Reviewer's report

Title: Can cancer patients assess the influence from pain on functions? A randomised, controlled study of the pain interference items in the Brief Pain Inventory.

Version: 1 Date: 19 September 2006

Reviewer: Karen Anderson

Reviewer's report:

General
This very interesting study investigates the construct validity of the pain interference items from the Brief Pain Inventory. Fifty-five adult cancer patients completed the original and a revised BPI on two study days. In the revised BPI, the patients were asked to rate general interference with function. With the exception of mood, no significant differences were found between the two sets of interference scores. The authors concluded that cancer patients may not be able to separate the contribution of pain to loss of function from the contribution of other factors.

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

The BPI was not designed to measure interference with health related quality of life. Thus, the first sentence in the second paragraph on page 3 should be changed. Health-related quality of life is generally considered a broader concept than pain-related interference in daily life. The BPI was designed to measure pain severity and pain-related interference with 7 areas of daily life (general activity, walking, work, mood, relations with other, enjoyment of life, sleep). Similarly, the first sentence in the last paragraph on page 3 indicates that the aim of the study was to evaluate if the BPI pain interference scores are related to pain-limited HRQOL. The authors do not seem to follow this aim. Rather, they investigated whether pain interference items are answered independently of decreased function due to other factors than pain.

The authors designed a modified version of the BPI. The instructions for the interference items on the modified version seem awkward, which may be due solely to the translation issues (“Circle the one number that describes how, during the last 24 hours, these functions are interferenced.”) We do not know how the modified instructions were interpreted by the patients. Did they really understand the intent of the instructions? It would have been helpful to do cognitive debriefing with some of the patients in order to understand how the patients interpreted these instructions and what thought processes they were using when they answered the questions. In spite of the new instructions, in the context of the BPI pain intensity items, the patients may have still been rating pain-related interference. The authors should at least address in the Discussion the issue of how the patients interpreted the instructions.

How many of the patients had to have their answers recorded by the research staff? Were there any differences in their BPI responses as compared to the patients who completed the questionnaires without assistance?

How were missing data handled?

The authors estimate the within subject standard deviation in BPI interference scores in order to make a sample size calculation. Do their data confirm this estimation as appropriate? The sample size is very small, and the cancer patients in the study cannot be considered representative of the larger cancer population. The authors should address in the Discussion the multiple factors that limit the generalizability of their findings. The differences between the original and revised BPI interference scores for walking, general activity, and the summed score approach statistical significance and might have been different with a larger sample size.

Twenty-six patients had higher summed interference scores on the modified BPI, and 19 had higher scores on the original BPI. Were these differences statistically significant?

In the second paragraph on page 9, the authors should indicate that mean pain ratings were generally low. Thus, many but not all of the patients did not suffer from severe pain. The BPI standard deviations,
however, indicate that some patients did suffer from moderate or severe pain. Thus, the conclusions in paragraph two are questionable. The results do not support “pain interference in patients without any major pain.” About 40% of the patients were taking analgesics that presumably helped to reduce their pain. In addition, some patients may limit their daily activities in order to avoid exacerbating their pain.

The last sentence in the second paragraph on page 10 is not clear. Again, the authors were investigating patients’ judgments of interference rather than quality of life.

The last sentence in the Discussion seems a bit premature as a conclusion, given the small sample size and the question of how the patients interpreted the revised BPI directions.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Line 3 in the abstract on page 2 should probably be “interference with functions…”

The first sentence of the last paragraph on page 4 should begin “The first part of the BPI measures…”

In the second paragraph on page 5, the phrase “notified in the questionnaires” should probably be “recorded in the questionnaires.”

The last sentence on page 5 is awkward. Perhaps “clinical difference of interest” would be clearer.

In the first sentence on page 8, statistical should be “statistically.”

“Clinical” should be “clinically” in the second-to-last sentence on page 9.

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Discretionary Revisions (which the author can choose to ignore)

How did the EORTC scores correlate with the BPI scores? It would be interesting to see how the different versions of the BPI correlate with quality of life scales.

The sample size is small, but it would be interesting to know if there were any gender differences in the two sets of BPI responses.

Were the patients naïve to the BPI or had they completed it prior to this study?

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

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

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests.