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Low Acceptance of Treatment in the Elderly for the Secondary Prevention of Osteoporotic Fracture in the Acute Rehabilitation Setting

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Abstract

Background & Aims—Given the high risk of subsequent fracture among elderly persons with fracture, it is important to initiate secondary treatment for osteoporosis. Acute rehabilitation centers may offer a unique opportunity to introduce treatment. Therefore, we evaluated willingness-to-participate and compliance with evidence-based interventions for the secondary prevention of osteoporotic fracture in a non-randomized study conducted in the acute rehabilitation setting. We also described differences in baseline characteristics between study participants and non-participants.

Methods—All consecutive, community-dwelling admissions to an acute rehabilitation unit (Boston, MA) with the diagnosis of fracture were screened for enrollment. Eligible subjects were offered a *free, 6-month supply* of alendronate/cholecalciferol (70mg/2800 IU weekly), calcium and vitamin D supplements, and fall prevention strategies. Six-month compliance ($\geq 75\%$ consumption of medication or supplement) with the interventions was determined at a home visit.

Results—Among 62 eligible subjects, 25 agreed to participate. Non-participants were older than participants (86 vs 80 years, $p < 0.01$). There was no significant difference between other characteristics of participants and non-participants including sex, weight, type of fracture, cognitive status, and functional status. The most common reason for non-participation was reluctance to take another medication. Among participants, only 52% were compliant with alendronate and 58% were compliant with calcium and vitamin D supplementation at 6-months.

Conclusions—Willingness-to-participate and compliance with secondary prevention strategies for osteoporosis was low in the acute rehabilitation setting, even when medications were provided free of cost. Educating individuals with fracture and their families on the consequences and treatment of osteoporosis may help to improve willingness-to-participate in this setting.

Keywords

secondary prevention; osteoporosis; fracture; rehabilitation

Introduction

Secondary prevention of osteoporotic fracture is defined as treatment of osteoporosis and fall prevention measures following a fragility fracture. In 2004, the United States Health Plan Data and Information Set (HEDIS) reported for the first time on poor adherence with evidence-based guidelines for secondary prevention of osteoporotic fracture in women.(1) Current U.S. guidelines recommend that all persons with a hip or vertebral fracture be treated for osteoporosis.(2) However, less than 50% of all women and 5% of men with a fragility fracture receive any treatment for osteoporosis, with even fewer elderly patients receiving bisphosphonate therapy.(3) As patients with osteoporotic fracture have a high likelihood of future fracture,(4,5) it is imperative that this problem be addressed.

Acute rehabilitation centers may offer a unique environment to initiate therapy for the secondary prevention of osteoporotic fracture. Currently in the U.S., almost 25% of persons with hip fracture are discharged to an acute rehabilitation center.(6) Patients typically spend several weeks in rehabilitation, allowing ample time for therapy to be monitored and recommendations to be reinforced. Given the close proximity of fracture and goals of rehabilitation, one might also anticipate a high degree of motivation to accept treatment offered in the rehabilitation setting.

To date, no information exists on the secondary prevention of osteoporotic fracture in the rehabilitation setting. Therefore, the purpose of this study was to evaluate willingness-to-participate and compliance with evidence-based interventions for the secondary prevention of osteoporotic fracture introduced in the acute rehabilitation setting. We also described differences in baseline characteristics between elderly patients who agreed to participate and those who refused, in order to better understand reasons for refusal among non-participants.

Methods

Study Design

Evidence-based pharmacologic and non-pharmacologic interventions for the secondary prevention of osteoporosis were offered in a non-randomized, feasibility trial. The study was approved by the Institutional Review Boards at Hebrew Rehabilitation Center and Beth Israel Deaconess Medical Center (Boston, MA).

