Introduction

• Bisphosphonates have shown proven efficacy in randomized clinical trials for increasing bone mineral density (BMD) and reducing risk of osteoporosis-related (fracture) fractures.1,2
• Poor adherence with osteoporosis treatment regimen is a well-recognized problem, and the risk of having osteoporosis-related fractures increases among patients with poor adherence.3-6
• However, fractures may be recorded even in patients who are adherent to osteoporosis treatment.7,8

Objective

• To examine the rate of osteoporosis-related fractures over 2 years of treatment among women adherent to osteoporosis (OP) therapy for at least 1 year.

Methods

Study design

• A retrospective cohort study was conducted using Med IQ Data Mart, a large U.S. claims database from January 1, 2000 to December 31, 2010 (study window).
• The date of first prescription of an oral bisphosphonate (BIS) during the study window was the index date.
• There were three consecutive, one-year time periods during which OP-related fracture rates were determined (Figure 1): 1. Baseline period prior to the index date, 2. Adherence period during which adherence with osteoporosis treatment was calculated (Year 1 after index date), 3. Study period (Year 2 after index date).
• OR-related fractures included non-traumatic fractures occurred at the hip, vertebrae, and non-vertebral sites.9,10
• Adherence with treatment was defined as having a medication possession ratio (MPR) of 0.6 or above.
• MPR was defined as the total number of days’ supply of all BIS treatment received (alendronate, ibandronate, and risedronate) in the compliance period, divided by 245 days.
• Disease diagnoses and comorbidities were identified based on ICD-9 codes, medications were identified based on NDC codes.

Figure 1. Study time period

Study sample

• Included osteoporotic women 50 years or older whose first osteoporosis treatment was prescribed with medication possession ratio (MPR) of 0.6 or above from 2001-2010 and continuously enrolled for three consecutive years i.e., one year before the index date and two years after the index date.
• Women who were on treatment had a diagnosis of malignant neoplasm or Paget’s disease (Figure 2).
• Oral bisphosphonate treatment included alendronate, ibandronate, or risedronate.

Data analysis

• The main analysis was conducted among patients who met the selection criteria and who were adherent (MPR ≥ 0.6) in the adherence period (Figure 2). A sensitivity analysis using adherence defined as MPR ≥ 0.8 was also conducted.
• The primary outcome was the frequency of OP-related fractures during the baseline, adherence, and study periods.

Results

Patient characteristics in the Baseline period

Table 1. Patient characteristics in the Baseline period

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Adherent patients (MPR ≥ 0.6), N (%)</th>
<th>Adherent patients (MPR ≥ 0.8), N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at index date (mean, std)</td>
<td>60.7 ± 8.5</td>
<td>60.7 ± 8.5</td>
</tr>
<tr>
<td>Charlson comorbidity index (mean, std)</td>
<td>0.37 ± 0.62</td>
<td>0.37 ± 0.62</td>
</tr>
</tbody>
</table>

Osteoporosis-related fractures during the study period by history of fractures or by adherence in the study period

Table 3. Fracture rates in the Study period by fracture history or adherence in the study period

<table>
<thead>
<tr>
<th>Fracture history</th>
<th>Adherent patients (MPR ≥ 0.6), N (%)</th>
<th>Adherent patients (MPR ≥ 0.8), N (%)</th>
</tr>
</thead>
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<tr>
<td>Fractures</td>
<td>Baseline</td>
<td>Adherent</td>
</tr>
<tr>
<td>Hip fractures</td>
<td>3,157 (4.2%)</td>
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<td>Knee fractures</td>
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Conclusions

• Osteoporosis being adherent to bisphosphonate treatment for one year, 3.3% of women 50 years and over experienced a fracture in the subsequent year.
• Results indicate an urgent need related to level of osteoporosis control and an opportunity for newer therapies to help address this need.

Reference:

1. MacLean C, Newberry S, et al. A retrospective cohort study was conducted using i3 calculated 8.5 15, 2 1,389 %. Osteoarthritis Desai SS, Duncan BS, Sloan AS. The Cost of Treating Osteoporosis in a Managed Health Care Organization. J Care Pharm. 2003 Mar 10,948 %.

Figure 2. Sample selection

Patients whose first OP treatment is a bisphosphonate (BIS), the initiation of the first BIS is defined as the index date.

Table 4. Fracture rates in the study period by adherence in the study period

<table>
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*Numbers are presented in (%) unless otherwise indicated.

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