

[2005] [SAT0361] REDUCTION IN THE RISK OF BACK PAIN PERSISTS AT LEAST 30 MONTHS AFTER DISCONTINUATION OF TERIPARATIDE TREATMENT: A META-ANALYSIS

J. Reginster¹, M.C. Nevitt², P. Chen³, R.K. Dore⁴, D.P. Kiel⁵, J.R. Zanchetta⁶, E.V. Glass³, J.H. Krege^{3,1} University of Liège, Liege, Belgium, ²UCSF, San Francisco, ³Eli Lilly and Company, Indianapolis, ⁴UCLA, Anaheim, ⁵Hebrew Rehabilitation Center for Aged and Harvard Medical School, Boston, United States, ⁶Instituto de Investigaciones Metabólicas, Buenos Aires, Argentina

Background: Vertebral fractures are the most frequent outcome in osteoporosis and may result in back pain with functional limitations and diminished quality of life.

Objectives: Evaluate the risk of developing new or worsening back pain during treatment with teriparatide [rhPTH (1-34), TPTD] or control + 30 months of additional follow up in patients with osteoporosis.

Methods: All four TPTD trials with posttreatment follow-up were included in our analyses: two placebo controlled trials,^{1,2} one alendronate 10 mg daily comparator trial,³ and one study of hormone replacement therapy (HRT) versus HRT plus TPTD.⁴ During follow-up, patients were allowed to receive other osteoporosis treatments. Back pain was defined as either new or worsening in severity after the initiation of study drug through the end of posttreatment follow-up. The interaction of treatment and study in a multivariate Cox proportional hazards model was used to assess the heterogeneity of results among studies and to estimate the relative risk of back pain after adjusting for other osteoporosis drug use following discontinuation of TPTD.

Results: Findings were not statistically heterogeneous among trials ($P = 0.66$) and there were no differences between groups administered TPTD20 or 40 mcg/day doses ($P = 0.31$). Therefore, placebo, HRT, and alendronate groups were pooled as a control group and compared with pooled TPTD groups. Relevant data are listed in table below. Overall, patients in the pooled TPTD group had reduced risk for any back pain, moderate or severe back pain, and severe back pain compared with pooled control from initiation of study drug through the end of follow-up. A sensitivity analysis showed that the results were consistent among trials and robust to the removal of each individual trial from the meta-analysis.

Endpoint	Group	N	Cases	Patient-years at risk	Rate (per 100 patient-yrs)	RR (95% C.I.)
Any back pain	Control	691	203	2187.2	9.28	
	TPTD	1222	285	4157.2	6.86	0.73 (0.61-0.87)
Moderate/severe back pain	Control	691	144	2340.8	6.15	
	TPTD	1222	196	4354.9	4.50	0.72/ (0.58-0.89)
Severe back pain	Control	691	45	4761.8	1.73	
	TPTD	1222	33	2607.9	0.69	0.39P (0.25-0.61)

Conclusion: The results demonstrate reduced back pain risk in patients with osteoporosis treated with teriparatide and then followed for 30 additional months in four clinical trials.

References: 1. Neer et al. NEJM 2001.

2. Orwoll et al. JBMR 2003.

3. Body et al. JCEM 2002.

4. Ste-Marie et al. Endo Soc (Abstract) 2001.

Back pain

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