Study Population

Subjects were identified from consecutive, community-dwelling admissions with the primary or secondary diagnosis of fracture between May 2007 and January 2008 from the Recuperative Service Unit, a 40-bed rehabilitation unit within Hebrew Rehabilitation Center. Potential subjects were identified by the unit administrative coordinator and pre-screened for eligibility by hospital discharge summary review. Eligibility criteria included age ≥ 65 years (or ≥ 50 years if on chronic corticosteroids). Exclusion criteria included: pathologic fracture, abnormalities limiting esophageal emptying, creatinine clearance < 30 mg/dL, serum calcium < 8.0 mg/dL, kidney stones within past year, life expectancy < 6 months, inability to cooperate or communicate in English, or concurrent therapy with bisphosphonates. Subjects with cognitive impairment were eligible provided a health care proxy was available and consented for the patient

Osteoporosis Intervention

The purpose and process of our study was discussed with all eligible patients, whom were offered both pharmacologic and non-pharmacologic interventions for the secondary prevention of osteoporosis. Interventions included a *free, 6-month supply* of an oral

bisphosphonate (alendronate 70mg/2800 IU cholecalciferol). Alendronate with cholecalciferol was chosen as it contains a potent oral bisphosphonate as well as 2800IU of vitamin D, making it easier to achieve targeted vitamin D intake. Calcium and additional vitamin D supplementation were offered *free* as 500mg calcium carbonate/200 IU cholecalciferol twice daily (total=1000mg calcium carbonate and 1200 IU cholecalciferol/day). Participants were also given information on dietary sources of calcium with a recommendation for total calcium intake $\geq 1200\text{mg/day}$.

Fall prevention measures were offered to all participants including optimization of visual acuity, a medication review, personalized strength and flexibility exercises, and a home hazards assessment for persons returning to the community. These interventions were selected as evidence suggests these strategies are effective in reducing falls among community dwellers.(7)

Visual screening was performed using a Snellen eye chart. Participants were notified of their visual acuity and those with poor vision (best corrected vision $< 20/50$) were advised to follow-up with an ophthalmologist after discharge. A medication review was completed by a board-certified geriatrician (SB, DM), with attention to newly added or ineffective psychotropic medications. If indicated, the patient, rehabilitation provider, and primary care physician were notified of the recommendation to decrease or discontinue medications. Individualized progressive resistive strengthening exercises were determined by staff physical therapists with recommendations to perform at least one set daily after discharge. Subjects with weight bearing fractures were also instructed to perform daily flexibility exercises. Finally, participants returning to the community received a home hazards assessment from a skilled nurse or occupational therapist.

In an effort to improve compliance, recommendations were discussed with participants and their next-of-kin. A letter was mailed to participants' primary care providers describing individual recommendations.

Baseline measurements

We collected baseline information for all eligible patients, regardless of participation, including sex, weight, type of fracture, cognitive status, and functional status. Weight was measured during rehabilitation to the nearest pound with light clothing. Type of fracture was obtained from the hospital discharge summary. Cognitive status and functional status were determined by the validated Functional Independence Measure,(8) which is routinely completed by staff physical therapists. Cognitive and functional items were scored between 1 (dependent) and 7 (independent). Comprehension, problem solving, memory, eating, bathing, and toileting items scoring <5 were defined as poor or dependent.

Willingness-to-participate

Patients who chose not to participate in our study were asked to report their primary reason. We grouped responses into the following categories: reluctant to take another medication, concerned about gastrointestinal side effects of the medication, felt recommendations were too burdensome, did not feel the recommendations would help given advanced age, did not believe he or she had osteoporosis, did not want to participate in a study, or "other" response.

Compliance

Among study participants, we determined compliance with the interventions during a home visit conducted 6-months after discharge from rehabilitation. Compliance with alendronate and calcium and vitamin D supplements were determined *separately* by a pill count.

Subjects were considered compliant if they took $\geq 75\%$ of the medication/supplement, or if they were taking an alternative calcium and vitamin D supplement ($\geq 1000\text{mg}$ calcium *and* ≥ 800 IU vitamin D/day). Compliance with exercises, recommendations to improve home safety, and ophthalmology follow-up were determined by self-report. Subjects were considered compliant if they performed any recommended exercises ≥ 5 days/week. If any medications were recommended for discontinuation, we determined whether the physician had followed the recommendation by comparing the recommendation with a current medication list. Participants who were not compliant with the interventions were asked to report their primary reasons separately.

During follow-up, one subject died and 5 subjects refused or were too ill to participate in a home visit. For these subjects, information on compliance was obtained by telephone interview with the participant or their next-of-kin.

Statistical analysis

We compared characteristics between participants and non-participants using a T-test or Wilcoxon rank sum for continuous variables, and a Chi-square test for categorical variables.

