ADVERSE EVENTS AND MANUAL PHYSIOTHERAPY

ADVERSE EVENTS IN CANADIAN MANUAL PHYSIOTHERAPY: THE PATIENT, PRACTITIONER AND RESEARCH EXPERIENCE

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ABSTRACT

Background and objectives: Physiotherapists provide conservative treatment for neck pain utilizing manual therapies (MT), including spinal manipulation. Adverse events (AE) have been associated with manipulation provided mainly by other professions. Physiotherapy specific data are lacking. Definitions of AEs following MT require clear standardized criteria informed by both practitioners and patients. The objectives of this thesis were to: a) establish practice patterns of spinal manipulation in Canadian manipulative physiotherapists (CMPTs), b) establish patients' perceptions of an AE related to MT and c) pilot the collection of AE data reported by practitioners and patients.
Methods: For the first objective, multiple linear regression of survey data determined the association between experience and frequency of use of manipulation amongst CMPTs. For the second objective, Poisson regression identified predictors of patients more likely to report the occurrence of an AE. The final objective utilized descriptive statistics of patient and practitioner reported AE to assess feasibility for a future large-scale study.
Results: For the first, increased experience was associated with increased use of upper cervical manipulation in males (14% more often for every 10 years after certification; beta 1.37, (95% confidence interval) (0.89,1.85) $p<0.001$). For the second objective, lumbar spine dysfunction was a significant predictor of all AEs [Incidence Rate Ratio] = [1.513 (1.025, 2.235) p=0.037] compared to those with an extremity disorder. Expectation of soreness was a significant "protective factor" against reporting a major AE [0.915 (0.838, 0.999) p=0.047] relative to those without this expectation. For objective three, the study as designed was deemed not feasible as it failed to meet pre-set criteria for success.
Conclusion: Manipulation by CMPTs remains a valued option as experience increases. Adverse events reported by patients are influenced by expectations. A large cohort study attempting to accurately define and measure AE rates following manipulation will be challenging to perform in private practice settings.

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DECLARATION OF ACADEMIC ACHIEVEMENT

This thesis is a 'sandwich thesis' that combines three separate papers, two of which are 'in press' and one that has been submitted and is in revisions, all in peer reviewed journals. Lisa Carlesso contributed to all aspects of the papers and includes: for chapter 2, generating the research design, constructing the survey questions, analyzing the data, and writing the manuscript, for chapters 3 and 4, generation of the research questions and study design, ethical approval, survey instrument creation and administration, setting up of the database with the data management company, therapist recruitment and training, study administration, data collection and analyses and writing of the manuscripts and respectively. The work was performed between September 2008 and January 2013.

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CHAPTER 1

INTRODUCTION

This thesis will address gaps identified in the literature on neck pain by 1) surveying Canadian manipulative physiotherapists about their practice patterns regarding the use of manual therapy (MT), 2) surveying patients receiving MT in physiotherapy clinics across Canada about their perceptions of the nature of adverse events (AE), how they are defined and when they perceive that they occur, and 3) conducting a rigorous pilot and feasibility study of AE associated with cervical MT amongst Canadian manipulative physiotherapists. Together these three chapters will add to the knowledge base regarding effective collection of harm data pertaining to AE in MT. In particular, the pilot and feasibility study will identify issues relevant to recruitment and enrolment strategies, primary and secondary outcome measures, and data collection methods to inform a larger international multicentre study. Collectively they will inform researchers and clinicians about important methodological considerations to optimize the risk benefit analysis of MT in patients with neck pain.

Epidemiology of neck pain

Neck pain is a common problem that affects a large proportion of the population. Prevalence estimates are variable ranging from 0.4% -86.8% (mean 23.1%) in the general population. One year incidence has been reported to range from 10.4%-21.3%, thereby affecting most people in their lifetime.[1] Neck pain has an episodic course. [2, 3] Risk factors for neck pain include being female, between the ages of 35-49 years and having a

previous episode.[1, 4, 5] Neck pain is more prevalent in higher income countries, and urban areas. This higher prevalence may be due to the association of neck pain in office workers (34%-57%) and the use of motorized transit found in developed countries.[3, 6] Estimated expenditures on spine related care in the United States have almost doubled in the last decade.[4, 7] The number of emergency room visits related to motor vehicle accidents (MVA) has been steadily increasing in the last three decades.[8] Direct healthcare costs may only be a small piece of this burden, while the indirect costs of work absenteeism and disability are much greater.[1, 2]

Motor vehicle accidents are the most common cause of whiplash type injuries, which can lead to a complex presentation of symptoms resulting in the coining of the term, whiplash associated disorder (WAD).[9] Common symptoms range from pain in the neck, upper limb and back, to headache, dizziness, numbness, and cognitive deficits.[10] Psychological aspects such as pain catastrophizing, fear avoidance, depression and anxiety are also frequently reported in the more severe and chronic patients with WAD.[11, 12] A recent study reported that more than 58% of people with neck pain following MVAs were work-disabled [13].

The association between severity and disability of neck pain has been established by numerous studies [12, 14-16] and pain is often found throughout all stages of a neck injury. Other commonly measured constructs in patients with neck pain are fear avoidance, satisfaction, global rating of change and pain catastrophizing. [11, 17-19] These

concepts are usually collected with condition specific or general patient self report measures.

Measurement of neck symptoms and disability

The Neck Disability Index (NDI) is the most common condition specific measure used.[20] The NDI, is a 10 item scale that assumes that all items are equally important to all people. It also contains items that may not be pertinent for some people (e.g. driving). It is mainly considered a one-dimensional measure that can be interpreted as an interval scale. The minimal detectable change ranges from 5-10/50 representing uncomplicated neck pain at the lower end and cervical radiculopathy at the higher. [21, 22]There is even less agreement on the clinically important difference which ranges across different studies from 5/50 to 19/50. [21, 23] The measure has been shown to have acceptable reliability.[24]

Pain measures are also used such as the numeric pain rating scale (NPRS), or visual analog scale. The NPRS is easy to use and can be administered verbally or in written form. The patient is asked to rate their pain (e.g. current, pain in last week, or last 24 hours) on a scale of zero-10 with zero representing no pain and 10 the worst pain imaginable. A psychometric study of the NPRS was performed in people with nonspecific neck pain and reported that a change of less than 1.5 is insignificant. It reported that beyond a change of 1.5 points, clinically relevant values vary depending on the method of estimation used.[25] This finding is supported by another study that assessed

the minimal clinically important change of the NPRS and the NDI in patients with neck pain. It too reported that the threshold changes depending on the methods used.[22] The range of the minimal detectable change in the NDI ranged from 4.0-10.2.[22, 25]

One of the clinical implications of standardized measurement of pain and disability is the ability to predict which patients are likely to respond to treatment. High pain and disability scores are often indicative of patients who have a poor prognosis.[17, 26, 27] It is these patients who pose the greatest burden on the healthcare system. It is important for insurers and policy makers to be aware of these costs, in conjunction with the costs and effectiveness of available treatments so that proper resource allocation can occur and treatment guidelines can be established. It is therefore important that treatment provided by healthcare practitioners is evidence based to optimize the delivery of care.

Manual therapy

Practitioners such as physiotherapists, osteopaths and chiropractors treat patients with neck pain with a variety of modalities such as acupuncture, electrotherapeutic agents, thermal agents, exercise and MT such as mobilization and manipulation.[28] The effectiveness of MT in combination with exercise provides some of the best effect size estimates. [28-33] Outcomes such as better pain reduction, better patient satisfaction, improved function, increased range of motion and increased strength for neck pain [34-37] have been reported in patients who received MT alone or in combination with other modalities. Manual therapy is typically comprised of two broad categories of techniques,

mobilization and manipulation and these terms are used to describe interventions that involve passive joint movement. Mobilization is defined as a low velocity small or large amplitude passive movement of a spinal segment undertaken within the normal physiological range of the joint.[34] Manipulation is a high velocity, low amplitude movement of the joint, taking the joint beyond its normal physiological range.[35]

To our knowledge, utilization of both MT treatment techniques amongst physiotherapists for neck pain has not been published. However, studies examining practice patterns for the treatment of low back pain suggest an increased utilization of manual therapy in the last two decades.[36-38] Factors associated with this increase have not been evaluated, but the increasing evidence base for its effectiveness may be one potential factor. If the evidence base for these techniques is a factor, one may speculate that the same could be true for patients with neck pain. However MT techniques performed on the neck carry with it far greater risks than those on the low back.

Adverse events

Unfortunately, there has been a history of AE reported with MT for more than 50 years [39], ranging from transient and benign events to catastrophic ones; the history and frequency of events is greater for manipulation than for mobilization techniques.[40] Mild, transient AE, such as dizziness and increased soreness are frequent and common across professions treating neck disorders.[41, 42], while the majority of the literature reporting catastrophic AE (such as stroke or death) has been associated with chiropractic care.[43, 44] The reasons for this are unknown but it may be due to a variety of factors such as a

difference in the application of the technique, differences in population or frequency of use in clinical practice. Surveys of chiropractors have indicated that they manipulate the neck approximately 40 times per week in the United Kingdom and in the United States that more than 95% of chiropractors manipulate more than 71% of the patients in their caseload. Compared to osteopaths and physiotherapists, manipulation is at the core of chiropractors education and appears to be seminal to treatment plans for spinal disorders.[45, 46]

Since physiotherapists perform neck manipulation, it is important to establish safety data that is profession specific that may address variation between professions. Doing so will allow practitioners administering and patients receiving the techniques to have greater confidence in choosing the best available treatment options that are based on the presentation of information about potential benefit and harm. There are many components that affect the acquisition of accurate estimates of risk for neck manipulation. This includes the ability to meta-analyze homogenous data on AE related to neck manipulation and to be familiar with practice patterns of manipulative physiotherapists that affect the delivery of manipulation. Collection of homogenous data for AE is predicated on being able to classify AE appropriately and this requires standardized definitions and an agreed upon framework.

A systematic review of harms associated with cervical manipulation and mobilization was conducted and identified inconsistent terminology with respect to unexpected unfavourable events (harm) that occurred following treatment.[47] Common terms for harm that were reported within the eligible studies included: adverse events,

adverse reactions, adverse effects, side effects, complications, and safety.[40] Only two observational studies provided definitions of the symptoms or events that would constitute an adverse event and the related categories of severity. Consistent reporting of harms in both research and clinical practice requires professional consensus on terminology pertaining to harms, as well as, defining what constitutes an adverse event or an adverse reaction. Widespread consultation and consensus should support optimal definitions and processes, and facilitate their implementation into practice.[47]

Carnes et al.[48] have provided a framework from which the process of standardization can begin. They presented a hierarchical system to help define and categorize the range of possible adverse events. The study employed the Delphi process consulting a heterogenous group of experts to provide an initial taxonomy. The one notable oversight in the Carnes study was the exclusion of patients in the consensus exercise. Previous studies have indicated that patients have a different view of complications than clinicians, [49]specifically for acute injuries like distal radius fracture.[50] This previous research suggests that patients view adverse symptoms as an adverse event when these are associated with an injury and not the intervention administered by the clinician. Furthermore, patients may have difficulty distinguishing symptoms of their problem, from adverse events symptoms that arise following treatment. This highlights the difficulty in defining when a symptom becomes an adverse response.

Patients' views are essential in all aspects of healthcare. Understanding their interpretation, expectations, and perceptions may help guide definitions of harm in orthopaedic physical therapy, or illuminate how clinicians and patients can come to a

shared understanding of the response to orthopaedic physical therapy interventions. Understanding how clinical experience, the evidence, and patient values and perspectives intersect in this process is critical. A starting point is clear and consistent terminology that is consistently used by clinicians and incorporated into routine documentation of responses to orthopaedic physical therapy.[47]

The current knowledge base regarding the occurrence of AE related to MT is heterogeneous. Different professions, different study designs with varying analyses, and a lack of comparable categories results in a wide estimate of the incidence rate of AE. The variation in estimates around the more common, benign and transient AE is smaller than that around the rare catastrophic AE. Two systematic reviews reported the occurrence of the former to range from 17-22% [40, 41], meaning that approximately one in five patients with neck pain will experience an AE that is benign and transient. Studies that have attempted to estimate the incidence of rare catastrophic AE associated with MT are wide ranging in their results and the statistic in which they are presented. Recent estimates report the rate at 1 in 10,000 manipulations performed[51], or patients with neck pain who receive manipulation are three times more likely to stroke after a chiropractic visit. [52] Providing profession specific data is important, as it is commonly known that chiropractors manipulate the spine more frequently than physiotherapists, as it is the mainstay of chiropractic treatment. Differences in technique delivery and populations seeking care may also affect estimates. As there have been no similar estimates provided in the physiotherapy profession and patient population, it is important to establish the feasibility of running a large-scale study. A pilot study will identify issues that may

impact on the collection and analyses of AE data specific to manipulative physiotherapists and their patients. Data specific to manipulative physiotherapists will allow practitioners to provide a balanced risk-benefit profile of neck manipulation and alternative treatments so that patients can make an informed choice.

This thesis is aimed at building the necessary components of being able to provide practitioners with this knowledge base by examining practice patterns, patient beliefs and the profession specific incidence of AE.

CHAPTER 2

Beliefs and Practice Patterns in Spinal Manipulation and Spinal Motion Palpation Reported by Canadian Manipulative Physiotherapists

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ABSTRACT

Purpose: This practice survey describes the use of spinal manipulation and mobilization and perceived competency in performing spinal assessment among Fellows of the Canadian Academy of Manipulative Physiotherapy (FCAMPT); and quantifies relationships between clinical experience and use of spinal manipulation. **Methods**: Items were derived from experts and the literature. A cross sectional survey was administered to a random sample of the FCAMPT mailing list. Descriptive and inferential statistics included frequencies and linear regression respectively. **Results**: The response rate was 82% (n=278/338 eligible FCAMPTs). Most (99%) used spinal manipulation. Two-thirds (62%) used clinical presentation as a factor when deciding to mobilize or manipulate. The least frequently manipulated spinal region was the cervical spine (2% of patients); 60% felt that cervical manipulation generated more adverse events. Increased experience was associated with increased use of upper cervical manipulation in males (14% more often for every 10 years after certification; beta 1.37, (0.89,1.85) $p<0.001$). This relationship was not present in females. Confidence in palpation accuracy decreased in lower regions of the spine. **Conclusion**: Spinal manipulation/mobilization use is prevalent among FCAMPTs; however there is reduced usage in the neck due to perceptions about the association of adverse events.

INTRODUCTION

Manual therapy techniques are effective for the treatment of spinal disorders.[1, 2] Physiotherapists use manual techniques for assessment and treatment. Mobilization and manipulation are terms used for manual physical therapy interventions that involve passive joint movement. Mobilization is defined as a low velocity small or large amplitude passive movement of a spinal segment undertaken within the normal physiological range of the joint.[3] Manipulation is a high velocity, low amplitude movement of the joint, taking the joint beyond its normal physiological range.[4] Manual techniques developed by Geoffrey Maitland, passive physiological intervertebral movement (PPIVM) and passive accessory intervertebral movement (PAIVM),[5] are taught by Canadian manual therapy education programs for the assessment of motion between two adjacent spinal segments. James Cyriax suggested the use of manual spinal traction and compression as pain provocation techniques to help inform clinical judgments about the intervertebral structure at fault.[6]

Clinical examination is used to determine when mobilization or manipulation is needed for patients with joint dysfunction. Assessing the reliability and validity of these clinical assessment skills is important because they underlie the judgment of who receives these treatment options. Previous research has established that manual therapists can reliably assess motion characteristics during passive shoulder movement assessment[7] and that the quantity of movement reported in a manual therapy assessment was valid in comparison to blinded goniometric assessment ($r=0.79-0.94$).[7] However, the degree of reliability and validity of spinal joints assessment has been more controversial.[8]

The debate about validity of manual spinal assessment techniques is unresolved because of adequate reference standards that discriminate quantity and quality of the range of motion between segments and subjects. Najm et al.,[9] have systematically reviewed spinal motion tests for their discriminative validity. Using biomechanical models and self-report measures as the reference standards, their analysis indicated that practitioners are more likely to detect unrestricted intervertebral motion and that the greatest sensitivity (82%) and specificity (79%) for pain provocation was in the cervical spine. Some of the poor accuracy reported can be attributed to the lack of an accepted gold standard for assessing the parameters being evaluated by passive spinal joint motion tests.

