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Randomized Trial to Improve Fracture Prevention in Nursing Home Residents

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Abstract

BACKGROUND—Interventions to improve the fracture prevention in nursing homes are needed.

METHODS—Cluster-randomized, single-blind, controlled trial of a multi-modal quality improvement intervention. Nursing homes ($n = 67$) with ≥ 10 residents with a diagnosis of osteoporosis or recent hip fracture ($n = 606$) were randomized to receive an early or delayed intervention consisting of audit and feedback, educational modules, teleconferences, and academic detailing. Medical record abstraction and the Minimum Data Set were used to measure the prescription of osteoporosis therapies before and after the intervention period. Analysis was at the facility-level and Generalized Estimating Equation modeling was used to account for clustering.

RESULTS—No significant improvements were observed in any of the quality indicators. The use of osteoporosis pharmacotherapy or hip protectors improved by 8.0% in the intervention group and 0.6% in the control group, but the difference was not statistically significant ($P = .72$). Participation in the intervention activities was low, but completion of the educational module (odds ratio [OR] 4.8, 95% confidence interval [CI], 1.9–12.0) and direct physician contact by an academic detailer (OR 4.5, 95% CI, 1.1–18.2) were significantly associated with prescription of osteoporosis pharmacotherapy or hip protectors in multivariable models.

CONCLUSIONS—Audit-feedback and education interventions were ineffective in improving fracture prevention in the nursing home setting, although results may have been tempered by low participation in the intervention activities.

Keywords

Nursing homes; Osteoporosis; Quality improvement

Fracture prevention in nursing homes is important for several reasons. With the prevalence of low bone mineral density near 90%,^{1,2} and a high rate of falls,³ the nursing home population has one of the highest fracture rates at 13 fractures/100 person-years.^{1,4} In addition, 60%–75% of patients with an acute hip fracture spend time in nursing facilities.⁵ This group also has an

elevated risk of subsequent fractures.^{6,7} Clinical trials suggest that bisphosphonates are safe and effective in nursing home residents.⁸ Although few clinical practice guidelines specifically address the nursing home population, pharmacologic therapies are recommended for most hip fracture patients and selected long-term care residents at the highest risk.⁹

Despite the importance of fracture prevention in the nursing home, previous studies have demonstrated low rates of evaluation and treatment.^{10–13} We reported that only one third of ambulatory nursing home residents known to have osteoporosis or recent hip fracture receive any osteoporosis pharmacologic therapy or external hip protectors.¹⁴ Moreover, there is substantial variation in the performance of nursing homes (range of 0%–85% of residents receiving therapies), suggesting that substantial improvements are possible in many facilities.¹⁴

Changing provider behavior is, however, a challenging proposition. Studies in other settings have identified interventions that are sometimes effective,¹⁵ such as contact with opinion leaders, audit and feedback,¹⁶ faxed reminders,¹⁷ and educational materials to providers and patients.^{18,19} Little is known about which interventions are effective in the nursing home.

We developed a multi-modal intervention to improve fracture prevention in residents with documented osteoporosis or recent fracture.

METHODS

This analysis combines data from studies completed with the Quality Improvement Organizations in Arizona and North Carolina. The studies were approved by the Duke University and University of Alabama at Birmingham Institutional Review Boards. The Clinical Trial Registry number is NCT00280943 (<http://www.clinicaltrials.gov>).

Facility Selection and Randomization

The Minimum Data Set, a database of clinical and demographic information collected quarterly on all Medicare and Medicaid eligible residents, was used to identify nursing homes in North Carolina and Arizona, with at least 10 residents diagnosed with osteoporosis or a hip fracture within 180 days. Administrators from 67 of 249 eligible nursing homes agreed to enroll. The nursing homes were randomized within each state to receive the study intervention immediately (intervention group) or after the follow-up chart abstraction was completed (control group) using a random number generator.

Resident Selection

Residents aged 50 years or older with either a history of hip fracture or a diagnosis of osteoporosis during a 6-month time period were identified. Residents had to be ambulatory or transfer independently, and have a length of stay of at least 4 weeks. In order to obtain a sample of residents most likely to be candidates for the full range of fracture prevention therapies, we excluded residents with active cancer, severe dementia, end-stage renal disease, extensive assistance in physical functioning, hospice care, or estimated life expectancy ≤ 6 months. Although fracture prevention may be warranted in many of the excluded residents, including them in our sample would lead to lower rates of response to the intervention because some residents would be deemed unlikely to benefit from most of the therapies.