Results

115 patients (25 men, 90 women) with fracture were screened for enrollment. Fifty-three patients were ineligible. The most common reasons for ineligibility were the current use of bisphosphonates ($n=23$), renal failure ($n=12$), and non-English speaking ($n=10$).

Sixty-two patients (11 men, 51 women), mean age 84 years, were eligible for study participation. The most common fracture sites were hip ($n=32$), humerus ($n=15$) and vertebra ($n=10$). Among eligible subjects, 25 participated and 37 refused to participate. Table 1 shows the comparison between baseline characteristics of participants and non-participants. Non-participants were older than participants (86 vs 80 years, ranges 69–98 vs 54–95; $p<0.01$). Non-participants also weighed less than participants (142 vs 156 pounds, $p=0.17$), were more likely to be dependent in toileting (58% vs 32%, $p=0.06$), and were more likely to have poor comprehension (17% vs 4%, $p=0.23$), although these results were not statistically significant. There was no difference in site of fracture between participants and non-participants.

Among non-participants, (Table 2) the most common reason for not participating was due to reluctance to take another medication ($n=10$). Six patients felt the recommendations were too burdensome, and 5 patients were concerned about medication side effects. Four patients cited a belief that the medication would not help given their advanced age.

Among the 25 study participants, 52% were compliant with alendronate and 58% were compliant with calcium and vitamin D supplementation at 6-months (Table 3). Participants were most likely to comply with recommendations based on the home safety evaluation (100%) and least likely to comply with personalized exercises (21%). The most frequent reasons cited for non-compliance with individual recommendations are listed in Table 3.

Discussion

We found a low rate of participation among elderly patients in a study of the secondary prevention of osteoporotic fracture in the acute rehabilitation setting. Non-participants were more likely to be older. There were no other statistically significant differences between participants and non-participants including sex, weight, type of fracture, or cognitive and functional status. The most common reason for non-participation among elders screened was

reluctance to take another medication, in this instance, a once weekly oral bisphosphonate. Among patients who agreed to participate in our study, less than 60% were compliant with the bisphosphonate and calcium and vitamin D supplementation at 6-months.

Consistent with our results, previous studies have demonstrated that older adults are less likely to receive treatment for osteoporosis compared with younger adults. A retrospective cohort study found that among persons with a recent fracture, those older than 80 years were 60% less likely to receive medications for osteoporosis compared with men and women ages 65–79 years.(3) It is imperative to address this discrepancy as both previous fracture and older age are strong predictors for subsequent fracture,(5,9) and thus, elderly patients with fracture may be the most likely to benefit from treatment for osteoporosis.

There are many possible explanations for the low rates of participation we observed among older adults in a study of the secondary prevention of osteoporotic fracture. We found that the most common reason cited for non-participation was reluctance to take another medication. In designing our recommendations, we hoped to minimize this concern by choosing a once weekly formulation of a bisphosphonate that included vitamin D. However, surveys indicate that patients newly diagnosed with osteoporosis may be more willing to take yearly infusions of intravenous bisphosphonates compared with weekly oral formulations.(10) Similarly, a cross-over study of once weekly alendronate versus once monthly ibandronate, found a greater patient preference for the monthly formulation.(11) It is unclear whether the use of an intravenous bisphosphonate or a less frequently dosed oral bisphosphonate would have improved willingness-to-participate and compliance with osteoporosis treatment in our study, particularly among our older patients.

It is also possible that older adults may have been reluctant to participate given the limited existing data on secondary fracture prevention in this group. To date, one randomized controlled trial confirms a reduction in subsequent fractures among men and women with hip fracture who received yearly intravenous zoledronic acid (mean age 74.5 years).(12) A recent meta-analysis of alendronate and risedronate among post-menopausal women with a history of fracture, also found a 5–6% absolute risk reduction of vertebral fracture and a 2% reduction of non-vertebral fracture among women treated with a bisphosphonate.(13,14) However, few individual trials included sufficient numbers of women over the age of 80, and thus, it is less clear whether pharmacologic treatment is beneficial in this group.