Expert opinion has commonly been used to validate items on self-report measures. While some authors have explored expert opinion as a means of evaluating "content validity" of spinal motion assessment techniques, it might be questioned whether this approach measures content validity or practice beliefs. For example, manual therapists in the Netherlands believe strongly in the conclusions drawn from PPIVM assessment because they played an important role in determining the appropriate treatment.[10] In contrast manipulative physiotherapists in New Zealand and the United States strongly endorsed the face validity of PPIVM and PAIVM techniques based on the belief that these two techniques can determine the quantity of intervertebral movement and the quality of the force-displacement relationship throughout this range of motion. Given the limitations in perception, more investigation into the validity of manual spinal assessment is required. [8]

Spinal manipulation and mobilization are treatment techniques used to decrease pain and improve joint mobility and overall function.[5] However, media attention on the association of neck manipulation with adverse events has increased awareness of this issue in the Canadian public.[11] If the media and scientific evidence influence views within the physiotherapy profession about the potential for serious adverse events, this impact may be reflected in practice patterns. For example, a pattern of relatively lower utilization of manipulation in the cervical spine versus other joint use has been reported in physiotherapy practice surveys.[12, 13] Jull[14] suggested that the lower use of cervical spine manipulation compared to mobilization by Australian manipulative physiotherapists might reflect judicious application of manipulation. Grant and Niere[15] examined the use of spinal manipulative techniques by Australian manipulative physiotherapists who regularly treated persons with headache complaints. In this population, spinal manipulation was performed at the C2/C3 intervertebral joint more often than the occipito-atlantal or the C1/C2 articulation. The authors hypothesized that less frequent manipulation of the two highest cervical spine levels may have been due to clinicians' awareness of the increased potential for adverse effects from manipulation of these intervertebral joints.[15] Consistent with these studies, Adams and Sim[16] found that 'non- and partial-users' of spinal manipulation in the United Kingdom avoided the technique because of the possibility that complications might result from manipulation. In Canada, Hurley et al., [17] surveyed Canadian physiotherapists who used spinal manipulation and showed that only 35% manipulated the cervical spine.

Knowledge of the use of spinal manipulation and mobilization techniques is important to establish clinical practice patterns and compare them to published clinical practice guidelines or evidence-based treatment. Practice pattern data can also inform educational curricula or the need for knowledge translation interventions to change practice patterns that are discordant from those suggested by best evidence. In the case of cervical spine manipulation, comparing practice patterns with results of meta-analyses of efficacy and adverse events may influence future decisions regarding ongoing instruction of these techniques. For example, if the evidence regarding neck pain continues to show no substantial benefit of using spinal manipulation over mobilization,[18] this may diminish the clinical value of this technique and educational programs may limit the instruction of cervical spinal manipulation techniques.

The investigation of Canadian manipulative physiotherapists' beliefs about and use of spinal motion palpation, spinal mobilization and manipulation would inform the debate about the clinical value of these manual techniques. The overall objective of this study was to document the use of and perceptions towards spinal manipulation and mobilization and the perceived accuracy of PPIVM and PAIVM techniques among Canadian manipulative physiotherapists. A secondary objective was to ascertain the relationship between years of clinical experience following certification as a Canadian manipulative physiotherapist and use of manipulation in various regions of the spine.

METHODS

A 16-item questionnaire was developed in Canada's two official languages (see appendix A). Questions were developed by LC, JM and BC after review of the relevant literature for gaps needing to be addressed. Questions were then pilot tested with a small group of local FCAMPTs and physiotherapists in the Masters of Manipulative Therapy program at the University of Western Ontario. The same was done for the French version. Translation was done forwards and backwards to check for accuracy. Items were ordered so clinicians not practicing orthopaedic manual therapy or not performing spinal manipulation were directed to not answer items pertaining to the use of spinal mobilization and manipulation.

The target population was certified Canadian manipulative physiotherapists. In Canada, there are two certification programs, the first developed in 1985 by the Orthopaedic Division of the Canadian Physiotherapy Association [19] and the second in 2007 at the University of Western Ontario. The International Federation of Manipulative Physical Therapists (IFOMPT) accredits both programs and graduates are eligible to be certified as a Fellow of the Canadian Academy of Manipulative Physiotherapists (FCAMPT).

Using the FCAMPT membership list (n=485) as of February 2010, 359 potential respondents were randomly sampled [or drawn] using statistical software, from six geographic regions of Canada: British Columbia, Alberta, Sasketchewan/Manitoba, Ontario, Quebec, New Brunswick/Nova Scotia/Newfoundland (there were no FCAMPTs in Prince Edward Island). Individuals excluded from this sampling frame were

FCAMPTs who did not provide a mailing address, or worked/resided outside of Canada, or were members of the research team. Sample size calculations used the formula for stratified random sampling with proportional allocation described by Schaeffer et al. (1996), [20] meaning that the number of potential respondents selected from a given region was based on the proportion of the full list comprised by that region. The sample size was sufficient to estimate a proportion = 0.5. A confidence limit approach was used, whereby the limit on the error of estimation = 0.05. Adjustments were made for ineligible respondents identified during mail-out (10%) and non-respondents to the survey (30%).

A cross-sectional survey was conducted by mail, from March to June 2010, following Dillman[21] to maximize response rate. This consisted of the following: all FCAMPTs in the sample received three contacts by first-class mail: a pre-notice letter advising of the impending arrival of the survey package, a survey package and a post card reminder or thank you. The time between mailings was 7 to 10 days. Two weeks after the third contact, the remaining non-respondents were mailed a second survey package. For the remaining non-respondents after the fourth contact, a fifth and final contact was made of a third survey package.

To assess the quality of data entry, 10% of the dataset was randomly selected and checked for accuracy. Discrepant entries (<1%) were resolved. As the sample was drawn from the previously specified six geographic regions, a weighted analysis by region was conducted. Responses to each item were summarized with descriptive statistics. Multiple linear regression was used to examine the relationship between frequency of use of manipulation for each region of the spine, cervical, thoracic, lumbar or sacroiliac,

(dependent variable: % of patients manipulated) and a) years of experience since FCAMPT certification controlling for b) beliefs of which region of the spine generated the most adverse events, c) the effectiveness of manipulation and mobilization, d) the occurrence of adverse events related to manipulation and mobilization, and e) gender. The following interaction terms were included: gender and years of experience since FCAMPT certification, beliefs about the occurrence of adverse events for each region of the spine and years of experience since FCAMPT certification and beliefs about the effectiveness of manipulation/mobilization and years of experience since FCAMPT certification. There is evidence that females may use manipulation less than males due to fear of adverse events;[12] perspectives about adverse events may change with use; and beliefs about the effectiveness of these techniques may change with the ability to perform both. Each model was run entering all of the independent variables and interaction terms together. Following a significant interaction, we split the sample into appropriate subgroups. In the absence of a significant interaction, the regression was rerun with the interaction terms removed. Residual and model diagnostics were conducted to assess for severe violations of the assumptions about the errors.

Responses for each of the three palpation accuracy items in the questionnaire were dichotomized to portray the presence or absence of doubt about motion palpation accuracy. *'No doubt'* about motion palpation accuracy was defined as a respondent's belief that he or she was '*highly accurate'* when performing the assessment technique. All other response choices defined *'some level of doubt'* about one's accuracy with spinal motion palpation. It is commonly known that as therapists gain more experience in their

hands, their sensitivity and confidence in what is being perceived increases. For each accuracy item, Cochran's Q test[22] was used to determine if the proportion of FCAMPTs who had no doubt about the accuracy of their spinal motion palpation varied by spinal region. All statistical analyses were performed with SPSS version 19.

RESULTS

After removing 26 ineligible respondents identified during the mail-out process, the response rate was 82.2% (n=278/338 eligible respondents). Table 1 presents respondent characteristics, showing their high use of the manual therapy approach to assessment and treatment. Comparison of the geographic distribution of survey respondents with the FCAMPT mailing list revealed provincial areas were under/over-represented in the sample by < 2%/ ≤2.8%, respectively. The table also shows the sample was comprised of relatively experienced clinicians, most of whom had earned their FCAMPT qualification from the continuing education program in manipulative physiotherapy developed by the Orthopaedic Division of the Canadian Physiotherapy Association (86%). The mean (SD) number of years since attaining FCAMPT status was 8.8 (0.2) years. All remaining reported results are weighted findings.

Utilization of and beliefs about spinal manipulation and mobilization

A majority of respondents (62.9%) relied on clinical presentation when deciding to use spinal mobilization or manipulation, while 40.9% usually or always chose mobilization first. Frequency of spinal manipulation was highest for the thoracic spine

(50.0%) and substantially lower for the upper cervical spine (2.0%), the mid cervical (10.0%), lumbar (25.0%) and sacroiliac regions (20.0%). Across all geographic regions, the top two reasons for choosing to manipulate rather than mobilize the spine were: the spinal joint is fixated or stuck (54.5.1-83.6%), and to improve joint mobility (36.3-59.1%). Conversely, when choosing to mobilize rather than manipulate the spine, the top two reasons were: manipulation is contraindicated (27.2 - 54.6%), or the client's condition is too irritable for manipulation (31.8-38.7%).

When respondents were asked if they agreed that their use of spinal manipulation led to quicker discharge, a majority (66.0%) agreed, while one fifth (20.0%) neither agreed nor disagreed. With respect to overall effectiveness, 24.9% of respondents believed spinal manipulation is more effective than mobilization, while 68.2% believed the two treatments are equally effective. When asked about their beliefs regarding adverse events following these techniques, 50.1% indicated spinal manipulation leads to more adverse events, while 47.0% believed the two techniques create an equal number of adverse events. When asked which spinal region in their own clinical practice generates the most adverse events following manipulation, 55.0% chose either the upper or the mid cervical spine (see Figure 1).

For each region of the spine, respondents' beliefs regarding "no doubt" about their accuracy of detecting PPIVM, PAIVM and pain provocation is shown in Figure 2. The proportion of respondents with no doubt about their accuracy decreased in lower regions of the spine (PPIVM Cochran's $Q_{4df} = 64.768$, $p < 0.001$; PAIVM Cochran's $Q_{4df} = 37.991$, $p < 0.001$; pain provocation testing Cochran's $Q_{4df} = 15.678$, $p = 0.004$).

Association between frequency of spinal manipulation and clinical experience

Regression diagnostics revealed all models did not violate the error assumptions. When modeling frequency of manipulation in the upper cervical spine, the interaction term (gender x years of experience since FCAMPT certification) contributed significantly to the full model ($p < 0.001$). Based on this interaction the determinants of frequency of manipulation were analyzed separately for males and females. For males, frequency of upper cervical manipulation was associated with years of experience since FCAMPT certification, [beta (95% CI) =1.37 (0.89,1.85), $p < 0.001$]. This effect was not observed for females. For the remaining levels of the spine, there were no significant interactions so the effect of predictors was examined across both males and females.

In the mid cervical and lumbar spine, frequency of manipulation was associated with years of experience since FCAMPT certification [beta (95% CI) =0.68 (0.32, 1.03) $p < 0.001$ and 0.48 (0.03, 0.93) $p=0.04$, respectively]. In the thoracic spine and sacroiliac joint, there was no significant association between frequency of manipulation and years of experience since FCAMPT certification ($p>0.05$).

DISCUSSION

This study surveyed beliefs of FCAMPTs with respect to usage of assessment and treatment of passive joint motion in patients with spinal disorders. Overall the findings indicate that both techniques are commonly used, but there is substantial variation related to the region of the spine being treated, differences in beliefs about assessment accuracy, indications for treatment, and relative efficacy. The results are representative of Canadian

FCAMPTs because of the 82% response rate, the stratified random sampling and the use of a French version of the questionnaire for Francophone physiotherapists.

The finding that spinal manipulation was used most often in the thoracic spine and least in the cervical spine may be explained by existing evidence of relative efficacy and potential adverse events. There is an increasing pool of evidence supporting the use of thoracic spine manipulation for treating neck pain.[23, 24] Concurrently, there are increasing safety concerns about manipulating the cervical spine.[13, 16] This study shows that Canadian FCAMPTs have similar concerns since they reported that cervical spine manipulation creates the greatest number of adverse events in their clinical practice, particularly in the mid cervical compared to the upper cervical spine. This appears to be in contrast to respondents' report that they manipulate the mid cervical spine more often than the upper. This may simply be a result of recall bias, but it is beyond the scope of this paper to understand this conflict as we could not ask about this finding. Regardless, the observed practice pattern is consistent with practitioners gravitating towards a treatment option that appears to be safer. There is little published evidence regarding the safety of thoracic spine manipulation[16, 25] and respondents concurred that thoracic spine manipulation generates fewer adverse events. Interestingly, when asked whether spinal manipulation or mobilization leads to more adverse events, respondents were equally divided between those who felt spinal manipulation was more risky versus those who felt both techniques have an equal amount of adverse events. This dichotomy may indicate some practitioners were focusing on the more severe and rare adverse events associated with cervical spinal manipulation,[26] while others may have been acknowledging the more

frequent occurrence of benign and transient adverse events commonly observed with both techniques.[27-29] Unfortunately, there are no large cohort studies that have accurately established the rates of mild to severe adverse events following mobilization and manipulation techniques applied by physiotherapists. Further, data existing from other professions who use different types of manipulation are unlikely to apply.

The most common rationale for choosing a specific technique was based on clinical presentation. While surveys might be able to identify simple parameters like indications and contraindications, they are not ideally suited to understanding complex clinical reasoning processes that might be involved. Since the majority of respondents are using the information presented during the clinical assessment to guide treatment decisions, qualitative studies that would inform our understanding of what goes into these complex decision-making processes are warranted.

In this study, the majority of FCAMPTs reported that they are highly accurate with PPIVM and PAIVM testing. This finding is similar to the beliefs held by manipulative physiotherapists in other countries for PPIVM[10]and segmental spinal motion (PPIVM AND PAIVM). [8] While confidence in a technique is not certainty that it is valid, consensus can be considered one form of support for a practice behavior.

Ideally, assessment principles should be able to pass "proof of concept" testing where the underlying principles upon which the test is based can be established to be true. Fewer respondents may have reported "no doubt" in their accuracy with PPIVM and PAIVM testing in the thoracic and lumbar spine because their beliefs about coupled motion in these regions reflect the state of the literature contrasted with the lower cervical

spine, where agreement of the coupling biomechanics in the literature exists, and respondents had 'no doubt' about their accuracy with PPIVM and PAIVM testing. Therefore clinical assessment techniques that are based on biomechanical principles should have sound supporting biomechanical evidence that the joint surfaces behave in the manner prescribed by the test performance. The evidence around these foundational principles has been reviewed.[30-32] A systematic review of coupling motions in the cervical spine[31] evaluating agreement between studies of the coupling behaviour, suggests that coupling in the upper cervical motion segments should be questioned. Conversely, there is complete agreement on the coupling behaviour of the motion segments in the lower cervical spine. In the thoracic spine there is no consistent coupling pattern[32] and it also varies in the lumbar spine. [30] Lack of agreement about the coupling behaviour in a spinal area may be interpreted as making it more difficult to accurately assess that region because of a developing foundational knowledge base. Also, these accuracy beliefs could have been influenced by the curricula of Canadian advanced manipulative physiotherapy programs, because content regarding spinal coupling behaviour was obtained from the literature. Both Canadian programs teach the same coupling patterns.[19, 33]

We were interested in the effect of clinical experience on frequency of use of manipulation since one might anticipate that therapists who experience good outcomes with a technique and minimal adverse events might increase their utilization over time. Frequency of use might also vary with the nature of the learning curve for the techniques. We found that there was an increase in utilization of spinal manipulation among

therapists with more experience and that it was greatest for the cervical spine. In the upper cervical spine, the relationship between frequency of spinal manipulation and clinical experience was found for males only. Potentially, estimates of risk or the manner of dealing with risk varies across genders. Our survey is not able to differentiate the reasons for this finding. A previous survey of FCAMPTS in 2005 showed that females were manipulating the cervical spine less often due to fear of adverse outcomes[12] and there is limited evidence that manipulation is more effective than mobilization for any region of the spine.[1] As attention continues to focus on cervical manipulation and serious adverse events regardless of their rarity, it is important that educators focus on the clinical reasoning processes surrounding its use[34] as well as other treatment options.[35]

Defining practice patterns by self-report, despite the inherent limitations, is a useful preliminary step in investigating the potential for adverse events in manipulative physiotherapy. At present, there is little evidence defining serious adverse events that have occurred following physiotherapy intervention. [26, 36] The evidence for adverse events following manipulation is primarily from chiropractic practice data. [26, 37] Differences in rates of adverse events between professions may be due to differences in 1) manipulative techniques, 2) rate of use (i.e. chiropractors exceed other disciplines), and 3) that these are rare events. One study reported that chiropractors in the United Kingdom average 40 cervical spine manipulations per week.[38] While it seems plausible that chiropractors perform spinal manipulation more frequently than physiotherapists as it is commonly known that spinal manipulation is at the core of their education, we are unaware of any study that has reported similar figures for manipulative physiotherapists.

Considering this evidence and the increased public concern around the safety of this intervention, it is necessary to have discipline specific, high quality cohort data before physiotherapists can be confident in their safety.

