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By

Joseph Anders

Bachelor of Science, Kinesiology
University of Nevada-Las Vegas
2007

A research article submitted in partial fulfillment of
the requirements for the

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ABSTRACT

Safety of Cervical Manipulation: Are Adverse Events Preventable and Are Manipulations Being Performed Appropriately?

by

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Objectives: Documented case reports found in medical literature describing adverse events associated with cervical spine manipulation (CSM) were reviewed to determine if the CSM was used appropriately and if the events could have been prevented. Our hypothesis was that CSM had been used inappropriately and that adverse events could have been prevented. This study also looked to identify potential characteristics that may put the patient at risk for injury, or even death as a result of a CSM. **Methods:** One hundred and thirty four cases, reported in 93 articles, published between 1950 and 2010, were reviewed. CSMs were categorized as 'appropriate' or 'inappropriate', and adverse events associated with the CSM were categorized as 'preventable', 'unpreventable' or 'unknown'. **Results:** Chi square analysis showed no significant difference in proportions between appropriateness and preventability, $p=.459$. Of the 134 cases, 60 (44.8%) were categorized as preventable, 14 (10.4%) were unpreventable and 60 (44.8%) were categorized as 'unknown'. CSM was performed appropriately in 80.6% of cases. Death

resulted in 5.2% (n=7) of the cases, mostly caused by arterial dissection. **Discussion:** There is no association between appropriateness of cervical manipulation and preventability of adverse events. If all contraindications and red flags have been ruled out, there is potential for a clinician to prevent 44.8% of adverse events. Additionally, 10.4% of the events were unpreventable, suggesting there may be some inherent risk associated with CSM even after a thorough exam and proper clinical reasoning.

Introduction

Cervical spine manipulation (CSM) is utilized by physical therapists, chiropractors, and other healthcare practitioners to treat a multitude of disorders, most commonly headaches, neck pain and stiffness.¹ For the purposes of this study, CSM is defined as a passive manual therapy intervention utilizing high velocity low amplitude movement that cannot be prevented by the patient.²⁻⁴ The safety of CSM has been an issue of significant debate since 1907, when the first adverse event was reported.⁵ Much of the debate regarding the safety of CSM may be attributed to the lack of agreement between incidence reports of serious adverse events following CSM, which vary between 1 per 50,000 to 1 per several million.^{6,7}

While there is little agreement between incidence figures, it is evident that there is some risk associated with CSM. Several literatures reviews have suggested that the risks associated with CSM outweigh the benefits.^{1,2,8,9} This conclusion was made due to the lack of evidence supporting any benefits of CSM to offset the risks associated with the technique.² Additionally, after retrospective review of cases involving cerebrovascular accident (CVA) following CSM, Haldeman et al (2002) concluded the risks associated with CSM are inherent and the occurrence of serious complications appears to be unpredictable.¹⁰

Some have speculated that adverse events following CSM are predictable and may be attributed to insufficient judgment and examination by the clinician.¹ It has been suggested that, when deciding whether or not to use CSM, a clinician should determine if the technique is both appropriate and safe.^{11,12} CSM may be considered an appropriate treatment technique if it is indicated by the patient's presenting condition. Such

conditions indicating the use of CSM include neck pain, cervicogenic headache and cervical radiculopathy.¹² A 1996 study by the RAND group, examined the appropriateness of CSM by surveying the opinions of a nine member multidisciplinary expert panel. The panel was presented with clinical scenarios including patient history, symptoms, results from radiographic imaging and response to previous treatment. Patient conditions ranged from acute neck pain to cardiovascular pathology. The panel found CSM to be an appropriate technique to use in only 11.1% of the 736 clinical scenarios.¹² The study emphasized the importance of proper clinical reasoning, so as to not place a patient at risk for adverse event following CSM if they are not likely to benefit from the technique.

