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Original Article

National Healthcare Budget Impact Analysis of the Treatment for Osteoporosis and Fractures in Korea

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Background: This study was to determine the impact on the national healthcare expenditure for the treatment of osteoporosis and fractures if the coverage period for osteoporosis medication was extended from maximum a year to continuous period as required. **Methods:** Preserving the current reimbursement guidelines, maximum one year's coverage for osteoporosis medication was set as scenario A. Continuous coverage for patients who require medication was set as scenario B. As costs of medical service utilization are paid by the Korean National Health Insurance Program, all items were investigated and analyzed from the payer's perspective. The combined treatment costs for osteoporosis and osteoporotic fractures were assessed for each scenario. **Results:** Over five years the cost of osteoporosis medication in scenario A will increase from 184.3 billion KRW to 204.6 billion KRW. The cost of osteoporotic fracture treatment will increase from 1,037.3 billion KRW to 1,822.7 billion KRW. In scenario B, the cost of osteoporosis medication will increase from 209.5 billion KRW to 388.1 KRW. The cost of osteoporotic fracture treatment will increase from 600.0 billion KRW to 1,054.3 billion KRW. The result showed savings of 2.50 trillion KRW cumulatively for five years when reimbursement coverage for osteoporosis treatments is extended from one year to as long as it's clinically required. **Conclusions:** This study demonstrates that effective osteoporosis management through appropriate insurance coverage for osteoporosis medication should be considered not only for the patient's viewpoint, but in terms of national insurance budget as well.

Key Words: Economics, Fractures bone, Health expenditures, Osteoporosis, Republic of Korea

INTRODUCTION

Osteoporosis is a chronic disease leading to low bone mass and increased bone fragility with increased risk of bone fractures. It is more than three times common in postmenopausal women than in men and the risk of osteoporotic fractures increases with age. The average lifetime risk in a 50-year-old Korean of an osteoporotic fracture is 59.5% for women and 23.8% for men.[1] Among those aged 50 years or older, the incidence of vertebral fracture was highest (969 per 100,000 persons), followed by distal radius (422), hip (157), and humerus (81) in 2008.[1]

Hip fractures are associated with considerable morbidity and mortality and re-

duced quality of life. As hip fractures generally require hospitalization, surgery, and subsequent rehabilitation, the treatment costs for hip fractures are hig h, and osteoporosis induced costs to the health care system are substantial. [2-5]

In Korea, total costs of these diseases were estimated to be 796 billion KRW for the year 2010, and roughly 321 billion KRW in 2005. Moreover those figures captured just the expenditure from the Korean National Health Insurance (NHI) Program, so the total disease-related cost in the society would be much higher.[6]

To increase universal coverage of healthcare service especially for patients with osteoporosis and osteoporotic fracture, Ministry of Health and Welfare (MOHW) extended the reimbursement period for osteoporosis treatment from six months to one year in October 2011.[7] According to new reimbursement guideline, when patients' bone mineral density (BMD) tested with dual energy X-ray absorptiometry (DXA) is lower than -2.5, their pharmacological interventions will be covered. In the past a patient whose BMD score was lower than -3.0 got reimbursement for their drug cost.[7]

Although MOHW extended reimbursement period and T-score range in osteoporosis treatment, there is still unmet need from the viewpoint of osteoporosis patients. Based on current reimbursement guidelines for osteoporosis in 2012, limitation of one year's reimbursement coverage for osteoporosis medication causes inappropriate management in osteoporosis. Therefore, patients who need continuous administration of osteoporosis medication could not comply with clinical treatment guideline. This inappropriate discontinuation of osteoporosis medication results in increases of fracture patients and increased fracture patients will be a huge burden to both patients and society.

Hence, we made a hypothesis that the cost of osteoporosis treatment would be increased, but the cost of fractures treatment would be decreased. We performed a simulation study for extending reimbursement period of osteoporosis medication from a year to as long as it's clinically required.

The purpose of this study was to determine the national healthcare budget impact with different reimbursement period on osteoporosis medicines in Korea.

METHODS

The Korean NHI Program as a single payer covers 96% and the remaining 4% is covered by a separate program, Medical Aid. Thus, all information about the volume and burden of a disease can be obtained from a centralized database, with the exception of procedures not covered by insurance, such as cosmetic surgery or traffic accidents (which are covered by automobile insurance).