An important consideration when evaluating practice patterns is whether they indicate evidence practice gaps, which exists if clinicians are underutilizing effective treatments or over utilizing interventions that are not supported by evidence. Current literature suggests that when used in a multimodal approach [18, 39] spinal manipulation is as efficacious for neck pain as spinal mobilization alone; also, there is increasing evidence for the efficacy of thoracic manipulation [23] for the treatment of neck pain. Given the lack of sufficient clinical trial data comparing neck manipulation with thoracic spine manipulation for the management of neck pain, and a lack of documentation, it would be premature to suggest that manipulation is not a suitable treatment alternative. Belief about higher rates of adverse events with cervical spine manipulation may indicate that FCAMPT practice is moving away from manipulation of the cervical spine and towards techniques where there is more perceived confidence regarding clinical safety.

As with all practice pattern surveys there are limitations that should be considered when interpreting our data. Self-reporting of practice behaviors is susceptible to recall bias and social desirability bias.[40] Relying on memory has been shown to be problematic and can under or over estimate incidence, [40] possibly resulting in respondents under or over reporting their practice behaviors or beliefs in our study. Another limitation in our findings is the lack of a standard definition of adverse events in manual therapy,[41] which

means that respondents may have interpreted the term differently. This gap would be expected to contribute to random error to our estimations.

CONCLUSIONS

The finding of lower use of manipulation in the cervical spine suggests that professional physiotherapy associations in Canada and other countries with similar practice patterns will need to monitor usage rates of cervical spine manipulation. Repeating this survey in other IFOMPT member organizations will help achieve this and validate this trend. These findings suggest that there is a need for definitive information on the actual rates of adverse events so that practice beliefs may be based on actual data. If cervical manipulation is not performed frequently by FCAMPTs, then this might affect the way that training and competency testing is conducted. For example, there might be a decreasing supply of evaluators who feel they practice/value the technique enough to act as mentors. More comparative evidence regarding the efficacy of cervical mobilization, thoracic manipulation and cervical manipulation is needed to insure that the beliefs around manipulation are grounded in evidence. If usage rates continue to decrease and evidence continues to show no clear advantage from cervical manipulation; the greater safety of cervical mobilization and thoracic manipulation suggests that reassessing the value of teaching cervical manipulation should be contemplated.

KEY MESSAGES

What Is Already Known on This Subject

The validity of assessing spinal joint motion dysfunction through manual examination has been controversial in the literature. Despite this debate, international

surveys of orthopaedic manipulative physiotherapists show continued use of, and confidence in, manual assessment techniques to guide manual treatment interventions, including spinal manipulation. Cervical spine manipulation has a low utilization rate among international orthopaedic manipulative physiotherapists and is associated with fear of adverse events associated with the technique. Population-based Canadian data on beliefs about and use of spinal manipulation do not exist.

What This Study Adds

This study confirms that most FCAMPTs use spinal manipulation, with clinical reasoning driving decisions to use mobilization or manipulation. FCAMPTs have greater confidence in their accuracy when assessing the cervical spine compared to lower spinal regions, although therapists acknowledge that the cervical spine has a higher rate of adverse events. Practice patterns suggest that manipulative therapists may choose treatments, such as thoracic spine manipulation for neck pain, due to safety considerations. As the evidence continues to emerge about the relative effectiveness of manipulation and mobilization it will be important for FCAMPT training programs to revisit the curriculum and certification criteria, and to consider knowledge translation strategies if practice patterns indicate variances between evidence and practice.

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Table 1. Respondent characteristics (n=278)

Characteristic	n (%)
Gender, *female*	155 (55.8)
Currently practicing orthopaedic manual therapy, *yes*	271 (97.5)
If yes, using high velocity spinal manipulation, *yes*	268 (97.6)
Total experience as a physiotherapist, *years*	
< 5	2 (0.7)
5-9	39 (14.0)
10-14	87 (31.3)
15-19	66 (23.7)
≥ 20	84 (33.2)
Educational program used to obtain FCAMPT* designation	
In Canada	
Orthopaedic Division of CPA†	239 (86.0)
University-based Master's degree in manipulative therapy	12 (4.3)
Outside of Canada	15 (5.4)
IFOMPT‡ *accredited program*	12 (4.3)
More than one of above	

* Fellow of the Canadian Academy of Manipulative Physiotherapy

† Canadian Physiotherapy Association

‡ International Federation of Manipulative Physical Therapists

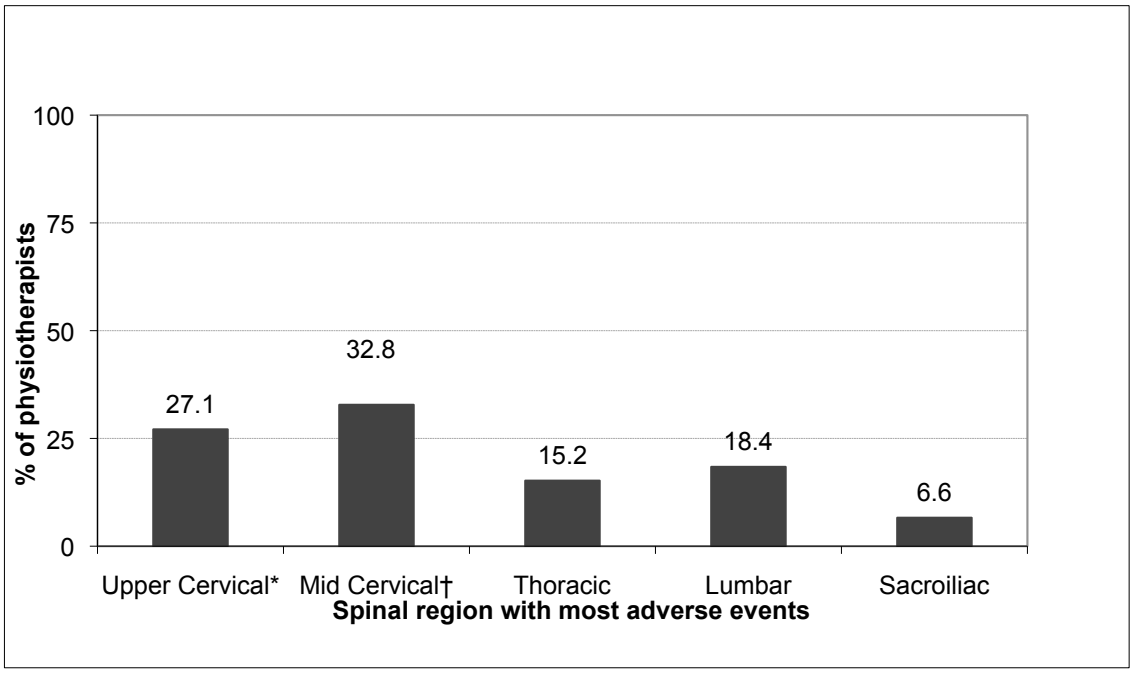

Figure 1. Spinal region generating the most adverse events from spinal manipulation in respondents' clinical practice (n=244)

* occiput to C2

† C3 to C7

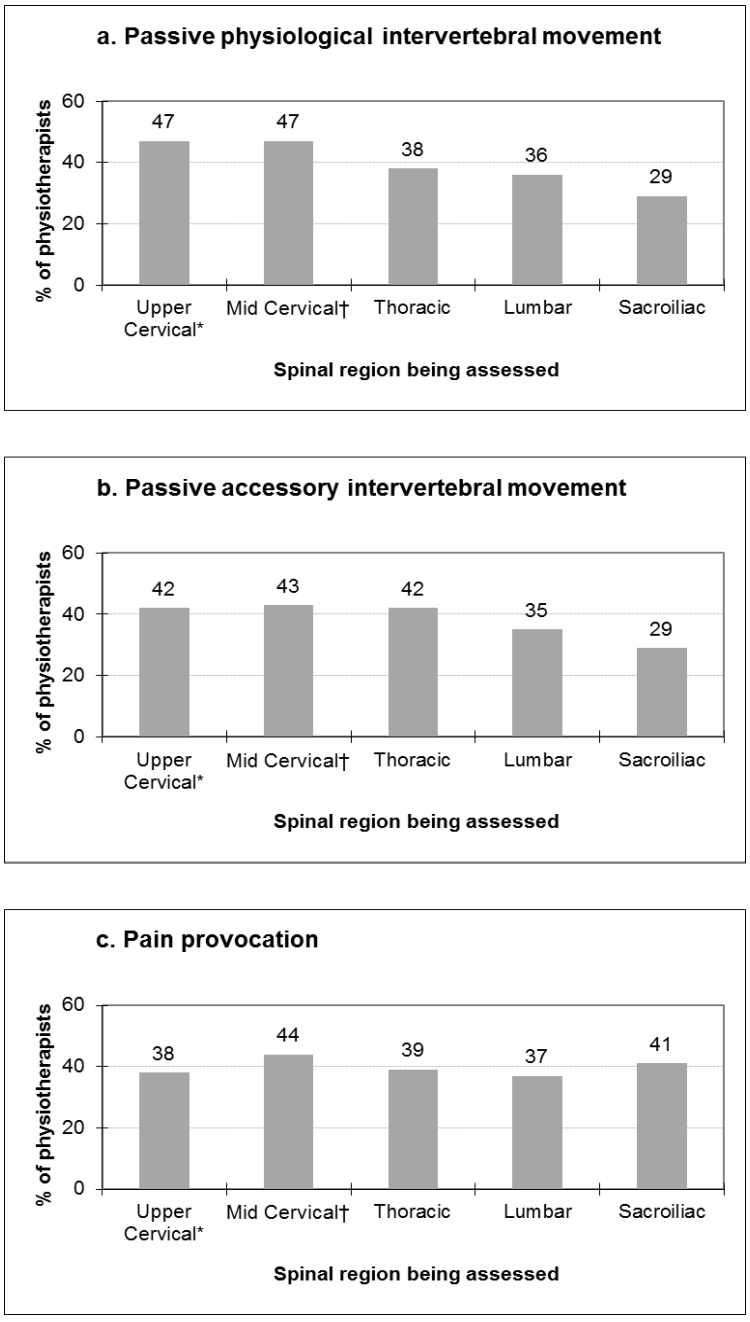

Figure 2. Percentage of respondents who had 'no doubt' about their accuracy of performing three spinal assessment techniques, by spinal region being assessed (n=278)
occiput to C2
† C3 to C7

Appendix A

Summary of questionnaire content*

Demographics

Q1- currently practicing orthopaedic manual physiotherapy? (yes/no)

Q2- use high velocity thrust spinal manipulations in clinical practice? (yes/no)

Q3- gender (male/female)

Q4- year obtained FCAMPT (within Canada-Orthopaedic Division of CPA / within Canada-University-based Master's - Manipulative Therapy specialization / outside of Canada-International IFOMPT trained / Other)

Q5- total years of clinical practice (<5 / 5-9 / 10-14 / 15-19 / ≥20)

Use of mobilization and manipulation

Q6- Choose statement that best represents your use of orthopaedic manual therapy treatment techniques: always use mobilization first/ usually use mobilization first / mobilize or manipulate first based on the clinical presentation of each patient / usually use manipulation first / always use manipulation first.

Q7- For each spinal region (upper cervical-occiput to C2 / mid cervical-C3 to C7 / thoracic / lumbar / sacroiliac), indicate the percentage of patients on whom you perform manipulation.

Q8- When choosing manipulation over mobilization, rank the following reasons most reflective of your practice: patient's progress has reached a plateau / spinal joint is fixated (or stuck) / alleviate pain / alleviate muscle spasm or tone / improve joint mobility / achieve quicker results / indicated by clinical prediction rule / other.

Q9- When choosing mobilization over manipulation, rank the following reasons most reflective of your practice: manipulation contraindicated / patient too irritable for

manipulation / only use manipulation as last resort / can be just as effective using mobilization / lack of indications for manipulation / other.

Q10- Choose level of agreement with statement; 'When indicated, I believe that by using spinal manipulation my patients will be discharged sooner': strongly agree / agree / neither agree or disagree / somewhat disagree / disagree / strongly disagree.

Q11- Choose spinal region that generates the most patient reports of adverse events following spinal manipulation in your practice: upper cervical-occiput to C2 / mid cervical-C3 to C7 / thoracic / lumbar / sacroiliac.

Beliefs about mobilization, manipulation and accuracy of PPIVM, PAIVM and pain provocation techniques

Q12- Choose statement that best represents your beliefs regarding effectiveness of spinal mobilization and manipulation: mobilization is more effective than manipulation / mobilization and manipulation are equally effective / manipulation is more effective than mobilization.

Q13- Choose statement that best represents your beliefs regarding adverse events associated with spinal mobilization and manipulation: mobilization leads to more adverse events than manipulation / mobilization and manipulation create an equal amount of adverse events / manipulation leads to more adverse events than mobilization.

Perceived accuracy of PPIVM, PAIVM and pain provocation techniques

Response options for Q14, Q15, Q16: highly accurate / moderately accurate / somewhat accurate / unable to say / somewhat inaccurate / moderately inaccurate / highly inaccurate.

Q14- For each spinal region (upper cervical-occiput to C2 / mid cervical-C3 to C7 / thoracic / lumbar / sacroiliac) indicate your accuracy of detecting passive physiological inter-vertebral movement (PPIVM).

Q15- For each spinal region (upper cervical-occiput to C2 / mid cervical-C3 to C7 / thoracic / lumbar / sacroiliac) indicate your accuracy of detecting passive accessory inter-vertebral movement (PAIVM).

Q16- For each spinal region (upper cervical-occiput to C2 / mid cervical-C3 to C7 / thoracic / lumbar / sacroiliac) indicate your accuracy when performing pain provocation/alleviation testing.

* The formatted questionnaire used in the project is available from the corresponding author on request.

CHAPTER 3

A survey of patients' perceptions of what is 'adverse' in manual physiotherapy and predicting who is likely to say so.

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Abstract: Objectives: The primary objective was to describe the patient perspective regarding the identification and occurrence of adverse responses (AR) related to manual therapy. A secondary objective was to evaluate predictors of the incidence rate of AR reported by patients receiving orthopaedic manual physiotherapy. **Study design and setting**: This study conducted a cross sectional survey questionnaire of patients with musculoskeletal pain receiving orthopaedic manual physiotherapy recruited by physiotherapists in Canada. Survey questions asked which symptoms patients consider to be adverse, causal associations with treatment and the impact of contextual factors. Descriptive statistics are reported and Poisson regression modelling was used to predict factors associated with reporting of AR. **Results:** A response rate of 76.2% (324/425) was obtained. Having lumbar spine dysfunction was a significant predictor of all AR [Incidence Rate Ratio [IRR] (95% confidence interval [CI]) = 1.513 (1.025, 2.235) p=0.037]. Having lumbar spine dysfunction was associated with a 51% greater identification of an AR compared to those with an extremity disorder. Expectation of soreness was a "protective factor" against identifying a major AR [IRR (95%CI) = 0.915 (0.838, 0.999) p=0.047; they had a 8.5% lower rate of identifying a major AR relative to those without this expectation. **Conclusions:** The patient perspective including contextual factors is important to consider if a comprehensive framework for defining AR in manual therapies is to be developed.

Key words: adverse events, manual therapy, patient beliefs, physiotherapy, classification, survey

What's new

- Patients with low back dysfunction (ie. lumbar spine) are about 50% more likely to identify adverse responses than patients with extremity disorders
- Patients with an expectation of post treatment soreness are 9% less likely to identify an adverse response compared to those without this expectation
- Contextual factors such as whether the patient is advised about potential adverse responses by the physiotherapist or if the patient is getting better overall, are important to how patients decide whether a symptom is adverse
- A comprehensive framework for adverse response definition in manual therapy should include the patient perspective as it is reflective of the complex decision making process undertaken by patients

Introduction

Part of the validity of a clinical practice guideline is based on its inclusion of patient viewpoints when consolidating the evidence base and making recommendations for clinical practice. (1) Using a patient centred approach is also considered to be good clinical practice so that a shared decision making process can arrive at 'optimal' treatment options. (2) In the area of manual therapy, recent publications have drawn attention to the need for a standard definition of adverse responses (AR), their classification and terminology, (3, 4) but patient perspectives have not been included as of yet. Differences in patient values from those of practitioners have been demonstrated in their perspectives on AR.(5, 6)

A qualitative study (7) with patients receiving manual therapy from different disciplines has provided some pilot data that both overlaps and diverges from that proposed in an initial framework for defining AR in manual therapy created by varying practitioners and researchers. (4) The area of greatest similarity between the two studies pertained to the consideration of function within the mild AR category. Both the patients

and practitioners agreed that a mild AR would have no functional impact. There was divergence regarding the duration of an AR. Patients described a mild AR as lasting hours to two days, whereas the practitioner framework limited a mild AR to hours only. Further comparison was limited due to differences in study design. Additionally, the qualitative data suggests that contextual factors surrounding the patients' judgment influence whether a symptom is perceived as an AR or not. Contextual factors that have been identified, such as communication and expectation of the treatment, have been linked to patient satisfaction. (8) Extrapolating this reasoning it is obvious that patient's satisfaction with care may in turn be influenced by the occurrence (or their perceptions) of ARs. This qualitative study provides the first framework for patients perceptions regarding ARs related to manual therapy. Its two overarching themes, post treatment responses to manual therapy and beliefs and expectations of manual treatment, and the related sub themes informed the development of this study providing material for each section of the questionnaire.

