Endocrinología, Diabetes y Nutrición 72 (2025) 160

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94 - TEPROTUMUMAB EFFICACY AND SAFETY IN AN OPEN-LABEL (OL) EXTENSION IN PATIENTS WITH CHRONIC THYROID EYE DISEASE (TED)

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Resumen

Introduction: Thyroid Eye Disease (TED) can lead to chronic and symptomatic disease with pain and proptosis. Teprotumumab has demonstrated efficacy in patients with acute and chronic TED. In the first placebo-controlled, double-blind trial (NCT04583735) in patients with chronic TED (2-10 years disease duration and clinical activity score #2 1), teprotumumab improved proptosis and visual function-quality of life.1 We report teprotumumab safety and efficacy in the open-label extension of this trial.

Methods: Proptosis non-responders (< 2 mm improvement) from the randomized period of the trial could receive open-label teprotumumab (8 infusions over a 24-week treatment period).

Results: Of 24 patients in the open-label extension, 12 patients who were previously treated with placebo received a first course of teprotumumab (PBO/TEP) and 12 patients who were previously treated with teprotumumab received a second course (TEP/TEP). At week 24 of the open-label extension, mean (SD) proptosis change from pre-teprotumumab was -2 (1.2) mm for PBO/TEP and -1.6 (1.2) mm for TEP/TEP; and 7/12 (58.3%) PBO/TEP and 5/12 (41.7%) TEP/TEP were proptosis responders. Adverse events (AEs) were reported in 11 (91.7%) PBO/TEP and 8 (66.7%) TEP/TEP patients, with no serious AEs or deaths. No TEP/TEP patients and 3 PBO/TEP patients reported hearing AEs (eustachian tube dysfunction, hypoacusis, tinnitus).

Conclusions: Delayed treatment (PBO/TEP) had similar outcomes as teprotumumab in first 24 weeks. Additional teprotumumab therapy (TEP/TEP) proved beneficial without added safety concern in about 40% of patients with prior non-response.

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