To Treat or Not To Treat, That Is the Question: Proceedings of the Quebec Symposium for the Treatment of Osteoporosis in Long-Term Care Institutions, Saint-Hyacinthe, Quebec, November 5, 2004

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Objectives: Patients in long-term care institutions (LTCI) are especially at risk for osteoporotic fractures owing to their lack of mobility, poor nutrition, and limited sun exposure. Previous reports have shown that osteoporosis is underdiagnosed and undertreated in LTCI despite the high incidence of osteoporotic fractures in these settings. This document has been developed to assist clinicians practicing in LTCI with the diagnosis and treatment of osteoporosis in their institutionalized patients. These proceedings offer an overview of the particular characteristics of patients at LTCI. Management strategies include both nonpharmacological and pharmacological interventions for the prevention and treatment of osteoporotic fractures in very frail older subjects.

Participants: This guide is an edited review of presentations and discussions held by specialists in osteoporosis in the elderly together with physicians and pharmacists practicing in LTCI in the province of Quebec. This symposium was held in Saint-Hyacinthe, Quebec on November 5, 2004.

Values: The value of a given diagnostic test or treatment option was determined based on the clinical experiences and opinions of the participants and a review of the literature from an evidence-based perspective.

Recommendations: All patients located at LTCI are at potential risk for osteoporotic fractures. Global interventions should include vitamin D, calcium, and a comprehensive exercise program. In patients who are at high risk for osteoporotic fractures or with previous fractures, pharmacological treatment should be started.

Validation: These recommendations were approved during the final plenary of the symposium. All the prevailing opinions were summarized and included in this article. (J Am Med Dir Assoc 2007; 8: E.67–E.73)

Keywords: Long-term care; osteoporosis; bisphosphonates; vitamin D; calcium; fractures

Long-term care institutions (LTCI) have become an important resource for the continuity of care in geriatric medicine with a highly regulated system of care for individuals with severe physical and mental disabilities that make them unable to cope with their life in the community. These institutions offer a set of care measures that improve their patients’ quality of life and provide relief to caregivers and families.

Among the major “geriatric syndromes,” osteoporosis and osteoporotic fractures have become an important health problem in LTCI. Despite the underuse of diagnostic procedures, it is known that the incidence of osteoporotic fractures in LTCI is higher than in the community with a significant impact on quality of care and, most importantly, on patient quality of life and mortality.

Due to this underdiagnosis and undertreatment of osteoporosis in LTCI, a symposium with health professionals representing LTCI from across the province of Quebec (Canada) was organized in an attempt to pinpoint the reasons for these
misdiagnoses as well as to define, jointly with recognized experts in the field of osteoporosis, the most relevant strategies for improving the quality of care related to the treatment and prevention of osteoporotic fractures in this particular population. The symposium was held in Saint-Hyacinthe on November 5, 2005, with a total of 45 participants and 6 experts. All participants received a discussion document 4 weeks before the symposium. The symposium consisted of 2 plenary sessions (D.P.K., L.M.) followed by small group sessions focused on specific discussion topics: vitamin D, bisphosphonates, other pharmacological treatments, and nonpharmacological approaches. These small groups were chaired by experts in their respective subjects (R.K., L.-G.S.-M., G.D., S.G., respectively). The relevant literature concerning each subject was reviewed and discussed. Finally, the conclusions from each group were presented at the plenary for agreement and discussion purposes.

This is a final report of the conclusions from the symposium. An introductory review for each of the subjects will be followed by a set of recommendations based on the participants’ experiences and the literature available. The organizers expect that this innovative experience will be the starting point for future initiatives designed to pursue better care for our institutionalized elderly patients.

OSTEOPOROSIS IN LONG-TERM CARE INSTITUTIONS

Identifying the Problem

Although there are no reports of the incidence of osteoporosis and osteoporotic fractures in LTCI in Quebec, other studies have demonstrated that prevalence rates of osteoporosis, as defined by World Health Organization criteria, have been reported in up to 80% to 85% of our target population. However, not all bone mineral density (BMD) decrements are necessarily due uniquely to long-term nursing home stays, but to diseases, dysfunction, and disability that ultimately lead to admission. Chandler et al. studied a prospective cohort of white female nursing home residents (n = 1427) over 18 months. A total of 223 osteoporotic fractures occurred among 180 women, with low BMD and transfer dependence being the most significant independent risk factors for fractures. In addition, among residents dependent in transfer, those with a BMD below the median had a 3-fold increase in fracture risk when compared with other residents dependent in transfer. This and other studies demonstrate that institutionalized patients have not only a poor baseline BMD at admission but also that dependence in transfer is a major risk factor for fractures in this population.

