Reviewer's report

Title: Insomnia among hospitalised patients with advanced disease admitted to a Palliative Care Unit: a prospective observational study on its prevalence and association with psychological, physical and environmental factors.

Version: 2
Date: 14 February 2014
Reviewer: Eva Schildmann

Reviewer's report:

Thank you very much for asking me to review this manuscript about insomnia among hospitalized patients with advanced disease in a Palliative Care Unit (PCU) which I read with great interest.

While the topic and approach of the study are interesting, I have a number of concerns including questions regarding the match between methods and aims of the study:

Major Compulsory Revisions

1. Sample size: I am not a statistician and this is not my area of expertise, but the sample size of n = 60 seems too low for the stated aims of the study: These were, amongst others, to evaluate the prevalence of insomnia among patients admitted to a palliative care unit and to evaluate which factors may influence insomnia, using multivariate regression analysis.

a. The authors only mention (Methods, „participants and setting“) that the sample size was calculated „assuming that psychological distress would be comparable to the prevalence in previous studies, and hypothesising that psychological distress would be associated with insomnia“. However, I suggest it should be explicitly stated which assumed prevalence and which precision and level of confidence they used to calculate the sample size for the assessment of prevalence.

b. Just doing a quick sample size calculation by the calculator “sampsize” (http://sampsize.sourceforge.net/iface), assuming a prevalence of 75% with precision of 5%, level of confidence interval 95% and unknown population, gives an estimated sample size of 289, i.e. almost 5 times higher than the actual sample size of 60. On this basis I think the authors cannot say they have assessed prevalence, but only frequency of insomnia in their small sample.

c. Also for the multivariate analysis, the authors should state more clearly how they calculated sample size and how many factors were actually considered for the multivariate analysis. From the information given it is not clear whether the sample size was large enough to do this analysis.

Given the above mentioned methodological challenges I suggest that the limited robustness of the findings should at least be emphasized. Furthermore the authors may adapt the aims of the study and the conclusion in light of the
methodology.

2. Included patients: Only 34% of the consecutively admitted patients fulfilled the inclusion criteria. This seems a small proportion of patients with Karnofsky status of at least 30, acceptable cognitive status and staying for more than 2 nights, compared to my experience of patients admitted to a PCU, and raises the question of the characteristics of the excluded patients. In this respect my suggestions would be that

a. The authors should provide the numbers of patients for each reason of exclusion as well as the reasons for not assessing 23 patients with the numbers of patients for each reason.

b. The authors provide the basic demographic and clinical data of all excluded and not assessed patients, e.g. in a table like table 1. These characteristics of the non-included patients should then be compared to the ones of the included patients to determine whether the included patients are representative of all admitted patients.

c. The above-mentioned facts should be discussed in more detail in the limitation section of the discussion (last paragraph).

3. Regarding the choice of measurement tools, it is another limitation of the study that the used questionnaire was only translated by one person and especially that the Catalan version was not formally validated. This should at least be mentioned in the discussion in the „limitations“ section (last paragraph) in addition to the limitations already mentioned regarding translation.

4. It is not clear to me why the insomnia single question was also used in addition to the Sleep Disturbance Scale (SDS) questionnaire. It is said in the methods section (assessment of insomnia – insomnia single question), that it was „considered that it could have a clinical interest as a screening“ and in the first paragraph of the discussion that it „might be a sensitive method for detecting insomnia“. However, the results from the single question were not compared with the ones of the SDS questionnaire.

5. I am not sure what additional value it had to give also the answer option „sometimes“ for the single question. Additionally, I wonder whether classifying the answer „sometimes“ as „no insomnia“ „with the intention of being more specific in detecting insomnia“ (methods section – assessment of insomnia – insomnia single question) does not distortion the results. The authors should explain in more depth why they decided to use these answer options and this classification in the methods section, give also the number of patients who said „sometimes“ as result and discuss possible problems associated with these decisions in the discussion.

6. The „internal reliability“ (= internal consistency?) with „coefficient alpha“ (= Crohnbach´s alpha?) of the SDS and whether it had one or more underlying constructs were not posed as questions/aims and therefore should not be reported (results section – prevalence of insomnia...
7. From the background section that presents data for insomnia in different patient groups it is not clear to me why the authors wanted to assess insomnia during the stay on PCU and not the insomnia the patients had had prior to admission. This should be explained more clearly.

8. In the section Methods – „Procedures“ it should be clearly stated when the interview took place – after 2 nights on the PCU? It should also be pointed out in the methods section on what day after admission patients actually were interviewed.

Minor essential revisions

1. Why were patients asked whether psychological symptoms were present, but whether physical symptoms INTERFERED with their sleep quality? Would it not have been better to be consistent? When reporting the results for the physical symptoms in the abstract, it is not clear that these are the numbers of patients who had e.g. pain INTERFERING with sleep quality, not just the number of patients with pain.

2. Discussion, second paragraph: Why do the authors state that the single question could favour the selection of a subsample of patients with a higher emotional distress, “since patients who complain of poor sleep are generally more anxious”? Would this not also be true for the SDS? In this study, they did not find an association between anxiety and insomnia assessed by either of these two measures.

3. Discussion 3rd paragraph: The sentence „In palliative care, the most affected sleep item might differ…“ does not make sense to me, as the authors state in the sentence before that their data coincide with other studies in cancer patients (who are not necessarily palliative care patients). Even if it differed from other groups, why does this fact highlight the importance of individual assessment of each sleep item?

In summary, there are important issues to be considered, including sample size, reporting of included and excluded patients, choice of measurement tools and measurement time point, and this manuscript needs a major revision.

**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.

**Declaration of competing interests:**

I declare that I have no competing interests