On-treatment safety and efficacy and short term efficacy of 1-34 parathyroid hormone treatment in severe osteoporosis

Vicenç Torrente-Segarra, Daniel Roig, Dacia Cerdà, Delia Reina, Silvia García-Diaz, Paula Estrada, Ramon Fíguls, Hector Corominas

Hospital Sant Joan Despí Moisès Broggi-Hospital General Hospitalet, Consorci Sanitari Integral Hospitalet Llobregat/Sant Joan Despí, Barcelona, Spain

Objectives

To assess safety and clinical efficacy during 1-34 parathyroid hormone treatment (1-34-PTH) in real clinical practice; to describe fracture outcome after 1-34 parathyroid hormone discontinuation in real clinical practice.

Methods

We performed an observational study in real clinical practice of all consecutive severe osteoporosis (sOP) patients referred to our Rheumatology Department from Feb'10 until Jan'14. All patients were referred both by general practitioners and geritricians from a 150.000 population community (Hospitalet Llobregat). Patients were classified as sOP if they accomplished one of the following: incidental osteoporotic fractures during previous anti-OP treatment, need of chronic systemic steroid treatment and presence of previous osteoporotic fracture, several previous osteoporotic fractures, and serious risk of fall with previous osteoporotic fracture. 1-34-PTH was given to all of them. The incidence of clinical vertebral and nonvertebral fragility fractures were assessed, and fractures outcome were requested at 6-month-follow-up visits. All safety issues were registered in a questionnaire-sheet. A 12-month vertebral X-ray was performed during treatment, and blood tests (assessing bone metabolism and renal function after 1-34-PTH treatment) and previous-BMD were collected. All data concerning to age, 1-34-PTH onset/discontinuation, previous treatment, number of fractures, side-effects, incidental fractures and fractures outcome were registered in a database.

Results

A total of 111 patients fulfilled our sOP criteria. All patients showed OP-BMD level. 83% retained an 18-month course of 1-34-PTH. 17 patients discontinued treatment due to mild side-effects (12 by GI intolerance, 4 by headache, 1 due to pain at the injection site), all recovered. No serious side-effects were found. A total of 79.8% were women, mean age 71.3 (SD ±6.7), 38% had one previous fracture (63% vertebral, 19% hip, 18% other), and 62% ≥1 previous fracture; mean number of fractures was 1.94 (SD ±1.49). The 38% had suffered fracture during previous treatment (95% on byphosphonates).No new fractures were observed during treatment follow-up. Fifty-four (57%) had finished the 18-month course 1-34-PTH (mean follow-up 9.2 months; SD ±2.4). Of these, 3 patients showed one each new vertebral fractures (5.2%) after 1-34-PTH discontinuation.

Conclusions

1-34 PTH showed benefit during treatment and a very low rate of fracture after its discontinuation in sOP in real clinical practice. Safety issues were mild and fully recovered, and observed in only 15% of patients. Longer follow-up time is needed to elucidate post-1-34 PTH fracture outcome. These results should be interpreted in the context of the design of an observational study