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Research Priorities and Methodological Implications

The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and Its Associated Disorders

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Study Design. Best evidence synthesis.

Objective. To report on gaps in the literature and make methodologic recommendations based on our review of the literature on frequency and risk factors, assessment, intervention, and course and prognostic factors for neck pain and its associated disorders.

Summary of Background Data. The scientific literature on neck pain is large and of variable quality. We reviewed 1203 studies and judged 46% to be of sufficient scientific validity to be included in the best evidence synthesis. Scientific quality varied across study topics, and fundamental questions remain about important issues.

Methods. The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and its Associated Disorders (Neck Pain Task Force) conducted a critical review of the literature published between 1980 and 2006 to assemble the best evidence on neck pain and its associated disorders. Studies meeting criteria for scientific validity were included in a best evidence synthesis.

Results. We outline a large number of gaps in the current literature. For example, we found important gaps in our knowledge about neck pain in children (risk factors, screening criteria to rule out serious injury, management, course and prognosis); and in the prevention of neck pain-related activity limitations. Few studies addressed the impact of culture or social policies (such as governmental health policies or insurance compensation policies) on neck pain. A number of important questions remain about the effectiveness of commonly used interventions for neck pain.

Conclusion. The Neck Pain Task Force undertook a best evidence synthesis to establish a baseline of the current best evidence on the course and prognosis for whiplash-associated disorders. We identify a number of gaps in the current knowledge, and provide recommendations for the conduct of future studies.

Key words: neck pain, systematic review, epidemiology, research recommendations.

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The scientific literature on neck pain is large and of variable quality. The Bone and Joint Decade 2000–2010 Task Force on Neck Pain and its Associated Disorders (Neck Pain Task Force) performed a comprehensive search and critical review of the literature on this topic. Our focus in this endeavor was on the study of neck pain that is not associated with serious local pathology (examples of serious pathology include myelopathy, fracture) or systemic disease (examples of systemic disease include inflammatory joint diseases), although we included diagnostic and assessment studies where they related to ruling out fractures and dislocations.

Our goal in doing so was to produce a best evidence synthesis on the prevention, risk and determinants of neck pain (and disorders associated with neck pain); its assessment and diagnosis; effectiveness of intervention strategies; and its course and prognosis.[1–9] Details of our methodology are reported in detail elsewhere,[10] and the criteria used in the methodologic appraisal of the studies can be seen online through Article Plus.

Our critical appraisal of studies focused on identifying sources of potential selection bias, information bias, and confounding. We also considered whether or not these biases would likely result in erroneous or misleading conclusions. After discussions of each article, decisions were made about the article's scientific merit. Studies judged to have adequate internal validity and to be methodologically rigorous, such that the results could be accepted with reasonable confidence, were considered to be scientifically admissible. Findings from these studies were summarized in evidence tables and used to formulate a best evidence synthesis.

The Neck Pain Task Force judged 46% of the 1203 reviewed studies to be of sufficient scientific validity to be included in the best evidence synthesis. However, scientific quality varied across study topics. Whereas 53% (249 of 469) of the studies pertaining to frequency and risk factors of neck pain, and 47% (170 of 359) of the studies of interventions for neck pain were judged to be of sufficient methodologic quality to form part of the best evidence synthesis, this number fell to 35% (95 of 274) for studies of diagnosis and assessment and 31% (70 of 226) for studies of the course and prognostic factors for neck pain.

To the extent that policy and clinical practice are informed by research studies, these numbers should engender concern among stakeholders about the quality of much of the published literature. However, even so, the proportions are favorable in comparison with those reported by the Québec Task Force on Whiplash-Associated Disorders (WAD). In that best evidence synthesis, the acceptance rates for methodologic quality were only 21.7% for studies of incidence and risk factors (*vs.* 53% in the Neck Pain Task Force), 26.2% for intervention studies (*vs.* 47% in the Neck Pain Task Force), 20.4% for studies of diagnosis and assessment (*vs.* 35% in the Neck Pain Task Force), and 16.7% for prognostic studies (*vs.* 31% in the Neck Pain Task Force).[11] This may mean that the quality of research may have improved substantially over the past decade since the Québec Task Force report was published, although there are certainly many other possible explanations.

