Reviewer's report

Title: Lifestyle and metabolic factors in relation to shoulder pain and rotator cuff tendinitis: A population-based study

Version: 2 Date: 15 April 2010

Reviewer: Kurt T Hegmann

Reviewer's report:

* Major Compulsory Revisions

1. The data need to be reported with univariate analyses. Without these, there cannot be reasonable assurances that the multivariate models were appropriately constructed from a statistical standpoint. If on the other hand, the variables were forced into the model without regard to statistical considerations, this is not wholly unsupportable, but needs to be stated as such and the univariate results should still be reported.

2. There may be other issues that are major compulsory revisions depending on the univariate results.

3) Definitions of disease and exposures are not always as clear as they might be. This could impact the interpretation of the results and discussion.

Overall, the authors report on important issues in an under-researched area that has considerable morbidity. In this reviewer's opinion, the research findings appear likely to merit publication after several issues are resolved.

* Minor Essential Revisions

1. It is suggested the results and discussion need a bit better structuring. Until seeing the results of the univariate analyses, it is difficult to provide specific recommendations throughout, although some are able to be provided.

2. Abstract: The fact a diagnosis was made clinically is a bit worrisome to this reader if there was no structured approach to making the diagnosis, as a lot of subjectivity can be incorporated. As the methods in the text do not make this clear, it is difficult to suggest a solution. If the diagnosis was purely unstructured clinical examinations, then it is recommended this should be discussed in a new paragraph that either way it is suggested is needed in the discussion on 'limitations.'

3. This reviewer believes these estimates of shoulder pain and RC tendinosis are low, thus I would seek additional language in the discussion for why that is the case. (FYI, our cross sectional analyses of approx 800 at baseline were 22-25% glenohumeral shoulder pain and 8.6-10.7% RC tendinosis at baseline depending on the side examined).

4. Abstract: This reviewer’s reaction at this point is also that there are differences between the various purported associated factors, yet there is no cogent reason to expect this. (The later discussion section does not well address these
concerns.)

5. Abstract: While I don’t dispute the last sentence as potentially true, the lack of positive findings throughout the results table for CV risks is a concerning. It would seem quite a bit more research is needed before being able to clearly support this view, the discussion section does not address this concern, and it is suggested this sentence be eliminated.

6. Methods. It is recommended the study design be specified. Presumably it is cross sectional (noted 1x in the discussion section).

7. Methods: The methods for sampling are not very clear and another couple sentences are recommended to better explain the 2-stage sampling process so the reader knows how the population was constructed. Are people in Finland assigned to one hospital? If so, that also should be specified as it is important to understand the design and sampling.

8. Methods: Figure 1. It is nice to have a flow chart. It is suggested there be side boxes to both account for the dropouts at each step, as well as to note the reasons for those dropouts.

9. Methods: There are some questions that arise based on para 2. How can only 93 people have RA? This sounds like incomplete data to this reviewer (or are the Finns protected genetically from RA?). Missing shoulder disorder information is mildly concerning especially when added to the prior RA issue as presumably these were structured interviews (?) The term “qualified subjects” presumably means people included in the study (?)

10. It is unclear throughout this document what is included in “shoulder” pain. Was a figure used with the people? If so, it is suggested it be included. There are many surveys that have aggregate upper arm, glenohumeral, scapular, trapzius, interscapular/paraspinal, nape of the neck and even neck pain in “shoulder” pain. What was included, as well as what was not included should be specified. (Text notes use of a manikin, yet it is unclear what the interviewer/examiner did with a person pointing to various locations…e.g., what did they do if someone pointed to the mid-upper trapezius?).

11. What was used to assure the examiners or researchers all used the same definitions of “shoulder pain”? The para references ‘trained” and perhaps this is intended to indicate structuring in the research protocol. Another sentence could help make this clear.

12. Is the outcome being evaluated in the paper prevalence of shoulder pain of at least 30 days duration? If so, suggest that be made clear throughout. Since the article also primarily analyses chronic RC tendinosis of at least 3 months duration, presumably questions were asked about duration of the pain as the question included in the manuscript would not yield those relevant data.

13. Outcomes, Para 3. The case definition of rotator cuff tendinosis should be specified (e.g., specific pain location(s) at least 3 months plus XYZ). Examination components should be specified. Was the examination standardized. If not, this weakness should be noted both here and in the suggested limitations para.

14. Were the examination maneuvers performed in all subjects? Only those with
symptoms? Up to the examiner? (these issues may explain the low prevalence rates as noted above).

