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Title **Sevelamer in Patients with End-Stage Renal Disease: A Systematic Review and Economic Evaluation**

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Aim

To systematically review the efficacy and harm of sevelamer, and to conduct a primary economic evaluation and budget impact analysis of its use when compared with calcium-based phosphate binders in patients with end-stage renal disease (ESRD) who are on dialysis.

Conclusions and results

There was no convincing evidence that substituting sevelamer for calcium based binders reduced all-cause mortality, cardiovascular mortality, hospitalization, or the frequency of symptomatic bone disease, and no evidence that sevelamer improved quality of life. Sevelamer therapy results in a smaller decrease in phosphate levels, and fewer episodes of hypercalcemia of unknown clinical significance, compared with calcium-based phosphate binders. Even if sevelamer is assumed to be more effective than calcium-based phosphate binders, it is associated with a cost per quality-adjusted life year gained ranging from 127 000 to 278 100 Canadian dollars. It is possible that sevelamer use, restricted to patients ≥65 years of age, might be more economically efficient, but improved effectiveness in this group requires confirmation from future studies.

Recommendations

Not applicable.

Methods

Using two search terms, sevelamer and Renagel, we conducted a comprehensive search to identify all relevant studies of sevelamer use. We assessed the study quality of randomized controlled trials (RCTs), using a condensed version of the Chalmers Index, and a standard data extraction method to record the data elements of interest into a database. We assessed the following outcomes: mortality (all-cause, and cardiovascular); cardiovascular events; hospitalizations; quality of life; levels of serum phosphate, calcium, parathyroid hormone (PTH), bicarbonate, calcium-phosphate product; and occurrence of adverse events. Because of the differences expected between trials, we decided *a priori* to combine results in a conservative fashion using a random effects model.

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