Moreover, despite the large number of studies about neck pain, fundamental question remain about important clinical issues such as best practices for diagnosis and interventions, especially among children and the elderly. Studies on prevention of neck pain were rare, as were studies identifying modifiable prognostic factors. Our goals for this paper are (a) to identify priorities for conducting future research and (b) to provide methodologic recommendations to rectify common deficiencies in published research reports.

■ Important Gaps in the Current Literature

We have identified the following gaps in our current knowledge, which need to be filled with high quality studies. This list should not be considered exhaustive. The following topics and questions remain as a priority:

Research Priorities

Studies of Risk and Prognostic Factors (Carroll *et al,* Carroll *et al,* Carroll *et al,* Côté *et al,* Hogg-Johnson *et al, and* Holm *et al*)[2–8]

1. We still know little about the actual course of neck pain, and determinants of that course. Most studies of incidence and course of neck pain used follow-up points that were too infrequent for us to determine precise onset of neck pain, or to permit us to distinguish continuous from recurrent neck pain. These 2 courses of neck pain may have different prognostic factors and different consequences for the person with neck pain.That distinction might also be important in identifying targets for intervention.
2. We need to give clear priority to investigations of modifiable risk and prognostic factors. In particular, we need further well designed, confirmatory (Phase III studies are discussed elsewhere)[2–7] studies to examine the role of exercise/physical activity in both risk and prognosis of neck pain. Physical activity and fitness are potentially modifiable, which makes this topic especially important to understand, both as preventative measures and as means of enhancing recovery for those who develop neck pain. Such studies should use good quality, accurate and specific measures of fitness and exercise levels. In studies of prognosis, changes in exercise levels and sports injuries should be tracked over the follow-up period so that the temporal order of these factors can be understood. In particular, studies should target common physical and sporting activities, such as bicycle riding, swimming, golfing, bowling, and other activities that might stress (or strengthen) the upper body.
3. We need further studies on the course and prognostic factors of neck pain in children. This includes, but is not limited to, studies examining the risk and recovery of WAD in children; the role of backpack use in neck pain in children and adolescents; and the impact of sporting activities and fitness levels in risk of neck pain and in outcome of children/adolescents with neck pain.
4. We need studies examining how to prevent neck pain-related activity limitations and/or disability. For example, what are the individual and societal factors that determine (or prevent) the transition from neck pain which is not associated with limitations in activities of daily living, to neck pain which is associated with such limitations?
5. We need large, good quality studies testing the widespread view that degenerative disc changes are risk factors for onset of neck pain, and prognostic of recovery for those who experience neck pain. This question should be addressed with good quality measures of degenerative changes

(*e.g.*, radiographic imaging); with careful tracking to determine onset of neck pain (for those with no initial neck pain) and recovery from neck pain (for those with neck pain at the outset).

6. Several studies have identified psychological factors (*e.g.*, pain coping style) as important in the outcome of persons with WAD,[3] and of persons in the general population with neck pain.[2] However, few studies have examined the same factors, and further confirmatory evidence is needed before it is clear which psychological factors should be targeted in intervention trials.
7. We need studies specifically examining how physical, psychological, and societal factors interact in both the risk of neck pain and in recovery from neck pain; at work, in the general population and in WAD.
8. We need studies directly examining cultural factors in the onset or prognosis of neck pain, or directly comparing neck pain incidence, risk factors or prognosis across cultures. For example, although there has been much speculation about the cultural influence on onset and recovery of WAD, no studies judged to be scientifically admissible have directly addressed this issue. We are encouraged by the COPCORD initiative, which has studied neck pain prevalence in settings other than Europe and North America, and reports similar 1-week prevalence proportions, using comparable case definitions and age groups. Similar studies should examine neck pain incidence, risk factors and prognosis in developing nations.
9. Although we have many studies examining a large number of work-related ergonomic risk and prognostic factors, we have no scientifically admissible large, well conducted, longitudinal studies assessing the role of work-related vibration (such as use of a jack hammer) or long hours of work-related driving (such as driving a truck or bus) in risk or prognosis of neck pain. These have been studied in low back pain, but not in neck pain.
10. We have little good quality evidence regarding the importance of direction of collision in onset and recovery in WAD. Similarly, we need further good quality, large studies to assess the effect of whiplash-protection devices in cars in reducing the incidence of WAD or severity of symptoms after a crash.
11. Social/societal factors have received little attention in the research literature. We need studies identifying the role of different insurance compensation systems, policies, and practices on recovery of neck pain. Likewise, health care policies and health care delivery systems should be studied for their impact on the course and prognosis of neck pain.

