Author's response to reviews

Title:Is the state of health of rheumatoid arthritis patients receiving adequate treatment, predictable? - Results of a survey

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Version:3 Date:5 November 2014

Author's response to reviews: see over
Author’s response to reviews

Title: Rheumatoid arthritis patients are not in a position to plan their near future – results of a survey

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Version 2 Date:

Authors’ responses to reviews: see over
Reviewer's report

Title: Rheumatoid Arthritis patients are not in a position to plan their near future. Intra-subject correlation in personal assessment of health levels over two months - Results of a survey

Version: 2 Date: 23 June 2014

Reviewer: Lindsay Bearne

Reviewer's report:

Thank you for asking me to review this manuscript which represents a considerable amount of work by the research team. There are a number of issues which the authors should address to improve the manuscript.

Title

This may benefit from being more succinct and representative of the primary research question

The title of the manuscript has been changed as the reviewer suggests.

Is the state of health of rheumatoid arthritis patients receiving adequate treatment, predictable?

Results of a survey

Abstract

The abstract would be enhanced by including more detail of the study methods and key results.

Try to avoid using vague (and possibly inaccurate terminology) e.g. p3 line 4 'holds true', line 7 'roughly')

Done

We have revised our abstract and include more details:

Abstract

A survey was conducted to evaluate whether a steady improvement in the quality of life of Rheumatoid Arthritis (RA) patients as frequently reported in clinical studies, does actually occur. The focus of this study lay on the personal perception of these patients. How do patients with RA who have been treated along accepted guidelines see the state of their health and their joint pain at different points in time?
Methods: Rheumatoid Arthritis patients were asked to complete a questionnaire and return it to an opinion research centre. The questionnaire, which was developed by the authors, was divided into the areas: demography, symptom description and medical care, as well as the illness in a personal context. Three telephone interviews followed at monthly intervals when the patients’ feelings about their illness, their every-day coping mechanisms and their social lives were rated. Intra-subject correlation and the level of agreement among patients when assessed at three different points in time within a two month period, was determined.

Results: One hundred and twenty-seven patients replied to the questionnaire. RA exerts a significant impact on an RA patient’s daily life. Average ratings of current state of health and joint pain (answered on a 5-part scale extending from 1 (very good) to 5 (very bad)) range from 2.6 to 2.9 all three times. However, intra-subject correlation among the different points in time, is in general, quite modest. Concerning the question, “How is your joint pain today?” only 14 of 127 participants express identical ratings all three times. In 40 of the participants, there is even a difference of two digits on the 5-part scale, at least twice. The intra-class correlation coefficient (ICC) among answers at different times is often much lower than 0.5.

Conclusion: On an individual level, personal assessment of health, well-being and joint pain, and also of quality of life are nevertheless unsteady even within a time frame of two months. This is why, even now, RA patients cannot plan their lives as non-affected people can.

Background

P4 Line 18. Could the authors substantiate the claim that combined PROs are not ‘generally accepted’.

The sentence has been changed in the manuscript and now appears as follows:

(quotation of Prof. E. Grominca-Ihle: Treat-to-target from the patient perspective. Z Rheumatol 2011;70:678–684 [12]

Until now, no combined patient reported outcome (PRO) score exists which is generally accepted for monitoring rheumatoid arthritis exclusively, and which focuses on the perspective of the patient as the primary outcome value [12, 14]. Composite indexes, primarily focusing on the opinions of physicians are still applied in RA assessment.

P5 line 3 - This is an enormous list of research questions and the research (and the manuscript) would be improved if it is focussed on a primary research question. Some of the questions stated are more novel and interesting than others and you should be guided by the existing literature when choosing your primary research question.
As stated, it makes it difficult for the reader to determine exactly what the aim of the research is.

**We shortened and rewrote this paragraph:**

The primary research question of the study was: How do patients with RA who have been treated along accepted guidelines [19, 20] see the state of their health, their joint pain and accordingly their well-being at different points in time. Respectively, what is the intra-subject correlation in quality of life assessment when measured at different times?

**Methods**

A justification needs to be provided of how the proposed methodology answers the research question(s) e.g. why were interviews chosen at these intervals - would a longer duration of the study yield more pertinent results.

A clear case needs to be made for NOT using valid and reliable outcomes to answer your research question- particularly those which are widely used such as Pain visual analogue scales, RA QoL (quality of life) etc.

What are the psychometric properties of the questionnaire developed?

Please state the validation process and provide some details of the reliability of this questionnaire. If the questionnaire has not been rigorously tested prior to the study the results are likely to be unreliable.

**We added the following paragraph in the methods section as the reviewer suggests.**

*We have discussed this limitation before: please see also the discussion section (P13 L18 – P14L8): Another shortcoming of the study...*)

After having formulated our research questions, a topic guide akin to an interview schedule was developed by the authors. The authors (most of them board members of the Austrian Society of Rheumatology) intentionally did not use any of the existing tools as they did not fit our research question, but agreed to create a new questionnaire using the Delphi approach for validation. A pilot interview with volunteer participants was performed, ensuring that all of the interview questions were relevant and appropriate.

P7 line 3 - details of the interview schedule and development of the topic guide should be provided in the methods section.

**We changed the details of the interview schedule in the methods section.**

Justify the sampling for the interviews (why not interview a sub sample in detail and analyse thematically?)
We added this sentence to the methods section as the reviewer suggests.

A nationwide sample was found to be more representative for this research question.

We added this paragraph to the results section.

The sample includes patients from the whole of Austria with a particular emphasis on Lower Austria, Upper Austria and Tyrol. These three federal provinces are very similar with respect to their history and their socio-economic status compared to the other six provinces of Austria, but do display minor topographical differences, the Tyrol being more mountainous.

