Use of a Case Manager to Improve Osteoporosis Treatment After Hip Fracture
Results of a Randomized Controlled Trial

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Background: Patients who survive hip fracture are at high risk of recurrent fractures, but rates of osteoporosis treatment 1 year after sustaining a fracture are less than 10% to 20%. We have developed an osteoporosis case manager intervention. The case manager educated patients, arranged bone mineral density tests, provided prescriptions, and communicated with primary care physicians. The intervention was compared with usual care in a randomized controlled trial.

Methods: We recruited from all hospitals that participate in the Capital Health system (Alberta, Canada), including patients 50 years or older who had sustained a hip fracture and excluding those who were receiving osteoporosis treatment or who lived in a long-term care facility. Primary outcome was bisphosphonate therapy 6 months after fracture; secondary outcomes included bone mineral density testing, appropriate care (bone mineral density testing and treatment if bone mass was low), and intervention costs.

Results: We screened 2219 patients and allocated 220, as follows: 110 to the intervention group and 110 to the control group. Median age was 74 years, 60% were women, and 37% reported having had previous fractures. Six months after hip fracture, 56 patients in the intervention group (51%) were receiving bisphosphonate therapy compared with 24 patients in the control group (22%) (adjusted odds ratio, 4.7; 95% confidence interval, 2.4-8.9; \( P < .001 \)). Bone mineral density tests were performed in 88 patients in the intervention group (80%) vs 32 patients in the control group (29%) \( (P < .001) \). Of the 120 patients who underwent bone mineral density testing, 25 (21%) had normal bone mass. Patients in the intervention group were more likely to receive appropriate care than were patients in the control group (67% vs 26%; \( P < .001 \)). The average intervention cost was $50.00 per patient.

Conclusion: For a modest cost, a case manager was able to substantially increase rates of osteoporosis treatment in a vulnerable elderly population at high risk of future fractures.

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OSTEOPOROSIS IS A COMMON and costly condition; more is spent each year on treating the complications of osteoporosis than on conditions such as myocardial infarction or asthma. The most serious complication of osteoporosis is hip fracture, a condition associated with substantial morbidity and mortality. Those who survive a hip fracture are at 2- to 3-fold increased risk of future fracture, including a 5% to 10% incidence of another hip fracture within 1 year of discharge from the hospital. Treatment with the bisphosphonates alendronate sodium and risedronate sodium hemi-pentahydrate can reduce the risk of future fractures by about 50%. Nevertheless, underdiagnosis and undertreatment of osteoporosis in patients with fragility fractures is a problem, and many audits report rates of testing and treatment for osteoporosis within 1 year of hip fracture are less than 10% to 20%.

Few controlled intervention studies have demonstrated valid improvements in the quality of osteoporosis care for patients with fractures, and, to our knowledge, there has been only 1 previous trial directed exclusively at patients with fractures of the hip. In that study, Gardner et al randomized 40 patients to education and counseling during hospitalization and 40 patients to usual care. On an intention-to-treat basis, their intervention was unable to increase rates of osteoporosis treatment: 10 of 40 patients in the intervention group (25%) received bisphosphonate therapy vs 6 of 40 patients in...
the control group (15%) (P = .26 for difference). This demonstrates that there is an important care gap in osteoporosis treatment after hip fracture and that it will be difficult to improve quality of care.

There are many barriers to improving quality of care for patients with hip fracture, including issues related to therapeutic nihilism on the part of patients and clinical inertia on the part of physicians, assignment of responsibility for initiating preventive measures (ie, orthopedic surgeon, hospitalist, or primary care physician), agreement about whether bone mineral density (BMD) testing is needed in these patients (vs empirical osteoporosis treatment) and concerns about whether bisphosphonate therapy might impair fracture healing in the early postoperative period and thereby worsen long-term outcomes. Therefore, based on literature reviews and qualitative in-depth interviews with health professionals, we designed an osteoporosis case manager intervention to overcome the barriers to best practice for patients with hip fracture. We compared this intervention with usual care in a randomized (allocation-concealed) controlled trial with blinded ascertainment of outcomes.

METHODS

SETTING AND SUBJECTS

This was a population-based study conducted at all 3 hospitals that manage hip fracture in Capital Health (Edmonton, Alberta, Canada). Capital Health is the largest integrated health delivery system in Canada, with a population of about 1 million persons with universal health care coverage and an annual budget of about $2 billion Canadian. All patients with hip fracture in the region are managed according to a standardized care map that addresses both preoperative and postoperative management including standardized rehabilitation procedures during the acute care hospitalization. The care map does not address osteoporosis or fall prevention. Previous studies have demonstrated that patients with hip fracture in this region are similar to patients elsewhere in Canada, the United States, and Europe. The study was approved by the University of Alberta Health Ethics Research Board.