Studies of Assessment (Nordin *et al*)[9]

1. We urgently need Phase III and IV studies establishing screening criteria for infants, children, and adolescents seeking care in an emergency room after blunt trauma to the neck.
2. We urgently need to validate "red flags" for patients presenting to clinicians for nonemergency neck pain.
3. We need studies identifying the most effective means of training emergency physicians in the interpretation of imaging studies in emergency situations for patients with blunt trauma to the neck.
4. Phase I–IV diagnostic studies are needed to establish the reliability, validity, and utility of the following: (a) screening patients (nontraumatic) for "neck pain red flags" in nonemergency settings and (b) functional capacity testing of patients with and without radiculopathy.
5. Phase II–IV diagnostic studies are needed to (a) establish the reliability, validity, and utility of muscle strength and endurance testing of the neck and (b) to validate the utility of computed tomography-scan in the assessment of root compression in patients with neck pain and radiculopathy.
6. Phase III and IV diagnostic studies are needed to establish the validity and utility of (a) clinical musculoskeletal neck examination in patients without radiculopathy, (b) the use of nonorganic-signs test in patients with chronic neck pain, and (c) the use of special magnetic resonance imaging studies of upper cervical ligaments in patients with acute and chronic WAD I–II. Phase III and IV studies are also needed in order to identify clinical subgroups of patients (with neck pain and radicular pain) most likely to respond to specific types of treatment (standard surgical treatment or conservative treatments).
7. Neck specific self-assessment questionnaires should be further studied for utility in clinical practice (Phase IV studies).
8. We need studies that examine, not only the accuracy, but cost-effectiveness of diagnostic procedures and tests.
9. There is a need to question and examine the clinical criteria for many common neck pain diagnoses, especially 'cervical strain,' 'spinal malalignment,' 'cervical instability,' 'zygapophysial pain,' 'cervicogenic headache,' internal disc derangement' or 'discogenic neck pain,' and 'minor disc protrusion' as a cause of neck pain without radiculopathy.

Studies of Interventions (Hurwitz *et al* and Carragee *et al*)[1,8]

1. There is a need for studies examining the effectiveness of population-based community prevention programs for neck pain. Given the evidence from the back-pain literature that a population-based community intervention program was effective in reducing the incidence and burden of

low back pain,[12–15] there may be a similar impact of such a program on neck pain.
2. Further large, high quality studies examining the effectiveness of intervention strategies for prevention of neck pain in the workplace are needed.
3. We have little scientifically acceptable evidence about the effectiveness of intervention strategies for nontraumatic acute neck pain. Specifically we need to identify what compensation, workplace and healthcare policies and clinical practices are the most effective in improving recovery in the acute stage of nontraumatic neck pain in workers.
4. Good quality evidence is lacking about effectiveness of interventions for cervicogenic headache in WAD.
5. Given the widespread use of cervical manipulation, thoracic manipulation, traction, nonsteroidal anti-inflammatory drugs, and other medications in the treatment of WAD, we need large, well-designed and well-conducted trials comparing these treatment methods.
6. We need large, multicentered randomized controlled trials to evaluate the effectiveness of open surgery for neck pain that is not associated with serious local pathology or systemic disease. Similarly, we need large, multicentered studies to determine the long-term prognosis of surgically treated neck pain *versus* conservatively treated neck pain.
7. We need large randomized controlled trials (preferably multicentered) to evaluate the efficacy of percutaneous neurotomy for suspected facet joint pain.
8. We need studies that assess the effectiveness in WAD patients of upper cervical or cranio-cervical fusion on the basis of magnetic resonance signal changes in the upper cervical ligaments.
9. We need large randomized studies to identify the risk and benefit of commonly used medications (nonsteroidal anti-inflammatory medications, analgesics, muscle relaxants) in Grade I and Grade II neck pain (that is, neck pain that is not associated with radiculopathy, serious local pathology or systemic disease).
10. We need large trials examining the efficacy of conservative interventions for radiculopathy (Grade III Neck Pain).
11. We need studies that examine not only efficacy, but cost-effectiveness of commonly used interventions (including multidisciplinary interventions) for neck pain.
12. We need studies examining the role that patient expectations, preferences, and cultural factors play in treatment effectiveness.

