Efficacy and tolerability of Sevelamer in the treatment of hyperphosphatemia in Indian patients on dialysis

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ARTICLE

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Abstract

A multicentric, open label, non-comparative clinical trial was conducted in dialysis patients with serum phosphorus ≥ 6 mg/dl. All the patients received Sevelamer 800 mg orally at a dose of 1 or 2 tablets three times daily with meals depending on their baseline serum phosphorus levels for 4 weeks. Dose was increased or decreased after 2 weeks according to serum phosphorus level. All the patients were examined and investigated for serum phosphorus, serum calcium and the safety laboratory parameters on days 1, 7, 14, 21 and 28 of the Sevelamer therapy. A total of 26 ESRD patients on maintenance dialysis (19 males and 7 females) were included in the trial out of which 4 patients discontinued the study. Out of the 22 patients who completed 4 weeks therapy, 18 patients (81.82 %) responded. There was a significant reduction of 1.64 ± 1.18 mg/dl (mean ± SD) in serum phosphorus level after 4 weeks of treatment with Sevelamer. A clinically significant reduction of 0.97 mg/dl was observed as early as after 2 weeks of treatment. The calcium x phosphorus product reduced from a baseline of 59.38 ± 11.79 mg/dl to 45.16 ± 10.60 mg/dl after 4 weeks of treatment; (P< 0.01). There was no significant change in serum calcium levels or in any of the safety laboratory parameters during treatment with Sevelamer. Adverse effects were not reported by any patient who completed the study. Sevelamer was found to be effective and well-tolerated in the treatment of hyperphosphatemia in dialysis patients.

Key words: Sevelamer, hyperphosphatemia, serum phosphorus, serum calcium, calcium x phosphorus product.

Introduction

Elevated serum phosphorus concentration is an established independent risk factor for increased mortality in patients with end stage renal disease (ESRD) requiring hemodialysis. Phosphorus retention in these patients is a major contributor to the development of secondary hyperparathyroidism, osteitis fibrosa and extraosseous calcification of both vascular and non-vascular tissues[1, 2]. Dialysis patients are placed on phosphorus restricted diets; despite this, the phosphorus absorbed exceeds the amount of phosphorus removed by dialysis. As a result, dialysis patients must take phosphate binders to decrease the absorption of dietary phosphate.

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An ideal phosphate binder should be safe and well tolerated, palatable, non-absorbable, cost-effective and have good efficacy and specificity. Furthermore, it should not add to the aluminium or calcium burden nor should it accumulate in bone or other vital organs[3]. The most commonly used phosphate binders contain aluminium or calcium. Aluminium causes neurological, skeletal and hematopoietic toxicities[4, 5], while calcium can lead to hypercalcemia and soft tissue and cardiac calcification[5, 6, 7]. Concerns about the toxic effects of calcium-based and aluminium-based binders have fuelled interest in alternative calcium-free, aluminium-free phosphate binders[3]. Lanthanum and Sevelamer are new calcium-free, aluminium-free phosphate binders. Lanthanum is a rare earth metal used as carbonate salt as a phosphate binder. Though lanthanum is an effective phosphate binder, there are concerns regarding it being absorbed from the gastro-intestinal tract and getting accumulated in the body tissues[8]. Sevelamer is a novel phosphate binder polymer free of aluminium and calcium. Sevelamer also binds bile acids leading to increased