All patients with hip fracture undergoing surgical fixation were potentially eligible for the study. We included community-dwelling patients 50 years or older who were able to provide (or have a proxy provide) informed consent and who did not have contraindications to bisphosphonate therapy. We excluded patients with delirium or dementia precluding informed consent, those already receiving prescription treatment for osteoporosis, those with pathologic fractures, and patients residing in nursing homes or other long-term care facilities but not patients in assisted-living arrangements or retirement communities. These institutionalized patients were excluded a priori because in previous studies, we documented that at least 84% would be unable to provide (or have a proxy provide) informed consent, because these patients tend to have restricted access (eg, often no personal telephone, inability to arrange transport for a BMD test, or unable to have their own prescriptions filled), and because their in-hospital rehabilitation and length of stay are markedly foreshortened compared with community-dwelling patients. Patients who met inclusion and exclusion criteria and provided informed consent were randomized (allocation-concealed) to either the case manager intervention or usual care.

OUTCOMES AND MEASURES

The primary study outcome was receipt of bisphosphonate therapy within 6 months of hip fracture. Secondary outcomes included BMD testing and a composite outcome we designated guideline-concordant appropriate care. Specifically, this was defined as a BMD test performed and osteoporosis treatment provided to those with low bone mass. This was done to better capture overall quality of care by acknowledging that a substantial minority of patients with hip fracture do not have low bone mass and should not be given antiresorptive agents. We defined low bone mass according to the guidelines available at the time of study design. Specifically, Canadian guidelines recommended pharmacologic osteoporosis therapy in patients with a fragility fracture after age 50 years or menopause and a BMD T score of −1.5 or worse. (The T score compares bone density with that of healthy young people.) Other outcomes included recurrent fractures, admissions to hospital, and death. At baseline, we measured the comorbidities that are included in the Charlson Index and cognitive status. To ensure that there were no adverse consequences (eg, impaired healing or fixation leading to pain or limited ambulation) or unintended harm (eg, distress related to receiving a new medical diagnosis requir-
ing treatment) related to the intervention, we collected information on changes in self-reported pain and ambulation and generic health-related quality of life. In a random sample of 15 patients in the intervention group, we performed detailed time-motion studies and directly measured all intervention-related activities. We expressed all costs in constant 2006 US and Canadian dollars. All outcomes were collected in an independent and blinded fashion, without knowledge of allocation status; investigators and analysts (all of the authors) were masked to allocation, without knowledge of allocation status; investigators and analysts (all of the authors) were masked to allocation status at all times.

SAMPLE SIZE AND ANALYSIS

In previous studies, we used surveys to determine that the minimal important difference that providers would consider worthwhile would be a 20% absolute improvement in osteoporosis treatment at 6 months. With the patient as the unit of analysis and causal inference, and with \( \alpha = 0.05, \beta = 0.90, \) a 20% absolute intervention effect, and usual care treatment rates of 10%, we calculated that we would need a total sample size of 184 patients. To allow for losses to follow-up and death, as well as the ability to explore secondary outcomes in some detail, we increased the total sample size to 220 patients.

All analyses were according to the intention-to-treat principle. For patients lost to follow-up because they withdrew from the study or died (n=14), Figure 1, we used baseline values carried forward. The primary outcome (percentage of patients who received bisphosphonate therapy at 6 months) was analyzed with the \( \chi^2 \) test. Multivariate logistic regression analyses were used to adjust for clinically important (10% difference) or statistically significant (\( P < .10 \)) imbalances in baseline patient characteristics and to adjust for study hospital. Primary data are presented as simple percentages and as odds ratios adjusted for age, female sex, previous fracture, weight less than 57 kg, and study hospital.

We screened 2219 patients with hip fracture and excluded 1999. The most common reasons for exclusion were residence in a long-term care facility (696 patients [35%]), study refusal (380 [19%]), and already receiving osteoporosis treatment (365 [18%]). Two hundred twenty patients were randomized; after allocation, 6 patients in the intervention group and 8 patients in the control group were lost to follow-up (they died, withdrew, or withdrew and died); all 220 patients were analyzed for primary outcomes (Figure 1).