Methodologic Recommendations

Our in depth reviews of over a thousand studies has lead us to the following methodologic recommendations.

General Methodologic Issues Common to Most Study Designs

1. The research question should be explicitly stated in the introduction. This permits the reader to evaluate whether the methodology was appropriate and whether the findings answer the question(s).
2. The source of study participants must be well described and inclusion/exclusion criteria clearly outlined and appropriate to ensure that the study population is representative of the population of interest. The Neck Pain Task Force proposes a set of case definitions to be used for this purpose.[16] Likewise, sampling procedures must be well described.
3. The study should have a sufficient number of participants to ensure adequate precision around the estimated effect. This can be addressed, in part, by greater use of *a priori* sample size calculations, which consider the number of subjects needed to minimize the probability of type II error (failing to find an effect that is truly present because of "chance error").
4. Many studies reported "underpowered" multivariable analyses, in which too many explanatory variables (or predictors) were included for the number of participants. This can lead to unstable models with misleading results.[17] One "rule of thumb" is to include at least 20 subjects per explanatory variable in multivariable analyses with continuous outcomes, and at least 10 subjects per "event" in multivariable analyses with categorical outcomes.[18]
5. An additional consideration is relevant for randomized trials. Even random assignment may not equalize groups on baseline characteristics if the sample size is small. The smaller the sample size, the more likely it is that group differences will occur "by chance" despite random assignment, and despite *a priori* sample size calculations designed to minimize type II errors.
6. The case definition (or diagnostic criteria, depending on the type of study) must be clear, specific, and relevant. For example, in much of the current literature, findings report information about "neck and shoulder" pain, with no clear differentiation of upper trapezius pain from specific shoulder diagnoses (such as tendonitis).
7. Case definitions using self-reported pain presence must also specify a time frame, such as presence and/or frequency of pain in the past week or month. In addition, reporting not only the presence of pain, but its frequency, duration and severity (*e.g.*, pain intensity, pain-related limitations) provides much more useful data. A proposal for a set of case definitions is outlined by Guzman *et al.*[16]
8. The data analysis and multivariable modeling strategies should be well described. For example, in many studies we reviewed, it was impossible to determine what factors had been included as potential explanatory factors in multivariable analy-

ses, and some studies did not report the statistical tests used to obtain their reported p-values. All factors included in the models should be reported, whether or not they were statistically significant. The test statistic used and effect size obtained should be reported, rather than just the *P*-value. Estimates of variability of the effect size (for example, confidence intervals) should also be reported. In some studies that omitted measures of variability, sufficient information was provided for the reader to calculate these, but in many other studies, this was not possible.

9. Conclusions should be consistent with the findings and should be in accordance with the study design. For example, studies using cross-sectional designs do not lend themselves to conclusions about risk factors or prognostic factors, both of which require a clear temporal relationship between exposure(s) and the outcome. As another example, studies using case series designs cannot be used to draw conclusions about effectiveness of treatments.

In addition, different study designs and study topics are especially susceptible to certain types of methodologic inadequacies, and we report some of the most common inadequacies we observed in our review of the literature. We review each study type below.

