**Reviewer's report**

**Title:** Transdermal fentanyl for the treatment of pain caused by osteoarthritis of the knee or hip, an open, multicentre study

**Version:** 1 **Date:** 16 March 2005

**Reviewer:** Tuan V Nguyen

**Reviewer's report:**

**General**

The authors conducted an open clinical trial to assess the efficacy and safety of transdermal fentanyl (TDF) in the treatment of pain due to osteoarthritis of the knee or hip. Data from 159 patients with OA knee and 44 with OA hip indicated that after 4 weeks of treatment, 88% of patients had adequate pain control. However, almost a-third of patients experienced nausea and another a-quarter of patients suffered from vomiting. The authors conclude that TDF significantly increased pain control and improved functioning and quality of life.

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**Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)**

1. Since this is a clinical trial I suggest the authors adhere to the CONSORT format of reporting data (see for example: http://www.consort-statement.org/revisedstatement.htm).

2. The lack of a control group in this study is a potential weakness. Could the authors justify or elaborate on this issue further in their Discussion. In fact, it is appropriate to consider the efficacy and safety observed in this study in relation to previous findings in the literature to see whether the magnitude of effect is comparable.

3. In the analysis, it seems that the authors did not control for the potential differences among the participating centers. This important effect should be taken into account in the analysis and interpretation of data.

4. The proportion of patients with adequate pain control is impressive: from 4-27% during the run-in period to 88% after 4 weeks of TDF treatment. Since this is a key feature / claim of the paper, I suggest the authors show the data in a formal way (eg in a table with the number of patients being classified by each pain score). Was the improvement consistent throughout centers? However, almost a-third of patients experienced nausea and 25% of patients experienced vomiting were quite substantial, and I suggest the authors specifically report these figures in their Abstract.

5. Table 2. Is it true that the “Physical functioning” score reduced from 30 to 4.0? Please clarify whether the figures after +/- sign refer to SD or SE? Please show confidence intervals of change in scores between baseline and follow-up. I suspect the authors mean “follow-up” when they write “Change at endpoint”. Is

6. Table 3. Please show confidence intervals of change in scores between baseline and follow-up.

**What next?:** Accept after minor essential revisions
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: No