Median age of the 220 study patients was 74 years, 60% were women, 96% were white, and 37% reported 4 comorbidities or more before sustaining the hip fracture. In terms of risk factors for osteoporosis-related fractures, 37% reported a previous fracture, 27% reported a previous BMD test, 20% reported a previous fall with injury, and about 50% weighed less than 57 kg. Table 1 gives baseline patient characteristics stratified by allocation status. In general, patients in the intervention and control groups were comparable, although those in the control group were more likely to be women (72% vs 57%) and to report having had a previous fracture (42% vs 33%).

OSTEOPOROSIS TREATMENT

In terms of the primary study outcome, patients in the intervention group were more likely than those in the control group to be treated for osteoporosis with bisphosphonate therapy 6 months after hip fracture.
(Figure 2). Specifically, 56 patients in the intervention group (51%) vs 24 in the control group (22%) were treated with a bisphosphonate 6 months after fracture (P < .001 for difference; adjusted odds ratio, 4.7; 95% confidence interval, 2.4-8.9). All treated patients received either alendronate or risedronate.

BMD TESTING

Patients in the intervention group were more likely than those in the control group to undergo BMD testing within 6 months of hip fracture (88 [80%] vs 32 [29%]; P < .001; Figure 2). The adjusted odds ratio for the effect of the intervention on BMD testing was 11.6 (95% confidence interval, 3.8-32.5). Of the 120 patients who underwent BMD testing, 25 (21%) did not have low bone mass at either hip or spine. Of the 95 patients with low bone mass, 41 (43%) had a T score at hip or spine between −1.5 and −2.5 and 54 (57%) had a T score of −2.5 or worse.

APPROPRIATE CARE

More patients in the intervention group compared with the control group achieved the composite outcome of guideline-concordant appropriate care within 6 months of fracture (74 [67%] vs 26 [26%]; P < .001; adjusted odds ratio, 6.6; 95% confidence interval, 3.5-12.6). Of the 36 patients in the intervention group who did not receive appropriate care, 21 (58%) did not undergo BMD testing despite the case manager’s best efforts. Reasons for not having a BMD test included death (n = 3), loss to follow-up (n = 6), self-reported ill health (n = 6), or refusal (n = 6). In another 15 patients in this group (42%), BMD test results indicated low bone mass, but no treatment was given. Reasons for not taking osteoporosis medications included a T score of −1.5 at the spine only (n = 2), the patient wanted the primary care physician to manage the osteoporosis (n = 4), or treatment was refused (n = 9).

OTHER OUTCOMES

Within 6 months of hip fracture, 4 patients had already sustained another fracture. However, there were no significant between-group differences in terms of repeat fractures or admission to hospital, death, hip pain, independent ambulation, or health-related quality of life (Table 2). In terms of the formal costing study we undertook in a random sample of patients in the intervention group, the case manager spent a median of 70 minutes per patient. This time was essentially divided among 4 activities including patient education, arranging for and interpreting BMD tests, providing prescriptions and medication counseling, and communicating with the primary care physician. We used the midexperience hourly pay scale on our local salary grid for a registered nurse ($29.00 [Can$32.00] per hour plus 15% benefits), with an additional 30% overhead charge typical for Capital Health. Thus, the case manager intervention cost $50.00 (Can$56.00) per patient.

Table 2. Secondary Outcomes and Other Measures 6 Months After Hip Fracture According to Allocation Status

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention Group (n = 110)</th>
<th>Control Group (n = 119)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional fractures</td>
<td>2 (2)</td>
<td>2 (2)</td>
<td>&gt;.50</td>
</tr>
<tr>
<td>Admission to hospital</td>
<td>15 (15)</td>
<td>11 (12)</td>
<td>&gt;.50</td>
</tr>
<tr>
<td>Death</td>
<td>3 (3)</td>
<td>2 (2)</td>
<td>&gt;.50</td>
</tr>
<tr>
<td><strong>Generic health status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical component, mean (SD)</td>
<td>46.4 (10.1)</td>
<td>45.4 (9.7)</td>
<td>.47</td>
</tr>
<tr>
<td>Mental component, mean (SD)</td>
<td>49.2 (11.0)</td>
<td>50.0 (10.3)</td>
<td>&gt;.50</td>
</tr>
<tr>
<td><strong>Disease-specific health status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent ambulation</td>
<td>37 (40)</td>
<td>44 (48)</td>
<td>.30</td>
</tr>
<tr>
<td>No hip pain</td>
<td>76 (78)</td>
<td>70 (75)</td>
<td>&gt;.50</td>
</tr>
</tbody>
</table>

Values are given as number of patients (percentage) unless otherwise indicated.

