Author's response to reviews

Title: Visually assessed severity of lumbar spinal canal stenosis is paradoxically associated with leg pain and objective walking ability

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Version: 2
Date: 27 June 2014

Author's response to reviews: see over
Dear editor Tim Shipley

cc: Ms. Ma. Luz de Guzman

Manuscript: 1873630550991257

Title: Visually assessed severity of lumbar spinal canal stenosis is paradoxically associated with leg pain and objective walking ability

Authors: Pekka Kuittinen and colleagues

We are grateful for the encouraging comments and constructive criticism of the Editor and the Reviewers concerning our research article. We have read the comments and have revised our manuscript accordingly. Our detailed response to the comments is enclosed on the following pages. We hope that the resulting revised manuscript adequately addresses all the points noted by the reviewers, and that it is now ready for publication in the BMC Musculoskeletal Disorders.

Yours sincerely,

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Reviewers’ comments with responses

Referee: 1

1. Inclusion criteria: Were patients required to have low back and lower extremity pain, or were patients with just back pain included?

We thank for this important annotation.

Patients were required to have severe back, buttock, and/or lower extremity pain. Patients with just back pain were not included. Patients required to have had neurogenic claudication also.

We added this important information to the material and methods section (page 5).

2. Was there a standard for the imaging for inclusion?

Thank you for pointing out this aspect.

After inclusion, all patients were imaged prospectively with the same study protocol for study purposes. The imaging protocol conformed to the requirements of the American College of Radiology for the performance of MRI of the adult spine. The details of sequences are shown in the methods section. Briefly, imaging included T1 and T2-weighted images in the sagittal and transversal orientation. Sagittal images covered neural foramina and transverse images were obtained from the inferior aspect of L1 to the inferior aspect of S1 (page 5-6).

3. Is a previous spine surgery not a confounding variable?

Thank you.

Previous spine surgery was not used as adjusting variable in the analysis. It has been reported to have no effect on functional outcome by authors (Aalto et al. 2012, Scand J Surg).

4. Where did the method for visual analysis come from? Is it a recognized/published reliable method? If not reliability analysis should be conducted.

Thank you for this annotation.

Reliability of a qualitative grading of lumbar spinal stenosis has been described and evaluated previously and it has shown to have substantial intraobserver and moderate interobserver agreement in multicenter study setting (Constantin et al, SPINE Volume 35, Number 21, pp 1919–1924). In the original method 7-grade classification has been used. We have recently extended the method in the assessment of lateral stenosis using 3-grade classification which has demonstrated to have acceptable repeatability for research purposes (Sipola et al. Acta Radiol. 2011 Nov 1;52(9):1024-31).

We have now added to the discussion these information/comments (page 11).
5. You did not indicate specifically where on each image the quantitative measurements were taken. Please include.

Thank you.

Each level from the inferior aspect of L1 to the inferior aspect of S1 was analyzed separately. In quantitative image evaluation each level was first assessed visually. Of the image with visually smallest cross-sectional area of the dural borders of dural sac were manually traced (page 6).

6. Where did the cut points for the VAS and ODI come from? Are these published?

Thank you for this annotation.

In statistical analyses we used continuous outcome measures (ODI, VAS, LBP, LP, BDI and walking distance). We represent categorized ODI, VAS and BDI data to explore patients symptoms better. Four scale ODI cut points come from paper JM Fairbank. The Oswestry Low Back Pain Questionnaire. Physiotherapy 1980; 66: 271-273.

7. Was the treadmill test validated for use with LSS patients?

Thank you for this annotation.

No. When we started to plan this study, treadmill test was rarely used in LSS studies as an objective method for walking ability. Our method was based on clinical experience of Kuopio University Hospital, where LSS studies have been done since 1980’s.

8. Why did you choose a ramped protocol? Ramped protocols are meant to test cardiovascular fitness and not walking capacity.

Thank you. Please, see answer number 9.

9. A self-selected speed is much more appropriate for this population given that speeds of 0.67m/s -1m/s may be too slow (or too fast) for some participants. Why did you select these speeds?

Thank you for this annotation.

Older patients might have difficulties to start with 1 m/s speed. If the patient was not able to start with a speed of 0.67 m/s, another test with a starting speed of 0.5 m/s was applied. Slower walking starting speed allows older patients to perform adequately.

We did not select self-selected speed because, this could give us diverse results and comparing results could be more difficult. Because of practical timetable reasons we had to limit walking time to 20 minutes, which we consider as adequate time to test objective walking ability and neurogenic claudication.
10. The first paragraph of the discussion requires some clarification. Please indicate which type of assessment (visual or quantitative) was used to obtain the stated results.

Thank you for this annotation.

We have now added information to the discussion (page 9).