This high incidence of osteoporotic fractures has had a major impact on the finances of LTCI. As demonstrated by Zimmerman et al. with nursing home residents in Maryland, in the month following the fracture, those who experienced fractures were hospitalized more than 15 times as often as those who did not. This significant burden on the health system also has an important impact on medical expenditures and health budgets representing 28.2% of total expenditures for the treatment of osteoporotic fractures in the American population. A similar situation happens within the Canadian Health System.

How To Carry Out the Diagnosis

The validation of BMD is the most useful diagnostic method of osteoporosis since it usually identifies osteoporotic patients as well as their risk of fracture. However, much evidence is available to support the notion that treatment can be initiated in patients with fragility fractures without necessarily performing a bone density assessment. This concept is extremely useful in long-term care settings where mobilizing a patient to perform a bone densitometry represents a significant burden for institutions and patients. Moreover, the performance of a BMD did not modify physicians’ treatment of osteoporosis. In a recent publication by Gupta and Aronow only 49% of 136 postmenopausal women in a nursing home population had BMD measurements. Of these 66 women, 31 (47%) had osteoporosis, 21 (32%) had osteopenia, and 14 (21%) had normal BMD. Most importantly, only 55% of patients with documented osteoporosis were being treated, which illustrates the underuse of both diagnostic and therapeutic approaches for osteoporotic patients in nursing homes.

An important question may be: Is there any alternative approach for the assessment of bone density and/or risk of fractures in institutionalized patients? In a study by Elliott et al. in 49 institutionalized women aged 68 to 100 years bilateral calcaneal BMD was measured as well as vitamin D levels. This study showed that osteoporosis was highly prevalent (39%) and poorly documented in the nursing home. Additionally, it is considered that ultrasound, despite its known limitations, may be a useful tool to the diagnosis and, in some cases, the follow-up of osteoporotic patients in nursing homes because of its usefulness for screening purposes with sensitivities and specificities of 70% to 85%.

In summary, the diagnosis of osteoporosis in LTCI mostly should be based on a combination of patient risk factors, clinical findings (kyphosis, clinical fractures), radiological findings, and height reduction. Most importantly, clinicians should be aware of the high incidence of this problem in LTCI and that underdiagnosis may have severe consequences in our institutionalized patients.

THE TREATMENT OF OSTEOPOROSIS IN LONG-TERM CARE PATIENTS: HOW AND WHEN TO TREAT

Defining Who Should Be Treated

The recent clinical practice guidelines for the diagnosis and management of osteoporosis in Canada did not include a specific section for the treatment of osteoporosis in this particular population. By contrast, a national panel of nursing home experts in the United States developed a set of specific care processes associated with better outcomes for general medical conditions including osteoporosis. The participants in our symposium agreed that their suggested care processes for osteoporotic patients fulfilled the same criteria for Quebec
Compliance has shown earlier effectiveness in fracture prevention. Factors are shown in Table 1. Falls risk factors are simultaneously pursued. A list of those risk factors is shown in Table 1. Mean life expectancy in Quebec institutions. Finally, it was remarked that despite these clear recommendations and quality markers, only 55% of women with osteoporosis in LTCI are receiving calcium and only 42% are receiving vitamin D.18 may be the most simple and harmless method of intervention for osteoporosis in LTCI. When looking at the use of pharmacological treatments the picture is even worse. The question that arises from this consideration is: Are LTCI undertreating patients who have osteoporosis? Several reports agree that this is the case14,19 and that some physicians working at LTCI undertreat their patients based on a set of assumptions that are not supported by the available evidence. Some of these assumptions are largely based on the length of treatment versus patient life expectancy and/or prognosis, compliance, tolerability, pharmacoeconomics and finally prevention of polypharmacy. The arguments against this assumption were well explained by the panel of experts as well as the participants and will be mentioned later in this document.

