.

The main side effect reported with the use of oral bisphosphonates is gastrointestinal intolerance and patients are advised to stay upright for 30 minutes following the ingestion of these medications to reduce the risk of esophageal irritation [88–90]. Although tolerance of the oral bisphosphonates in clinical trials has been good overall [75,91,92], some patients report dyspepsia or gastroesophageal discomfort as the reason for discontinuation. Oral bisphosphonates have poor absorption unless taken according to the dosing instructions (on an empty stomach with only water and no further oral intake for at least 30 minutes). If oral bisphosphonates cannot be taken appropriately or tolerated, alternate therapies such as intravenous bisphosphonates should be considered.

Other possible side effects associated with both oral and intravenous bisphosphonates, (more common with the intravenous forms) are flu-like symptoms that typically resolve with subsequent doses and are partially mediated by pre-treatment acetaminophen [9,85,86]. Another finding with zoledronic acid was an increased incidence of serious atrial fibrillation events among postmenopausal women [86]. There was no increase in total atrial fibrillation events (serious and non-serious) and no mechanism for the arrhythmias has been found. A subsequent study showed that persons both recently started on and those continuing on bisphosphonate therapy had no significantly increased risk of developing atrial fibrillation when compared to non-users (RR 0.75, 95% CI 0.49 to 1.16 and 0.95, 95% CI 0.84 to 1.07, respectively). However, a recent case-control study reporting increased risk among alendronate users suggests the potential for possible class effect [93]. This finding has been reviewed by

the Federal Drug Administration and is thought not to be a concern [9,86]. Suspicion of delayed healing of new fractures in patients treated with bisphosphonates has been reported [94]. However, neither human nor animal studies have shown significant impairment in bone healing after substantial exposure to bisphosphonates prior to fracture [9,95–97].

Osteoporosis Management in Patients with Mild Chronic Kidney Disease

Patients with chronic kidney disease require thoughtful consideration when determining the diagnosis of and treatment for fractures and osteoporosis. In a study of osteoporotic women with varying degrees of renal insufficiency, no significant differences in side effects or renal outcome were seen between women with mild (Creatinine Clearance {CrCl} 50–79 ml/min), moderate (CrCl 30–49 ml/min), or severe (CrCl < 30 ml/min) renal impairment when treated with daily risedronate [98]. Zoledronic acid has been associated with a few cases of renal impairment when used in patients with multiple myeloma or bone metastases [99] but in osteoporosis studies, no significant renal detriment has been seen [9,86]. Based on this evidence, it appears safe to treat patients with mild renal impairment with FDA prescribed doses of bisphosphonates. Although half-dose bisphosphonates have been sometimes advocated for patients with modest renal impairment (CrCl 15–30 ml/min), product labeling does not recommend the use of bisphosphonates in persons with a calculated CrCl of less than 30–35mL/minute [88–90]. Due to the risk of adynamic bone disease and osteomalacia in persons with tage 5 CKD (e.g. dialysis dependent), bone biopsy is recommended before the initiation of bisphosphonates to rule out adynamic or osteomalacic bone [100].

Teriparatide (Forteo)

Teriparatide, recombinant human PTH 1–34, differs from other osteoporosis therapies since it is anabolic, not anti-resorptive as are the other agents. Intermittent PTH exposure results in an overall increased bone mass and differs from the bone loss seen with constant endogeneous PTH exposure, as in primary hyperparathyroidism. The use of teriparatide results in significant improvement of BMD and reduction of vertebral (RR 0.35, 95% CI 0.22–0.55) and non-vertebral fractures (RR 0.47, 95% CI 0.25 to 0.88) [101]. When compared to alendronate in a double-blind randomized trial, teriparatide resulted in both greater improvement in BMD and reduced non-vertebral fracture risk [102]. This fracture risk reduction appeared to persist even after the medication was discontinued [103].

Therapy with teriparatide is currently approved for 18–24 months. Current literature supports the initiation of an antiresorptive medication, such as a bisphosphonate, following cessation of teriparatide to help calcify the newly formed bone remodeling space [104]. Despite differing mechanisms of action between bisphosphonates and teriparatide, concurrent use of these medications may lessen the effectiveness of teriparatide [105,106]. There has been concern that the effect of teriparatide may be reduced when used subsequent to a bisphosphonate. In this setting, there may be a short delay of benefit, but an increase in bone density does occur [107,108].

