Author's response to reviews

Title: Validation of a questionnaire for assessing fecal impaction in the elderly: impact of cognitive impairment, and using a proxy

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Author's response to reviews: see over
We appreciate the reviewer’s comments. They remarkably contribute to improve the manuscript.

Reviewer's report
Title: Validation of a questionnaire for assessing fecal impaction in the elderly: impact of cognitive impairment, and using a proxy
Version: 3 Date: 23 November 2012
Reviewer: SoraiaTahan
Reviewer's report:

Validation of a questionnaire for assessing fecal impaction in the elderly: impact of cognitive impairment, an using a proxy
Barcelo M, Jimenez-Cebrian MJ, Diaz-Rubio M, Rocha AL, Rey E.

General considerations
The fecal impaction in the elderly is a clinical condition with great relevance, especially considering that this population is more vulnerable to complications. This study is interesting, because a new model of questionnaire for assessing fecal impaction in the elderly was created and validated by a methodological process. The study also showed that questionnaire proposed was adequate for collecting information on fecal impaction in the population studied and the limitations imposed by cognitive impairment present in the portion of the population to answer the questionnaire were minimized by using a proxy.

Specific considerations
The title is adequate, clearly describes the study.
The abstract summarizes the study properly.
The rationale of the study was clearly described in the background/introduction.
The aim of study was well defined.
The population studied was adequate to propose.
The methods utilized were chosen correctly considering the type of study and all the necessary steps for the development of the questionnaire and evaluate the practical applicability of the instrument were realized. The validation process was carried out with great care, including the analysis of reproducibility of the test and evaluation about agreement between the self-reported occurrence of fecal impaction and the medical records.

I have some questions:
Page 5, Paragraph 2:
Population and methods
Development of the Instrument. We developed a five question questionnaire to gather information about self-reported episodes of faecal impaction, their frequency and therapeutic actions to remove them (manual removal, retrograde lavage-enema and anterograde lavage-intensive laxative use), with a recall period of one year.
You described the objectives of the five questions set for the questionnaire (history of fecal impaction, frequency and methods of removal); however these five questions were not described. I believe that the full description of the questionnaire would be important for the reader to understand the formatting of each question, as the terms and language used.

Answer: we have added questionnaire as a supplementary file.
Analysis. Faecal impaction was defined as an accumulation of hard faeces in the rectum that the subject was unable to evacuate themselves, occurring at least once in the last year.

What reference was utilized to this definition?

Answer: Definition of Fecal Impaction is elusive, even in the best review published in the literature (Wrenn K. Fecal Impaction. N Engl HJ Med 1989 Sep7;321(10):658-62). Definition was recently reviewed by Creason and Sparks (Creason N, Sparks D. Fecal impaction: a review. NursDiag. 2000 Jan-Mar;11(1):15-23) and among those definitions provided by the literature, we chose the more restrictive and, according to the first part of the design of the questionnaire, it was felt appropriate by gastroenterologists and nursing homes’ doctors.

We added a paragraph in the paper explaining the definition we used, according to the reviewer’ comment

Another question is: Which was the basis to choose the recall period of one year? The period of one year may be considered too long for the memory of an elderly person.

Answer: One year recall period makes easier to find a simple temporal reference (since last winter, last summer,…) by anyone. In addition, previous studies have shown that recall time of one year yields the same results as three months for bowel symptoms (Rey et al. Measurement of abdominal symptoms by validated questionnaire: a 3-month recall timeframe as recommended by Rome III is not superior to a 1-year recall timeframe. Aliment pharmacoTher 2010 Jun;31(11):1237-47). Moreover, one year recall period is more appropriate in case that identification of recurrent fecal impaction would be of interest (for research or clinical purposes). The concurrent validation with diagnosis in clinical records support a reasonable accurate recall

Furthermore, the discrimination of the period of occurrence of the fecal impaction may contribute to clinical interpretations. For example, the information that a fecal impaction occurred in a recent period may indicate constipation not controlled.

The results answered the objectives of the study. Thus, the description of the results focused the questionnaire development and features of validation, reproducibility and concurrent validity. Although the prevalence of fecal impaction in the study population was not the primary objective of the study, my suggestion is that this result deserves to be described in a similar format to other items, also highlighted. I think also that prevalence of fecal impaction must be included in the abstract.

Answer: This is the prevalence in one single nursing home, which may not be representative of the whole population of nursing homes’ residents. This study was a preparatory study of a nation-wide survey, which provides a more
accurate figure. For that reason, we do not consider that finding a relevant result.

The text is as follows (Page 9, paragraph 20):
Among those with faecal impaction (N=11), simple agreement was 54.5% for frequency, 81.8% for manual removal, 54.5% for retrograde lavage, and 45.5% for anterograde lavage.

Suggestion:
Fecal impaction: occurrence of fecal impaction was X % (11/X). Among those with fecal impaction (N=11/X), simple agreement was 54.5% for frequency, 81.8% for manual removal, 54.5% for retrograde lavage, and 45.5% for anterograde lavage.
The text described that “Among those with faecal impaction (N=11)”, but was not clear what was the total utilized for this evaluation (N=11/?). The authors did not describe the number of medical records that were adequate to realize the agreement analysis.

Answer: All medical records were suitable for the study purposes.