CLINICAL SIGNIFICANCE

- In nursing homes, many patients at high risk of fracture do not receive the fracture prevention therapies (bisphosphonates and hip protectors) indicated by clinical practice guidelines.
- In a study of 67 nursing homes, quality-improvement interventions (audit and feedback, educational modules, teleconferences, and academic detailing) only slightly (and nonsignificantly) improved adherence to anti-fracture practice guidelines.
- Systematic interventions that remove barriers to providing preventive care are needed.

Intervention

Nursing home staff in the intervention group received: continuing educational modules on osteoporosis evaluation and treatment; audit and feedback; academic detailing from osteoporosis opinion leaders; case-based teleconference on osteoporosis quality improvement; and an osteoporosis toolkit. Control nursing homes had no further contact until after the study was complete, at which time they received a similar intervention. The intervention period began January 3, 2005 and it ended May 13, 2005 in Arizona and July 1, 2005 in North Carolina.

Two case-based educational modules for medical staff and nursing staff were developed and pilot-tested based on recommendations from focus groups.²⁰ The modules could be completed over the Internet or on paper in less than 1 hour, and 1-hour CME/CEU (continuing medical education/continuing education unit) credit was provided. Recommendations in the modules were based on osteoporosis clinical practice guidelines⁹ and focused on secondary fracture prevention, including assessment for vitamin D deficiency; calcium and vitamin D supplementation; osteoporosis pharmacotherapy; hip protectors; and fall prevention. The director of nursing and all medical providers received at least 3 fax, e-mail, and telephone reminders to complete the modules.

Audit and feedback was provided on weeks 3, 8, and 18 to all administrators in the intervention group. The blinded report included graphics that compared their facility with other study facilities in the state (Figure). Because of privacy concerns, we did not supply the audit and feedback report to medical providers, but asked the administrator to do so.

Academic detailing to all medical providers was completed by osteoporosis opinion leaders. At least 3 attempts were made to reach each medical provider directly by telephone, and if unsuccessful, messages about the study were left.

Teleconferences were offered 4 times throughout the intervention period. Nursing staff and medical staff were invited to a case-based presentation on osteoporosis quality improvement via a faxed and mailed letter. One teleconference was audiotaped, and a compact disc sent to all medical providers.

Finally, a “toolkit” of materials was provided to each administrator. This included posters to hang in the facility and resident/family brochures. Fall prevention tools and links to osteoporosis clinical practice guidelines and patient information were provided on the module website.

Data Collection

Based on guideline recommendations, quality indicators for osteoporosis evaluation and fracture prevention were measured.⁹ The primary outcome variable was prescription of osteoporosis pharmacotherapy or hip protectors. We also measured a combined outcome

variable of prescription of osteoporosis pharmacotherapy or hip protectors or calcium and vitamin D supplements. We included measures with and without calcium and vitamin D supplements because many practice guidelines do not recommend them as mono-therapy for secondary fracture prevention, and because high baseline prescription rates might introduce a ceiling effect. Total daily dose of calcium and vitamin D were not assessed because they could come from multiple sources and were difficult to abstract reliably. Facility fracture rates were an exploratory outcome measure.

Trained data collectors, blinded to intervention status, abstracted data from the medical record before and after the intervention. Data collectors reviewed prescriptions in a 6-month time period beginning at the first time a fracture or osteoporosis diagnosis was recorded in the Minimum Data Set. The entire medical record was reviewed for selected comorbidities, bone mineral density, and laboratory testing. A random 10% of charts was re-abstracted by a second data collector, and inter-rater reliability was maintained at >90%.

Facility characteristics were obtained from public use datasets (<http://www.medicare.gov/NHCompare>). Some resident characteristics were obtained from the Minimum Data Set.