Due to high cost and daily subcutaneous administration, teriparatide should be reserved for those at high risk of fracture such as those who repeatedly fracture on a bisphosphonate, or those for whom there are no other suitable treatment options [109,110]. Teriparatide should not be used in persons with Paget's disease, cancerous boney lesions or a history of radiation to the bone (due to increased risk of osteosarcoma), hypercalcemia, or metabolic bone diseases other than osteoporosis [109]. Occasionally, teriparatide can result in hypercalcemia, although this is usually mild and asymptomatic. If elevated calcium levels occur, resolution typically occurs when calcium supplement doses are decreased[110].

Other osteoporosis treatments

Other available osteoporosis treatments include selective estrogen receptor modulators (raloxifene) and calcitonin. Raloxifene has been found to reduce the risk of vertebral fractures (RR 0.7 95%Cl 0.5–0.8) in postmenopausal women with and without prevalent vertebral fractures [111]. Nasal calcitonin (200IU dose only) has also been shown to reduce the risk of recurrent vertebral fractures in postmenopausal women (RR 0.64, 95% Cl: 0.43–0.96) [112]. Although these options have some benefit in the reduction of vertebral fracture risk, no significant risk reduction at non-vertebral sites has been found [113,114].

Conclusion

A recent fracture is an ideal opportunity to confirm the diagnosis of osteoporosis amongst older persons. Figure 1 illustrates a treatment algorithm for the treatment of nursing home residents or those receiving home health care with a history of recent fracture. Due to very high risk for recurrent fracture, initiation of osteoporosis treatments and fall prevention strategies in this population are compelling, and continued efforts to improve the quality of care for older adults with osteoporosis are needed.

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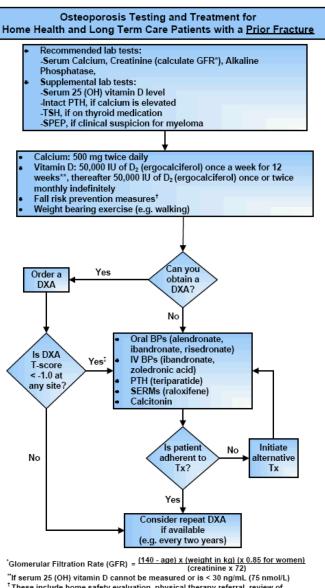
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¹ These include home safety evaluation, physical therapy referral, review of medications (specifically psychoactive medications), vision test, alcohol moderation, and orthostatic blood pressure assessment. ² Assuming no contraindications (e.g. GFR <30-35 mL/min for BPs, male sex for</p>

raloxifene) BP – bisphosphonate; DXA – dual energy X-ray absorptiometry; IU – international unit; IV – intravenous; PTH – parathyroid hormone; SERM – selective estrogen receptor modulator; SPEP – serum protein electrophoresis; TSH – thyroid-stimulating hormone; Tx – treatment

Figure 1.

Osteoporosis Management Recommendation for Home Health and Long Term Care Patients with Prior Fracture

	Cauca	isian F	Caucasian Female Caucasian Male	Cauc	asian]	Male
Age	65	65 75 85		65	75 85	85
Risk Factors						
None	26%	46%	26% 46% 51% 16% 24% 26%	16%	24%	26%
Corticosteroids	39%	61%	39% 61% 60% 24% 33%	24%	33%	32%
Currently smoking 27% 48% 50% 16% 24% 25%	27%	48%	50%	16%	24%	25%

Relative Risk of a future fracture with use of bisphosponates in a person with a prior fracture; RR (95%CI) [9,76,77, 82]

Bisphosphonate	Vertebral Fracture	Non-vertebral fracture	Hip fracture
Alendronate	0.55 (0.43-0.69)	0.77 (0.64–0.92)	0.47 (0.26-0.85)
Risedronate	0.61 (0.50-0.76)	0.80 (0.72-0.90)	0.74 (0.59–0.94)
Ibandronate*	0.62 (0.41–0.75)	not significant	not significant
Zoledronate	0.54 (0.32–0.92)	0.73 (0.55-0.98)	0.70 (0.41–1.19)

Results based on daily dosing