Author's response to reviews

Title: Compliance and treatment satisfaction of post menopausal women treated for osteoporosis

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Author's response to reviews: see over
Reviewer’s report

**Title:** Compliance and treatment satisfaction of post menopausal women treated for osteoporosis

**Version:** 2 **Date:** 12 March 2010

**Reviewer:** Marco Gambacciani

**Reviewer’s report:**

**MAJOR REVISION**

1. Present paper describes the information given by MDs and Patients. 
   This is correct. Data was collected from both physicians and patients. See p.6 of the manuscript.

2. The AA should quote and discuss different papers reporting the pharmacy data providing a real use and thus the real adherence to medication, that are quite different from those reported.

   Our results indicate that 65.5% of women considered themselves to be fully compliant (MMAS score = 4) in consistency with a previous database study in tree countries: US, UK, and France showing 61% (95% CI, 59-62), 74% (95% CI, 73-75) and 58% (95% CI, 56-59) in France, respectively. Please note that only daily and weekly BPs were available at the time of the study in France.

   Different methods to measure adherence are now cited in discussion as well as similarities and limits of pharmacy data and patients-reported outcomes (MMAS) (see p.15).

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.
Reviewer: Jose Alberto Hernandez Bueno

Reviewer's report:

a) There could be a selection bias thru the physician selected to participate, and I don't know if the proportion reflects the "real world" treatment of osteoporosis by specialities/GP's.

There are several potential sources of bias in the attempt to reflect 'real-world' management of osteoporosis:

a) Choice of physician type: we attempted to match the proportion of physician treating women with osteoporosis in France. For example, it is known from prescription claims data that around 70% of anti-osteoporotic drugs in France are prescribed by GPs. Our goal was to recruit GPs, rheumatologists and gynaecologists in a ratio of 3:1:1 in order to reflect this. In fact, the recruitment was 420 GPs (61.4%), 154 rheumatologists (22.5%) and 110 gynaecologists (16.1%), which respects this target reasonably well.

b) Choice of physician: there is obviously a bias due to physicians who decline to participate in the study who may have different practices to those who participate. However, this bias is intrinsic to any physician survey. This is identified as a potential weakness of the study p.13§1.

c) Choice of patient: in an attempt to avoid bias related to patient selection, we used a patient registry in which all patients were recorded and only the first three patients spontaneously consulting their physician were effectively included. Through these design features, we have attempted to minimise selection bias, which is clearly very important when adherence is the primary objective of the study.

b) It's a very short term study.

Yes, the study used a cross-sectional design in order to recruit a large number of patients rapidly. It is clearly important to replicate these findings in longitudinal prospective studies. A statement to this effect has been added to the conclusions p.11§2.

c) The SF 12 questionnaire is not specific for osteoporosis-related QoL, specially having the QUALIOST available.

Many disease-specific questionnaires for osteoporosis are available, including the QUALIOST which is effectively one of the most relevant to assess effects of a specific medical or surgical intervention over a long period. However, in our study, assessing quality of life was a separate objective from the evaluation of treatment compliance and satisfaction presented in this paper. This objective was to compare quality of life in women with osteoporosis to that in women suffering from other chronic diseases. For this reason, a generic HRQoL questionnaire such as SF-12 was clearly needed. We only mention SF-12 data in this paper because of the interesting role of quality of life on compliance rates. Complete data on QoL in this study population will be published elsewhere.

d) Compliance could have been assessed via refill of prescriptions (if applicable in France).

See reply to Comment 2 of Reviewer 1.

e) They draw conclusions regarding HRT from really tiny numbers, according to their table.
This comment is perfectly justified. For this reason, the precision of the compliance rate for HRT should be considered as low. A statement to this effect has been added to the Discussion p.11§2.

f) There is no concordance in their statements of compliance between daily vs weekly vs monthly regimes with the figures.
The statement in the text (p11§2) comparing compliance rates between different frequencies of administration refers to the information from the multivariate logistic regression analysis of determinants of compliance presented in Table 5. The text states that there was ‘an increased probability of being compliant to a monthly treatment over twofold higher than for a daily treatment’. This refers to the odds ratio of 2.232 for being compliant on a monthly treatment with regard to a daily treatment (Table 5). The information is thus concordant.

g) They don’t register if the patient participated in the elected treatment. It seems to me that there is a tendency to favor ibandronate, not substantiated in the article, that looks larger than it really was. I think it's not an addition to what BALTO studies reflect, so I don't see any benefit of its publication.

The patient’s contribution to the choice of treatment is indeed not determined in this study. The patient’s input may vary between the treatments they effectively received, as a function of treatment preference, and this may indeed influence treatment compliance. This is one potential variable that may influence compliance that was not investigated in this study. A statement to the effect that the list of determinants of compliance identified in this study is certainly not exhaustive has been added to the ‘limitations’ section of the Discussion (p.12-13, overlapping §).

Nonetheless, it is important to emphasise that the goal of this study was not to investigate preferences (as in BALTO) but to evaluate real-world adherence, which is likely to be determined by factors other than those influencing treatment preference. Preference studies and adherence studies both have their own inherent strengths and weaknesses, and thus are complementary to one another. The fact that the present adherence study and the BALTO studies both identified treatment frequency as an important determinant of patient-treatment interactions reinforces the credibility of both.