

A Real-world Cost-effectiveness Analysis of Sevelamer Versus Calcium Acetate in Korean Dialysis Patients

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ABSTRACT

Purpose: Sevelamer, a noncalcium phosphate binder, has been shown to attenuate the progression of vascular calcification and improve survival in patients with chronic kidney disease undergoing dialysis compared with calcium-based binders. Using real-world data from a cohort study and the Health Insurance Review and Assessment Service database, we conducted a cost-effectiveness analysis comparing sevelamer with calcium acetate in dialysis patients from the perspective of the National Health Insurance Service in South Korea.

Methods: Data (demographic, diagnostic, laboratory, and survival) from 4674 patients undergoing dialysis enrolled in a multicenter prospective cohort study conducted in South Korea between September 2008 and December 2012 were linked to phosphate binder use, hospitalization, and cost data available from the Health Insurance Review and Assessment Service database. After propensity score matching, a dataset comprising comparable patients treated with either sevelamer (n = 501) or calcium acetate (n = 501) was used in the cost-effectiveness analysis. A Markov model was used to estimate costs, life years, quality-adjusted life years (QALYs), and cost-effectiveness over each patient's lifetime. Forty-month treatment-specific overall survival (OS) data available from the dataset were

extrapolated to lifetime survival with the use of regression analysis.

Findings: Patients had a mean age of 56.3 years and were treated with dialysis for a mean duration of 67.6 months. Compared with calcium acetate, sevelamer was associated with an incremental cost of South Korean Won (₩) 12,246,911 (\$10,819) and a gain of 1.758 life years and 1.108 QALYs per patient. This outcome yielded incremental cost-effectiveness ratios of ₩6,966,350 (\$6154) and ₩11,057,699 (\$9768) per life year and QALY gained, respectively. Conclusions regarding sevelamer's cost-effectiveness were insensitive to alternative assumptions in time horizon, discount rate, hospitalization rate, costs, and health utility estimates, and they remained consistent in 100% of the model iterations, considering a willingness-to-pay threshold of ₩31,894,720 (\$28,176) per QALY gained.

Implications: This analysis of real-world data found that sevelamer's higher cost relative to calcium acetate was adequately offset by improved survival among patients undergoing dialysis in South Korea. As such, sevelamer offers good value for money, representing

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a cost-effective alternative to calcium-based binders. (*Clin Ther.* 2017;■■■■-■■■) © 2017 Elsevier HS Journals, Inc. All rights reserved.

Key words: calcium acetate, cost-effectiveness, dialysis, sevelamer.

INTRODUCTION

Patients with chronic kidney disease (CKD), particularly those requiring dialysis, are at significant risk of mineral abnormalities, including hyperphosphatemia, hypercalcemia, and hyperparathyroidism.¹ Hyperphosphatemia, in particular, is the most prevalent mineral abnormality among patients undergoing dialysis and is independently associated with increased risks of vascular calcification, cardiovascular disease, cardiovascular events, metabolic bone disease, bone fractures, and mortality.^{2,3}

Most patients undergoing dialysis inevitably require a phosphate binder to control serum phosphate levels and improve outcomes associated with hyperphosphatemia.¹ Traditional calcium-based binders (CBBs) such as calcium acetate and calcium carbonate have recently come under scrutiny because of concerns that CBBs may contribute to positive calcium balance, vascular calcification, and cardiovascular disease.⁴⁻⁸ In response to these concerns, Kidney Disease: Improving Global Outcomes guidelines recommend restricting or avoiding use of CBBs in patients with known vascular calcification, persistently low parathyroid hormone levels, low/dynamic bone turnover, and persistent/recurrent hypercalcemia.

Non-CBBs such as sevelamer hydrochloride and sevelamer carbonate lower serum phosphate levels without contributing to positive calcium balance in patients with CKD and receiving dialysis.⁹ Compared with CBBs, sevelamer has been shown to reduce serum calcium levels, attenuate the progression of vascular calcification, reduce hospitalizations, and improve both cardiovascular and overall survival in patients undergoing dialysis.¹⁰⁻²⁶

In South Korea, the annual cost of sevelamer is nearly 7 to 8 times that of calcium acetate.²⁷ Particularly in universal health care coverage systems such as South Korea, evidence of good value for money is required to justify increased expenditures. The Health Insurance Review and Assessment Service (HIRA) database provided the real-world health care utilization and costs experienced by the patients undergoing dialysis enrolled in a prospective,

multicenter observational study in South Korea. These data provided the inputs for a cost-effectiveness analysis (CEA) comparing sevelamer with calcium acetate, conducted from the perspective of the National Health Insurance Service (NHIS) in South Korea.

PATIENTS AND METHODS

From September 2008 to December 2012, a total of 4674 patients undergoing dialysis were enrolled in a nationwide, multicenter, prospective, observational cohort study of the Clinical Research Center for End Stage Renal Disease in South Korea.²⁸ All patients provided their written consent to participate in this study, and the study protocol was approved by the institutional review board of Kyungpook National University Hospital (2011-01-041). All clinical investigations were conducted in accordance with the guidelines of the 2008 Declaration of Helsinki.

At the time of enrollment, clinical data (including age, sex, dialysis modality, dialysis duration, primary renal disease, co-morbidities, body mass index, and laboratory information) were collected. Patient survival was surveyed until December 2012. After all traceable identifiers were removed, the patients' data were integrated with the HIRA database. As of 2011, the HIRA database contains data for 46 million patients (~90% of the total population) and includes claims for >80,000 health care providers across South Korea.²⁹ Data related to patients' sociodemographic characteristics, diagnosis, health care services (including hospitalization and prescription drugs), as well as cost estimates (total cost, payer's amount, and patient out-of-pocket costs) are provided by the HIRA claims database. The integration of the HIRA data with the prospective cohort study data resulted in a dataset of South Korean patients undergoing dialysis featuring clinical and survival data, as well as real-world phosphate binder use, hospitalizations, and associated reimbursement payments by the NHIS. In aggregate form, this information facilitated a modeled CEA from the perspective of the NHIS in South Korea.

Model Overview

The CEA was conducted by using a previously published Microsoft Excel-based Markov decision-analytic model (Microsoft Corporation, Redmond,

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