In our study, four of the 38 non-participants cited a disbelief that they had osteoporosis as their primary reason for not participating, and 2 cited a disbelief that medications would help given their age. Thus, we believe that patient knowledge of osteoporosis and preferences for treatment may be important barriers in the acceptance of secondary prevention strategies for osteoporosis in the elderly. A survey of 127 elderly men and women with a low-trauma fracture supports this finding, as the authors found that only 17% of participants believed they had osteoporosis.(15) In a smaller study of 21 elderly women with recent hip fracture (mean age 81), only 38% of participants were aware they had osteoporosis or had ever considered pharmacologic therapy despite the fact that half of the women had a history of a prior fragility fracture.(16) It is important that both physicians and researchers strive to improve patient understanding of osteoporosis as poor knowledge of osteoporosis and a lack of understanding of the role of osteoporotic medications have been shown to be critical in a patient's willingness to initiate treatment for osteoporosis.(17)

We found that even among patients who were willing to participate in our study, a lack of understanding of osteoporosis and personal preferences seemed to be major factors in the low 6-month compliance that we observed. For example, 5 subjects reported that their primary reason for not taking alendronate was either because a family member advised

against it, they were too stressed, or they did not feel that it would make a difference. At least one participant cited their primary reason for non-compliance with calcium and vitamin D supplementation, follow-up with an eye doctor, and taper of medications as a lack of belief that these interventions would make a difference.

We found that among participants, 6-month compliance with specific home safety recommendations was excellent (100%). This likely reflects the fact that a home health agency guides these decisions, such that patients may take a passive roll in compliance with this one-time intervention. In contrast, compliance with personalized exercise plans, which require a high level of patient motivation and participation, was quite poor (21%). Low compliance with home exercise programs in the elderly has been previously described with lack of interest and poor health reported as major barriers.(18) Among our study participants, the most common reason cited for non-compliance with exercise was pain. It is important that physicians address pain in order to encourage mobility and exercise among elderly persons with recent fracture.

Cross-sectional studies of post-menopausal women have demonstrated that increased knowledge of osteoporosis is associated with greater utilization of health related behaviors including calcium and vitamin D supplement use and exercise. One small, randomized controlled trial suggests that education may influence acceptance of osteoporosis medications as well given a non-statistically greater prevalence of bisphosphonate use 6-months post-hip fracture among subjects receiving education on osteoporosis and treatment options.(19) Increasing patients' knowledge of osteoporosis among persons with recent fracture is an obvious area on which to focus; however, it may prove challenging given the high prevalence of dementia and delirium in this population.

The optimal time to introduce treatment for osteoporosis following fracture is unclear, especially among elderly patients with competing health concerns and polypharmacy. However, 41% of subsequent fractures in women and 52% in men occur within the first two years of a fragility fracture,(20) making timely treatment essential. While orthopedists may have the first and sometimes only opportunity to see elderly patients following fracture, the fear of medication side effects and limited time for follow-up have led most orthopedists to conclude that secondary prevention of fracture is the responsibility of primary care providers.(21) At the same time, morbidity from the fracture may prevent many older patients from visiting their primary care provider in a timely manner. Consequently, it would seem that the acute rehabilitation setting should provide an opportune time to introduce and reinforce secondary prevention strategies for osteoporosis.

Despite the modest participation rate that we observed in our study, we believe that future studies should consider the acute rehabilitation setting in trials of the secondary prevention of osteoporotic fracture. Although bone mineral density (BMD) testing is not required to make the diagnosis of osteoporosis in the presence of a low trauma fracture, willingness to participate may have been improved if bone mineral density (BMD) testing was part of the screening process. A Canadian study supports this hypothesis as it found that community-dwelling women who received BMD testing were more than 3 times as likely to fill a prescription for an osteoporosis medication independent of fracture status. (22) Similarly, a recent large U.S. study demonstrated that women who received BMD testing were 60% more likely to be highly adherent to a bisphosphonate ($\geq 80\%$ medication possession ratio) at one year.(23) However, it is possible that BMD testing might negatively impact willingness to participate among persons with osteopenia or normal BMD. It is important that these persons are not falsely reassured as fractures may occur among persons without osteoporosis as defined by BMD testing, and evidence-based clinical guidelines recommend initiating pharmacologic treatment for osteoporosis in persons with a history of a hip or

vertebral fracture regardless of BMD.(2) Nonetheless, we recommend that future trials of secondary prevention incorporate both BMD testing and osteoporosis education strategies in an effort to improve study participation.