1. Scenarios

The cost involved in both osteoporosis and osteoporotic fractures should be considered in order to estimate burden of disease. Therefore, we developed two scenarios; scenario A showed expenditure for the treatment of osteoporosis and fracture under the current reimbursement guideline in 2012, MOHW notification 2011-116. Scenario B showed expenditure for the treatment of osteoporosis and fracture with an extended period of coverage for osteoporosis medication. We estimated total budget impact of osteoporosis treatment and osteoporotic fractures over five years, from January 2013 to December 2017 (Table 1).

2. Patients

The number of osteoporosis patients who were receiving reimbursements from the NHI program was calculated as the sum of 'osteoporosis without pathological fracture (International Classification of Disease [ICD]: M81)' and 'osteoporosis with pathological fracture (ICD: M80)' from the disease statistic data between 2008 and 2010 from the Korean NHI Service.[8]

The osteoporotic fracture was defined the patients who had been treated with fracture in femur, vertebrae, humerus and wrist.[1] Fracture patients were categorized by using the four characters of the disease code in the previous study

Table 1. The assumption of national healthcare expenditure for osteoporosis by scenario

National healthcare expenditure of osteoporosis	Cost of osteoporosis medication + Cost of osteoporotic fracture treatment
Scenario A	Cost of osteoporosis medication (reimbursement for max. 1 yr) + Cost of osteoporotic fracture treatment
Scenario B	Cost of osteoporosis medication (as long as needed) + Cost of osteoporotic fracture treatment

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Table 2. The identified osteoporotic fractures by International Classification of Disease (ICD)

Anatomic location	ICD	Fracture name
Femur	S72	Fracture of femur
Vertebrae	M48	Other spondylopathies
	S22	Fracture rib(s), sternum and thoracic spine
	S32	Fracture of lumbar spine and pelvis
Humerus	S42	Fracture of shoulder and upper arm
Wrist	S52	Fracture of forearm

by Health Insurance Review and Assessment Service (HIRA). As the disease statistic data from HIRA and NHI service were released to public with only the first three characters of the disease code, we redefined fracture patients and then the number of fracture patients was accordingly calculated (Table 2).

In case of fracture due to car accident, it was not covered by NHI Service, but Automobile Insurance. So we didn't conduct any exclusion process.

After we assumed the number of fracture patients in scenario A, and then for scenario B we removed certain number of fracture patients whose fracture was prevented out of them. To project how many fractures are prevented, we applied clinical efficacy of osteoporosis drug. Of them, alendronate, which is the most commonly used agent for osteoporosis treatment in Korea, showed relative risk (RR; 95% confidence interval [CI]) values for femur (0.61, 0.40-0.92), vertebrae (0.55, 0.45-0.67), wrist fracture (0.84, 0.66-1.06) in the previous study.[9] Because the RR for the humerus was not reported, we extracted 0.62 (P=0.013) from one of major clinical studies for alendronate, by Black et al.[10]

3. Cost

Costs related to osteoporosis and fracture included drug, clinic visit, and adverse event treatment etc. after diagnosis and costs involved in fracture treatment if it occurs. To evaluate budget impact of osteoporosis treatment, we only forecasted drug cost and fracture treatment in this study.

Since other costs such as clinic visit cost, confounding cost, pharmacy management cost, and adverse event treatment cost etc. were too various among each patient with their disease status, type of clinic, and frequency of visit to capture.

Medication for osteoporosis treatment in Korea is classified into hormonal and non-hormonal treatment, and includes bisphosphonate, calcitonin, active vitamin D, ipriflavone and raloxifene. Since there are several drugs available in Korea, and it's a little complicate to forecast each drug's expenditure during study time frame. Thus we projected osteoporosis drug cost from the sales forecasting of one of major prescribed drugs.

Previously HIRA reported 58.72% of patients filling their prescription in 2007. Approximately eighty percent of prescribing osteoporosis medications was bisphosphonate agents, and 43.7% of those taking bisphosphonate agents were receiving alendronate.

