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LETTER

Once-weekly teriparatide administration for 24 weeks in postmenopausal women with osteoporosis

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Dear Editor,

Sugimoto and colleagues conducted a follow-up study of 28 postmenopausal women with osteoporosis to clarify the effect of once-weekly teriparatide administration for 24 weeks using several biologic markers [1]. After 24 weeks of treatment, significant increase of the serum osteocalcin, a bone formation marker, and significant decrease of the urinary deoxypiridinoline, a bone resorption marker, were observed. In contrast, no significant change of the serum procollagen type I N-terminal propeptide (PINP), a bone formation marker, or urinary cross-linked N-telopeptide of type I collagen (NTX), a bone resorption marker, was observed. I have two concerns on their study.

First, the authors conducted their study without setting a standard protocol for the daily teriparatide administration, which is described in the last paragraph of the Discussion section as a study limitation. They measured four biological markers at four time-points, including measurements before the start of treatment. Unfortunately, there are differences in the test situations in the past several studies, which makes the comparability not satisfactory. For example, the authors have quoted two references [2, 3] related to the effects of two treatment regimens on fracture risk reduction, and I have a question as to their reason for arriving at the conclusion of no difference in the relative risk reduction between 80 and 65 % in these studies. There is no way to adjust for ethnic differences in the study, and comparison of data within the study should be conducted. In addition, the characteristics of their population should be checked for its representativeness of Japanese postmenopausal women.

Second, distributions of PINP and NTX are logarithmic-normal in general, and Wilcoxon's matched–pair signed–rank test should be applied if Friedman's test with a strict criteria of alpha/3 shows significance. Alternatively, paired *t* test with logarithmic transformation of variables should be conducted after repeated-measure analysis of variance. The number of patients in the study is limited (n=28), and power analysis is indispensable for repeated measures [4].

Finally, the authors have mentioned in the last paragraph the advantage of sustainment for up to 72 weeks in their trial. But I feel that there is no clear evidence for their proposal. The lack of statistical significance does not mean the lack of clinical effectiveness, and setting of a control group as standard protocol should be considered for accurate analysis.

A reply to this comment can be found at doi 10.1007/s00198-014-2722-5.

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