In the table 3 (page 19), the authors did not describe the number of questionnaire and medical records and the number of agreement and disagreement for each variable studied. In the last line of table 3 (about use the proxy), the somabetween those that used a proxy (140) and those that did not used the proxy (19) is 159, but IS described in the validation of results (last paragraph of page 8) thatone hundred and sixty (80.4%) subjects completed the questionnaire... But, the authors did not describe the number of medical records that were adequate to realize the agreement analysis.

Answer: Following the reviewer comment, we reviewed table 3 and there is a mistake in the number of subject who use a proxy among disagreement (N=20); we also corrected the percentage of females among disagreement; other results are correct. All records were available for the analysis; we included the number of subjects with agreement and disagreement in the identification of fecal impaction (self-reported questionnaire and medical records) in the table to state it.

Discussion: The principal points of the study were discussed, including your limitations. There is none discussion about the prevalence of fecal impaction found in the study, and I think that this result deserves to be discussed, considering that are few studies realized with this specific population.

The references chosen were appropriate to the theme; however there are some interesting recent articles that may be included in the study. Some suggestions are listed below.

One cross-sectional study realized in USA with 33,413 patients 65 years from 2004 National Nursing Home (NNHS) evaluated the prevalence of undertreatment of nonpain symptoms and factors associated. Nearly half of patients were aged 85 years. Constipation/fecal impaction occurred in 8.8% of patients and were one of the most common nonpain symptoms (Rodriguez KL etal, 2010).

This study may be added in the background/introduction/discussion.


In this descriptive multicenter cross-sectional study, also realized in Spain, the objectives were to establish screening criteria for constipation, to determine data for diagnostic suspicion of constipation and to investigate the incidence of fecal impaction in palliative care patients (debilitated oncology patients with an average age of 70, the majority received opiates and also laxatives). A questionnaire with signs and symptoms of constipation and a verbal numerical scale (VNS, 0-10) about “discomfort or difficulty with constipation” was added with the purpose of finding a simple way to screen for constipation. The patients were asked about fecal impaction in the last 3 months. One hundred twenty patients completed the study. A diagnosis of suspicion of constipation was established in 48% of patients. VNS with cutoff point of 3 or more of 10, showed a sensitivity of 0.70 and specificity of 0.74 and positive predictive value (PPV) of 73% positive and negative predictive value of 70%. A number of 20% of the palliative patients studied reported episodes of fecal impaction in the last 3 months.

I think that this study may be added on discussion.


This retrospective study evaluated the medical records (clinical outcome and complications) of 130 patients, with mean age of 67.1 years, who were attended with fecal impaction in a tertiary medical center in Beirut, Lebanon. Patients with more than 80 years of age, or patients with heart or neurological disease presented higher risk of developing complications.

This study may be added in the background/introduction.

Answer: We appreciate the comment and reviewed the three suggested articles, and added to the background as suggested.

See the correct form to describe the reference 10.

Reference 10.


Suggestion:

Answer: Thanks for the comment. We have been corrected it in the revised manuscript.
Reviewer's report
Title: Validation of a questionnaire for assessing fecal impaction in the elderly: impact of cognitive impairment, and using a proxy
Version: 3 Date: 12 October 2012
Reviewer: MARIA NABAL
Reviewer's report:
General comments:
This paper is interesting and will offer a good methodological approach to a difficult problem. The question posed by the authors is well defined. Methods are appropriate and well described. The manuscript achieves the standards for reporting and data deposition. The English is adequate.

Major Compulsory Revisions:

1. Abstract should be revised because the “method” chapter does not reflect the methodology developed and it does not allow a good understanding of the research. The “results” chapter does not offer any result about the tool developing process.

Answer: We have revised the abstract, and we have modified it according to your suggestions.

2. From my point of view, Background is a bit short and could be completed with references to the assessment tools development and validation in elderly. It could be interesting to discuss about changes in faecal impaction treatment by having this new tool.

Answer: The questionnaire is not intended to monitor treatment of fecal impaction. The main objective is to develop a self-reported tool able to identify fecal impaction, for either research or screening purposes. Changes in fecal management will follow a better identification of cases.

3. “Results” chapter does not include the 5 questions questionnaire. It does not offer any data from the gastroenterologist and nursing home doctors suggestions.

Answer: We have included the questionnaire as a supplementary file. We have attached the questionnaire in English and Spanish, although the English version is not validated.
Suggestions from gastroenterologists and nursing homes’ doctors lead to minor changes of the draft questionnaire, all of them focused on grammatical issues.

4. “Discussion” chapter does not include the limitations of the study, or possible sources of bias. There is no comment on the medical and nursing records as a gold standard to assess the concurrent validity. Authors do not discuss the real utility of the questionnaire and the improvements that could be achieved by using it. There are few references to other similar publications.
Answer: Regarding the selection of the gold standard there is no objective gold standard accepted and is the medical diagnosis is the best option in our opinion.
Regarding the real value of the questionnaire, our aim is to develop a tool for research in population, such as screening questionnaire in clinical populations.

5. Bibliography offers only 3 authors. In cite number 10, authors are missed (Dewey, Micheal E; Parker, Christine J.)

Answer: We have indeed made a mistake in this bibliographic citation, which has already been corrected in the revised version of the article

**Level of interest:** An article whose findings are important to those with closely related research interests  
**Quality of written English:** Acceptable  
**Statistical review:** No, the manuscript does not need to be seen by a statistician.