Analysis

Data were analyzed at the facility level. Nursing homes in Arizona and North Carolina were combined for the main analysis. The change in the proportion of residents receiving therapy between the pre- and postintervention periods was compared between the intervention and control nursing homes using *t* tests. All randomized facilities were analyzed regardless of their participation in the study. In order to adjust for characteristics that might impact prescription of osteoporosis therapies, multivariable logistic regression models with generalized estimating equation adjustment for repeated binary outcomes were constructed with backwards selection, using all variables with a baseline univariate $P < .20$ and variables with high clinical significance (age, race, state). The intervention time period by group interaction term was tested using chi-squared as a test of the impact of the intervention on prescription of therapies. This method accounted for the complex nesting of residents within providers and nursing facilities.

A prespecified exploratory analysis compared fracture rates in the intervention period between intervention and control facilities using *t* test. In order to examine the impact of participation in the intervention components, we constructed Generalized Estimating Equation models using backwards selection, with covariates significant at the $\leq .20$ level and the intervention participation variables.

Sample Size Considerations

Originally, we calculated that enrolling 128 nursing homes would provide 80% power to detect a 10% difference in the change in prescription of any fracture protection between the 2 arms. However, recruitment was challenging, and 67 nursing homes were ultimately enrolled. Post hoc, we determined that our sample size provided 80% power to detect a 17% difference, and 98% power to detect a 20% difference in the change in proportion of residents receiving any fracture protection in the intervention facilities compared with the control facilities.

RESULTS

Baseline characteristics of the 67 nursing homes and 606 residents are shown in Table 1. Intervention residents were more likely to be African American, younger, and use tobacco; and less likely to have previous fracture or dysphagia.

The use of fracture prevention strategies in the preintervention and postintervention periods is shown in Table 2. The primary endpoint of osteoporosis pharmacotherapy or hip protectors improved in intervention homes from 32.6% to 40.6% (difference 8.0%) and remained unchanged in control homes from 38.6% to 39.2%, (difference 0.6%), but the differences were not statistically significant ($P = .72$). The combined endpoint of osteoporosis pharmacotherapy or hip protectors, or calcium and vitamin D supplements showed a 7% improvement in both intervention and control homes, but baseline treatment rates exceeded 70%, suggesting a possible ceiling effect. Nonsignificant trends toward greater improvement in intervention versus control homes were seen for most other indicators. There were no significant differences in performance on the quality measures between the states.

Multivariable models testing the impact of the intervention on the primary and combined outcome measures were not statistically significant (odds ratio [OR] 1.0, 95% confidence interval [CI], 0.9–1.2, $P = .18$) even after adjusting for baseline factors that were imbalanced, including bed size, age, race, sex, previous fracture, insurance status, ambulatory status, gastrointestinal reflux, breast and endometrial cancer, dysphagia, and tobacco use. Incident fracture rates during the 6-month intervention period were similar between intervention (4.3%) and control facilities (4.1%), and were unchanged from the preintervention period. Fall rates were unchanged in the pre- and postintervention periods at 50%–51%.

Among the intervention facilities, participation in intervention activities was generally low except for audit feedback, which was provided to 100% of homes (Table 3). Intervention homes with at least 1 participant in the nursing educational module tended toward greater improvement in prescription of osteoporosis pharmacotherapy or hip protectors (19.5%) than either control homes (0.6%) or intervention homes without a nursing educational module participant (6.4%, $P = .36$). Participation in the medical provider educational module showed a similar pattern. In a multivariable Generalized Estimating Equation model including all covariates used above and participation variables, direct physician contact with the academic detailer (OR 4.5, 95% CI, 1.1–18.2, $P = .03$) and physician completion of the CME module (OR 4.8, 95% CI, 1.9–12.0, $P = .001$) were significantly associated with prescription of osteoporosis pharmacotherapy or hip protectors compared with control nursing homes and intervention homes without participation. No significant associations were observed when calcium and vitamin D supplements were added to the primary outcome measure, although treatment rates in the follow-up period exceeded 80% for all groups, again suggesting a ceiling effect.

DISCUSSION

We demonstrated a small, nonsignificant improvement in the prescription of fracture prevention therapies after the implementation of a quality improvement intervention. Although our study cohort had high fracture risk given their fall rate (35% fell within 90 days) and previous fracture history (20%), prescription of fracture prevention therapies other than calcium and vitamin D remained low. The magnitude of provider behavior change is consistent with that found in similar osteoporosis quality improvement studies in other settings,²¹ but is likely insufficient to have an impact on fracture rates.