11. Table 1. You compare results of moderate and severe stenosis as assessed visually. If the method for visual assessment is flawed or unreliable then these results are also flawed and unreliable.

Thank you for this annotation.

Reliability of a qualitative grading of lumbar spinal stenosis has been described and evaluated previously and it has shown to have substantial intraobserver and moderate interobserver agreement in multicenter study setting (Constantin et al, SPINE Volume 35, Number 21, pp 1919–1924). In the original method 7-grade classification has been used. We have recently extended the method in the assessment of lateral stenosis using 3-grade classification which has demonstrated to have acceptable repeatability for research purposes (Sipola et all. Acta Radiol. 2011 Nov 1;52(9):1024-31). Based on the previous validation, we suggest visual evaluation as reliable.

12. The most important results of this study are the correlations between outcomes and the objectively measured canal. Please highlight these results. They are much more powerful than a comparison of two groups created through visual assessment.

Thank you.

The correlation of radiological spinal stenosis and clinical symptoms is summarized in Table 1. In the visual classification of the central spinal canal, the leg pain was significantly higher and walking distance was lower in patients with moderate central stenosis than in patients with severe central stenosis (7.33 ± 2.29 vs 5.80 ± 2.72; P = 0.008 and 421 m ± 431 vs 646 m ± 436; P = 0.021, respectively). Patients with severe stenosis in only one level had also shorter walking distance than patients with severe stenosis in at least two levels.

No correlation between quantitatively assessed stenosis and clinical findings was found (table 2).

We did not find any correlation between objective quantitative radiological findings and patient symptoms which support also this paradoxical visual finding.
- Minor Essential Revisions

1. Spelling of central in Table 2. (spelled Sentral)

- Discretionary Revisions

Thank you for carefully pointing out this misspelling.

We corrected this.

1. In the introduction you state that most previous studies on this topic have had major methodological errors. I do not believe this is the case. The issue is more that the relationship you are investigating remains unclear. I suggest re-wording the 2nd paragraph in the introduction to reflect this.

We thank for the comment: We have now reworded the 2nd paragraph of the introduction.

2. Recent research suggests that measurement of provoked pain is more appropriate in LSS patients. Is it possible that if you had measured provoked pain a more clear relationship would have emerged?

Thank you.

In the leg pain, we used “leg pain at walking”. We agree that this is important point to consider in outcome measures.

3. It is apparent from this study and previous studies that we need a standardized method for visual assessment of LSS. Consider discussing the future of this endeavour.

Thank you for this important aspect.

We have added this point to the discussion (page 11).

4. Did you control for BMI? The average BMI is almost 30 which is considered obese. Do you think this had an effect on your results?

Thank you for this annotation.

Yes, the BMI was based on measured weight and height done by physiotherapist. The BMI (cut-off 30) did not effect on two-year outcome (Aalto et al. 2012 Scand J Surg).
- Needs some language corrections before being published (I would suggest consulting an editor given that there are numerous grammatical, spelling, and syntax errors. I was able to understand the writing, but more work is definitely required to produce a polished English language manuscript.)

Thank you, we have now done language editing.
Reviewer's report:

Kuittinen and colleagues studied associations between quantitative radiological measures and clinical findings in patients with LSS. They found no clear association between imaging findings and patient symptoms or functional restrictions. This research question is not new, and the fact that anatomical features of LSS are often not correlated with clinical findings is widely accepted. However, as the authors rightly point out, previous studies on the subject were often methodologically flawed. I therefore believe this prospective study adds important information and is worth being published.

I have only a few comments and suggestions the authors may wish to consider.

Minor essential revisions

1) The paper has clearly been written by non-native English speaking authors. There are minor grammatical and typographical errors throughout the manuscript, and I would recommend the manuscript to be reviewed by a native speaking person.

Thank you, we have now done language editing.

2) Results section: I prefer a more consistent reporting of quantitative measures in the text. For example, the age distribution is given as mean and range, while standard deviations are reported elsewhere.

Thank you.

Age distribution is changed to standard deviation, most of measures are reported in standard deviations and some also in range which in our opinion complete data reporting.
3) Discussion: This is somewhat repetitive. For example, the statement “...that LSS is not solely an anatomical disorder but the disease may have also other pathobiological mechanisms to be discovered” can be found in two places. The discussion could also be structured more clearly. For example, I could not locate the description of the weaknesses and strengths of the study. An introductory sentence at the beginning of each paragraph would help readers navigate through the paper.

Thank you for this annotation.

Discussion is now rewritten as suggested.

Discretionary revisions

4) Figures 2 and 3 could be better represented by box plots rather than mean and SD alone.

Thank you for this annotation.

We would still like to prefer original Figures.

Level of interest:

An article of importance in its field

Quality of written English:

Needs some language corrections before being published

Thank you, we have now done language editing.

Statistical review:

No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests