1.0 Abstract

Title

Quality of Life in Greek Hemodialysis Patients Receiving Zemplar I.V. – Qualitize Study

Keywords

end stage renal disease, secondary hyperthyroidism, paricalcitol, health-related quality of life, patient reported outcomes

Rationale and Background

Paricalcitol, a third generation vitamin D analogue, is used for the management of secondary hyperthyroidism (sHPT), a disease that develops frequently in patients with end stage renal disease (ESRD). Results of a small-scale study have indicated that treatment with paricalcitol improves the quality of life (QoL) of chronic renal disease patients undergoing hemodialysis. Larger scale studies are warranted in order to evaluate the effect of paricalcitol on the QoL of this patient population.

Research Question and Objectives

Thus, the present observational study was conducted in order to obtain data on the use of intravenous (i.v.) paricalcitol in real-life clinical practice and to examine its effect on the patients' QoL assessed by the RAND 36-Item Health Survey questionnaire. In addition, the study assessed changes in parathyroid hormone (PTH) and other laboratory parameters monitored in routine clinical practice of this patient population.

Study Design

This was a multicenter, post-marketing, non-interventional, observational study conducted in a real-life clinical setting in Greece.

Setting

A total of 11 investigators from 11 hemodialysis units across Greece enrolled patients with ESRD and sHPT in the present study. The study period was between 19 August 2011 and 26 June 2013.

Subjects and Study Size, Including Dropouts

In the context of this study, 265 patients were planned to be enrolled and were actually enrolled. Of these, 11 did not fulfill all of the enrollment criteria; thus, the patient analysis set comprised 254 patients. A total of 19/254 patients prematurely discontinued study participation (14 due to death, 2 due to loss to follow-up and , 2 due to transport to another chronic dialysis facility and 1 due to transplantation).

Variables and Data Sources

The primary variable of the study was the assessment of changes in the eight different concepts (scales) of the RAND 36-Item Health Survey questionnaire. This questionnaire is self-completed by the patient and includes 36 questions. Serum laboratory parameters were assessed according to routine clinical practice examinations.

All adverse events meeting the definition of a serious AE (SAE) observed during the study or reported by the patient himself/herself were collected and recorded by the study investigator regardless of causality.

Results

The patients' male-to-female ratio was 1:7 and the mean age 67.8 ± 12.0 years. Improvements in the QoL from baseline to the 6-month study visit were noted in 7 of the 8 concept scores of the RAND 36-Item Health Survey questionnaire. The changes were evaluated through Wilcoxon signed rank test for paired samples. The mean increase from baseline to Visit 3 was the greatest for the ***'Energy/Fatigue'*** concept (12.5 ± 30.5; $p < 0.001$), followed by the concepts of ***'Role Limitations Due to***

Emotional Problems' (10.8 ± 56.4; p = 0.003); ***'Bodily Pain'*** (10.7 ± 34.8; p < 0.001); **'*Social Functioning*'** (10.3 ± 35.3; p < 0.001); ***'Emotional Well-Being'*** (8.4 ± 27.2; p < 0.001); ***'Role Limitations Due to Physical Health'*** (7.3 ± 57.2; p = 0.05); and **'Physical Functioning'** (5.7 ± 32.9; p = 0.03). The patient-perceived ***'Health Change'*** showed a statistically significantly improvement from baseline (mean score increase at Visit 3, 14.0 ± 32.0 points; p < 0.001). The median decrease in PTH levels at 6 months was 39.2 pg/mL (p = 0.02), while no significant changes from enrollment were observed in serum calcium, phosphorus and the Ca×P product. Overall 28 patients (11.0%) reported 104 serious adverse events (SAEs); 2.9% (3/104) were assessed as drug-related.

Discussion

The results of this study support a favorable risk-benefit profile of paricalcitol in the patient population under study. Paricalcitol significantly improved the QoL and decreased PTH levels after 6 months of treatment. In terms of its safety, paricalcitol demonstrated a manageable toxicity profile.

Marketing Authorisation Holder(s)

AbbVie Pharmaceuticals S.A. (formerly the specialty pharmaceutical business of Abbott Laboratories Hellas S.A.)