15. What defined the differences between “possible” and “probable?”

16. Determinants, para 1. ?Structured interviews? What is an “occasional” smoker? Is it possible to categorize the pack-years for all current and former smokers? If so, and if the data suggest a lack of consistent, dose-response relationship across the data, this would seem to raise questions about the conclusion in the abstract.

17. Determinants, para 2. Were the distribution based cutpoints quartiles? If so, suggest using that term. If not, suggest explaining how cutpoints were determined. Light, moderate, excessive should be defined.

18. Determinants, para 3. This para, as well as above/below, suggest it may be helpful to append the questionnaire, as there are many variables included and they are not apparent in the results.

19. Determinants, para 4. This population may be relatively homogeneous, but it would seem the waist circumferences should be adjusted for body frame (e.g., height adjusted).

20. What percentage of the study population was covered by these criteria? That should be specified. If it was 1867/6354 (29.4%), then the percentage is so small that a careful review of the variables in Table 1 differ is required as a selection bias could be present (e.g., more ill people locating closer to medical facilities). If they do differ, it is suggested the table will need additional columns and statistical testing to define the differences. If not, then it is suggested a sentence to that effect may suffice and help clarify that that issue was examined and presumably the results are then generalizable to the rest of the study population.

21. The statistical analysis section does not note clearly how the overall approach was conducted. Were univariate analyses performed? How were the multivariate models constructed? Did the authors have preconceived ideas and force variables into the model to produce the final models?

22. It is unclear how the physical factors were incorporated in the models, as there are multiple different categories and domains.

23. The results later specify unilateral vs. bilateral outcomes. What is unclear is whether this was by history or simultaneously they were required to have shoulder pain in the structured interview of BOTH shoulders to be a bilateral case (e.g., rather than a history of right shoulder pain 5 years previously and currently have left shoulder pain to also be a bilateral case)

24. Results. Para 1. A key issue is how well this population mirrors the Finnish population. If unknown or if different, this is a limitation. This references comparison with “reference values” but what the comparison(s) is(are) or what those values are is unclear. Suggest changing the sentence a bit “….Women reported being more active…”

25. Results. This reviewer believes it would be best if there was a table with univariate analyses presented after the demographic table. This would help the reader better understand the data and the subsequent model building. Without
the univariate analyses, subsequent analyses of the results and discussion is a bit impaired.

26. The results could benefit from some structure. For example, as currently structured the results discuss smoking at 10-20 pack-years is a risk for women is a risk, but more than that is not. This is not logical. It is suggested this lack of dose-response be clearly pointed out. Later, this should be discussed in the limitations. As currently structured, the results ramble a bit with multiple subjects in one paragraph.

27. Table 2. The occupational physical factors adjusted are unclear. The table’s footnote could help clear that up. What is unilateral vs. bilateral is unclear as noted in the statistical analyses section above. Definitions of the various conditions are suggested to be footnoted, similar to table 1 as suggested above.

28. Discussion. As noted above, until univariate analyses are presented, the discussion suggestions below are somewhat preliminary. The discussion section would be improved with additional work and structuring. Most paragraphs mix topics, including outcomes, literature review, and conjecture, making it a bit difficult to read.

29. It would seem the biggest finding of this study is a lack of consistent support for the metabolic/vascular supply theory of RC tendinosis and shoulder pain that the authors’ approached in their hypothesis. This is not made clear in the abstract, results or discussion. It is suggested that this be the first para of the discussion, then adjustments made to the other sections.

30. The first para’s first sentence does convey some of the primary findings, although the results are not consistent across all measures. The next sentence is a non-seq. One possibility is for this para to solely deal with the obesity issues. The next could deal with the other issues.

31. This reviewer noted the issue of increased weight lifting being the strongest limitation for job physical performance in a series of 4 experimental studies, 3 in the peer-reviewed literature and all presented at PREMUS or IEA (Garg et al. Short-Cycle Overhead Work and Shoulder Girdle Muscle Fatigue. International Journal of Industrial Ergonomics. 2006;36:581-597; Garg et al. Maximum One-Handed Shoulder Strength for Overhead Work as a Function of Shoulder Posture in Females. Occupational Ergonomics 2005;5:1-10; and Garg et al. The effect of maximum voluntary contraction on endurance times for the shoulder girdle. Int J Ind Ergonomics 30:103-113, 2002). From that, we hypothesized that obesity was a potential risk for RC tendinosis due to increasing weight lifted, performed a study and appear to have supported that supposition (Wendelboe et al. Associations between Body Mass Indices and Surgeries for Rotator Cuff Tendinitis. J Bone Joint Surg 2004;86A(4):743-747.). A recent excellent review by these authors is included in the reference list. However, inferences that the mechanism is solely vascular including from obesity is heavily discounted in the orthopedic literature, is controversial, remains to be proven and this text does not fully note these issues. (This reviewer is not seeking to have the above included in the reference list, rather merely trying to highlight these issues.)