In a publicly funded system in which patients have universal health care coverage, we found that having an osteoporosis case manager could lead to substantial improvements in the quality of osteoporosis care after hip fracture. Compared with usual care, our intervention led to a 29% absolute increase in osteoporosis treatment, a 51% increase in BMD testing, and an overall 41% increase in the delivery of appropriate care. For every 2 patients with hip fracture exposed to our intervention, 1 additional patient received appropriate osteoporosis care, at a modest cost of $50.00 (Can$56.00) per patient. Inasmuch as measuring BMD and treating osteoporosis with bisphosphonate therapy do not directly improve quality of life, perhaps it is not unexpected that there were no differences between patients in the intervention and control groups in other patient-centered outcomes. At the least, we are confident that there were no measurable harms or unintended consequences of
being exposed to the case manager intervention soon after hip fracture.

The improvements in quality of care we report do, however, mask the fact that even with our intervention, further improvements could be made. Only 51% of patients in the intervention group were receiving bisphosphonate therapy 6 months after hip fracture, acknowledging that another 21% had normal bone mass and would not be considered eligible for treatment by current evidentiary standards.2,3,6,7,11 Using a composite appropriateness index that considers this, 67% of patients received appropriate care. Our results indicate that even in the population with hip fracture, BMD testing is important in terms of risk stratification and evidence-based pharmacotherapy.

Our study did have limitations. First, our outcomes are process-of-care measures, and some might argue that what is needed is a trial sufficiently powered to detect reductions in the risk of fractures. However, the efficacy of bisphosphonate therapy has been demonstrated in large randomized trials involving thousands of patients;11,12,30-32 the intent of our intervention was to improve quality of care by accelerating the adoption of evidence-based therapies and not to repeat observations related to efficacy. When processes of care are tightly linked to important outcomes, it is usually the case that improvements in these processes are a more sensitive measure of improved quality than observable clinical outcomes.25,30

Second, there may be concern about the quality of usual care in our health region, in which only 22% of patients with hip fracture received osteoporosis treatment and 26% received appropriate care. This represents higher standards of usual care than practice audits elsewhere in Canada, the United States, and Europe, where rates of testing and treatment are reported to be less than 10% to 20% in the year after hip fracture.17,21 Because of the education and attention our control group received as part of being in our trial and because our control patients were relatively healthier than most survivors of hip fracture, our control group received better quality osteoporosis care than reported in most other settings. This also means that our estimate of effect likely underestimates the benefits of our intervention if adopted in other settings.

Third, policy makers and payers might be concerned that our intervention is too laborious (approximately 70 minutes per patient) and too expensive (approximately $50 [Can$56] per patient) to apply outside the trial setting. While a formal health-economic analysis is beyond the scope of this article, 2 facts stand out. The cost of this intervention is only about one-fifth of the cost of 1 year of bisphosphonate therapy in Alberta, Canada, and however laborious our intervention may seem, one-third of elderly patients who received the intervention still did not receive appropriate care.

Fourth, there might be concern related to the wider applicability of our results. Although we excluded 90% of potentially eligible patients, we believe this should not necessarily be a concern because most of the exclusions were related to issues of enrollment in a randomized trial and providing truly informed consent. Concerns about applicability may be most justified with respect to the use of a hospital-based case manager intervention in patients institutionalized in long-term care facilities. These patients accounted for one-third of all hip fractures in our region and were excluded from our study. Future work should determine whether our intervention might be effective in this population or if other approaches should be considered (eg, standing orders for initiating treatment during hospitalization using less validated peripheral measures of BMD for screening or even empirical treatment without BMD testing).

In conclusion, a pragmatic and inexpensive case manager intervention can substantially improve quality of osteoporosis care for community-dwelling elderly patients who survive a fracture of the hip.

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Author Contributions: Dr Majumdar had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Drs Majumdar and Morrish contributed equally to this work. Study concept and design: Majumdar, Harley, Hanley, Juby, Maksymowych, Cinats, Bell, and Morrish. Acquisition of data: Majumdar, Beaufre, Lier, and Morrish. Analysis and interpretation of data: Majumdar, Beaufre, Lier, Maksymowych, and Morrish. Drafting of the manuscript: Majumdar. Critical revision of the manuscript for important intellectual content: Majumdar, Beaufre, Harley, Hanley, Lier, Juby, Maksymowych, Cinats, Bell, and Morrish. Statistical analysis: Majumdar, Beaufre, and Lier. Obtained funding: Majumdar and Morrish. Administrative, technical, and material support: Majumdar, Beaufre, Cinats, and Bell. Study supervision: Majumdar and Morrish.

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Additional Contributions: Holly Wong-Mah, BSc (OT), Lori Schaump, and Pat Goodwill, DPT, assisted with data collection and entry.
REFERENCES