This study has several strengths. The multi-modal intervention included multiple proven techniques. We targeted not only medical providers, but also the nursing staff and administrator, who have considerable influence on decision-making. The study was randomized, outcomes assessment blinded, and powered to detect a clinically meaningful difference. Regulations for documentation in nursing homes make it unlikely that medication therapies were not recorded in the medical record. We included only residents with clear indications for osteoporosis therapy and the fewest comorbidities that would limit the

applicability of clinical practice guidelines in the nursing home setting. Despite these strengths, there are several potential explanations for the lack of effect.

First, we had difficulty engaging nursing homes and providers in our study. Although previous research has shown that a large majority of Medical Directors and Directors of Nursing believe that fracture prevention is important and effective,²² we successfully recruited only about half of the number of facilities we had anticipated. Administrators most often cited staff turnover, regulatory survey demands, and competing clinical projects as reasons for not participating in the study. As a result, our final number of nursing homes allowed sufficient power to detect a 17% or greater improvement. After enrollment, few providers participated in the elements of our intervention despite repeated encouragement. The issues of engagement and timing have been shown to be important in behavior change interventions. It is clear that engagement was critical in this study, because those providers we successfully engaged were more likely to improve their osteoporosis management compared with those who did not participate. Providers who engaged in the intervention are likely to be more motivated, knowledgeable, and willing to change. This may partly explain the association between participation and improvement in our study. Previous studies have suggested that interventions work best when the timing of the intervention is soon after the triggering event;¹⁸ in our study, an intervention occurring sooner after a fracture may have been more effective in assisting providers to change their behavior. An important goal in future research is to either identify ways to engage a broader range of providers, or to use systems that do not require individual physician practice change to improve quality.

Second, there may be barriers to fracture prevention in the nursing home environment that were not sufficiently addressed by our intervention. In a survey of more than 1000 medical directors and directors of nursing, reimbursement issues, short length of stay, and regulatory oversight about the number of medications prescribed were endorsed as the primary barriers to adhering to osteoporosis practice guidelines.²² For example, a nursing home receiving a capitated reimbursement for the rehabilitation of a hip fracture patient has little incentive to add an expensive osteoporosis medication during their stay. Bone density scans are logistically difficult to obtain for frail residents, and Medicare reimburses for testing only every 2 years. These factors cannot be easily addressed by an intervention such as ours, and may require systems and health care policy change so that the goals of residents, administrators, and practitioners are better aligned.

Third, the osteoporosis guideline recommendations themselves may not be optimally suited for the frail nursing home population. Applying guideline recommendations to residents with competing comorbidities, surrogate decision-makers, and varying goals of care is challenging; for example, nearly 25% of our sample had peptic ulcer disease, esophagitis, or dysphagia that would preclude use of oral bisphosphonates (Table 1). Most fracture prevention studies included postmenopausal women, and generalization to frail older populations also is problematic, although previous surveys have shown that a large majority of nursing home medical directors believe that osteoporosis guidelines are relevant to their patients.²² Guidelines specific to the nursing home population that assist providers in determining residents most likely to benefit are needed.⁹

There have been relatively few published randomized trials of quality improvement initiatives in the nursing home to compare with our results. Effective interventions generally require on-site personnel or extensive provider involvement in intervention development.²³ Other studies have shown a limited effect of group training sessions such as Quality Improvement Collaboratives²⁴ and highlighted the lack of effective quality improvement infrastructure in nursing homes.²⁵ To circumvent some of these issues, systematic interventions that remove the responsibility for providing preventive care from individual practitioners are needed.

Examples of such interventions might include standing orders for osteoporosis care that are implemented routinely unless a provider or patient “opts out,” or automated telephone reminders or letters to patients and families on discharge from the hospital after a fracture.

Fracture prevention remains challenging in the nursing home setting. Further studies are needed to identify effective means of changing clinicians’ behavior and testing system-wide interventions that could prove more effective than traditional quality improvement approaches.

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Figure.

Sample audit and feedback report provided to facility administrators, comparing their use of osteoporosis therapies for high-risk residents compared with other study facilities in their state.