While this qualitative analysis provided insight into the patient perspective on ARs, it did not allow understanding of the prevalence of these attitudes or their relative importance. Previous studies that have reported AR or side effect data with manual therapy have typically done so with a list of symptoms generated by practitioners, researchers, or the literature. (9, 10) The evidence suggests that patient perceptions of ARs differ from that of practitioners. There is evidence that practitioners' report ARs that predicts clinical events whereas patients' report ARs that reflects health status (6); also, practitioners have reported observable signs while patients have reported subjective

events.(5) This suggests that the lack of patient input regarding what symptoms they actually consider to be adverse is important.

The primary objective of this study was to describe the patient perspective regarding identification and occurrence of ARs related to manual therapy and secondarily to identify predictors of the incidence rates of symptoms identified by patients as ARs.

Methods

A cross-sectional survey of patients currently receiving outpatient orthopaedic manual physiotherapy was conducted from September 2010 to January 2011. The survey tool was developed based on findings from previous studies and consisted of 18 questions and a patient characteristics section. (See web appendix A)

Orthopaedic manual physiotherapists working in private clinics across Canada were contacted electronically via the Canadian Academy of Manipulative Physiotherapy and the Orthopaedic Division of the Canadian Physiotherapy Association's email lists and invited to recruit eligible patients to complete the survey. The membership lists were 485 and 4336 respectively. Eligible patients included those who were at least 18 years of age, currently attending physiotherapy treatment for any musculoskeletal problem where manual therapy treatment had been deemed appropriate by the treating physiotherapist, and had received at least one treatment of manual therapy to any part of the body. We specifically did not require that patients had experienced an AR, as this study is part of the ongoing process of trying to determine what types of symptoms and reactions patients actually define as adverse. This will then contribute their unique perspective when considering a comprehensive framework for definition and classification of ARs in

manual therapy. Patients were excluded if they were not receiving manual therapy as part of their care and were not fluent in the English language. Sample size calculations used the formula for proportions from Aday et al. 2009(11) with proportions set at 50.0%, a precision of 0.05 and adjustments made for non-respondents (10%). The target sample size was 422. Patients who were approached and expressed an interest in completing the survey, were given a letter of information and a copy of the survey. Those patients wishing to complete the survey online provided their e-mail address and consented to being contacted by the investigators. Patients completing the paper version of the survey were provided with the survey at their appointment and asked to complete it immediately after treatment or were allowed to take it home and return it.

Data quality was assessed by randomly sampling 10% of the dataset to check for errors. Discrepant entries were resolved (<1%). Descriptive statistics were used to summarize participants and their responses to each question. Poisson regression was used to determine factors associated with the number of symptoms that a patient would consider to be adverse. Patients were asked "Assuming one of the following symptoms happened to you after your treatment, which ones would you consider to be an AR? Mark all that are applicable." Table 1 includes the list of variables chosen for the model and the rationale.(12) Three interaction terms were also included in the model and these were: 1) participants with neck pain and who were in classified as chronic (> 3 months), 2) participants with neck pain and their self-rated state of recovery for the condition they were seeking treatment for and 3) participants with neck pain and their level of trust in the practitioner. Patients with neck pain were chosen as it is the area most widely reported

with ARs in manual therapy, and they were combined with chronicity due to known increased sensitivity to pain in this population. Therefore patients with this combination may have the potential to be more likely to report a symptom as adverse. The interaction with the patients self rated state of recovery was chosen as a qualitative study(7) suggested that a patient who perceived they were improving overall, may be less likely to label treatment experiences as adverse. Finally, trust in practitioner was combined with patients with neck pain, due to reports of catastrophic ARs associated with neck manipulation and qualitative data indicating that the degree to which a patient trusts a practitioner could affect whether a symptom is identified as adverse.(7) Data analysis occurred in the following order. An initial Poisson model was run using all of the above predictors. A second model was performed including only predictors with $p < 0.20$ from the first model. The modelling was then repeated using two separate outcomes, major symptoms (stroke, spinal cord injury, loss of bowel and bladder control, death) and minor to moderate symptoms (all other types). This dichotomization of the outcomes was undertaken as it was hypothesized that the predictors of these two categories were markedly different. Given the rarity of serious ARs, it would be useful to identify these differential predictors, as the repercussions for serious ARs are significantly greater for the patient and therapist. Each of the dichotomized outcome categories was run with a Poisson model. All variables were entered simultaneously. Sensitivity analysis for overdispersion, which is representative of excessive variance (deviance value/df > 1), was conducted using a Negative Binomial model on the final three models. Negative binomial models were used as they produce more reasonable standard errors of the estimate. The

results are reported as estimates of incidence rate ratio [IRR] (95% confidence interval [CI]) and associated p-values. The criterion for statistical significance was set at alpha = 0.05. We did not adjust the overall level of significance for multiple testing since the analyses are mainly exploratory. Missing data were not replaced. All analyses were conducted using SPSS version 19 (Chicago, IL).

Results

Thirty-one physiotherapists representing 19 private clinics participated representing 6.39% of CAMPT members and 0.71% of Orthopaedic Division members respectively. While this is a low proportion, the therapists are representative of the membership of these groups as 86% of the Orthopaedic division membership (a prerequisite for CAMPT membership), work in private practice (13) and it is commonly known that these clinics specialize in the treatment of orthopaedic disorders. Figure 1 represents the flow of participants. A sample of 425 patients was approached to complete the survey, of which 324 agreed, (response rate 76.2%). Patient characteristics are presented in Table 2.

Post treatment symptoms, adverse responses and causation

Table 3 provides the symptoms that were reported after manual therapy treatment as well as whether they where identified as an AR. Table 4 presents the top three reasons for considering whether a symptom is adverse.

A majority (80.3%) agreed that the impact of treatment on function was the most important factor in deciding whether or not one experiences an adverse response. Figure 2 summarizes categorization of ARs as not adverse, mild, moderate or major for function and duration of symptoms. Responses were collapsed using three categories of agreement and the neither agree nor disagree was grouped with the disagreement responses.

A definite time trend was noted regarding confidence that the "hands-on" part of the treatment caused their experience of an AR (see Figure 3).

There was majority agreement with the statement that "part of figuring out the cause of an AR involves considering other factors that may be contributing to the response" (95%). Table 5 lists factors considered to be causative and those that were not.

Predictors of adverse responses

Table 6 provides results for the three final models run with Poisson and negative binomial models. Overdispersion, was present in the 'all symptoms' and 'minor moderate' Poisson models. The 'major' Poisson model demonstrated better fit (deviance value/df = 0.795 than in the negative binomial model (deviance value/df = 0.038). In the 'all symptoms' model, the lumbar spine variable was significant [IRR (95%CI) = 1.513 (1.025, 2.235) p=0.037] inferring that the incidence rate of adverse symptoms among the group who had a lumbar spine problem is 51% more than among those who had an extremity problem. There was one significant predictor of major ARs, the expectation of soreness [IRR (95%CI) = 0.915 (0.838, 0.999) p=0.047)]. Those respondents who had an

expectation of being sore after manual therapy treatment had an incidence rate of major adverse symptoms that is 8.5% less than those who did not have this expectation.

Other Contextual factors

The majority (98%) agreed about the importance of the physiotherapist providing a warning that an AR after treatment was possible and that the warning made the experience of an AR more acceptable (93%).

Respondents agreed (90%) that trusting their physiotherapist is important and it lessens concern if an AR is experienced. The statements 'I expect to be a bit sore after treatment' and 'it is normal to be a bit sore after treatment' received 81% and 78% agreement respectively. Familiarity with sensations also lessened concern about an AR (93%).

Respondents felt that mild short term ARs are acceptable if one is getting better overall (96%), while 60% agreed that there is no risk of harm in manual therapy treatment. Lastly we presented respondents with a question modeled after the time trade-off technique. Almost half of respondents (49%) chose a risk between three and 20% chance of permanent disability with a 97% to 80% chance of recovery, while 45% chose a risk of 1% chance of permanent disability for 99% chance of recovery. The remaining levels of risk were sparsely selected.

Discussion

Although ARs following physical therapy interventions have previously been evaluated, these studies have not surveyed patients about their perceptions of what is adverse. This survey supports findings of a previous qualitative study of patient perspectives on ARs and the agreement between it and a previously established AR framework on the importance of function and the categorization of mild ARs.(4, 7)

This data builds on the qualitative study by providing insight into the symptoms that patients identify as adverse and how patients attribute causality. This patient perspective has some common elements with the Bradford Hills criteria of causation(14), such as temporality and explanation of alternate causes, and may have important clinical implications for the therapeutic relationship. Greater understanding of why some symptoms are labeled as adverse and how patients will rule some alternative causes in or out in their determination is likely valuable in factors mediating patient perceptions, which we identified in the survey. This understanding is likely a key factor in the establishment of patient – practitioner trust and communication. In this survey population, it was shown that those symptoms positively identified as ARs to manual therapy are for events that are more serious in nature.

Having low back dysfunction was predictive of higher reporting of ARs and this is concordant with previous studies. (15, 16) We did not find that having neck dysfunction was predictive of experiencing an AR. This was an unexpected finding since the neck has the largest evidence base associated with ARs and manual therapy. Possible reasons for

the absence of this finding include that the survey tool did not include other potentially important predictors or our model was not robust enough to include ones we did capture.

We also found that the variable of "expecting soreness" was predictive of having a lower incidence rate of major ARs than those who did not have this expectation. This is challenging to explain since this variable specifically referred to soreness that is commonly transient and benign and is clearly not a major adverse symptom. Perhaps it is the notion of expectation that is the important one here. There is some evidence for the role of expectation in manual therapy.(17) Bishop et al. 2011, found that in people with low back pain, there was an expectation of benefit related to receiving manual therapy treatment. Since 1/5 of our sample had low back pain and the majority had spinal pain, we could hypothesize that if this subgroup (low back pain patients) also had this expectation of benefit related to receiving manual therapy, that it could potentially lessen their expectation of having a major AR. Further exploration of this is required in future studies to understand this relationship.

The survey also identified contextual factors that include: temporality, affecting the patient's ability to function, symptom duration, patient expectations about treatment, being advised about potential symptoms, experience with similar symptoms, and trust in the practitioner. It is likely that very complex reasoning process occurs with some or all of these factors being integrated by patients that ultimately determine whether less serious symptoms are adverse from the patients' perspective. It is notable that most respondents agreed that mild short-term ARs are "acceptable", as long as these experiences were also linked to a trend towards overall improvement. These results, in combination with

agreement of post treatment soreness being ‘expected’ and ‘normal’, may infer that mild to moderate ARs are generally of little concern to this patient population. All of this would suggest that the onus falls on the practitioner to encourage a dialogue with the patient addressing all or some of these factors to determine patient values. Doing so may help inform treatment choices suitable for the patient, as well as the magnitude and frequency of the intervention to be aligned with their stated preferences.

The respondents’ greater level of agreement in consistently identifying major ARs as more serious has implications for standardizing terminology and definitions going forward. Adopting a patient centered approach would suggest that ARs may be grouped into two categories - major and all others. This is different from the initial framework that grouped moderate and major together separately from minor and not adverse. (4) While we did not ask patients to categorize adverse symptoms into mild, moderate or major, the frequencies of those symptoms positively identified as adverse, would suggest further exploration of symptom categorization. There is however, notable overlap in some categories obtained by the multidisciplinary Delphi process, such as mild ARs being acceptable and short term and major events impacting on function. There was general agreement between the patients in this survey and the Delphi study with professionals in the categorization of duration of ARs. This is promising as these two studies provide a starting point for further development of the framework that would include the patient perspective, thereby expanding and enhancing the previous research. (4)

There are limitations in this survey study that would suggest caution in interpreting these findings. An important consideration is that not a single respondent in this survey had ever experienced a major AR with respect to their manual therapy treatment. Clearly, we must question the extent to which people can accurately represent or judge the impact of how they would interpret an event that has never occurred to them. The lack of occurrence of a serious AR in a sample of 425 patients is encouraging for clinicians practicing manual therapies. However, this presents a challenge when trying to determine either event rates or their predictors and continuing research on the merits of this form of therapy. Until the perspective from those who have sustained a major AR can be gained it may be premature to develop a comprehensive framework if the indications of this survey data regarding patient's concern predominantly with major ARs is shown to be true in subsequent research. Secondly, these results may be specific to the context of the sampling that included physiotherapy patients in Canada. Replication of this data is needed in patient groups with different characteristics receiving the same or other manual therapy and in different countries to increase confidence in these findings. Also our survey was cross sectional and although the majority of respondents had previous experience with manual therapy based treatment and were currently in treatment, we cannot exclude the possibility of recall bias. (18) Relying on memory can under or over estimate incidence and result in biased estimates by respondents actively or inadvertently under or over reporting their experience or perceptions of ARs. Lastly, a low proportion of therapists volunteered to recruit patients. Those therapists that did may

be more inclined to participate in research and may differ from the rest of the membership.

Conclusion

This patient survey has provided to our knowledge the first patient generated list of potential ARs where a specific set of symptoms were identified as being perceived as ARs. These included symptoms of breathing difficulties, spreading of symptoms, loss of movement, loss of bowel and bladder control, stroke, death, broken bone and dislocated joint. Our review of the available literature has shown that the majority of these symptoms are rarely reported. Support for other more commonly occurring symptoms, such as headache, increase in pain and dizziness may be perceived as adverse with less certainty due to contextual factors that may influence the patients' judgment. Our survey data suggests that major ARs can be more easily defined than minor to moderate. These findings support and build on the qualitative data previously reported and should be considered in a comprehensive patient centered framework for classifying ARs in manual therapy.

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Table 1. Factors associated with patients nominating an experience as an adverse event: variables considered and rationale

Potential Predictor entered into the model	**Hypothesis**	**Rationale (Supporting references)**
Body part treated: extremities*, neck, thoracic spine, low back	People with spinal problems may be more likely to report adverse events	7
Phase of healing: acute*, subacute, chronic	People in either acute or chronic pain may be more likely to report adverse events	7
Experience with manual therapy: first time*, repeat with same problem, repeat with different problem	People without experience of manual therapy may be more likely to report adverse events	7
Pain NRS (0-10) – amount of increase considered to be adverse	The amount of increase in pain for an adverse event may be less than that for the minimal clinical important difference in effectiveness studies	4,7
Importance of receiving a warning about potential adverse events	Being warned of an adverse events, may lessen the likelihood of reporting them	7
Familiarity with post treatment soreness	Being familiar with post treatment soreness lessens the likelihood of reporting it as an adverse event	7
Expectation of post treatment soreness	Expecting post treatment soreness lessens the likelihood of reporting it as an adverse event	7
Trust in practitioner	People with greater trust are less likely to report an adverse event	7
Acceptance of short term mild adverse response if getting better overall	People getting better overall can accept short term mild adverse events	7
Agreement with statement that there is no risk of harm in manual therapy	Generally people agree that there is little risk of harm in manual therapy	7
Self rated state of recovery	The closer a person is to being recovered, the less likely the reporting of adverse events	7
Rating of a time trade off type scenario using combinations of permanent disability and full recovery	Risky behaviour may influence views of what is adverse	12
Gender	Standard to include	
Age	Standard to include	

* Denotes reference category

Table 2. Respondent Characteristics (n=324)

Characteristic	n (%)
Body part treated	
Arm/leg	124 (39.5)
Neck	83 (26.4)
Mid back	25 (8.0)
Low back	69 (22.0)
Pelvis	13 (4.1)
Phase of healing	
Acute (<2 wks)	12 (3.8)
Subacute (2wks-3 months)	83 (26.4)
Chronic (> 3months)	219 (69.7)
Experience with Physiotherapy	
First time	55 (17.5)
Treated for same problem before	111 (35.4)
Treated for different problem before	148 (47.1)
Stage of recovery	
Recovered	55 (17.5)
Better	213 (73.5)
Neither	24 (7.6)
Worse	4 (1.3)
Gender, female	203 (64.6)
Age (years)	
18-30	44 (14.0)
31-45	94 (29.9)
46-60	123 (39.2)
>60	53 (16.9)

Table 3. Reporting of symptoms post manual therapy treatment and consideration as 'adverse': n = 324