The daily cost of alendronate medication multiplied by the number of osteoporosis patients was the estimate of annual alendronate medication cost, and then we projected total osteoporosis treatment cost from these estimations. In this assumption, the weighted average daily cost of alendronate was forecasted in terms of dosage, strength, market performance and price changes during study period, and it was assumed that the medication was taken for 365 days as reimbursement covered a year in 2012.

For osteoporotic fractures, medical service utilization differs from the site of the fracture. For example a femur fracture requires hospitalization, while many spine patients are unaware or neglect appropriate treatment. The duration of the treatment differs for each patient as well.

In consideration of difficulties to estimate cost of fracture treatment, the average cost of treating a fracture patient was calculated by dividing the total amount paid out of the insurance budget for each fracture site, as recorded in the disease statistic data from the NHI Service.[8] Therefore, treatment cost (Won) for osteoporotic fracture was shown for femur (2,530,885), vertebrae (332,754), humerus (623,551) and wrist (375,888).

4. Sensitivity analysis

To examine the impact of parameter uncertainties on the results of the analyses, probabilistic sensitivity analysis was performed for a key attribute parameter, continuous administration.

As current continuous administration rate on osteoporosis treatment is 15%, we implemented sensitivity analysis from 20% to 30%, which is twice than current.

RESULTS

1. Patients estimation by each scenario

1) Scenario A

In an analysis of the disease statistic data, the number of patients diagnosed with osteoporosis in 2010 was 754,000, and the number had been steadily increasing from 2008 to 2010 with 9.8% of compound annual growth rate. The number of patients was predicted to increase at the same rate from 2013 to 2017 in this study (Table 3).

Based on the number of patients who had visited hospitals due to fractures in 2008 to 2010, the number of fracture patients was estimated through the same method as above for the 2013-2017 time frames, when the reimbursement extension for treatment period takes effect. (Compound Annual Growth Rate [CAGR]: 15.1%) (Table 3).

2) Scenario B

In the number of predicted osteoporosis patients in scenario A, 15% of them were assumed to continue osteoporosis drug treatment in the following year. According to HIRA's report in 2009, the patient group who continued treatment for 12 months remained at 14.48% of the total in 2005 and 15.07% in 2007. Therefore osteoporosis patients in scenario B were assumed as the sum of new patients in each year (calculated with CAGR 15.1%) and patients continuously on the treatment from previous year (15% from patients in previous year) (Table 3).

The number of fracture patients was assumed to decrease from the number of predicted fracture patients in scenario A, as a result of clinical outcome with osteoporosis medication. To project how many fracture patients were prevented, we selected alendronate as the most prescribing agent in Korea, and applied clinical efficacy of alendronate (Table 3).

2. Budget expenditure by each scenario

The forecasted treatment costs of osteoporosis and fracture for each scenario were presented in Table 4. The treatment cost of osteoporosis decreased in 2014 compared to 2013 for both scenario A and B, but increased continuously after 2015 due to price rearrangement policy for osteoporosis drugs. The cost of osteoporosis treatment over a five-year period for scenario A was 899.5 billion KRW and for scenario B it was 1,357.6 billion KRW. An additional 458 billion was requested to execute scenario B. However, the cost of osteoporotic fracture treatment over a five year period for scenario A was 7,012.4 billion KRW and 4,056.1 billion KRW was for scenario B. In scenario B, 2,956.3 billion KRW in budget expenditure could be saved. Although the costs of osteoporosis drugs increased more in scenario B than scenario A, the cost of osteoporotic fracture treatment decreased drastically during five year study periods. Therefore, during five year time frame, scenario B would save up to approximately 2,498.2 billion KRW in national healthcare budget (Fig. 1).