32. The results for diabetes seem to be problems of small sample size, as most
results are trending, but statistically negative. The text as written does not make that clear. Additionally, discussion about unilateral outcome with a systemic disease is inadequate as it should affect both. This issue applies through most of the results section. It would seem if the issue is these are modest risks, but the study was underpowered, then stating it that way will make the results more clear. As written, this reader was initially confused how DM would be a risk for one gender and not the other.

33. One succinct paragraph on mechanism(s) of action may be helpful.

34. Para 7, last sentence is a non-seq. The first clause is probably correct, whether there is linkage with the last clause is speculative and suggest deleting.

35. Para 8 contains conjecture on gender differences. There are robust data from psychophysical experiments that men have far stronger shoulder joints than women (approx. 2.4-fold depending on the exact task), and those differences are more marked than other joints (see, e.g., Snook, Ciriello data on maximum acceptable weights and forces). The key for this conjectural statement would seem to be the percentage of maximum voluntary contraction at which the worker is operating. (Additionally, in our cohort study, women tend to do the more repetitive work in plants that involves less force and men tend to do the infrequent, but high force activities. This raises a lot of additional questions, as we simply do not understand which job physical factors, let alone combinations, are most relevant for producing increased risk of RC tendinosis.)

36. A para on limitations is very much needed. A para on study strengths may also be helpful.

* Discretionary Revisions

1. Title: consider “tendinosis.” Evidence of true classic inflammatory mechanisms is lacking. Suggest same throughout the manuscript.

2. Osteoarthritis. Suggest changing to osteoarthrosis for same reasons.

3. Abstract: it is recommended the study design be specified.

4. Throughout the document, it is suggested “diabetes mellitus” be substituted for “diabetes” to be more precise.

5. Abstract: It is suggested it would be helpful for readers scanning abstracts to be able to see quantification of the major results in the abstract (to decide if they want to read the full paper).

6. Abstract: It would be best to have chronic (>3months) defined in parentheses in the abstract as various definitions are used.

7. Introduction: Overall, the length and breadth of the introduction are reasonable. As a general principle, this reviewer is not particularly fond of using systematic reviews for evidence due to the number of mistakes incorporated in them and evidence and knowledge are primarily derived from original data. Line 4, suggest “the shoulder joint” as trapezius pain may be more common. The sentence should be referenced.

8. Intro: Last line of the first para, acromioclavicular OA is quite a bit more
common than glenohumeral. Also, suggest osteoarthrosis, rather than osteoarthritis for same reasons as above. Reference(s) needed.

9. Intro: First sentence, 2nd para, suggest softening the language as physical factors-related research is rather primitive for the shoulder at this point. Consider “…may increase the risk of…” Para 3, first two sentences need at least one reference. Last para of the introduction is a nice description of the hypothesis.

10. Outcomes. Para 1. Presumably, the question was of pain with motion. Tenderness is a term generally reserved for pain that is elicited with palpation.

11. Determinants, para 5. First sentence should define level of fasting glucose used to diagnose (X). “…or use of glucose lowering medications.” It is recommended the mmol/l values be translated into mg/dL or similar in parentheses. The last sentence presumably means a highly sensitive CRP (?)

12. Carotid intimal thickness. First sentence, suggest “Ultrasound measurements of carotid intimal thickness have been previously described [12].” Presumably, these measurements were performed blinded to disease status and if so, should be noted.

13. Statistical Analyses. The term “determinants” is used here and a few other places in the manuscript. Realistically, this apparently is a cross sectional study, so whether the paper identifies true risk factors, or disease determinants, is unknown. Consequently, it is suggested that terms such as “associated factor” be used preferentially. This is another item suggested for the limitations paragraph I recommend be included.

14. This reviewer believes first person is generally suboptimal for scientific publications, although occasionally reasonable for the hypothesis or a concluding sentence.

15. Table 1. If appropriate, the title may be more clear to state “….free of a diagnosis of rheumatoid arthritis.” The Confidence Interval may be a suboptimal method of defining the differences between the data, as standard deviations are more familiar for many. Suggest metabolic syndrome, shoulder joint pain, RC tendinosis all get footnoted definitions to help the table stand alone. Are the data presented those of a history of DM? if so, suggest noting that. If incorporating serological testing, suggest noting that.

16. Discussion. Para 2, last sentence, considering the substantial limitations, suggest changing to “…may be better…”

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.

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