Major Methodologic Issues in Studies of Incidence and Determinants for Onset of Neck Pain

1. *Study design issues*: In reviewing the literature, we frequently found that cross-sectional designs were used in an attempt to identify "risk" factors. Although factors found to be associated with neck pain in cross-sectional studies *might* be risk factors, they may instead be prognostic of failure to recover; alternatively, these factors might be consequences, rather than determinants, of neck pain. Case series were also frequently used to determine risk and risk factors. However, these designs cannot be used to estimate incidence rates or identify determinants for a larger population of interest. Cohort studies to identify incidence and determinants of neck pain must begin with a clear population at risk of neck pain, that is, persons without neck pain at the outset. Case-control designs could potentially be used to identify determinants of neck pain; however, such studies must ensure that the "risk factor" in question precedes the onset of neck pain. The episodic nature of neck pain makes this requirement a challenge for case-control designs in attempting to identify the determinants of neck pain.
2. *Selection bias*: Selection bias can occur through differential enrollment into the study (*e.g.*, consent rates which are differential across exposure status) or through differential loss to follow-up. The Neck Pain Task Force did not set any arbitrary rules for an "acceptable" attrition rate, because even in studies with high follow-up rates, the attrition may still be differential, and may still bias the findings. However, in many studies we reviewed, there was no assessment of whether enrollment into the study or attrition to follow up was differential, and no consideration that this may have affected the findings.
3. *Case definition*: This is a common problem across all study designs and is discussed above. However, unclear case definitions were an especially frequent problem in studies of risk and determinants of neck pain.
4. *Analysis issues*: Colinearity of variables should be considered when model building. The Neck Pain Task Force frequently reviewed papers in which 2 or more risk factors assessing the same or similar constructs were included in the model with no comment on whether colinearity was considered. This can lead to findings that are misleading. Stepwise regression should not be used to build models aimed at measuring the association between a risk factor and neck pain because stepwise models select variables based on statistical significance rather than strength and direction of a regression coefficient. Similarly, stepwise modeling is inadequate to select confounders because the coefficient of the potential confounder is selected for its association with the outcome. This method ignores the association between the confounder and the exposure.[19]

Studies of Diagnosis and Assessment

1. *Study design issues*: Definitive recommendations can be made for use of a diagnostic procedure or test only on the basis of positive Phase III or Phase IV diagnostic studies in which a test's performance is compared against a gold standard, or its utility is established based on clearly described outcomes.[20] It is imperative that clinical tests which have shown promise in Phase I and II studies be subjected to the more rigorous and conclusive Phase III and IV designs *prior* to being adopted for clinical practice.
2. *Study samples must be selected with care*: For example, the predictive value of a test is highly dependent on the population in which it is being used. The test must be validated in the population for which it is intended to be used.
3. The "gold standard" comparison must be independent of the test being assessed, and must be clearly described, as must the test being assessed.

Studies of Interventions. One common problem in the intervention literature was the use of case series as a study design to determine effectiveness or efficacy of interventions. These designs cannot be used to determine effectiveness or to ascertain relative effectiveness of treatments.

We note that that reporting of RCT's has improved since publication of reporting guidelines. The CONSORT statement,[21] for example, has been widely publicized, is easily available, and provides an excellent guide

for authors, not only in reporting RCT's but in conducting such studies. For example, for intervention studies published in 1995, only 25% were rated as scientifically admissible. This proportion rose to 33% for intervention studies published in 2000; then jumped to 61% for studies published in 2003 and to 66% for studies published in 2005. This suggests that there has been attention paid by researchers and journals to endeavors to improve the quality of conducting and reporting findings from randomized trials. We recommend that not only those who produce research, but those who use research be familiar with these reporting guidelines.

Even within the randomized trials we reviewed, common reasons for finding that the scientific validity of intervention studies was compromised include:

1. *Inadequate sample size*: Sample size is important in randomized trials for 2 reasons. The most widely recognized reason for having an adequate sample size is to decrease the probability of type II error, that is, the probability, from chance, of failing to find associations that actually exist. The Neck Pain Task Force recommends that authors of RCT's report their *a priori* sample size calculations. This is especially important when no group differences are found, in order to assure the reader that this was not due to lack of power in the study. However, a larger sample size also increases the likelihood that random assignment to intervention groups will be successful in equalizing groups on both measured and unmeasured baseline characteristics. Inequality in baseline group characteristics opens the question of findings being a result of confounding.
2. *Failure to consider the clinical importance of findings*: Group differences may be "statistically significant," but yet too small to be of clinical relevance.
3. *Inadequate reporting of baseline characteristics*: Where important baseline characteristics (such as baseline values of postintervention outcomes or likely confounders) are not reported, it is difficult to ascertain whether postintervention differences are a function of the intervention or of pretreatment differences between groups.
4. Inadequate or inappropriate statistical analyses. Many reviewed studies presented significance tests to demonstrate that baseline differences were or were not significant (beyond chance). However, if one properly performs random assignment to groups, *any* observed differences between groups occur by chance. What is important is to assess the likely impact of this occurrence on the observed outcomes. Multivariable statistics should be considered in analyzing the findings of a randomized controlled trial, in order to adjust for baseline differences between groups.
5. High attrition rates or high cross-over rates, which introduces the possibility of confounding, even if baseline characteristics were similar.

