Author's response to reviews

Title: The Level of Recognition of Physical Symptoms in Patients with a Major Depression Episode in the Outpatient Psychiatric Practice in Puerto Rico. An Observational Study.

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Version: 5 Date: 13 May 2005

Author's response to reviews: see over
Dear Sir or Madam:

The purpose of this letter is to submit the revisions suggested by one of the reviewers of the article: “The Level of Recognition of Physical Symptoms in Patients with a Major Depression Episode in the Outpatient Psychiatric Practice in Puerto Rico. An Observational Study”.

These revisions were discussed and accepted by all the authors and they were included in the reviewed article. Each revision (in red) is preceded by the reviewer’s comments/questions (in blue) and the page and paragraph of the reviewed article where they can be found:

**Major Compulsory Revisions**

“If I understand the study method correctly, the psychiatrists recorded patients’ somatic symptoms from their own clinical evaluations, without having a checklist, and the patients responded to an actual checklist (the SSI). It is not surprising, therefore, that the number of somatic symptoms reported by the psychiatrists was far less than by the patients”.

The SSI is a 26-item questionnaire. In this inventory, the patients’ degree of discomfort for each symptom is rated from 1 to 5 (1=absent; 3= moderate; 5= a great deal). All the investigators received a structured training before the first patient visit. This training included a review of the protocol, the case report forms, and the SSI scale. With respect to the SSI, the psychiatrists were instructed to use the scale as a general reference during the patient interview and somatic symptom recording but not to follow the scale’s items or language literally because this could affect the patient’s spontaneous response to the self-administered SSI at the end of the visit.

[Page 9, 2nd Paragraph]
The marked difference between psychiatrists’ and patients’ somatic symptoms reports may be explained by the different methods used to document somatic symptoms and degree of discomfort caused by them, or may be due to a tendency by psychiatrists to dismiss certain type of pain or painless somatic symptoms in their usual clinical practice. This study was purposefully designed to avoid any intervention and allow for a naturalistic observation of usual clinical psychiatric care in Puerto Rico. The use of a structured symptom checklist for psychiatrists would not have been representative of the usual clinical practice and would not have allowed us to document the degree of recognition of somatic symptoms in MDE patients in this clinical setting.

[Page 21, 2nd Paragraph]

“However, one has to question the validity and significance of the somatic symptoms reported by the patients. The fact that 100% of the patients reported at least one somatic symptom certainly raises questions about these symptoms”.

As mentioned in the Methodology section, patient responses were used as points of reference for different comparisons. Somatic symptom SSI patient self-reports were correlated to psychiatrists’ somatic symptom reports, which the physician recorded during the patient interview by using the SSI as a general reference. All the patients included in the analysis reported at least one somatic symptom in the SSI.

[Page 13, last Paragraph]

In our study, a direct relationship between moderate to high degree of discomfort due to somatic symptoms and age, female gender and unemployment was also observed (Table 5). In this study of Puerto Rican patients with a MDE, 100% of patients reported somatic symptoms using the SSI scale. Although this percentage is very high, previous depression trials in primary care settings have also shown that 69% to 92% of MDE patients experience somatic symptoms. Somatization has been reported to be particularly more prevalent in Puerto Rican depressed patients than in other Hispanic populations. However, we cannot exclude the possibility that the use of an inventory such as SSI led to a higher number of somatic symptom reports than would have been spontaneously reported by patients. We could have avoided this potential bias by using a validated scale.
to collect information on somatic symptoms as a primary research tool. However, this would have precluded us from achieving the primary objective of our study.

[Page 19, last Paragraph]

**Minor Essential Revisions**

“It would be very helpful for the reader if table listing the somatic symptoms included on the SSI were available”.

We categorized total SSI scores as minimal (= \leq 52) and moderate to high (= \geq 52) according to the patients’ degree of somatic symptom discomfort. This post-hoc cutoff point was arbitrarily determined based on the high number (mean of 14) of reports by patients of somatic symptoms causing at least some degree of discomfort. Internal analysis supported this cutoff point to statistically differentiate between two groups of patients in terms of depression severity and other variables discussed below. We also conducted subscale analyses for both painless (SSI items 1, 4-8, 10-13,15-18, 20-26) and painful (SSI items 2,3,9,14,19) somatic symptoms (Table 4). Because the SSI that we used only included 5 painful somatic symptoms, limiting the options to detect any difference between the patients’ and physicians’ reports, we decided to ask the patients with painful symptoms to specify the location of their symptoms with the help of human silhouettes and to rate the impact of the treatments received on the magnitude of the pain using a Visual Analogue Scale (VAS).

[Page 9-10, last Paragraph; Table 4 at page 42]

“It is not clear what the authors mean by “individual emotional symptoms”.

Traditionally, diagnostic classification systems have focused on the emotional symptoms of a major depressive episode (MDE), such as depressed mood, markedly diminished interest or pleasure in almost all activities, and feelings of worthlessness, among others.

[Page 5, 2nd Paragraph]

The effects on the emotional and somatic symptoms of antidepressant therapy, as selected by the psychiatrists, were evaluated after the 8-week interval between the two study visits. The Clinical Global Impression – Severity (CGI-S) scale was used by the
psychiatrists to evaluate any changes in the severity of the MDE. Also, characteristic major depressive episode emotional symptoms such as depressed mood, guilt-related thoughts, feelings of worthlessness, anhedonia, psychomotor agitation or retardation, loss of concentration, anxiety, psychotic symptoms, and suicide behavior or thoughts, were each analyzed individually according to their clinically rated severity (1=absent; 3= moderate; 5= severe).

[Page 10, 2\textsuperscript{nd} Paragraph]

"The authors should explain the significance of the distinction between painful and not-painful symptoms, since this is referred to throughout the report”.

Studies conducted in primary care settings have shown significant association between major depression and painless somatic symptoms such as: vague and exaggerated multiple somatic complaints (usually more than three), fatigue, weakness, non-specific and painless musculoskeletal problems, sensations of heaviness or lightness in at least one part of the body, gastrointestinal dysfunction, shortness of breath, palpitations, dizziness, double vision, changes in sleep patterns and appetite, and polyuria. Similarly, significant association between major depression and painful somatic symptoms such as joint pains, lumbar pain and headache has also been reported.

[Page 5-6, last Paragraph]

Sincerely,

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