### Length of Treatment Versus Patient Life Expectancy and/or Prognosis

Although the mean survival time of institutionalized patients varies from site to site, because of the complexity of the concurrent diseases, quality of care, and mean age, in Canadian LTCI the average length of stay is about 2.5 years.20 Bone is a very active tissue that responds to the initialization of treatment in a very steadfast manner. Several major clinical trials of osteoporosis treatments have demonstrated that bone mineral density could be regained after 6 months of treatment and that fracture rates start decreasing after the first year in most cases.21 Furthermore, some studies using bisphosphonates have shown earlier effectiveness in fracture prevention.22 This justifies initiating treatment (both preventative and therapeutic) for osteoporosis in patients within the range of mean life expectancy in Quebec institutions. Finally, it was also stated that treatment for osteoporosis in elderly will only be effective if concomitant assessments and interventions of falls risk factors are simultaneously pursued. A list of those risk factors is shown in Table 1.

### Compliance

Compliance is known to be an important problem in ambulatory elderly patients receiving treatment for osteoporosis. Patients abandon their treatment because of several reasons including tolerance, costs, and misinformation in the media. This would not be a problem in patients at LTCI were the administration of their medications closely supervised by the nursing and, in some cases, pharmacy staff. Also the availability of once weekly and once monthly medications eases the burden on nurses administering medications. No measurements of compliance of osteoporotic treatments in these specific settings have been reported.

### Tolerability

In general, the tolerability of osteoporosis treatments is good. To avoid calcium intolerance, an initial dose of 500 mg of elemental calcium per day may be used for 1 to 2 weeks followed by the usually recommended dose. The appropriate administration of vitamin D does not have reported tolerability problems.25 Bisphosphonates are generally well tolerated; but erosive esophagitis, at times severe, can develop, particularly if dispensation directions are not adhered to. Patients with esophageal strictures, achalasia, or untreated symptomatic acid reflux should avoid bisphosphonates.14

### Pharmacoeconomics

A complete discussion of this issue was undertaken during our symposium and was also illustrated by L.M.’s lecture. It is clear that preventing and treating osteoporosis in LTCI represents an economic burden to their already limited budgets, but it is also true that vertebral, or more significantly, hip fractures represent an enormous burden for institutions owing to multiple factors such as analgesic treatments, functional deterioration, and use of nursing staff without considering that fractures are indicators of bad quality of management.17

### Polypharmacy

The conceptual definition of “polypharmacy” has changed from a simple count (> 4 medications) to the concept of “appropriate use of medications” based on their indications and benefits. As in the case of cardiac disease (where the use of lipid-lowering medications and beta blockers is increasing in older people because of the proven benefits of their use in preventing myocardial infarctions), in the case of osteoporosis the benefits of preventing a fracture in patients with indications for treatment surpass the considerations of polypharmacy.

To provide a basis for discussion during the symposium, the literature available was reviewed and an evidence-based approach was proposed for each one of the treatment choices. The recommendations are summarized in the tables that follow each section. Evidence was classified as follows: 1: properly designed double-blind placebo-controlled trial; 2: random controlled trials that contain design flaws preventing specification of class 1; 3: multicenter or population-based longitudinal (cohort) study; and 4: expert opinion. If possible, evidence was determined looking at studies performed in LTCI.

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<thead>
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<td>Muscle weakness</td>
<td>Environmental</td>
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<td>Gait/balance impairment</td>
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Table 1. Risk Factors for Falls in Long-Term Care Institutions23

**Intrinsic risk factors**
- Cognitive impairment
- Visual impairment
- Muscle weakness
- Neurologic impairment
- Gait/balance impairment

**Extrinsic risk factors**
- Medications
- Environmental

LTCI and therefore those criteria were also widely accepted by the participants to be applied to our population.

It was also remarked that despite these clear recommendations and quality markers, only 55% of women with osteoporosis in LTCI are receiving calcium and only 42% are receiving vitamin D,18 may be the most simple and harmless method of intervention for osteoporosis in LTCI. When looking at the use of pharmacological treatments the picture is even worse.

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THERAPEUTIC GUIDE PROPOSAL FOR THE PREVENTION AND TREATMENT OF OSTEOPOROTIC FRACTURES IN LTCI IN QUEBEC: CONCLUSIONS AND RECOMMENDATIONS FROM THE SYMPOSIUM

General Guidelines (Evidence Level 4)

- Comorbidities and life expectancy should be considered before starting treatment.
- ALL patients admitted in LTCI should be assessed for BOTH falls and non–fall-related risk of fractures.
- Bedridden residents unable to mobilize are excluded.
- The resident's opinion and/or that of the responsible party for health care decisions must be always considered (advantages and disadvantages).
- All patients should be assessed for the presence of fall risk factors. Subsequently, interventions targeting identified risk factors should be implemented.