Table 1
 Characteristics of the Intervention and Control Nursing Homes and Target Residents during the Control Period

	Intervention	Control	P Value*
Facility characteristics	n = 34 homes	n = 33 homes	
For profit (%)	75.8	82.4	.22
Total number of residents (mean)	110.3	109.3	.62
Rural location (%)	18.8	18.5	.93
Resident characteristics	n = 293	n = 313	
Women (%)	85.0	87.2	.43
Race/ethnicity (%)			
Caucasian	81.9	80.8	.73
African American	5.5	2.2	.04
Other	12.6	16.9	.14
Age (mean)	83.0	85.6	<.001
Insurance status (%)			
Medicare	30.4	34.5	.28
Medicaid	17.0	13.1	.17
Private	8.5	8.3	.92
Other	79.9	75.7	.22
Previous fracture (%)	16.7	24.6	.02
Resident ambulatory (%)	55.6	62.0	.11
Falls in last 90 days (%)	33.8	37.4	.36
Cognitive impairment (%)	43.3	46.0	.51
Gastroesophageal reflux (%)	39.0	43.8	.23
Ulcer disease or esophagitis (%)	7.5	10.5	.19
Breast cancer (females only) (%)	2.7	4.5	.25
Dysphagia (%)	14.7	20.8	.05
Thromboembolic disease (%)	8.5	8.3	.92
Tobacco use (%)	24.6	16.6	.015
Alcohol abuse (%)	5.1	3.8	.44

Table 2

Proportion of Residents with Osteoporosis or Recent Hip Fracture Receiving Fracture Prevention Interventions Before and After the Intervention Period in the Intervention and Control Homes

	Before		After		Difference	
	Intervention (n = 33)	Control (n = 34)	Intervention (n = 33)	Control (n = 34)	Intervention (n = 33)	Control (n = 34)
Diagnostic testing modalities						
Bone mineral density measurement (%)	1.2	1.1	0.3	0.8	-0.9	-0.3
Serum calcium level	58.0	61.2	77.5	73.8	19.5	12.6
25(OH) vitamin D level (%)	0.3	0	1.1	0.5	0.5	0.8
Fracture prevention modalities						
Calcium (%)	72.5	66.0	82.8	74.5	10.3	8.4
Vitamin D (%)	68.7	57.1*	76.3	70.5	7.7	13.3
Bisphosphonate (%)	17.9	20.2	25.8	20.6	7.9	0.4
Calcitonin (%)	11.5	17.3	9.5	15.6	-1.9	-1.7
Raloxifene (%)	2.7	3.7	2.8	2.8	0	-0.9
Teriparatide (%)	0.3	0	0	0	-0.3	0
HRT in women (%)	2.3	3.8	3.6	2.4	1.3	-1.4
Testosterone in men (%)	0	0	0	0	0	0
Hip Protectors (%)	2.8	1.3	7.0	3.4	4.2	2.1
Osteoporosis pharmacotherapy or hip protectors (%)	32.6	38.6	40.6	39.2	8.0	0.6
Osteoporosis pharmacotherapy or hip protectors or calcium and vitamin D (%)	79.0	72.8	86.8	80.1	7.7	7.3

HRT = hormone replacement therapy.

* Indicates $P < .05$ for intervention vs control in the specified time period.

Change in Prescription of Osteoporosis Pharmacotherapy or Hip Protectors by Level of Nursing Homes' Participation in the Intervention Activities

Table 3

Activity	Group		Intervention Homes with No Engagement in Activity		Intervention Homes with Engagement in Activity	
	Control		Intervention Homes with No Engagement in Activity		Intervention Homes with Engagement in Activity	
	Number of Nursing Homes	Absolute Change Any Fracture Prevention (%)	Number of Nursing Homes	Absolute Change Any Fracture Prevention (%)	Number of Nursing Homes	Absolute Change Any Fracture Prevention (%)
Audit feedback	34	0.6	*	*	33	8.0
Homes with academic detailer speaking directly to at least 1 physician	34	0.6	21	9.0	12	6.3
CME module completed by at least 1:						
Nursing staff	34	0.6	29	6.4	4	19.5
Medical staff	34	0.6	26	6.4	7	13.4
Teleconference participation by at least 1 staff	34	0.6	21	8.5	12	7.1

No statistically significant differences in the 2 intervention subgroups compared with the control group.

* Because all intervention homes received audit and feedback, the cell is not applicable.