Symptom	YES n (%)	Reported as adverse YES n (%)	Reported as adverse NO n (%)
Increased soreness	134 (42)	-	169 (58)
Increased pain	118 (37)	167 (56)	-
Increase in existing symptoms	101 (32)	155 (53)	-
Increased stiffness	93 (30)	-	164 (56)
Fatigue	66 (21)	-	181 (64)
Headache	49 (15)	145 (50)	-
Spreading of symptoms	46 (15)	173 (61)	-
Bruising	41 (13)	-	153 (53)
Altered sensation	41 (13)	-	142 (50)
Onset of new symptoms	34 (11)	169 (60)	-
Dizziness	31 (10)	160 (56)	-
Weakness	31 (10)	-	157 (56)
Increased swelling	25 (8)	-	156 (54)
Loss of movement	14 (4)	171 (61)	-
Anxiety	14 (4)	-	144 (51)
Nausea	13 (4)	154 (55)	-
Depression	11 (3)	-	147 (52)
Decreased balance	10 (3)	169 (59)	-
Breathing difficulties	8 (3)	171 (60)	-
Confusion	8 (3)	167 (59)	-
Loss of bowel and bladder control	-	175 (62)	-
Stroke	-	175 (62)	-
Death; broken bone	-	178 (63)	-
Spinal cord injury	-	179 (63)	-
Dislocated joint	-	184 (65)	-

Table 4. Top three reasons for considering whether a symptom is adverse: n=324

Most commonly reported as adverse	**n(%)**	**Most commonly reported as *NOT* adverse**	**n(%)**
Symptoms began immediately post treatment	242 (79)	Symptoms experienced before treatment	285 (92)
Symptoms affected the patient's ability to function	236 (77)	Having an expectation that a symptom could occur with treatment	236 (78)
Symptoms started during treatment	219 (71)	The physiotherapist provided information that the symptoms could occur	202 (65)

Table 5. Alternative causes for an adverse event: n= 324

Supported	**n (%)**	**Unsupported**	**n (%)**
Performing an activity that typically makes symptoms worse	279 (90)	Random fluctuation in symptoms	199 (64)
Performing non-regular household activities	267 (86)	Another part of my physiotherapy treatment	160 (52)
Being physically active	252 (81)		
Driving for longer than normal	235 (76)		
Working for longer than normal	224 (72)		
Sleeping in a different bed	220 (71)		
Stress	204 (66)		

Table 6. Estimates of incidence rate ratios based on Poisson and Negative binomial regression analyses

	All symptoms (p<0.20) Poisson model		**All symptoms (p<0.20) Negative binomial model**		**Major Poisson model**		**Major Negative binomial model**		**Minor moderate- Poisson model**		**Minor moderate- Negative binomial model**	
Goodness of fit – Deviance value/df	7.632		1.034		0.795		0.038		6.052		0.933	
Predictors*†	**P**	IRR (95%CI)	**P**	IRR (95%CI)	**P**	IRR (95%CI)	**P**	IRR (95%CI)	**P**	IRR (95%CI)	**P**	IRR (95%CI)
Intercept	<0.001	11.9 (9.63,14.6)	<0.001	11.94 (5.47,26.06)	<0.001	24.06 (18.92,30.60)	<0.001	23.88 (7.60,75.09)	<0.001	10.38 (8.26,13.05)	<0.001	10.56 (4.82,23.16)
Lumbar spine	<0.001	1.42 (1.29,1.57)	0.037	1.51 (1.03,2.24)	0.862	1.01 (0.91,1.12)	0.963	1.01 (0.61,1.68)	<0.001	1.38 (1.24,1.54)	0.057	1.47 (0.99,2.17)
Neck	0.121	1.17 (0.96,1.43)	0.663	1.20 (0.52,2.77)	0.463	0.92 (0.74,1.15)	0.880	0.92 (0.32,2.65)	0.222	1.15 (0.92,1.43)	0.719	1.17 (0.51,2.69)
Thoracic spine	<0.001	1.44 (1.25,1.65)	0.144	1.53 (0.86,2.72)	0.914	0.99 (0.85,1.16)	0.994	1.00 (0.48,2.08)	<0.001	1.41 (1.21,1.64)	0.181	1.48 (0.83,2.62)
Chronic	<0.001	0.78 (0.71,0.85)	0.125	0.74 (0.51,1.09)	0.884	0.99 (0.89,1.10)	0.975	0.99 (0.60,1.64)	<0.001	0.79 (0.71,0.87)	0.157	.76 (0.52,1.11)
Treatment for same problem	<0.001	0.81 (0.73,0.90)	0.211	0.76 (0.50,1.17)	0.084	0.90 (0.81,1.01)	0.714	0.90 (0.52,1.56)	<0.001	0.81 (0.72,0.91)	0.216	0.77 (0.50,1.17)
Treatment for different problem	0.264	0.95 (0.86,1.04)	0.923	0.98 (0.66,1.47)	0.669	0.98 (0.88,1.09)	0.944	0.98 (0.59,1.63)	0.365	0.95 (0.85,1.06)	0.939	0.98 (0.66,1.48)
Importance of PT warning	0.156	1.09 (0.97,1.23)	0.786	1.07 (0.66,1.73)	0.582	0.96 (0.84,1.10)	0.915	0.97 (0.50,1.85)	0.001	0.86 (0.79,0.94)	0.795	1.07 (0.66,1.72)

*Incidence rate ratio

† Confidence interval

Table 6. continued Estimates of incidence rate ratios based on Poisson and Negative binomial regression analyses

	All symptoms (p<0.20) Poisson model		**All symptoms (p<0.20) Negative binomial model**		**Major Poisson model**		**Major Negative binomial model**		**Minor moderate- Poisson model**		**Minor moderate- Negative binomial model**	
Goodness of fit – Deviance value/df	7.632		1.034		0.795		0.038		6.052		0.933	
Expectation of soreness	0.001	0.87 (0.81,0.95)	0.267	0.84 (0.61,1.15)	0.047	0.92 (0.84, 1.00)	0.670	0.91 (0.60,1.38)	<0.001	0.83 (0.76,0.92)	0.255	0.83 (0.60,1.14)
Familiarity with symptoms	<0.001	0.84 (0.77,0.91)	0.307	0.83 (0.58,1.18)	0.157	0.94 (0.85,1.03)	0.755	0.93 (0.60,1.45)	0.001	0.87 (0.80,0.94)	0.302	0.83 (0.58,1.18)
No risk of harm with MT	<0.001	0.85 (0.79,0.92)	0.119	0.79 (0.59,1.06)	0.499	0.97 (0.89,1.06)	0.868	0.97 (0.65,1.45)	<0.001	1.40 (1.20,1.61)	0.154	.8 (0.60,1.08)
Risk trade off	<0.001	1.43 (1.25,1.64)	0.073	1.53 (0.96,2.44)	0.700	1.03 (0.87,1.23)	0.931	1.04 (0.47,2.31)	<0.001	0.844	0.110	1.47 (0.92,2.34)
Gender	0.005	1.11 (1.03,1.20)	0.271	1.18 (0.88,1.58)	0.399	1.04 (0.95,1.13)	0.841	1.04 (0.70,1.55)	0.012	1.11 (1.02,1.21)	0.295	1.17 (0.87,1.57)
Age	0.010	1.10 (1.02,1.19)	0.498	1.11 (0.82,1.49)	0.124	1.07 (0.98,1.16)	0.745	1.07 (0.72,1.58)	0.015	1.11 (1.02,1.20)	0.506	1.11 (0.82,1.50)
Neck x chronic	<0.001	1.57 (1.31,1.88)	0.244	1.54 (0.74,3.19)	0.621	1.05 (0.86,1.30)	0.906	1.06 (0.34,2.83)	<0.001	1.53 (1.25,1.87)	0.276	1.50 (0.72,3.11)
Neck x trust	<0.001	0.76 (0.67,0.86)	0.358	0.77 (0.44,1.35)	0.625	1.03 (0.90,1.18)	0.919	1.03 (0.55,1.95)	0.001	0.78 (0.68,0.90)	0.404	0.79 (0.45,1.39)

*Incidence rate ratio

† Confidence interval

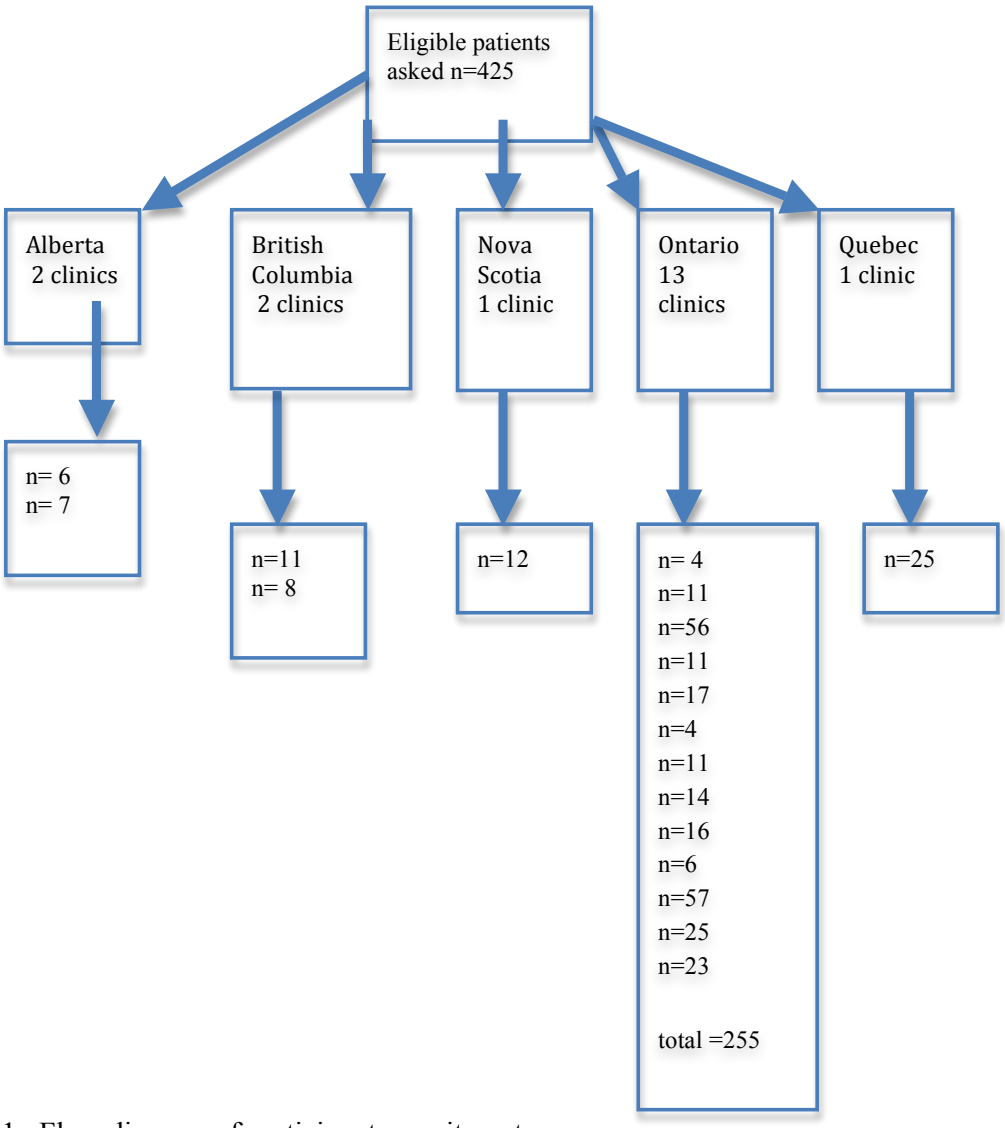

Figure 1. Flow diagram of participant recruitment

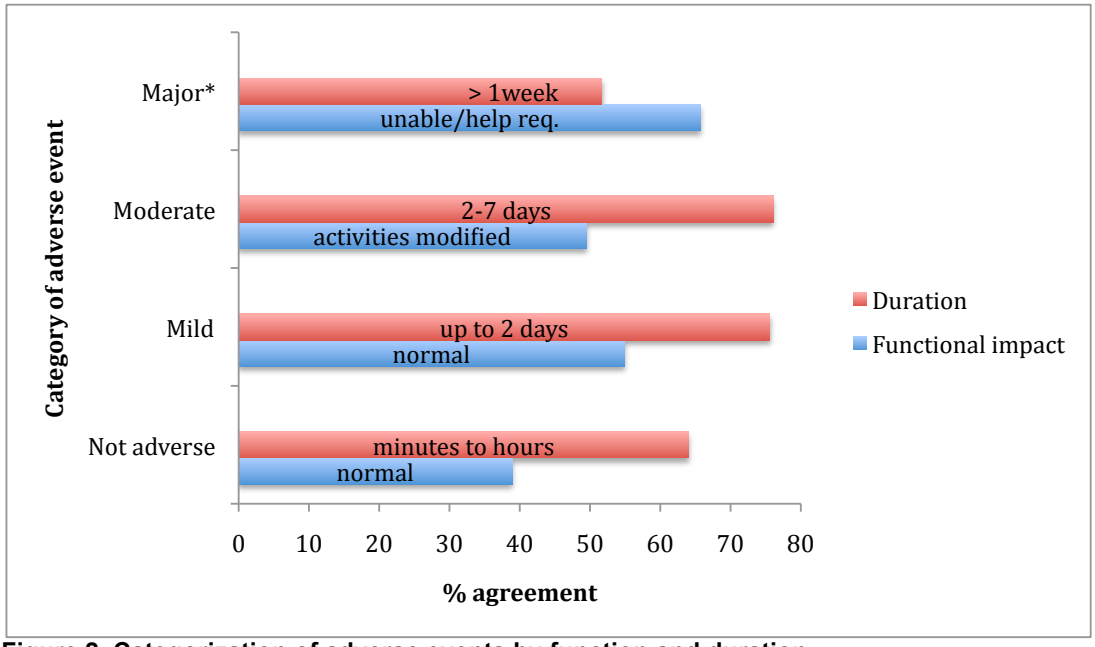

Figure 2. Categorization of adverse events by function and duration
*75.7% also felt that the Major category would require further medical attention

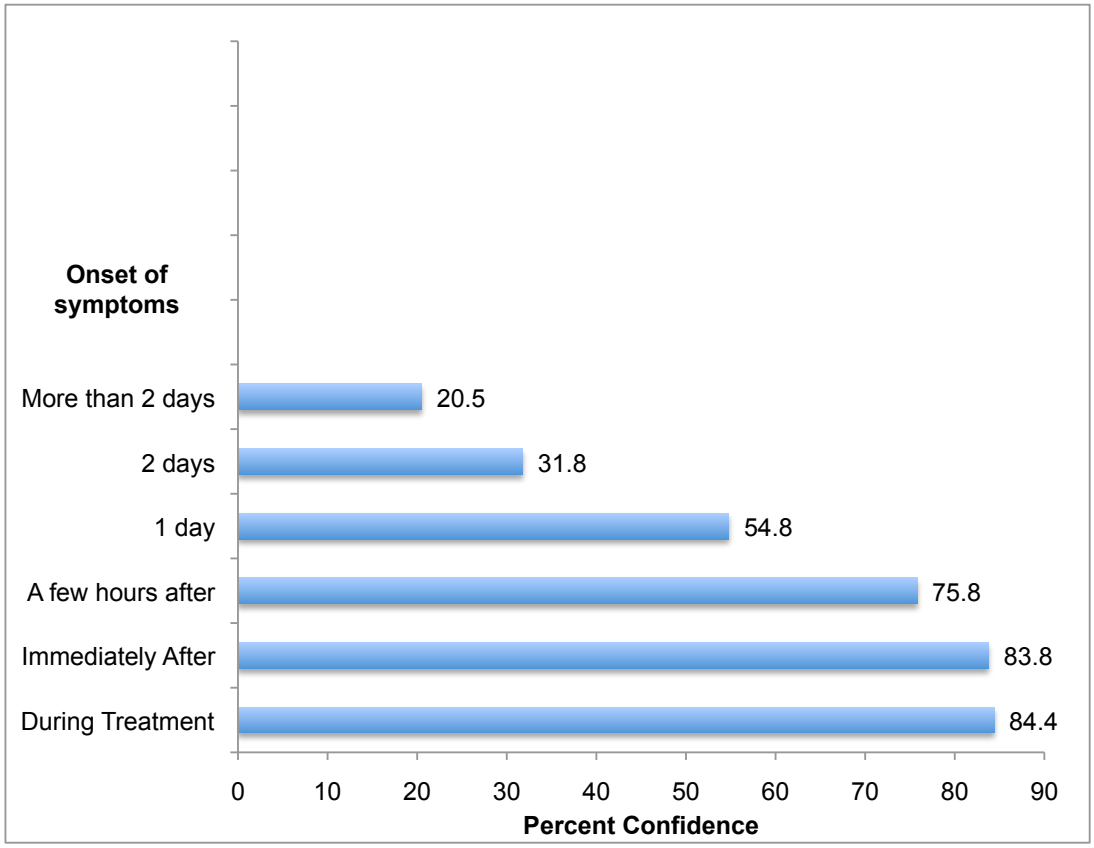

Figure 3. Confidence in cause of adverse events by time of onset

Appendix A

Summary of Questionnaire Content

1. Please indicate whether you have experienced any of the following symptoms *after* your hands on treatment. *Mark all that apply*

The following definitions are provided for you to help you answer the following survey questions.