Screening (Evidence Level 2)

- Although screening for BMD in all residents 65 years and older has been recommended, logistical considerations must be always taken into account. If possible, all patients with risk factors must be assessed for osteoporosis (Table 2).

Laboratory Tests (Evidence Level 3)

- The evidence shows that biochemical bone markers are not useful in general settings other than research centers.
- A secondary cause of osteoporosis should be eliminated with the following tests: serum calcium, albumin, serum phosphorus, alkaline phosphatase, thyroid-stimulating hormone, creatinine, and protein electrophoresis.
- Further investigation such as serum levels of vitamin D, parathyroid hormone, and active forms of vitamin D are not recommended and are left only to very severe cases or patients unresponsive to the usual treatment.

Indications for Starting Treatment (Evidence Level 4)

- Patients with risk factors for osteoporosis even though BMD is unknown because of logistical problems.
- Osteoporosis detected by densitometry.
- Previous history of osteoporotic fractures.
- Patients with new fractures (vertebral and nonvertebral).

Treatment

- Nonpharmacological interventions (Table 3): Several studies have demonstrated that nonpharmacological interventions are effective for reducing the number of fractures in elderly patients (evidence level 2). Cost-effectiveness analyses of the use of hip protectors in the prevention of hip fractures in nursing homes have shown that hip protectors could save money while preventing hip fractures and improving quality of life in nursing home residents with some limitations in compliance (evidence level 2). Uncertainty still exists as to the best hip protector, and even if hip protectors are effective in this population.
- Nutritional supplementation (Table 4): There is a major need to increase the use of calcium and vitamin D supplementation among the institutionalized elderly to decrease the risk of osteoporotic fractures, including hip fractures (evidence level 1). Although recent evidence has shown that vitamin D may be ineffective for the prevention of falls and fractures in the elderly population, those studies were performed either in ambulatory-

Table 2. Pharmacological Treatment of Osteoporosis in Long-Term Care Institutions

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<th>Consider:</th>
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<tr>
<td>● Mental and nutritional status</td>
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<tr>
<td>● Risk of falls and fractures</td>
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<tr>
<td>● Mobility</td>
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<tr>
<td>● Previous treatments for osteoporosis</td>
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<tr>
<td>● Other medical conditions and medications</td>
</tr>
<tr>
<td>● Patient's opinion (if competent)</td>
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</tbody>
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When to treat?

Bisphosphonates19,33–35 (Evidence 1)

- Patient at high risk of fractures
  ○ Risk factors
  ○ Previous fractures
  ○ Low BMD (≤2.5 SD) (if available)

SERMs

- Second choice if intolerance to bisphosphonates (Evidence 4)
- Female residents (Evidence 4)
- Calcitonin36
- Analgesic treatment of symptomatic vertebral fractures (Evidence 2)
- PTH39
- Not tested in long-term care institutions
- Approved only for postmenopausal ambulatory women with osteoporosis

Table 3. Nonpharmacologic Intervention in Individuals With Low Bone Density24–26

| ● Smoking cessation |
| ● Cutting down on alcohol consumption |
| ● Regular weight-bearing and strengthening exercises |
| ● Drinking coffee with milk |
| ● Avoiding medications known to decrease bone mass |
| ● Ensuring a well-balenced diet |
| ● Fall assessment and implementing interventions to decrease risk of falling |
| ● Recommending hip protectors for individuals willing to wear them |

Table 4. Treatment of Osteoporosis: Vitamin Supplements18,21,27,28

| Calcium |
| 1500 mg/d for all long-term care institution residents |
| Vitamin D₃ |
| 800 UI/d for all long-term care institution residents |
dwellings elderly patients\textsuperscript{29,30} (evidence level 2) or used a subtherapeutic dose of vitamin D\textsuperscript{31} (evidence level 2).

In some reports, food intake and sun exposure have been considered adequate to provide patients with good levels of vitamin D. In a recent study, Vecino et al\textsuperscript{32} analyzed vitamin D levels in an ambulatory elderly population in Quebec. They found that despite food supplementation with vitamin D and supposedly appropriate sun exposure there is still a prevalence of 16% vitamin D insufficiency in the ambulatory population. Although vitamin D levels in LTCI in Quebec have not been assessed, it is assumed that because of the characteristics of this population a more dramatic situation could be found. In fact, vitamin D administration at the usual dose (800 IU/d) has some additional effects other than fracture reduction such as fall prevention and increase in muscle mass\textsuperscript{21,28} (evidence level 1). In addition, to improve compliance or decrease nursing time, higher preparations of vitamin D may be used anywhere from 10,000 IU a week up to 300,000 IU every 3 months without affecting its safety or increasing the probability of side effects (evidence level 4).