Data analysis - P3 this should include how you analysed the qualitative data

We added the following sentences to the methods section:

Qualitative data of baseline characteristics was analysed descriptively, using counts and frequencies.

Confidence intervals for qualitative data were obtained using the bootstrapping method, based on 10,000 replications.

Further details, e.g. for Cochran’s Q or Cohen’s Kappa, are already included in the last two paragraphs of the method section.

Results and discussion

These sections need to be separated so that just the results are presented initially and then discussed in a separate section.

Done!

Results should be presented clearly and with as much detail as possible e.g. some measure of variability included (P9 line 12 - mean 95% confidence interval?)

Including measures of variability is a good suggestion. We included standard deviations and 95% confidence intervals in Table 2 and the text, as appropriate.

Details of the questions asked at interview need to go in the methods section and justification of measurement scales given

Done!

The format used for answers was chosen to make it as easy and straightforward as possible for the patient: Yes/no answers if possible, or an answer on the Likert Scale with five ordered response levels. This was manageable for the patient but also included enough gradation to implement analysis.
For the discussion section - this section should be used to discuss your results in relation to the existing literature and clinical practice however, justify all statements - please see p11 line 9.

*We would like to leave this part in the results section as it just describes a result of Q6. Due to the fact that it could be seen as an interpretation, we deleted the second sentence.*

Level of interest: An article of limited interest
Quality of written English: Not suitable for publication unless extensively edited

*After revision, the manuscript was edited by a native speaker.*
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:
I declare I have no competing interests
Reviewer's report

Title: Rheumatoid Arthritis patients are not in a position to plan their near future. Intra-subject correlation in personal assessment of health levels over two month - Results of a survey

Version: 2 Date: 29 September 2014

Reviewer: Ana-Maria Orbai

Reviewer’s report:

This is an interesting paper which involves quite some time commitment from the part of the patient participants and the investigators. Conclusions have potentially important implications.

Major Compulsory Revisions

1. Please provide a subgroup analysis for anti-TNF users (only 28% of your sample) and non-users (72% of your sample)

   We analysed the subgroup of those patients receiving biologics and those not receiving biologics, as requested. However, we did not find relevant differences between the two groups. The methods and results sections have been expanded accordingly and a new table has been inserted.

2. I am concerned some of your respondents had no variation in their responses at all 3 time points (figure 1: 28 out of 129 there was no variation; figure 2: 16 out of 129 had no variation) while others had great variation between the 3 time points - and this is just on the 2 questions presented. Is there more granularity to these data before we average and generalize? I suggest more subgroup analyses in addition to the above: please consider analysis by sex groups and by disease duration and others you may see fit. This will be very helpful for the final interpretation and discussion.

   We stratified also according to sex and disease duration and analysed the resulting subgroups. Again, we did not find relevant differences. Results are displayed in Table 4.

3. Methods: Please specify which ICC type was used/ calculation method for the ordinal data.

   We specified in the methods section and also in the footnote of table 3 that the ICC was calculated for one-way, random single measures (i.e. type (1,1)).

4. Results and Discussion. Results of the questionnaire: please specify from how many sites in Austria the 127 patients come from, how many academic, how many community and how many patients per each site.

   Please also see reviewer 1.
The sample includes patients from the whole of Austria with a particular emphasis on Lower Austria (57 patients, 45%), Upper Austria (31 patients, 24%) and Tyrol (25 patients, 20%). 14 patients (12%) come from other provinces. These three federal provinces are very similar with respect to their history and their socio-economic status compared to the other six provinces of Austria, but do display minor topographical differences, the Tyrol being more mountainous.

Level of education: 68 patients (54%) had completed compulsory education; 28 (22%) education to certificate level and 25 (20%) education to college/university level. 5 (4%) did not answer the question.

Size of community: 80 (63%) of the patients live in communities of under 5,000 inhabitants; a further 23(18%) in communities of under 50,000 inhabitants; 21(17%) in communities of over 50,000 inhabitants and 3(2%) did not answer the question.

5. How was RA diagnosed?

*We added the following paragraph in the methods section at the reviewer`s request.*

All of them fulfilled the 1987 American College of Rheumatology classification criteria.

6. Could you please provide any validity and reliability data in people with RA for the questionnaire used?

*We added the following paragraph in the methods section as the reviewer requests.*

*We have discussed this limitation: please see also in the discussion section (P13 L18 – P14L8): Another shortcoming of the study…) see also reviewer 1.*

After having formulated our research questions, a topic guide akin to an interview schedule was developed by the authors. The authors (most of them board members of the Austrian society of rheumatology) intentionally did not use one of the existing tools, as they did not fit our research question, but agreed to create a new questionnaire, based on existing validated generic tools from the field of motivation research. Subsequently a Delphi approach was applied for validation and pilot interviews with volunteer participants were performed, ensuring that all of the interview questions were relevant and appropriate.

Minor Essential Revisions

7. Table 1: suggest to replace "First occurrence of RA symptoms" with Disease duration calculations.

*Done!*

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests.

Editorial Requirements:
1. Please reformat the Reference section was reformatted.
   Done!
2. Please remove the suffixes in the Author's contribution section.
   Done!
3. Tables need formatting to remove footer and provide titles.
   Done!

Highlight: Please highlight (with 'tracked changes'/coloured/underlines/highlighted text) all changes made when revising the manuscript to make it easier for the Editors to give you a prompt decision on your manuscript.
   Done!

(Editorial requirements were not highlighted, in order to avoid confusion.)

Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals). It is important that your files are correctly formatted.

Done!