DISCUSSION

The treatment of osteoporosis is well known to prevent

Table 3. Estimated number of patients by scenario

Scenario	Patient No	2013	2014	2015	2016	2017
	Osteoporosis	996,947	1,094,431	1,201,448	1,318,929	1,447,898
A	Fracture	2,399,301	2,762,450	3,180,564	3,661,962	4,216,223
	Osteoporosis	1,133,168	1,413,947	1,764,299	2,201,461	2,746,945
B	Fracture	1,361,311	1,567,354	1,804,582	2,077,717	2,392,193

No: number

Table 4. Estimated treatment cost for osteoporosis and fracture by each scenario (unit: Million KRW)

Scenario	Treatment cost	2013	2014	2015	2016	2017	Total
	Osteoporosis	184,278	154,619	169,738	186,336	204,557	899,529
A	Fracture	1,037,258	1,194,253	1,375,011	1,583,127	1,822,743	7,012,392
	Osteoporosis	209,457	199,760	249,257	311,018	388,084	1,357,576
B	Fracture	599,972	690,782	795,336	915,715	1,054,314	4,056,119

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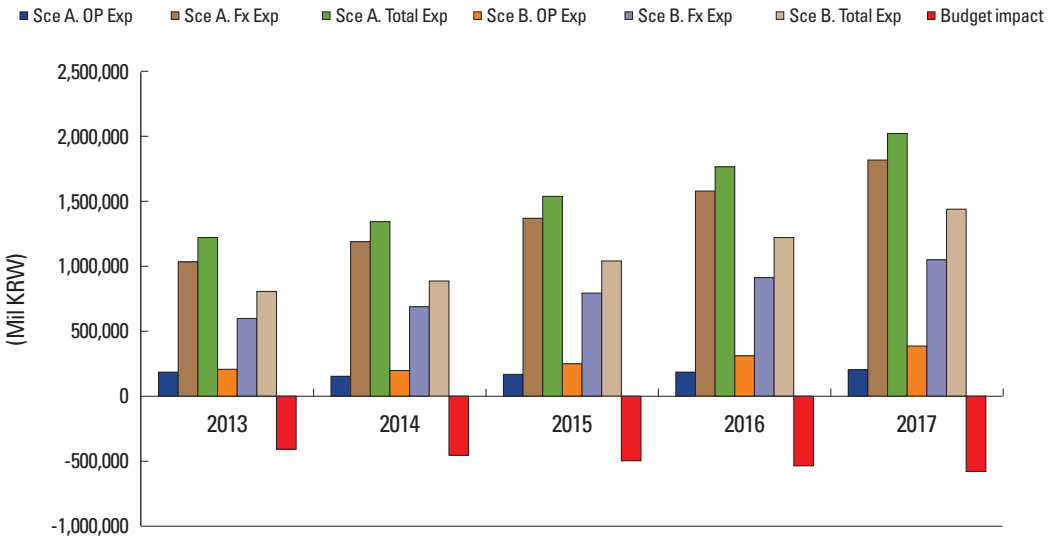

Fig. 1. Total national budget impact by each scenario shows that scenario B saved up to approximately 2,498 billion KRW in the national health budget during five year time frame. Sce A. OP Exp, scenario A. osteoporosis expenditure; Sce A. Fx Exp, scenario A. fracture expenditure; Sce A. Total Exp, scenario A. total expenditure; Sce B. OP Exp, scenario B. osteoporosis expenditure; Sce B. Fx Exp, scenario B. fracture expenditure; Sce B. Total Exp, scenario B total expenditure.

osteoporotic fractures. Many studies regarding budget impact analysis (BIA) of osteoporosis treatment have been reported in Western countries.[11-14] However, there is no study regarding BIA of osteoporosis treatment in South Korea. To our knowledge, this is the first study of budget impact and economic effect simulation study. In this simulation study, we found out that extension of reimbursement coverage in osteoporosis treatment as long as patients need continuous treatment resulted in saving of 2.50 trillion KRW for five years.

Zethraeus et al.[15] reported literature review of cost effectiveness study in osteoporosis and suggested Markov model which is flexible and allows for the estimation of the cost-effectiveness over different ranges for a selected number of variables. Johnell et al.[16] performed a simulation study of the cost effectiveness of alendronate using a Markov model with the risks and costs of fracture defined to be relevant for Sweden. They reported that treating 71-year-old osteoporotic women with a prior spine fracture with alendronate resulted in a cost per quality-adjusted life-year (QALY) gained of SEK76 000.[16] Our findings were consistent with previous reports that osteoporosis drug was cost effective in osteoporosis patients and/or higher-risk patients.

