Author's response to reviews

Title: An Investigation of Somatosensory Profiles in Work Related Upper Limb Disorders: A case-control study protocol.

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Responses to Reviewer's comments and corrections Jan 2nd 2010
Title: An Investigation of Somatosensory Profiles in Work Related Upper Limb Disorders: A cross sectional study protocol.
Version: 1 Date: 7 December 2009
Reviewer: Domhnall MacAuley

Dear Professor MacAuley,

Many thanks for reviewing this article and for your considered comments and corrections. I have reviewed the article with your suggested corrections in mind and will address each comment individually.

1. Comment: The overall rationale for the study is reasonable. But, the authors need to define their aims and specific objectives more clearly.

Response: The aims and objectives of the study have been reviewed and refined.

The primary aim of this study is to comprehensively describe the somatosensory profiles in patients with Non Specific Arm Pain (NSAP). The second aim is to compare somatosensory profiles in NSAP to asymptomatic subjects and a third group of symptomatic subjects. This group has now been changed to subjects with cervical radiculopathy. It is hypothesised that the NSAP group will demonstrate similar somatosensory profiles to that of cervical radiculopathy, indicating a probable neuropathic pain presentation.

The objectives of this study are to:

• Describe the somatosensory profiles of subjects with NSAP in terms of neurological examination, qualitative measures of pain, neural tissue provocation tests and QST.
• Describe impairment and disability associated with NSAP by means of the Disabilities of the Arm, Shoulder and Hand (DASH) and SF-36 questionnaires.
• Investigate any correlations between clinical examination findings, QST profiles and questionnaire derived pain profiles in subjects with NSAP to see if subjects with indicators of neuropathic pain on clinical examination and questionnaire results (Leeds Assessment for Neuropathic Signs and Symptoms - LANSS) demonstrate distinctive profiles on QST.

• Compare somatosensory profiles of subjects with NSAP to those with cervical radiculopathy and asymptomatic controls.

2. Method: It is described as a cross sectional observational study- this is not quite accurate. If the study were better defined, it would be better described as a case control study. But, the groups are very vague and it is difficult to know exactly what the inclusion criteria are. The cases, who will be identified by clinicians, need much more precise description. In a case control study the comparison groups should be similar – but I have doubts that the student and staff population, will be comparable. The cases will be from an aged range 18-65. The age profile of the sample frame of your proposed control group will be very different. You have already stated that they should not spend 40% of their time at a computer. So, irrespective of any clinical findings, the groups are likely to be fundamentally different.

Response: The groups to be studied have been altered and the description of the study has been changed to a “case-control study”. The groups to be investigated will now be as follows. (1) NSAP which will be identified as those presenting with arm pain in the absence of an identifiable pathology using classification criteria outlined by Boocock et al., 2009 and Harrington et al., 1998. (2) Cervical Radiculopathy. These subjects will be recruited pre-surgically from a Spinal Surgery Department and will have symptoms consistent with radiculopathy together with MRI evidence of nerve root compression. (3) The control group will consist of non-office workers as previously indicated. They will be recruited from the staff of local involved hospitals, non-academic staff and students at UCD and the general population. All efforts will be made to match these in age, gender and profile. The study has commenced and so far all controls have been age matched and are from a professional working population.

3. The physical examination, neurological tests and palpation is subjective and will be carried out by the principal investigator- hence there is great scope for bias.

Response: This is acknowledged as a limitation but due to limited resources we are unable to address it. Recognition of this limitation within the study has been included in the article manuscript.

4. When it is suggested there may be a neurological aetiology I am surprised that nerve conduction studies are not included.

Response: It is acknowledged that the inclusion of more objective measures for the assessment or neuropathic pain and dysfunction would make this a more robust assessment and in keeping with recent recommendations by Treede et
al., 2008. We understand, therefore, that at best we may be able to establish the presence of “possible” or “probable” neuropathic pain in this group but without confirmation from more objective measure we cannot establish “definite” neuropathic pain. Should we find consistent evidence of “possible” neuropathic pain, as well as perhaps similar findings in QST between the two patient groups, this would form the basis for an extension of this study whereby we would try to measure this with more objective means. This, obviously, would be subject to receiving further funding and ethics approval. The authors also acknowledge limitations associated with nerve conduction studies as only one measure of nerve dysfunction, which assesses large diameter A# nerve fibres. Other measures such as skin biopsy and/or Laser evoked potentials would also be required for a full assessment of all fibre types particularly as painful neuropathies are often characterized by the preferential involvement of myelinated and unmyelinated nerve fibres.

5. If these groups are to be compared, the clinical signs and measurements should, as far as possible, be undertaken by someone blinded to the groups.

Response: The authors acknowledge this limitation and have included this under a new section of the manuscript section on study limitations.

6. Non specific arm pain is very vague and, is rather complicated by the inclusion of other disorders. I do not feel the criteria for cases are sufficiently identified.

Response: NSAP is indeed a very vague presentation; hence the need for further studies clarifying underlying pain mechanisms. We hope that by changing the second patient group to cervical radiculopathy, this will serve as a more defined comparative group.

In the absence of any gold standard means of assessment, consensus documents on classification criteria of upper limb disorders by experts in the field will be used. The latest of these by Boocock et al., 2009 consists of a compilation of previous classification papers and is therefore considered the most comprehensive. An appendix of the latest clinical diagnostic criteria by Boocock et al 2009 is attached with the document. NSAP is defined as diffuse arm pain in the absence of signs of a specific disorder and so a full screening protocol will ensure exclusion of subjects with signs of other pathologies. Further investigations e.g. MRI in the absence of distinct clinical findings would be considered prohibitively expensive and time consuming for the purpose of this study.

7. The recruitment strategy is undefined. It would also be important for researchers to estimate how long recruitment will take.

Response: Recruitment is currently underway and the following strategies are being utilized i.e. email and poster campaign in universities and hospitals, as well as recruitment from a local hospital, occupational health service and a large physiotherapy practice. Data collection is expected to last for a further 12 months.
I hope that I have answered each comment satisfactorily and I look forward to hearing your response and any further comments in relation to the article.

Yours sincerely,

Niamh Moloney.