# Differences in Adherence to Osteoporosis Regimens: A 2-Year Analysis of a Population Treated Under Specific Guidelines

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#### **ABSTRACT**

Background: Patients' adherence to antiosteoporotic drug therapy is essential to prevent fracture and complications of osteoporosis over the long term. The guidance given in treating osteoporosis can potentially enhance adherence.

**Objective:** This study was conducted to compare adherence to osteoporosis regimens by patients treated under specific guidelines in a medical center.

Methods: This study used a database pertaining to the use of antiosteoporotic medication, including alendronate, raloxifene, and calcitonin, between 2001 and 2007. We selected patients who were being treated following the therapeutic recommendations of the National Osteoporosis Foundation or the guideline for glucocorticoid-induced osteoporosis recommended by the American College of Rheumatology. Adherence was determined by compliance and the persistence ratio (PR). Compliance was estimated by using the medication possession rate, and PR was determined by the percentage of patients with no medication refill gap for a period of ≥30 days.

Results: A total of 2975 patients met the inclusion criteria. The patients were grouped according to treatment regimen: alendronate, n=1745; raloxifene, n=711; and calcitonin, n=519. The good compliance rate (GCR; medication possession rate  $\geq 80\%$ ) for alendronate, raloxifene, and calcitonin was 61.9%, 54.6%, and 36.4% at year 1 (P < 0.001), respectively. The GCR of alendronate was significantly higher than that for either raloxifene (P = 0.001) or calcitonin (P < 0.001). The

GCR of the alendronate, raloxifene, and calcitonin groups at year 3 was 47.9%, 43.7%, and 36.4% of the included patients (P < 0.001). The PR of the alendronate, raloxifene, and calcitonin groups at year 1 was 57.1%, 50.2%, and 32.9% (P < 0.001) and 41.8%, 40.1%, and 23.5% (P < 0.001) at year 2.

Conclusions: Alendronate had a better adherence profile than raloxifene and calcitonin at the end of year 1 and a better adherence profile than calcitonin at the end of year 2. (*Clin Ther.* 2013;35:1005–1015) © 2013 Elsevier HS Journals, Inc. All rights reserved.

Key words: adherence, guideline, osteoporosis, Taiwan.

#### INTRODUCTION

Osteoporosis predominantly affects female subjects, especially postmenopausal women, but it also affects all races and both sexes. This condition is responsible for an increased risk of bone fracture, long-term pain, deformity, and reduced quality of life. Many antiosteoporotic agents such as alendronate, raloxifene,

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and calcitonin can prevent bone loss and increase bone mineral density (BMD). In clinical trials, these agents have been shown to reduce the incidence of vertebral fractures by 33% to 50%, 1-3 and drug adherence was generally high. However, the drug utilization pattern observed in randomized controlled trials is not reflective of adherence in real-world practice.4 Previously published studies of adherence by patients prescribed these agents used a large administrative claim database.<sup>5,6</sup> The rates of osteoporotic drug adherence reported in these studies varied but were generally suboptimal. The efficacy of osteoporosis medications when used to prevent osteoporosis and reduce fracture risk relies on sufficient drug adherence in patients. A comparison of adherence among different antiosteoporotic agents across published studies is difficult due to differences in study methodologies, enrollment criteria, adherence definitions, monosequential/sequential therapy, and study length. Although it has been reported that drug adherence did not differ among antiosteoporotic regimens in a large national managed care administrative claims database,8 we hypothesized that there is a difference in drug adherence among osteoporosis regimens in real-world settings. The goal of the current study was to explore the risk factors associated with poor drug adherence in patients who had been prescribed an antiosteoporotic agent.

## MATERIALS AND METHODS Participants

This was a retrospective medical chart review study. The charts of all consecutive adult (aged > 18 years) patients who had been diagnosed with osteoporosis or had been dispensed osteoporosis regimens between January 1, 2001, and July 31, 2007, in Chang-Gung Memorial Hospital, Kaohsiung Medical Center were retrieved. We searched the computerized database in the medical center for the following diagnostic codes (International Classification of Diseases, Ninth Revision, Clinical Modification): 733.0 (osteoporosis), 733.01 (senile osteoporosis), 733.02 (idiopathic osteoporosis), 733.03 (disuse osteoporosis), 733.00 (osteoporosis, unspecified), 733.09 (osteoporosis, others), 781.91 (loss of height), V17.81 (family history of osteoporosis), V82.81 (specific screening for osteoporosis), V07.4 (hormone replacement therapy, postmenopausal status), 8054 (spine fracture), and 82100 (hip fracture). Targeted osteoporosis regimens included

calcitonin 200 IU,\* alendronate 10-mg tablets,<sup>†</sup> alendronate 70-mg tablets,<sup>‡</sup> and raloxifene 60-mg tablets.<sup>§</sup> Alendronate 10 mg and alendronate 70 mg were regarded as 1 regimen in our study.

#### Inclusion and Exclusion Criteria

Because several studies investigating drug adherence have enrolled postmenopausal women 9-11 or targeted the diagnosis/regimen codes, 12,13 they might possibly miss prescriptions for glucocorticoid-induced osteoporosis (GIOP) and thereby bias the results of real-world studies. Hence, in the current investigation, only those medical records of patients during the period of interest and that fulfilled the following criteria were reviewed. The criteria included the following: (1) patients dispensed predefined regimens under the National Osteoporosis Foundation (NOF) treatment recommendations (2008)<sup>14</sup> or the American College of Rheumatology guidelines for GIOP (2001)<sup>15</sup>; (2) the first prescription of the predefined osteoporosis regimen during the study period was documented in the patient's chart; and (3) the first prescribed regimen was not switched to any other labeled osteoporosis regimen, not including calcium and vitamin D, available in Taiwan within 2 years after the index prescription. The exclusion criteria included the following: (1) the patient did not fulfill the inclusion criteria; (2) the patient had received an osteoporosis regimen 6 months before the beginning of the study period; (3) the patient's chart was destroyed or not traceable; (4) the patient had Paget's disease or a malignant neoplasm and had received chemotherapy or radiation therapy at any time during the period of interest; and (5) the patient died during the follow-up period.

#### **Data Collection**

The demographic and clinical characteristics of the study patients in each treatment group were examined. These characteristics included age, sex, selected comorbid conditions, baseline dual energy X-ray absorptiometry, BMD, evidence of previous fracture,

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<sup>\*</sup>Trademark: Miacalcics® nasal spray (Novartis Pharmaceuticals Corporation, East Hanover, NewJersey; code, PMF022E)
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Trademark: Fosamax<sup>®</sup> 10 mg (Merck Sharp & Dohme Cor Whitehouse Station, New Jersey; code, PMF050M).

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