There are several components to achieve well control of osteoporosis, such as development of innovative medical interventions, high quality of medical service, high accessibility of medical service and social programs.[3,17,18] Drug reimbursement in the perspective of healthcare system influences drug adherence, an essential component to manage osteoporosis and prevent fractures. According to our new osteoporosis reimbursement guideline, which took effect from Oct 2011, pharmaceutical interventions for osteoporosis can be reimbursed for maximum a year, and it has been almost a year. Patients and physicians are facing serious challenges for osteoporosis treatment prescription to apply reimbursement. This simulation study demonstrated that continuous reimbursement shows more budget saving effect than one year reimbursement coverage since its cost savings from fracture prevention offset increased osteoporosis treatment cost.

Other countries such as U.K., Australia provide health technology appraisal for osteoporosis treatment, but do not suggest any limitation on reimbursement period.[19,20] The American Association of Clinical Endocrinologists (AACE) suggests ten years treatment and drug holiday if fracture risk is high.[21] The American College of Physicians (ACP) 2008 and the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis 2008 (ESCEO) recommend continuous drug administration when patients' BMD score is less than -2.5.[22,23] However, we have a limitation on reimbursement period

of a year and patients are hugely challenged to discontinue their treatment. Hence we evaluated whether one year reimbursement is appropriate in Korea.

With limited resources and healthcare budgets, it is important to strive for the efficient use of scarce resources, so that health outcomes are maximized. BIA with different reimbursement scenarios can provide decision makers with useful information concerning the efficient allocation of insufficient resources in healthcare.

In this study we conducted full analysis with the payer's perspective using Korean data; the result gives vital information to decision makers.

We estimated fracture prevention based on the clinical efficacy of alendronate. Fracture prevention rate is varied in terms of among drugs and site of fracture. Since alendronate is more efficacious in fracture prevention, there is a possibility that estimated fracture cost in scenario B was overestimated.[10]

Because of the simulated nature of this study, there are several limitations.

First, in the estimation of fracture patients, we used fracture cases including less than 50 years, but not confirmed as osteoporosis related fracture. Because we are not allowed to access the original reimbursement claim data, we could not classify fracture into osteoporosis related fracture and age factor. Therefore, even though we selected fractures based on previous HIRA' report to minimize inclusion of non-osteoporotic fracture, the fracture cost can be overestimated, which means the total budget saving in our study will be less than we anticipated.

Second, only the costs involved in osteoporosis medication and fracture treatment were assessed in this study. The total cost of treating an osteoporosis patient includes not only the cost of medication but also the costs involved with examination by a physician, outpatient pharmacy management and medicine preparation. In addition, there are too many factors to estimate actual costs depends on patients' conditions, disease severity, type of osteoporosis medication, class of clinics, prescription day, adherence on the medication etc. Therefore we simplified budget impact model through macro-costing method, consequently the cost for osteoporosis in this report will be less than actual disease burden.

Moreover as we analyzed NHI Service data, which is reimbursed to clinics, hospitals and pharmacies, non-reimbursed cost including out of pocket is excluded. Hence disease burden for osteoporosis and fracture will be more than we estimated.

Third, we estimated the total treatment cost for osteoporosis from the medication cost of alendronate agent, as we assumed market leadership of alendronate molecules would be maintained during study period. Another leading ingredient, risedronate shows similarity with alendronate in terms of market share, average daily cost in each year, diverse strengths and formulations, and availability of generics. So even though we project drug cost with risedrnoate not alendronate, it will not bring big difference on our result.

However, if a new ingredient is launched in the market and performs well, it can affect our result. A recently launched selective estrogen receptor modulator (SERM), bazedoxifene is listed at a lower price than raloxifen's in 2011 which we used in this study.[24] Under the government's current drug policy, new product's daily cost will not be a lot higher than our assumption in the given study period, and already launched products' price will be reduced after their generics enter the market. Therefore there is low possibility to overestimate drug cost with alendronate.

CONCLUSION

Simple budget analysis is a necessary feature to make decisions for the efficient use of healthcare resources in the area of osteoporosis. The result of this study suggests that continuous reimbursement coverage for patients with osteoporosis whose BMD score is less than -2.5 reduce total national health budget expenditure through saving fracture cost which offsets the increased spending for osteoporosis treatment.

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