- Bisphosphonates: Alendronate, risedronate, and most recently, ibandronate have been approved for prevention and treatment of postmenopausal osteoporosis. Despite enough evidence demonstrating the effectiveness of bisphosphonates in the prevention of fractures, Jachna et al\textsuperscript{33} have recently found differing patterns of antiresorptive pharmacotherapy in nursing facility residents and community dwellers. They found that residents in LTCI are less likely to receive bisphosphonates and more likely to receive calcitonin, which is known to have a weak effect in fracture reduction.

Several randomized control trials (RCT) were reviewed for this document. Indeed, only one RCT was found using either alendronate (10 mg orally per day) or placebo in elderly women with osteoporosis residing in LTCI.\textsuperscript{34} Although the study demonstrates that alendronate increased BMD in both spine and femoral neck with good tolerance, the incidence of fractures although lower in the alendronate group did not reach statistical significance owing to the limited number of patients and short follow-up.

Additionally, several major trials reporting variable effects according to subgroups by age were found. Among them, the Fracture Intervention Trial (FIT),\textsuperscript{35} which did not analyze an elderly population, showed that after 3 years of therapy the rate of new vertebral fractures was reduced in 47% of the alendronate group compared with the placebo group. Similarly, a 51% reduction in hip fractures was seen. The more recent Hip Intervention Trial (HIP)\textsuperscript{35} in older populations showed a higher BMD in the treated group after 6 months and a reduction in the incidence of fractures of 41% in the treated group. Although studies comparing the benefits of different bisphosphonates have shown contradictory results the clinician should consider the period of time required to obtain not only a gain in BMD but also an effective reduction in the number of fractures (evidence 1). Although their tolerance has improved after the development of a once-weekly dose, there are still some limitations in compliance. Pamidronate infusion or newer bisphosphonates by injection may be a solution in the future.

- Calcitonin: Although calcitonin has the advantage of easy administration and tolerability, it is now widely known that its efficacy is much lower than other therapeutic choices because it has shown no significant effect on the incidence of nonvertebral fractures, which are by and large the most important events to be prevented in LTCI (evidence 2). Currently, the only recommended use of calcitonin is the relief of pain associated with osteoporotic fractures.\textsuperscript{36}

- Estrogen: Although results from the Women’s Health Initiative\textsuperscript{37} showed a significant protective effect of estrogen against hip fractures, this report also showed that the overall risks from estrogen use exceeded the benefits. Considering the mean age of our target population, and the negative risk/benefit analysis, we do not consider estrogens appropriate for the treatment of osteoporosis in LTCI.

- Selective Estrogen Receptor Modulators: A recent study by Hansdottir et al\textsuperscript{38} assessing the effect of raloxifene on markers of bone turnover in older women living in LTCI showed that while raloxifene reduces bone turnover, no effect on fracture incidence was assessed. In addition to this evidence, the safety of raloxifene in older populations remains unknown.

- Anabolic treatment: The only approved, but not widely implemented, anabolic compound is teriparatide. Its use has been approved only for the management of individuals at particularly high risk for fractures, including subjects who are younger than age 65 and who have particularly low bone mineral density measurements.\textsuperscript{39} Although the use of anabolic treatments for senile osteoporosis seems to be a step in the right direction, no studies using PTH in older populations have been pursued and no reports of ongoing studies are available. In addition, PTH is a costly treatment, which has several compliance limitations because of its way of administration (subcutaneously).

**CONCLUSION**

This initiative included not only the literature available on this subject but also the valuable experience of experts from 5 different recognized institutions in 2 countries. In addition, the experience of the participants in the “real life” environment played a pivotal role in producing a set of recommendations for the treatment of osteoporosis in these difficult settings. The authors expect that this will be a changing point in the way osteoporosis interventions are approached in LTCI with a subsequent benefit in patient quality of life and even life expectancy since hip fractures are a significant cause of mortality. Finally, a more significant amount of clinical research is required not only for the treatment of osteoporosis in institutionalized elderly patients but in general for the assessment and treatment of senile osteoporosis as a geriatric syndrome.
ACKNOWLEDGMENTS

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