Studies Course/Prognostic Factors for Neck Pain and its Associated Disorders. Prognostic studies of neck pain had the lowest acceptance rate, but the quality of these studies also appeared to improve over time. Of the prognostic studies published in 2005, the proportion deemed scientifically admissible was 41%, in comparison with 27% of those published in 1995.

These studies are prone to suffer from many of the same inadequacies as studies of risk and determinants of neck pain. Common flaws in this literature were

1. Failure to clearly define (and follow) a population of persons with neck pain at baseline.
2. Excessive loss to follow-up, and/or differential loss to follow up. This is a very common problem in cohort studies, and can be difficult to address. We did not set any arbitrary rules for an "acceptable" attrition rate, because even in studies with low attrition rates, this attrition may still be differential, and may still bias the findings. However, in many studies we reviewed, there was no assessment of whether attrition to follow up was differential, and no consideration that this may have affected the findings.
3. Misclassification of potential prognostic factors (exposures). This was especially problematic when participants were asked to recall characteristics or events occurring weeks, months or years in the past. However, other sources of potential misclassification frequently seen in the prognostic and risk literature included.

■ Conclusion

We need more conceptually sound and theory driven research in this area. Neck pain is multifactorial in its etiology and on its impact on the person. The complexities of the causal pathways and consequences of neck pain need to be acknowledged in the theoretical frameworks we develop to try to understand the issue. Neck pain is ubiquitous, but we have very little knowledge of its etiology, or, for example, about the pathways through which neck pain transitions from a single, transitory episode of Grade I severity to a problem creating great personal and societal burden.[16] A theoretical framework can help us to understand the current evidence and provide the groundwork for future research, within a framework that is useful for all stakeholders. We have proposed a conceptual model that we hope will be of use in furthering the understanding of neck pain.[16]

Future research on risk and prognosis should focus on modifiable factors. Although it is important to understand the nonmodifiable risk and prognostic factors for neck pain in order to predict its onset and course, it is even more crucial to identify modifiable risk and prognostic factors. Future research on prevention and intervention should be informed by findings about these modifiable risk and prognostic factors. Novel prevention, diagnostic and intervention strategies should be grounded in theory, informed by prior evidence and subjected to appropriate research before being promulgated.

The multifactorial nature of neck pain and the complex etiological and prognostic pathways leads to the need to use more innovative designs and analysis strategies. Qualitative methodologies can help us to understand the personal experience of neck pain and its consequences. Decision analysis methods may help us to better understand the choices made by policy makers, payers, clinicians, and persons with neck pain. Structural equation modeling approaches can help us to track the course of neck pain and the determinants and consequences of that course. Factorial designs in randomized trials of interventions can help to tease apart the effective aspects of these, sometimes complex, interventions. Knowledge transfer and exchange (KTE) endeavors can help bridge the gaps between the person with neck pain, clinicians, policy makers and payers and researchers, and the interactive nature of KTE permits each party to gain a wider perspective on this complex and multifaceted problem.

■ Key Points

- We performed a best evidence synthesis on the frequency and risk factors, assessment, intervention, and course and prognostic factors for neck pain and its associated disorders.
- Based on our review of the literature, we identify important gaps in our knowledge which require urgent attention.
- We know little about neck pain in children, for example, risk factors and preventive measures; screening criteria to rule out serious injuries; how best to manage neck pain in children; and its usual course and prognosis.
- We know little about the impact of culture or social policies on risk of neck pain and recovery from neck pain.
- Important questions remain about the effectiveness of commonly used interventions for neck pain.
- We provide methodologic recommendations for future studies on neck pain and its associated disorders.

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