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Adverse events following chiropractic care for subjects with neck pain

Sidney M. Rubinstein

Summary

This thesis focused on benign adverse events and to a lesser degree, addressed serious neurological complications following chiropractic care for subjects with neck pain. Based upon the data from a prospective, multi-center, observational cohort study, it was possible to answer a number of important clinical questions. Chapters 3 - 6 present the results of various analyses using this data. Additionally, two separate systematic reviews were conducted, one of which addressed the risk factors for stroke, including evidence on the risk associated with cervical spinal manipulation.

Chapter 1. Introduction

In chapter 1, a brief overview of the studies included in this thesis is provided, along with an overview of the clinical questions addressed in this thesis.

Chapter 2. A systematic review of the risk factors for cervical artery dissection

In chapter 2, the results of a systematic review of the risk factors for cervical artery dissection are presented. This topic should be of particular interest for chiropractors because of the association of stroke with cervical spinal manipulation. In total, 31 case-control studies fulfilled the inclusion criteria and were included for analysis. Selection bias, confounding, and inadequate data analyses were the most common identified methodological shortcomings. At the time that this review was published, only two studies of spinal manipulation had been identified, both of which demonstrated strong associations, but which also had significant methodological problems. Other risk factors which demonstrated a strong association with cervical artery dissection include enlarged diameter of the aortic root, migraine, and diameter change of the common carotid artery during the cardiac cycle. A weak association was found for homocysteine and recent infection.

Conclusion. Cervical artery dissection is a multi-factorial disease, as is evidenced by the numerous risk factors identified. Despite the fact that numerous case-control studies were identified, only one study, which investigated homocysteine was thought to have the lowest risk of biased results. This study also identifies the overall poor methodological quality of observational studies on this topic.

Chapter 3. The descriptive analysis of the cohort study

In chapter 3, the descriptive analyses of the cohort are presented. Patients with neck pain of any duration, who fulfilled the inclusion criteria, were recruited in a multi-center, practice-based study. Data were collected on the patients and from the chiropractors over the course of 12 months. Clinical outcome measures included neck pain, neck disability, treatment satisfaction, global assessment, and adverse events. In all, 79 chiropractors participated, recruiting 529 subjects, representing ~5,000 treatment consultations. Follow-up was possible for 92% at 12 months; therefore, response bias is unlikely. Most patients had chronic, recurrent complaints, mild to moderate disability of the neck, and a mild amount of neck pain at baseline. Adverse events following any of the first 3 treatments were reported by slightly more than half the population, and 13% of the study population reported these events to be high in intensity. The most common adverse events affected the musculoskeletal system or were pain-related. Only 5 subjects (1%) reported to be much worse at 12 months; however, only 2 subjects (<1%) reported to be worse at 3 months when most subjects would have discontinued or completed therapy. No serious adverse events were recorded during the study period. Many of the patients responded quickly to therapy, but there was no more improvement in patients beyond 3 months according to the principal outcome measures

Conclusion. Despite the fact that adverse events are common, and patients have chronic, recurrent complaints, many patients responded quickly to chiropractic care, and seemed to benefit from treatment. Based upon these findings, we suggest that the benefits outweigh the potential risks.

Chapter 4. Predictors of a favorable outcome

In chapter 4, the results of those clinical and sociodemographic baseline variables are presented, which were found to predict a favorable outcome in the cohort. Sources of data were questionnaires administered during the entire period of the study. In all, 29 putative prognostic clinical and

sociodemographic baseline variables were examined. Multivariate multilevel longitudinal regression analyses were conducted using the outcome variables neck pain intensity, neck disability, and perceived recovery. In total, 14 (48%) of the independent variables were statistically associated with at least one of the outcome variables in the final regression analyses. Shorter duration of neck pain at the first visit was the only variable retained in all three final regression models. The following were predictive of a favorable outcome for any 2 of the 3 outcome measures examined: intermittent neck pain, those not on sick-leave or receiving workers compensation at baseline, a higher level of education, less tiredness, higher expectations that the treatment would be beneficial, lack of morning pain, and worse perceived general health.

Conclusion. Based upon the patient's history, the clinician can identify a number of determinants, which are predictive of a favorable outcome. However, duration of neck pain at the first visit was the only variable consistently found to be predictive of a favorable outcome for all three outcome measures examined.