Adverse Response: an unintended response to treatment that may or may not be caused by the treatment.

Hands on treatment: the portion of your treatment when the physiotherapist is working on your body with his/her hands to improve the function of the injured area.

Symptom	YES n (%)	Reported as adverse YES n (%)	Reported as adverse NO n (%)
Increased soreness	134 (42)	-	169 (58)
Increased pain	118 (37)	167 (56)	-
Increase in existing symptoms	101 (32)	155 (53)	-
Increased stiffness	93 (30)	-	164 (56)
Fatigue	66 (21)	-	181 (64)
Headache	49 (15)	145 (50)	-
Spreading of symptoms	46 (15)	173 (61)	-
Bruising	41 (13)	-	153 (53)
Altered sensation	41 (13)	-	142 (50)
Onset of new symptoms	34 (11)	169 (60)	-
Dizziness	31 (10)	160 (56)	-
Weakness	31 (10)	-	157 (56)
Increased swelling	25 (8)	-	156 (54)
Loss of movement	14 (4)	171 (61)	-
Anxiety	14 (4)	-	144 (51)
Nausea	13 (4)	154 (55)	-
Depression	11 (3)	-	147 (52)
Decreased balance	10 (3)	169 (59)	-
Breathing difficulties	8 (3)	171 (60)	-
Confusion	8 (3)	167 (59)	-
Loss of bowel and bladder control	-	175 (62)	-
Stroke	-	175 (62)	-
Death; broken bone	-	178 (63)	-
Spinal cord injury	-	179 (63)	-
Dislocated joint	-	184 (65)	-

2. Assuming one of the following symptoms happened to you after your treatment. Which ones would you consider to be an adverse response? (See list above)

3. The table below lists possible reasons why you might think that a symptom is an adverse response to treatment.Please mark 'YES' to the reasons that would make you think a symptom should be called an *adverse response* and 'NO' to those that do not affect whether you call a symptom an *adverse response*. Please *mark all* that apply.

4. When you started your treatment, you might have been asked by your therapist to rate your pain on a scale of 0-10 with 0 representing no pain and 10 being the worst pain imaginable. For the following statement you are being asked to consider on a 0-10 scale, what amount of an increase in pain after treatment is indicative of an adverse response.

5. Based on your current treatment, please indicate your agreement with the following. 'The impact of treatment on one's function is the most important factor in deciding whether or not one has experienced an adverse response.

6. Rate each of the following statements as 'not an adverse response' or if it an adverse response then choose between 'minor', 'moderate' or 'major' in severity. Consider the overall impact of the adverse response.

7. This question asks about time. Choose how long each of the following adverse response categories might last and whether you think that the response might also require further medical treatment.

8. Please indicate how confident you would be that the 'hands on' part of your treatment caused your adverse response by considering the onset of the adverse response in relation to when you were treated. Rate your confidence in the table below.
Please indicate your level of agreement with the following statements:

Consideration of Alternative causes
9. Part of figuring out what has caused an adverse response after a treatment involves the consideration that other factors (e.g. a change in your normal activities) may be contributing to the response.

10. If an adverse response is experienced during treatment or immediately after treatment, one is less likely to consider other factors, not related to treatment, to be the cause of the reaction.

11. In the table below, please indicate which things, (other than your 'hands on' treatment) you would consider that might be the cause for an adverse response that happened after your treatment.

12. Physiotherapy treatment often consists of multiple components such as exercise, hands on mobilization, acupuncture, ultrasound, electrical modalities (e.g. TENS, muscle stimulation), ice or heat. Please indicate how you determine which component may be the source of an adverse response.

Education regarding treatment
Please indicate the level of importance to the following question
13a. How important is it that the physiotherapist provide a warning that one may experience an adverse response after treatment?

Please indicate your level of agreement with the following statements.
b. If the physiotherapist provides a warning that I may experience an adverse response after treatment, the warning makes the adverse response more acceptable
c. If the physiotherapist provides a warning that one may experience new symptoms after treatment, the warning will prevent one from considering it an adverse response.
d. If the physiotherapist provides a warning that one may experience new symptoms after treatment, it causes me to…(degree of worry)

Trust
14. The more that one trusts the physiotherapist, the less one will be concerned if an adverse response is experienced.

Expectations of treatment
15a. I expect to be a bit sore after treatment.
b. It is normal to be a bit sore after treatment.

Body awareness
16. If the sensations I experience with an adverse response after treatment are familiar to me, I will not be too concerned about them.

Weighing benefits vs. harms
17a. As long as I am getting better overall, I can accept mild short term adverse responses
b. I think that there is no risk of harm in manual therapy treatment.

18.Consider the following scenario. Imagine that you have to live the rest of your life with the condition you are currently receiving physiotherapy for, or you could receive a treatment that will give you full and permanent recovery. However, this treatment is associated with a risk of experiencing serious adverse outcomes (eg. paralysis, stroke or death). Please indicate below what degree of risk you are willing to accept in receiving this treatment before you decline it and choose to remain in your present state.

Characteristics

What area of the body are you currently in treatment for?

How long have you had your current problem for?

Please indicate your level or experience with physiotherapy treatment.

Please indicate your progress in your current treatment.

What is your gender?

What is your age range?

CHAPTER 4

Determining adverse events in patients with neck pain receiving orthopaedic manual physiotherapy: a pilot and feasibility study.

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ABSTRACT

Purpose: To pilot and determine the feasibility of estimating adverse events in patients with neck pain treated with cervical manipulation/mobilization by Canadian orthopaedic manual physiotherapists (OMPTs) using an online data collection system to provide estimates for a future larger multicentre international study. **Methods:** We conducted a prospective multisite two group cohort study of 28 patients/group receiving usual care and either: a) combined manipulation and mobilization or b) mobilization only. Study feasibility objectives and criteria for success were set a priori. Data analysis used descriptive statistics. **Results:** Twenty patients were recruited from 6 of 16 participating centres, 17 to the mobilization group and three to the combined group. Barriers identified to data collection included low recruitment, difficulties using the online data collection and clinicians and patients being too busy to participate. Missing data for the primary outcome averaged 28.5%. A total of 69 symptom occurrences were reported during the treatment phase, all benign and transient. Most symptom occurrences had an onset within zero to 12 hours post treatment 66/69 (95.6%). Duration of symptoms largely lasted from zero to two days 56/69 (81.2%). Kappa estimates of agreement between therapists and patients on reporting of adverse symptoms across visits one to five was substantial at Kappa=0.68, ($p<0.01$) 95%CI (0.52, 0.84). **Conclusions:** This pilot study demonstrated substantial challenges in conducting a large multicentre trial. Brief, benign and transient adverse events were common; no substantial adverse events were observed.

Key words: pilot study, feasibility study, neck manipulation, adverse events, physiotherapy

INTRODUCTION

The occurrence of adverse events associated with spinal manipulation, particularly when applied to the neck, has historically received much attention. In recent years, greater focus has shifted to helping clinicians with differential diagnosis and identifying people who may be at risk of sustaining catastrophic adverse events such as stroke or death.[1-4] Clinicians now have a better understanding of recognizing a patient presenting with neck or head pain/symptoms that may be precipitous of non ischemic symptoms of a stroke.[2] This information has benefitted all clinicians treating people with neck pain regardless of whether cervical manipulation is utilized.

The reports of adverse events with cervical manipulation have affected all practitioners employing this treatment technique. However, most evidence pertains to chiropractic manipulations.[5-8] Other health practitioners, such as physiotherapists and osteopaths, also practice spinal manipulation. The incidence of adverse events in either of these two professions has not been rigorously studied. It should not be assumed that rates associated with any one profession are transferable to another due to variations in practice patterns (indications, screening, contra-indications), patient populations, or technique execution.

Further complicating the estimate of adverse events is a lack of standard definitions and classification of symptoms.[9, 10] None of the published studies reporting estimates of adverse events are comparable since they commonly report events using nonstandardized definitions of mild, moderate, serious. Carnes et al.[10] proposed a framework for categorization and definition of adverse events. Carlesso et al.[11] and

Rajendran et al.[12] have since added to this evidence by providing the patient perspective, a population excluded in the initial framework. In combination, these studies provide a solid foundation from which to begin more standardized adverse event classification and definition in manual therapies.

Another element that has the potential to bias incidence rates is the difference in reporting between clinicians and patients. It is well documented in other areas of health care that reports of adverse events vary greatly depending on who is reporting them, clinician or patient.[13-15] To our knowledge this difference has not been studied amongst manual therapy practitioners. There is evidence that cervical manipulation has a higher association with adverse events compared to cervical mobilization irrespective of the clinician type.[16] Therefore, any study of adverse events must be powered to assess both. We know that the optimal design for establishing precise estimates of adverse events is a prospective cohort design. Due to the inherent difficulty, and potential large use of resources to conduct such a study it would seem appropriate for it to be internationally conducted so that results could provide stable estimates and generalizable data within a reasonable timeframe. It is therefore essential to test the process and feasibility of an online data collection system.

The purpose of this pilot and feasibility study was to determine estimates of adverse events in patients with neck pain treated with cervical manipulation/mobilization by Canadian orthopaedic manual physiotherapists (OMPTs) in private practice settings using an online data collection system to provide estimates for a larger multicentre international study.

Objectives

The objectives of the pilot and feasibility study were to:

1. To pilot study procedures that would be used for a future international cohort study
    a. evaluate recruitment strategies and enrolment rates
        i. identify barriers for clinicians and patients participating in the study
        ii. estimate accrual rates and consent rates
    b. pilot the use of a web-based collection system and operations of the associated database management centre
    c. pilot all study measures planned for a larger future study
        i. Identify potential interpretation issues including patterns of missing data
        ii. Identify potential problems with data distribution, including floor/ceiling effects in responses
2. Determine the standard deviation of the primary outcome measure (patient reported adverse events) and use this to inform sample sizes for a future international cohort study.
3. To determine preliminary estimates of the primary outcome, adverse events mild, moderate and major that would improve the estimation of sample sizes; also to inform our understanding about the importance of proceeding with the full cohort study.

The criteria for success of the pilot study were determined a priori as follows:[17-21]

a. One subject recruited per group per week
b. At least 70% of all eligible subjects can be recruited
c. At least 95% completion of data at all follow up points
d. Online data collection system less than 5% access or usability issues.

4. To determine preliminary estimates of agreement of adverse event reporting between therapists and patients.

METHODS

Design and sample

The study was designed to determine the feasibility and preliminary estimates of adverse events associated with cervical spine mobilization/manipulation administered by orthopaedic manual physiotherapists (OMPT) in primary care settings. A prospective two arm cohort design was employed to compare combined cervical spine manipulation and mobilization against mobilization only. These groups were chosen as they are representative of Canadian OMPTs use of these manual therapy techniques.[22] The two groups were: A. combined manipulation and mobilization, along with all aspects of usual care as determined by the treating physiotherapist, and B. a mobilization only group receiving usual care as determined by the treating physiotherapist. As randomization was not employed, the allocation of each patient was a shared decision after eligibility was determined. Through discussion between the treating therapist and patient, the appropriate group for each patient was chosen based on clinical presentation and patient preference. An absence of contraindications for neck manipulation was required in order

for the patient to be considered for the combined manipulation and mobilization group. Those patients who did not want to receive neck manipulation were allocated to the mobilization only group.

All new patients presenting with primary neck pain were screened for eligibility by the treating therapist and if appropriate offered the opportunity to participate. Neck pain was defined as the area between the occiput and the paraspinal area extending to the lower level of the scapulae and superolaterally to the tip of the acromion. Inclusion criteria were those between the ages of 18-70 years, with a primary complaint of acute ($\leq$2 weeks), sub acute (3-12 weeks) or chronic (>12 weeks) neck pain presenting for physiotherapy treatment at one of the participating clinics. Patients were excluded if they had contraindications to both cervical manipulation and mobilization interventions (e.g. signs and symptoms of any of these including: cervical artery dysfunction, spinal cord compromise, vertebral fracture, spinal ligamentous instability, central nervous system disorders, or nonmusculoskeletal based pain, cervical or thoracic spine stenosis),[23, 24] if patients had received any cervical manual therapy in the past three months or any patient currently receiving hands-on treatment for their neck disorder from other health care providers. Patients who were unwilling to receive neck manipulation and did not have any contraindications to mobilization were allowed to participate in the study to provide data on adverse events after mobilization. All participants were advised that they could withdraw at any time and have their data removed if they so chose. Once consent was obtained the OMPT registered the patient in the web-based data collection system by indicating his/her eligibility.

Sites

All participating therapists that had completed or were registered in one of Canada's post professional manual therapy certification program were recruited. Canada has two programs that have met the educational standards of and are approved by the International Federation of Manipulative Physical Therapists (IFOMPT). Therapists across the country (>500) were contacted via email with an information sheet providing study details and objectives. Those who were interested in participating were instructed to contact the primary investigator.

Treating therapists were trained in database use and management and study procedures (one session lasting approximately 45 minutes). These sessions were conducted by telephone and online simultaneously. Each therapist was provided with a database manual of operations prior to the session. The session reviewed how to enrol a patient, the subsequent filling out of forms for each visit and any other questions that the therapists had. Ethical approval was obtained from McMaster University, the University of Guelph and Western University's research ethics boards.

Upon entry to a clinic with a participating therapist, each patient underwent screening including a typical history and physical examination. If the patient was deemed eligible for the study, a report of findings was provided along with an invitation to participate in the study with a letter of information and consent package. On future visits, reassessment, treatment and post treatment assessment were conducted. Therapists recorded their findings on standardized forms indicating treatment and adverse events.

Interventions

Manipulation was defined as a low amplitude, high velocity force applied at the end of range of a joint. [25] Mobilization included low to high amplitude and low to medium velocity movements applied within the normal physiological range of a joint. Individuals without any direct contraindications or medical 'red flags' to cervical manipulation were not considered for enrolment in the combined group, but were approached to provide data for mobilization effects. Indications for manipulation included joint fixation, joint adhesion, inextensible scar, treatment plateaued with mobilization, loss of movement in two biomechanically linked directions, no contraindications to manipulation and confirmation of ligamentous integrity and the absence of cervical arterial dysfunction.[24, 26] Subjects enrolled in the combined group had to be receiving manipulation to the neck in order to be entered into this group.

Visits

Once enrolled, subjects were treated between one to five visits. Spacing of the visits was left to the discretion of the therapist. Treatment ended if the therapist decided to stop or change the manual treatment being delivered or when five visits was reached. For example, if a subject was entered into the combined group and after three visits that included neck manipulation, the therapist decided that it was no longer needed, the active treatment portion of the study would be concluded and the subject passed on to the follow up phase. The treating therapists control over the delivery of treatment, along with the

combined manual therapy group, allowed for a real world representation of daily practice of OMPTs.

Measurement of Outcomes

A published framework and a completed study on patient interpretations of adverse events were used to create a list of possible adverse events that were categorized into mild, moderate and major events (see Table 1). This framework utilizes a list of possible symptoms, severity of functional impact, and duration of the symptoms to categorize adverse events across the spectrum.

Data Collection and Analyses

As determining feasibility of the study was the overall objective, a small sample size of 28 participants per group was agreed upon to be sufficient to achieve this goal.[17, 18]

Patients were encouraged to enter data electronically. Upon enrolment, the data management company anonymized each patient by assigning unique identifiers to each patient. The patients' email address was provided to the data management company to allow for follow up reporting. Each patient was then sent an Internet address where they logged on to enter data electronically into web based forms. Reminders were sent via email. For those unable or unwilling to complete the forms electronically, paper copies were provided. For those patients completing paper copies, they were asked to return the forms on their next visit to the clinic. An administrative staff person not involved in

patient care faxed the forms to the data management company. OMPTs provided demographic information and also reported adverse events and treatment by completing web-based forms at the patient's next visit. The therapists would indicate adverse events according to the visit. Any adverse events that the patient reported before leaving the treatment were recorded for that day along with any reported upon the return visit. Descriptive statistics were used to summarize the participants and the therapists.