Our study has several limitations. First, our sample size was small, with limited power to detect statistically significant differences between subjects. Second, while our results suggest that non-participants were more functionally and cognitively impaired compared with participants, we had no information on how specific co-morbidities and medication use might differ between subjects. Future studies should consider the impact of individual co-morbidities and number of medications on willingness to accept treatment for the secondary prevention of osteoporotic fracture. Third, because study recommendations were offered together, we were unable to determine which individual recommendations may have motivated a subject's decision not to participate. However, 41% of non-participants reported "reluctance to take another medication" or "concerned about gastrointestinal side effects" as their reason for not participating, which implies the bisphosphonate was the main intervention that limited willingness-to-participate. Finally, this study was conducted at a single rehabilitation center. Patient preferences for treatment are likely to differ based on socioeconomic, cultural and educational expectations, and thus, other facilities may have different findings. For this reason, it is important that future trials of secondary prevention of osteoporotic fracture be performed in a more diverse, multi-institutional setting. Despite these limitations, this study is important as it demonstrates some of the challenges in offering older adults treatment for osteoporosis following a fragility fracture in the acute rehabilitation setting.

Conclusions

Each health care setting faces difficulties in successfully implementing treatment for osteoporosis, but it is critical that clinicians continue to address this problem. In our study, willingness-to-participate and compliance with treatment for osteoporosis was low among elderly patients with fracture in the acute rehabilitation setting, even when medications were provided free of cost. Use of BMD testing and educating elderly persons with fracture and their families on the consequences and treatment for osteoporosis may help to improve acceptance of secondary treatment for osteoporosis in clinical trials and clinical practice.

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Table 1

Characteristics of participants and non-participants in a study of the secondary prevention of osteoporosis in the acute rehabilitation setting

	Participants (n=25)	Non- participants (n=37)	P- value
Mean age (years)	80 ± 10	86 ± 7	< 0.01
Sex (% female)	84	81	1.0
Weight (pounds)	156 ± 46	142 ± 32	0.17
Dependence in eating (%)	14	19	0.73
Dependence in bathing (%)	96	97	1.0
Dependence in toileting (%)	32	58	0.06
Poor comprehension (%)	4	17	0.23
Poor problem solving (%)	13	31	0.21
Poor memory (%)	17	31	0.36
Hip fracture (%) *	52	51	1.0
Humerus fracture (%) *	24	24	1.0
Vertebral fracture (%) *	12	19	0.73
Other fracture (%) *	16	14	1.0

* percentages add to greater than 100% as 4 patients had fractures at multiple sites

Table 2

Primary reason for non-participation in a study of the secondary prevention of osteoporosis in the acute rehabilitation setting (n=37)

Reason for non-participation	N
Reluctant to take another medication	10
Did not want to participate in a study	7
Felt recommendations were too burdensome	6
Concerned about gastrointestinal side effects of the medication	5
Did not feel the recommendations would help given advanced age	4
Did not believe he or she had osteoporosis	2
Other response	2
Unknown	1

Table 3

6-month compliance among study participants (n=25) with interventions introduced in the acute rehabilitation setting for the secondary prevention of osteoporosis

Recommendation	Number of subjects with recommendation	% Compliance with recommendation	Primary reason for non-compliance	N
Alendronate/cholecalciferol	25	52	Family member advised against medication	2
			Health care provider advised against medication	2
			Medication side effect (non-GI)	2
			Stress	2
			Medication side effect (GI)	1
			Did not feel it would make a difference	1
			Cognitive impairment	1
			Unknown	1
Calcium and vitamin D supplementation	25	58	Taking inadequate dose of another supplement	2
			Stress	2
			Did not feel it would make a difference	1
			Other *	3
			Unknown	2
Personalized exercises for strength and flexibility	25	21	Pain during exercise	7
			Prefers alternative exercise or walking	3
			Lack of interest	2
			Fear of falling	1
			Stress	1
			Cognitive impairment	1
Specific changes based on home safety evaluation	11	100	N/A	--
Taper or discontinue newly added/ ineffective psychotropic medication	9	44	Unaware medication was recommended for taper	2
			Did not feel it would make a difference	2
			Clinician decided against taper	1
Follow-up with ophthalmologist	6	60	Transportation too burdensome	1
			Did not feel it would make a difference	1

* 1 subject each with the following reasons: difficulty swallowing the pill, cognitive impairment, elevated serum calcium while on supplement