Author’s response to reviews

Title: Second opinion for degenerative spinal conditions: an option or a necessity? A prospective observational study

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Author’s response to reviews:

James Mockridge, PhD
Editor, BMC Musculoskeletal Disorders
https://bmcmusculoskeletdisord.biomedcentral.com/

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Dear Dr Mockridge,

Re: Second opinion for degenerative spinal conditions: an option or a necessity? A prospective observational study" (BMSD-D-16-00415R1)
Thanks for your email informing us about the decision regarding our manuscript and reasons for the long delay. We note that Reviewer 2 has indicated that we had adequately addressed questions and made appropriate revisions.

We have responded to the additional comments of the new Reviewer (Reviewer 4) below noting that Reviewer 4 also acknowledged our work stating ‘it is a very interesting topic and original comparison! The results of the present research give a contribute to the current knowledge of back pain.’ We have made changes to the manuscript based upon these comments and we look forward to hearing from you in due course.

Yours sincerely,

Mario Ferretti on behalf of all authors

Response to Reviewer 4:

METHODS:

The statistical tests used are not clearly stated. You refer to descriptive statistics but you don't specify which kind of tests

Response: Descriptive statistics were the method that we used to quantitatively describe and summarise the descriptive comparisons between the community and hospital-based spine surgeons for diagnosis and management. We have added (N, %) after descriptive statistics in the text to clarify this further.

I don't see a typical table 1 with demographic characteristic of the sample.

Response: The only demographic information for participants was for age and sex, with only sex available for those refusing participation. This has now been added to the results as text as follows:
‘There were no sex differences between those who participated and those who refused participation (i.e. proportions of males refusing (46.5%) or participating (46.2%)). The mean age (standard deviation) of participants was 43.9 (11.3) years.’

How did you compare the different opinion of experts? Did you find any agreement? I think that reporting the level of agreement would be more interesting than only rates of patients with the same opinion.

Response: The Materials and Methods section describe in detail how diagnosis and management decisions were made. All participants had been referred for a second opinion following a recommendation for surgery by a spine surgeon not affiliated with HIAE (p 5, lines 21-23). The diagnosis of the community surgeon was recorded at the initial interview with a senior nurse (p 6, lines 20 -21). The process of assessment for diagnosis and management at HIAE is described from p 7, line 17 to p 8, line 8. Tables 1 & 2 show both the agreement and disagreement between decisions.

The MCID you defined for pain at VAS, was decided on which basis? Please add a reference or justify your decision clearly.

Response: We have altered the text to

‘For our primary outcome of pain we used the accepted minimal clinically important difference for pain (VAS of 1.5 units on an 11-point scale (0 to 10))’ and included the following two references:


In the table you report a p value, but it is not clear to which statistical test it comes from.
Response: The p-values in Table 3 were obtained from linear regression as described on p 10, lines 13-15. An explanation has now also been added below the table.

You didn't define if the sample showed a normal distribution and if you used parametric or non parametric tests. The methods section can be used by other authors to replicate the same study, so you have to give more details.

Response: There was little evidence of departure from normality for most outcome measures. The assumption of normality is not critical for large samples, such as this, unless there are extreme deviations. The central limit theorem offers protection but there could be some loss of statistical efficiency that is unlikely to influence the conclusions.

RESULTS

I think that the selection process illustrated in figure 1 pertains to the methods section rather than to the results one.


For the treatment outcome, I suggest to clearly define the outcome measures and then report the rate of subjects who reached the outcome, reporting only numbers is a limit.

Response: The outcome measures are defined in the Materials and Methods section (p7, lines 3-17). We have added a statement about the number of patients treated at HIAE who had a reduction in pain scores >1.5 as requested as follows:

‘Post-hoc analysis requested by a manuscript reviewer found that 46 patients (80.7%) in the surgery group and 50 (64.9%) in the CM group showed a reduction in pain VAS greater than 1.5 units ($\chi^2$ p-value=0.045).’
I also suggest to summarize more the results. I mean the numbers are listed in the tables and graphs please use few sentences which clearly describes your findings. It's very hard to focus on the main results for the reader, and considering the clinical impact that such study could have I think it is fundamental that all the readers have a clear idea of what you have found.

Response: We did not make detailed comments on the outcome variables because none showed significant differences between the two management groups and it is not usual to repeat in the text information that can be found in the tables.

DISCUSSION

The discussion should be organized a little better, with a general comment on the results, some comments on the interpretation and on previously published paper and then source of bias and limitation of the study. From line 8 you discuss about the limitation of the study, but in reality you are referring to source of biases, which is much more related to results interpretation and cautions.

Response: We feel we have all these elements in the order indicated. Biases are limitations and we have discussed these in relation to the interpretation of the results.

The limitation of the study includes the sample size, the large disagreement you found and the difficulties related to measuring pain. (did you consider pain a continuous variable ? and Disability ?

Response: We have acknowledged that we have follow-up data only for patients treated at HIAE i.e., on less than half of the initial participants and that there may be systematic differences between those treated at HIAE and by their community surgeon.

The primary aim of the paper was to determine whether or not there were differences between community surgeons and private hospital surgeons so the ‘large disagreement’ we found was the primary result of the study and not a limitation.

We had no difficulties in measuring pain. Pain was measured using a standard well-validated tool (VAS). Disability was assessed with the Roland Morris Questionnaire and the Oswestry Disability Index. In line with usual practice, these were treated as continuous variables.
Did you have an idea of the costs of second opinion and surgeons board evaluation? It would be interesting to add a cost analysis.

Response: We agree but did not perform an economic analysis.

I strongly encourage the authors to reorganize the article to make it suitable for publication.

Response: Our paper including its organisation conforms to the reporting of observational studies as per STROBE and the guidelines of the journal.