Baseline data collection for the patients included the following: the Neck Disability Index, the Pain Catastrophizing Scale, the 11 item version of the Tampa Scale for Kinesiophobia, the Comorbidities questionnaire, the Numeric Pain Rating Scale, the amount that they trusted their therapist, how satisfied they were with their treatment, both set on a 7 point likert scale, adverse event reporting and demographic data. The primary outcome of patient reported adverse events consisted of answering yes or no as to whether they experienced any adverse events on their most recent visits. If a patient answered 'yes' then they were prompted to indicate their symptoms from a list of 25 that was derived from the literature. The list included an'other' category. If they indicated that they had experienced a particular symptom, they were asked if it was the first time they had experienced it. They were also asked to indicate the onset of the symptoms, 0-12 hours, 13-24 or > 24 hours and their duration symptoms, 0-2 days, 3-7 days or > 1 week. Additionally, patients were asked to what degree the adverse reaction impacted on their functional ability, no impact/normal function, modifications or help required, or loss of function/incapacitated. Finally patients were asked if their physiotherapist advised them that they might experience some un-intended symptoms after treatment. On subsequent

visits, patients answered questions about trust, satisfaction, adverse events, and receiving a warning from their therapist.

Follow up occurred at 3 weeks and 3 months after the patients last treatment. Data collected at this time included the Neck disability Index, satisfaction, adverse events, global rating of change on a 11 point Likert scale, and the Numeric Pain Rating scale.

Adverse Events

Overall frequencies and those within each treatment group were calculated. No definition of adverse events was decided upon a priori or provided to the patients or practitioners. We anticipated that based on the framework we chose (Table 1) and the rarity of major adverse events, that only mild to moderate adverse events may be reported. The framework in essence defined what events were considered to be adverse by layering on the factors of duration and severity. The existing evidence supports that there is variability in how patients define what is adverse depending on numerous contextual factors, thereby making it difficult to define a priori. [11, 12]

Clinician vs Patient Reporting of Adverse Events

Proportions for all AE reported by both clinicians and patients were created. The measure of agreement between the two was calculated using kappa values. Kappa is ideal for assessing agreement between categorical data (yes/no) and was used for clinician and patient agreement. Weighted kappa can be used for agreement between ordinal data like

mild moderate severe and agreement between individual symptoms and the categories of mild, moderate and major were examined.

Study barriers

Participating therapists were contacted via email at the end of the study and asked two open-ended questions: What barriers did you experience that impacted on a) patient enrolment b) study procedures? What barriers did patients report as impacting on study enrolment?

RESULTS

Barriers to patient enrolment identified by therapists were as follows: no access to a computer at work, too busy to do consent and extra paper work, lack of eligible patients. Barriers to participation identified by patients and reported by therapists were: too busy/too much time required, not wanting details of treatment included in study and language barrier (in Quebec). Observations from the primary investigator were that despite the online/telephone training and provision of an operations manual and study procedures, some of the therapists appeared to be unclear about the opportunity for the patient to fill out paper forms. Also, the fact that the treatment schedule was flexible, i.e. it was not restricted to five visits but allowed for change in the treatment technique or the patient being discharged seemed to have little impact.

From more than 500 OMPTs approached, 24 completed training. Two immediately indicated that they would not be able to participate in recruitment, as they

were too busy. Six of the remaining 22 OMPTs enrolled patients from September 2010 to April 2011. In total 80 patients were asked to participate after initial screening and 20 enrolled, seventeen in the mobilization group and three in the combined group. The flow of study participants is summarized in Figure 1. Three participants withdrew immediately after providing informed consent and being sent initial forms to be filled out stating that they did not have time to participate.

The web based data collection system was developed between June and August of 2010. This included multiple iterations of mapping the various time points for the outcome measures used, checking the proper transcription of the measures into the database, and testing the functionality of the measures at each treatment site. Prior to recruitment beginning, the functionality of the database was satisfactory. After recruitment began, issues were identified regarding the functionality of email reminders, difficulties accessing data forms (e.g. forms did not appear once the patient was enrolled), data reports were incorrectly formatted and contained duplicates of data, difficulty with therapists and patients logging in/resetting password, and measures posted to an incorrect next visit date. All issues were addressed and fixed in as timely manner as possible as they occurred. The database coordinator or primary investigator undertook corrective actions immediately if the issue was effecting current data collection; the treating therapist or patient were contacted via email.

Compliance with scheduled visits was excellent as none were missed. Missing data occurred as follows: baseline measures 8.0%, and primary outcome measure as well as for all other questionnaires 29%. Missing data started at visit two, 1 (6.0%) and

peaked at the fourth and fifth visits and 90 day follow up at 5 (29%). Reasons from the therapists for such a high rate of missing outcomes were not collected.

Given the low enrolment, we did not attempt to calculate relative risk ratios for the AE or to categorize them into mild, moderate or major as it was felt that no meaningful interpretation could be achieved from such small numbers. Proportions for all AE are provided as well as the collected parameters concerning these events in Table 2. This table shows the adverse events reported in each group by visit. A total of 69 symptom occurrences were reported during the treatment phase. The reported adverse events across all visits and follow up included headache, soreness, stiffness, tenderness, fatigue, weakness, decreased neck range of motion, tingling in the spine or upper extremities, radiating pain, increased pain nausea/vomiting, and ringing in the ears. For the follow up at 21 and 90 days, one participant (33%) in the combined group reported adverse events of stiffness, soreness, decreased neck range of motion, ringing in the ears and tingling in the spine or upper extremity. In the mobilization only group at 21 days, four participants each reported adverse events of headache and nausea or vomiting 1 (7.0%) and tenderness and stiffness 2 (14%) each. At 90 days one participant (33%) in the combined group reported headache and stiffness. In the mobilization only group one participant (7.0%) reported headache. Table 3 shows the duration and onset of symptoms by group. Almost all reported reactions in both groups had onset of symptoms within the first 0-12 hours post treatment 66/69 (95.6%). Only three reactions (4.0%) were reported to have onset occurring between 13- 24 hours. Duration of symptoms largely lasted from

zero to two days 56/69 (81%), compared to those lasting from three -7 days 12/69 (17%) and one reaction was reported as lasting greater than 1 week (1.0%).

Agreement between therapists and participants on whether an adverse event occurred was substantial Kappa=0.681, ($p<0.01$) 95%CI (0.521, 0.841).

The mean age of participants was 45 years (standard deviation (SD) = 10.2) and 71% were female. Table 4 provides details of the patient characteristics.

Treatment provided by the therapists is detailed in Table 5 according to visit. Both groups utilized manual therapy to the neck and thoracic spine that was complemented by exercise, and other modalities such as acupuncture, ice/heat, education and electrotherapies.

Mean changes in the Neck Disabaility Index scores from baseline to 90 day follow up were 4.2 (SD 3.5) and 1.6 (SD 2.1) respectively. The mean global rating of change at 21 days was 2.37 (SD 1.35) and 3.37 (SD 1.06) at 90 days. Satisfaction with care during the treatment phase and at 21 day follow up remained fairly consistent ranging from 1.75 to 2.40 (SD 0.49-2.05) and mildly decreased at 90 day follow up to 1.17 (SD 2.13).

DISCUSSION

Given the paucity of harms related data pertaining specifically to orthopaedic manual physiotherapists a pilot and feasibility study was conducted in Canada to assess the feasibility of a large multicentre international study to determine the rate of AE associated with manual therapy interventions applied to patients with neck dysfunction.

Objectives

We did not meet all of our initial objectives, as the proposed methodology was limited in the prospect of a future larger multicentre study. Our recruitment objective was not met. Recruitment is always a concern in clinical studies and we anticipated difficulty with participation from qualified physiotherapists. As historically clinical research is often performed in teaching centres, we were aware that it would be important to establish its feasibility within private orthopaedic physiotherapy clinics in Canada. Our findings suggest that recruitment is even more problematic in this context. A recent survey of Canadian physiotherapists perceptions of barriers and facilitators of engagement in clinical research demonstrated that there are no significant differences in barriers between practitioners in private versus public/other settings; however, there were non significant trends in private practice practitioners towards concerns about time constraints and lost income.[27]

This challenge of participation is clear in that more than 500 therapists were sent invitations to achieve the 20 participants. Exploring non response was limited by changing membership/email lists making it difficult to consistently follow up with everyone. Given the record of sparse participation in clinical research of this group we felt that tracking this in an already detailed analysis plan would not do justice to this problem but would be better served by an independent study of its own. What was unexpected however, was the low participation by therapists who completed the study training session, as only a small number actually enrolled patients. Despite initial interest, most indicated that they were too busy to actually try to enrol patients. This is an

important issue since considerable resources must be allocated to centres that commit to enrolling patients. Furthermore, when applying for study funding, it would be important to demonstrate a high level of commitment from the enrolling centres, as funders are unlikely to support a study where there are concerns about the feasibility. For all of these reasons, it is important to have methods to ensure that centres that commit to a specific enrolment will be able to achieve their targets.

Patient response was also suboptimal. The burden of participation on participants requires re-examination as some reported that it would take too much time to participate. Like many studies ours required an initial commitment to complete baseline study measures and follow up time points, but perhaps less commonly, we asked that they answer measures after each visit. Being cognizant of this demand, the post visit questionnaires were designed to be brief and easy to complete. Without interviewing patients qualitatively post study completion, we are unsure of the degree to which this impacted on recruitment. Further, it is difficult to disentangle patient and therapist nonparticipation. If therapists do not provide adequate information about the burden of the study or fail to remind patients about completion of forms then the lack of enthusiasm of therapists for a study may affect patient participation.

Issues with the functioning of the online database were mainly limited to the front end of the study and dealt with as efficiently as possible but this still caused some delays and frustration for both the patients and therapists. The missing data was clearly high and therefore problematic. As we did not directly ask patients about reasons for missing data we can only speculate. Studies comparing Internet to paper based methods noted better

data completion rates in the Internet users and that the electronic methods were as good as paper.[28, 29] A Cochrane review of methods to increase response to electronic questionnaires suggests numerous strategies some of which we employed.[30] Considerations for future study include conducting pre-study focus groups to inquire about preferred collection methods and to use a mixed methods approach with a qualitative component post treatment to ask patients about reasons for missing data.

The low enrolment in the combined manipulation/mobilization makes comparison between the groups difficult and we were unable to make future sample size estimates. None the less, our results are similar to what other studies have reported.[31-33]

To our knowledge, this is the first time that agreement on reporting of adverse events has been published in our field. We observed that replication of adverse events reported between practitioner and patient was better than in other areas of healthcare showing that agreement is not consistent when identifying what AE have occurred.[14] In general when considering the nature and frequency of interaction of patients with therapists compared to patients and physicians, the strong Kappa value may not be surprising. Medical or surgical practice is often concerned about a complication i.e. those that are directly attributed to the treatment. Adverse events are not necessarily a result of treatment nor necessarily constitute a complication. For example, a small amount of pain might be a necessary result from mobilizing a joint or may occur due to increased activity following treatment. The therapist and patient would be likely to agree that increase pain had occurred-particularly if this was measured in practice. However, this would not be a

complication. Lack of clarity between adverse events and complications in the literature may contribute to variations in agreement between our study and others.

Criterion for success

The study ran for eight months and did not meet the criteria of enrolling one subject per group per week. One in four patients that were asked to participate enrolled, well below the criteria of 70% established as part of our success criteria. Upon considering the missing data rate, the results of this study may indicate that making provisions is advised to offer incentives to therapists and possibly to patients. We did not offer any incentives to either the therapists or the patients. While it is difficult to know without having offered an incentive, this omission may have impacted on therapist participation more than patient. The challenge in offering an incentive is to obtain substantial grant funding to provide something that is valued but not substantial enough to bias participation. This being the case, the value of an incentive is always questionable particularly when offered to the health professional and not the patients. The number of issues with the online database was larger than the criterion of five percent and was resolved as efficiently as possible. Unfortunately the costs of the data management system were high and the funds for this study were limited so justification for continuation was problematic.

Generalizability

Considering the low and uneven group numbers, it is difficult to interpret beyond this pilot and feasibility study to confidently apply our findings to those receiving these treatments. There were some differences between groups in the symptoms reported. The mobilization only group actually had more symptoms occurring. These findings are similar to a previous study that found that mobilization techniques created a larger number of adverse responses than manipulation.[33] It is clear that the adverse events that were reported were transient and would likely be considered mild to moderate in nature according to the existing evidence in this area. [10, 11] There is still no de facto framework for defining categories of adverse events in manual therapy and so this cannot be stated confidently in its absence.

Reflecting on the initial objectives of this study, it seems clear that there are many barriers to conducting the study on a larger scale. Several substantial changes addressing the issues identified need to be implemented in future. One issue that remains unanswered is the feasibility of clinical research in private orthopaedic physiotherapy clinics in Canada. While the climate may be changing, it is likely that unless there are active incentives and knowledge translation activities to affect attitudes towards research involvement, this may proceed at a very slow rate. Researchers wanting to conduct clinical research in this setting should be aware that they may face similar issues unless there are more proactive measures to ensure adequate recruitment, completeness of data collection and therapist incentives thus having a substantial impact on the budget required

to conduct research in that setting. However, since healthcare for neck pain is primarily conducted in this context, it is essential that new approaches be considered.

Methods to increase the technical feasibility of such studies in a cost-effective manner are also needed. The use of a web-based data collection system has promise since it can be cost-effective. However, our study suggests that in time data collection may be needed. With the decreasing cost of devices such as tablets it may be possible to give the convenience of a paper-based in clinic version; while retaining the electronic advantages. As the use of smart phones and tablets continues to increase, we suspect that barriers to electronic participation will decrease.

CONCLUSIONS

This pilot study was designed to assess feasibility of adverse event data collection in the Canadian manual physiotherapist patient population in a private practice setting. None of the feasibility criteria created were achieved. The receptivity of practitioners and patients were substantial barriers. Prior to embarking on a similar study focusing on prospective collection of adverse events, it is recommended that therapist and patient focus groups be conducted to identify barriers to study conduct. Areas to be examined include the use of attitudinal barriers, the nature of valued therapist incentives that would fit within acceptable scientific behaviour, paper forms of outcome measures for patients to fill out and a qualitative component to address issues such as missing data. Answering these and other questions may help inform the design of a new pilot study to maximize the potential for success.

KEY MESSAGES

What Is Already Known on This Subject

There is a large literature base associating mild to major adverse events with neck manipulation. The occurrence of major adverse events has gained scientific and media attention and these catastrophic events are largely reported in relation to chiropractic treatment. However other health professionals also use this technique, and there is a paucity of data of adverse events and neck manipulation administered by physiotherapists. It is important to establish profession specific data to provide adequate treatment profiles of benefit and harm. There are currently no rigorous estimates for the physiotherapy profession.

What This Study Adds

This study established that conducting a large-scale international multicentre study to provide profession specific estimates of adverse events associated with neck manipulation is problematic to implement. Based on this pilot, none of the criteria for success were met. The investigators, participating clinicians and patients identified several barriers for data collection. This includes issues that may be specific to the Canadian OMPT community as well as ones associated with using an Internet based data collection system. No accurate estimates of adverse events were obtained due to poor recruitment. Future studies should be aware of the possible challenges of conducting research in this community and consider offering online and paper copies of outcome measures. Funding may be a challenge given the resources needed and the professional commitment to conducting this study in a cost-effective manner.