Chapter 5. Predictors of adverse events

In chapter 5, the results are presented for predictors of adverse events from the cohort. Sources of data for this analysis were questionnaires administered during the first 3 treatments. In all, 60 putative prognostic variables were examined, including descriptors of the patient, chiropractor, and type of treatment delivered. Multivariate random coefficients logistic regression analyses were conducted in order to determine predictors for the following outcome variables: 1) Any adverse event following any of the first 3 visits, 2) any adverse event following the 1st visit, and 3) specific types of adverse events following the 1st visit. The reported use of a manipulative technique involving cervical rotation, and working status of the patient (sick-leave or workers compensation) were moderately associated with an adverse event following any of the first 3 visits. Patients who had visited their general practitioner in the 6 months prior to treatment, however, were less likely to have an adverse event. A longer duration with neck pain in the preceding year was moderately associated with specific types of events following the 1st visit, namely headache, or worsening of the presenting neck pain.

Conclusion. Of the 60 independent variables examined, only four were found to be predictive of adverse events following chiropractic treatment for neck pain, one of which was found to be protective. The practitioner can identify three of these prior to initiating treatment.

Comment: While cervical rotation is often implicated as a cause of minor and serious complications, specific chiropractic manipulative techniques, which employ an aspect of rotation were not found to be predictive of an adverse event. It was only in those cases where chiropractors indicated that they had used an aspect of rotation during their treatment was an association found. This discrepancy should be examined in future studies.

Chapter 6. The association between adverse events and outcome

In chapter 6, the association was examined between benign adverse events following chiropractic care and the outcomes measures perceived recovery, neck pain, and neck disability. Sources of data were from the first 3 visits and 3 months. Multivariate multilevel logistic and linear regression analyses were used in the modeling. In total, 36 association models were constructed using the following central determinants: 1a) Any type of adverse event or 1b) any type of intense adverse event following any of the first 3 visits; 2) any type of adverse event following the 1st visit; and 3) three specific types of adverse events following the 1st visit. Two measurement periods were examined (the 4th visit and 3 months). At the 4th visit, subjects who reported an adverse event following any of the first 3 visits were less likely to be recovered, and had statistically, but not clinically meaningful worse levels of neck pain or neck disability. At 3 months, an adverse event was not associated with a better or worse outcome for any of the three outcome measures examined.

Conclusion. Benign adverse events are associated with worse short-term outcomes, but not worse long-term outcomes for subjects undergoing chiropractic care for neck pain.

Comment: This is an important finding because the only other study, which has examined subjects with neck pain who underwent chiropractic care suggested that therapy was associated with not only worse short-term, but also worse long-term outcomes.

Chapter 7. A systematic review of the diagnostic accuracy of tests for cervical radiculopathy

In chapter 7, the results are presented of a systematic review on provocative tests of the neck for patients with a suspected cervical radiculopathy. A comprehensive search was conducted in order to identify all possible studies fulfilling the inclusion criteria. Two reviewers independently selected studies, and assessed methodological quality. Despite an exhaustive search, only six studies were found which met the inclusion criteria. These six studies evaluated five different provocative tests, including Spurling's test, traction/neck distraction, Valsalva's, the shoulder abduction test, and the upper limb tension test. Common methodological flaws included lack of an optimal reference standard, disease progression bias, spectrum bias, and review bias. Limitations included few primary studies, substantial heterogeneity, and numerous methodological flaws among the studies; therefore, a meta-analysis was not conducted.

Conclusion. Based upon this review it is suggested that, when consistent with the history and other physical findings, a positive Spurling's, traction/neck distraction, and Valsalva's be used to "rule in" a cervical radiculopathy, while a negative upper limb tension test might be used to "rule it out".

Comment: This review provides a more scientific basis for when and how to use these tests. It is somewhat remarkable that many orthopaedic textbooks include these and other tests as useful adjunctive tests when there is so little scientific basis for this assertion. More high quality studies are necessary in order to determine their role as a diagnostic procedure.

Chapter 8. General discussion

In this chapter, the principal findings of this thesis are presented and discussed, including a discussion of causality regarding cervical spinal manipulation as a purported cause of cervical artery dissection/stroke. The strengths and limitations of the analyses stemming from the cohort study are also discussed. The chapter concludes with a summary of the implications for the chiropractors and patients, as well as recommendations for future research.