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Table 1. Adverse events outcomes

Category	**Severity**	**Duration of symptoms or functional impact**	**Examples**
Mild	No impact on function	Up to 24 hrs	Headache, dizziness, bruising, increased stiffness, increased pain, nausea, radiating symptoms (pain, numbness, tingling)
Moderate	Function modified but intact, may require alteration in treatment	>24hrs – 1week	As above plus dislocation, loss of motion, breathing difficulties, visual disturbances, facial pain/numbness/tingling, ringing in ears, confusion/disorientation, vomiting
Major	Function absent, requires medical intervention	> 1 week	As per moderate plus transient ischaemic attack, stroke, fracture, loss of bowel/bladder control, coma

Table 2. Patient reported adverse events visits 1-5

Adverse events	Visit 1 n		Visit 2 n		Visit 3 n		Visit 4 n		Visit 5 n	
	Combined	Mob	Combined	Mob	Combined	Mob	Combined	Mob	Combined	Mob
Did you experience an adverse reaction? *	1	2	1	7	1	4	1	4	1	3
Headache	1	1	1	2					1	1
Tenderness		2	1	5				1		2
Stiffness		2	1	2	1	1	1	1	1	1
Soreness	1	2	1	5	2	2		2	1	
Fatigue		1	1	1				1		
Weakness		1		1						
Dizziness						1				
Breathing difficulties						1				
Decreased neck motion			1		1		1			
Nausea/vomiting				1						
Ringing in the ears			1		1		1			
Tingling			1		1			1		
Radiating pain				1		2				1
Increased pain								1		
Other: sore breast					1					

*values provided for Yes answers only

Table 3. Onset and duration of symptoms reported visits 1-5

Symptoms	Onset				Duration					
	0-12 hrs		13-24 hrs		0-2 days		3-7 days		> 1 week	
	Combined	Mob	Combined	Mob	Combined	Mob	Combined	Mob	Combined	Mob
Headache	3	4			3	4				
Tenderness	1	9		1		9	1	1		
Stiffness	4	7				7	4			
Soreness	5	10		1	5	10		1		
Fatigue	1	3			1	3				
Weakness		2				1		1		
Dizziness		1				1				
Breathing difficulties		1						1		
Decreased neck motion	3						3			
Nausea/vomiting		1				1				
Ringing in the ears	3				3					
Tingling	2	1			2	1				
Radiating pain		3	1			3				1
Increased pain		1			1					
Other: sore breast	1				1					
Total*	**23/225**	**43/2940**	**1/225**	**2/2940**	**16/225**	**40/2940**	**8/225**	**4/2940**	**0**	**1/2940**

* denominator represents the number of possible responses per group per category

Table 4. Patient characteristics (n=17)

Characteristic	**n (%)**
Gender	
Female	12
Education level	
High school	2
Post secondary	11
Graduate degree	4
Length of neck pain	
< 2 wks	2
3-12 wks	4
>12 wks	11
History of trauma to neck	7
Work status	
Full time	13
Part time	3
Not working	1
Professionals consulted for neck pain	
Family physician	6
Chiropractor	5
Specialist	1
Osteopath	0
Physiotherapist	9
Massage therapist	3
Medication Use	
Taking medications	9
Over the counter	6
Prescription for pain	2
Prescription not pain related	7
Number of days in preceding year with neck pain	
<30	5
30-60	3
>60	9

Table 5. Treatment parameters

Treatment	**Visit 1 n**		**Visit 2 n**		**Visit 3 n**		**Visit 4 n**		**Visit 5 n**	
	Combined	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**
Occiput – C2	2	9	1	9	0	8	1	7	1	7
C3 - C7	3	12	3	12	3	13	2	12	2	10
Direction of force										
- traction	0	4	3	3	0	4	0	3	0	3
- flexion	2	10	1	9	1	9	1	10	1	10
- extension	1	6	1	6	2	8	1	8	1	8
- rotation	1	3	2	5	1	3	2	3	2	3
- distraction	0	2	1	1	1	3	0	3	2	1
Passive stretching	2	7	0	7	0	7	1	6	1	6
Exercise prescription	2	11	2	12	2	9	2	9	2	8
Acupuncture	1	4	0	4	0	4	0	5	0	4
Myofascial release	0	0	1	0	0	1	0	1	1	0
Soft tissue massage	0	0	0	1	0	2	0	3	0	2
Ice/heat	2	3	0	3	1	2	0	0	0	0
Electrotherapeutic modalities	1	1	2	3	1	2	1	1	1	1
Laser	0	1	0	1	0	1	0	1	0	1

Table 5. Treatment parameters

Treatment	**Visit 1 n**		**Visit 2 n**		**Visit 3 n**		**Visit 4 n**		**Visit 5 n**	
	Combined	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**	**Combined**	**Mob**
Thoracic manipulation	2	2	2	4	2	4	1	1	1	5
Other:	0				0		0		0	
- education		1		2		1				
- lumbar mobilization		1 1								
- mechanical traction		2	1	5		3		3		2
- thoracic mobilization						1		1		
- snag										
- TMJ distraction										

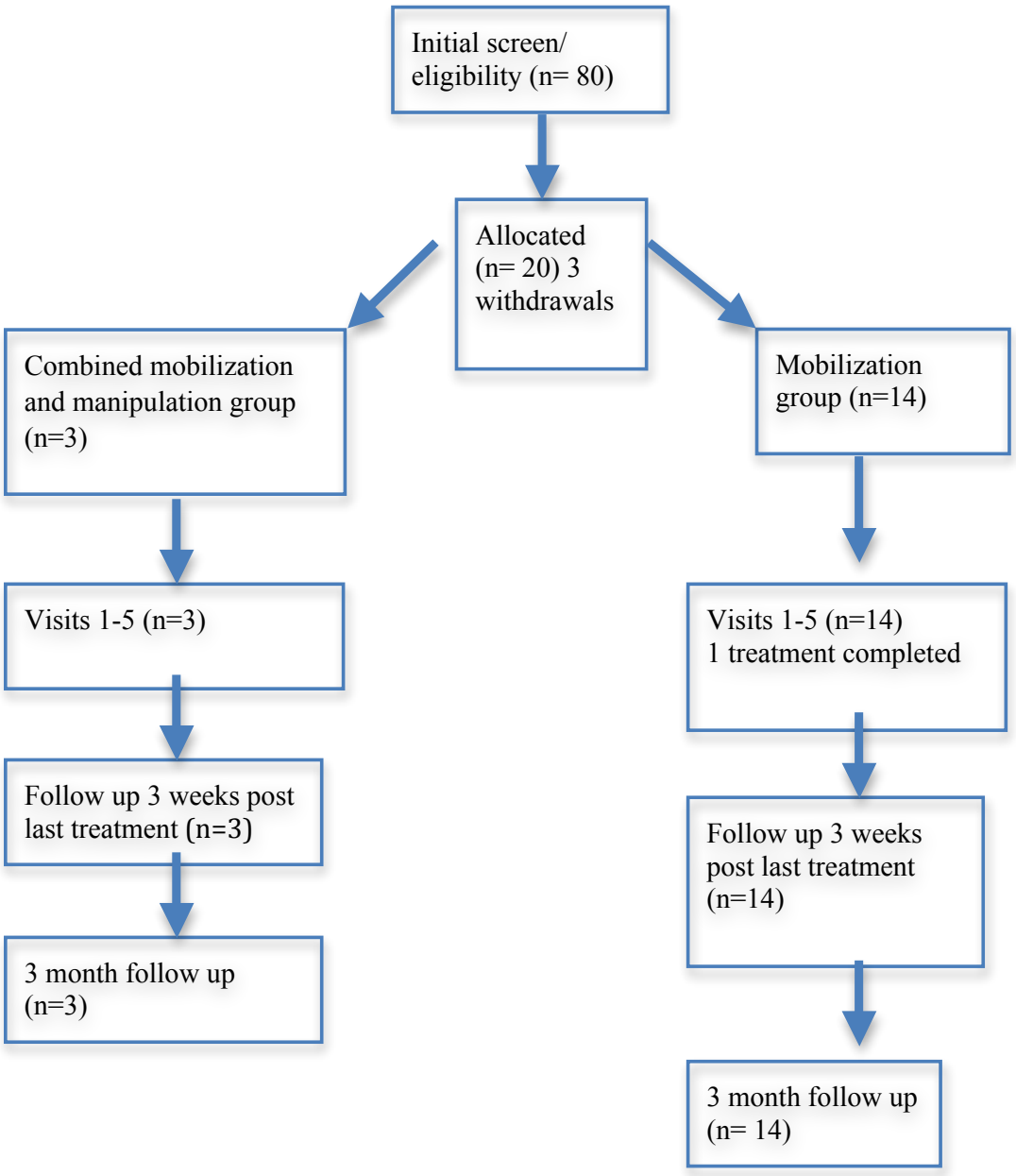

Figure 1. Participant flow and follow up

CHAPTER 5

DISCUSSION AND CONCLUSIONS

There are many factors affecting the collection of adverse event (AE) data associated with manual therapy (MT) for patients with neck pain. The preceding chapters have contributed to this knowledge base by providing the Canadian manual physiotherapy perspective of practitioner beliefs regarding the occurrence of AE, and practice variation in the use of assessment and treatment techniques; patient perceptions of an AE and identifying the barriers of collecting prospective AE data in the Canadian manipulative physiotherapist population and their patients with neck pain. Each chapter has addressed knowledge gaps within its own area. By assessing the interaction of all three papers a larger impact can be gleaned.

It is difficult to know based on the data presented, the exact nature of the relationship between these topics. It does seem clear that one exists, particularly around the perception by practitioners and patients alike about the occurrence of AEs in patients with neck pain treated with MT. These perceptions are affecting how practitioners treat patients with neck pain and how patients define whether an AE has actually occurred. This is concerning since we do not have any profession specific data on the rates of AEs in this population and it appears based on our research experience that it is quite challenging to obtain this data in Canadian private practice settings. Our pilot and feasibility study indicated that there are many barriers to successfully collecting such data.

These studies have determined that Canadian manipulative physiotherapists are manipulating the neck least frequently of all areas of the spine; they view thoracic manipulation as a safer alternative and believe that treating the neck generates the largest number of AEs. This last point concerning the decreased use of manipulation for neck pain lacked clarity in its reasoning around the types of AEs as similar numbers of respondents reported that manipulation and mobilization created an equal amount of AEs compared to manipulation creating more AEs than mobilization. This may be due to some respondents considering only major AEs and others regarding the whole range from mild to major. This is an important distinction however when it comes to the patients perception of an AE.

The survey of patient perceptions of AEs who are receiving MT indicated that when it comes to AEs, the ones that really matter to them are the major ones causing significant permanent harm. In fact, they are accepting of mild transient reactions to MT in light of the fact that they are receiving helpful treatment. Furthermore these reactions are subjected to a complex reasoning process, likely varying from person to person, in which the interplay of contextual factors are considered to determine causality. Finally, no association was found between patients with neck pain and the reporting of AEs, but was found in patients with low back pain.

In the third study of this thesis, a lack of feasibility for collecting AE data in the Canadian manual physiotherapy population was demonstrated. There was poor recruitment by the participating therapists and the groups were quite uneven with enrolment favouring the mobilization only group. The online data collection system,

which was chosen as an efficient and accessible means for data collection, presented challenges in its functionality and accessibility for both patients and therapists. Overall, the number of patients approached and the percentage recruited were quite low, leaving one to question what other factors might be influencing this poor recruitment and response rate.

Upon considering the totality of these results, one can query to what extent fear is driving the practice patterns of Canadian manipulative physiotherapists when treating people with neck pain. The extent to which fear impacts on the use of neck manipulation is unknown and would warrant further investigation to establish the future viability of ongoing treatment and teaching of neck manipulation. While the included practitioner survey provided some evidence describing current trends in practice, it did not assess possible reasoning behind the observed patterns and as such has generated a new set of questions to be addressed. If practitioners are going to continue this trend to decrease the use of neck manipulation and educators from teaching the technique, then more information about the rationale for deselecting this efficacious treatment would be important.

As a follow up to the current survey, Canadian manipulative physiotherapists can be asked several questions around the reasons behind their use of neck and thoracic manipulation. Inquiring about a) the extent to which fear of major AEs influences their use of neck manipulation and if it is different when considering treating the mid cervical spine or the upper cervical spine; b) whether they actively choose thoracic manipulation to treat patients with neck pain because they perceive it to be safer; c) the degree to which

they weigh the lack of profession specific AE data on either neck or thoracic manipulation and the paucity of efficacy data on thoracic manipulation for patients with neck pain compared to neck manipulation; d) if knowing that patients largely consider an AE to be one that is major in severity, and are more likely to report an AE if they have low back pain and not neck pain will influence their use of neck manipulation.

The intervention of thoracic manipulation requires closer examination. While there is efficacy for its use in patients with neck pain, are practitioners aware of the limitations of the evidence or are they choosing it more for its perceived safety? A recent systematic review of this literature concluded that the body of evidence has significant flaws[53] being limited to primarily short term follow up, generally from a few days to 7 weeks; only one study following up at 6 months. Another important flaw was the variation amongst the control interventions. There was no study included in the review that conducted a head to head comparison with cervical and thoracic manipulation; this limits the conclusions that thoracic manipulation is more effective than cervical manipulation for patients with neck pain. Since the publication of this review, there has been at least two studies that compared these two techniques with one concluding that there is no significant difference in terms of pressure pain thresholds, neck pain and range of motion [54] and the other concluding that cervical manipulation was superior for the outcomes of neck pain, disability and fear avoidance.[55] Ultimately none of these issues may matter. Even though the Canadian post professional education systems have minimized rotation in the teaching of neck manipulative techniques,[56] and there has not been any report of a Canadian manipulative physiotherapist involved in a case where

serious harm has been caused to a patient after neck manipulation,[57] at the end of the day if thoracic manipulation has any evidence of benefit and no evidence of harm, it is highly likely that practitioners who have any discomfort or doubts about neck manipulation, will gravitate towards the safer procedure.

Manual therapy educators in Canada are another group to be studied. They too can be asked about their comfort and perceived fears around teaching neck manipulation techniques versus thoracic manipulation and the influence of the evidence base as previously mentioned. As there are a relatively small number of teachers in Canada, it may be possible to include them all and get very robust data by employing a mixed methods study design. The combination of the results of these future studies has the potential to influence future curriculum development, research study design and clinical practice. Supplementing this data with actual AE rates associated with neck MT will provide a comprehensive picture of the Canadian MT landscape with respect to this issue.

The results of the pilot study on AE data indicated that it was not feasible to continue the study on a larger scale and that the methods used were not optimal for data collection. A larger concern existed around poor participation and recruitment by the manipulative physiotherapists. If another attempt were made at a feasibility study, these initial results suggest that further exploration of issues impacting on recruitment be assessed. Once therapists have indicated that they are interested in participating, focus groups could be held to address factors that would both negatively impact or optimize recruitment of patients with neck pain into both groups of the cohort. As well this would provide an opportunity to address some of the fear related issues mentioned above and

determine to what extent they are influencing participation. Is there any selection bias by practitioners in approaching potential study participants because of their own beliefs about neck manipulation? Focus groups with practitioners and patients could also allow for the inquiry of the most effective data collection methods. We thought that in our computer driven world, providing web-based methods for participants would be optimal. This was not the case and warrants assessment of what data collection methods would be best for all participants. Although the results of the pilot study were less than satisfactory, they were informative and they along with other pertinent results can effect change clinically and in research.

The results of the patient survey infer that if a framework for categorization of AEs be adopted, it should do so with two broad categories of major AE and all others events. This result differs from a previously published framework that did not include the patient perspective when deriving the framework for AE.[48] This broad categorization is supported by the data of our patient survey, the qualitative study (on which the survey was based)[58] and a recently published study of the osteopathic patient perspective. [59]The separation of mild and moderate categories appears to be more complex due to the impact of contextual factors that influence the decision making process of whether an AE has occurred. This complexity could pose a significant challenge for clinicians and potentially for researchers trying to determine if and why an AE has occurred. A new framework that is more systematic, allowing for easily definable categories with some flexibility is more desirable than one that creates more ambiguity, by permitting large degrees of interpretation and therefore variability.

Systematic categorization does not have to imply rigidity. A balance can be struck to find structure and flexibility that will capture the majority of cases. An effective classification system requires that it be utilized by clinicians and researchers alike, therefore necessitating sufficient detail and efficiency. If deemed necessary, clinician and researcher versions can exist with the latter providing the possibility for more detail often required for study data collection. The important common feature that must be shared by the two is that the information is transferrable and therefore capable of seamless communication.

An effective classification system would naturally lend itself to an effective reporting system. However the structure of an effective reporting system requires many elements, the scope of which is beyond this discussion. What does warrant discussion is addressing the fear and stigma around reporting. The media attention around major AEs related to neck manipulation has served to promote this.[60] As a profession that has the scope of practice to perform spinal manipulation and is impacted by the evidence base of AEs related mainly to other health professionals,[43, 44] manual physiotherapists would benefit from profession specific data to substantiate practice patterns and the beliefs driving them. Until they are substantiated, clinical practice patterns amongst manual physiotherapists that are influenced by the perceptions of AEs are largely unsupported. Effectiveness studies with head to head comparisons of neck manipulation and thoracic manipulation will also help with this validation process.

It is therefore important that effectiveness studies continue in this area to determine which techniques are most effective, safest, and in what dosages. A standard

of AE classification will enhance accurate and reliable data collection. Addressing the concerns of practitioners who are willing to participate in studies to determine profession specific AEs will help address the feasibility of future projects. This course of research will take some years to be realized. With ongoing research activity in these areas, the time to pursue these goals is at hand. Manipulative physiotherapists can choose to take control of the impact of this issue on the profession and establish practice patterns based on actual incidence rates than on extrapolation. Doing so will provide educational leadership and greater clinical certainty to establish the future course of manual interventions from which optimal clinical outcomes can be determined.

Collaboration and cooperation amongst manual practitioners is desired to acknowledge any distinct differences in clinical practice. This is important knowledge for the patient consumer particularly when attempting to address historical concerns of significant harm related to cervical manipulation. Establishing whether the use of different or similar manual techniques results in different benefit-harm profiles will serve the patient foremost. It is the safety of the patient and maximizing the benefit of treatment that should drive this course of research forward. The benefit of patient centred study designs will be felt across professions, and has the potential to improve the public perception of professional responsibility. If the public perceives the conduct of manual practitioners to be safe, effective and grounded in scientific evidence, the benefit seems obvious. Practitioners of MT from varying professions can initially approach these research goals by establishing foundational data with an eye towards interprofessional collaboration. The emphasis in health research on patient centred designs and outcomes

is requesting that MT practitioners shift their lens to keep focused on the patient, the people we serve and on whom our practice depends.

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