Once CSM is deemed to be appropriate for a patient's presenting condition, the clinician should determine the safety of the technique by identifying preexisting conditions that might indicate a patient's risk for adverse events. Absolute contraindications (table 1) and 'red flag' symptoms (table 2) have been identified to assist clinicians with decision-making.¹ 'Red flag' symptoms may indicate the presence of a contraindicated condition. CSM should never be performed when contraindicated conditions are present.¹ Childs et al (2005) recommend that contraindications and 'red flags' be used in conjunction with sound clinical reasoning as part of an examination scheme to assist in determining if CSM is an appropriate technique and to prevent adverse events due to CSM.¹¹

While suggestions have been made to guide clinical reasoning and reduce the risk of adverse events following spinal manipulation, there have been few studies examining the use of these suggestions clinically.^{10,13} Haldeman et al (2002) were unable to

recognize characteristics from a patient's history or examination that would indicate increased risk of CVA following CSM. To date, no study has investigated the use of examination procedures in patients experiencing adverse events other than CVA.

The purpose of the study was to retrospectively review all available documented case studies in the literature describing patients who had experienced severe adverse events after receiving CSM to determine if the CSM was used appropriately and if these types of adverse events could have been prevented using sound clinical reasoning on the part of the clinician. Our hypothesis was that, for reported cases of severe adverse events, CSM may have been used inappropriately and that those adverse events may have been prevented. Secondary analysis was performed to identify potential characteristics that may have put a patient at higher risk for an adverse event, as well as examine characteristics of cases leading to death.

Methods

Case reports published in peer reviewed journals involving adverse events following CSM were found by searching PubMed (1950-2010) and the Cumulative Index to Nursing and Allied Health (CINHAL, 1982-2010). Initial search terms included any combination of the following: *cervical manipulation, adjustment, chiropractic, manual therapy, physical therapy, physiotherapy, osteopathy, arterial injury, stroke, safety, adverse event, side effect, injury and risk*. Additional case reports were obtained from references of articles cited by Di Fabio (1999), Ernst (2007) and Terrett (1987).

Titles and abstracts of articles identified with search terms were screened by two independent reviewers. One hundred and five (105) articles were identified and further

evaluated for inclusion and exclusion criteria by three reviewers. Articles were included if they provided one or more case reports and excluded if the adverse events occurred without CSM (e.g. spontaneous); if the condition for which CSM was used was not reported; or if it was written in a language other than English, German, Spanish, Polish, French or Norwegian. Ninety-three (93) articles, describing 134 cases, were determined to be eligible for final review.^{3,14-105} Cases included in a language other than English were translated by native speakers or those fluent in the language prior to being evaluated. All case information was entered into a case analysis form which included: gender, age, who performed the CSM and why, presence of contraindications, the number of manipulations performed, initial symptoms experienced after the CSM, as well as type of adverse reaction that resulted.

All three reviewers completed a case analysis form and categorized each article individually. Based on the information gathered, CSMs were categorized as 'appropriate' or 'inappropriate', and adverse events were categorized as 'preventable', 'unpreventable' or 'unknown'. Appropriateness was based upon the patient's presenting condition. A case was determined to be 'appropriate' if CSM was used for an indicated condition such as neck pain, headache, or cervical radiculopathy and 'inappropriate' when CSM was performed for reasons that are not indicative to cervical disorders, such as low back pain, non-radicular shoulder pain or maintenance therapy. Preventability was based on the presence of factors that increase a patient's risk for injury. Cases were classified as 'preventable' when contraindications or red flags should have otherwise stopped the care provider from performing CSM and 'unpreventable' when the patient appeared to be clear of any contraindications or red flags to CSM either in current and/or past history

(see tables 1 & 2). Therefore, a CSM could have been performed for appropriate reasons, but if the clinician performed the CSM in the presence of contraindications or red flags, the adverse event would have been preventable. An 'unknown' category was created and used when an article did not provide enough information to allow it to be categorized as 'preventable' or 'unpreventable'. To improve accuracy of data, analysis of each case was then compared between all three reviewers and disagreements were resolved by consensus.

Once case reports had been categorized by 'appropriateness' and 'preventability', all reports were further categorized by severity of adverse reaction. These categories included: transient, severe reversible, and severe irreversible. Transient reactions were defined as symptoms that were minor and dissipated within 24 to 48 hours. Common transient reactions included: local increase in pain, headaches, fatigue, and radiating discomfort.⁴ Severe, but reversible, reactions included disc herniation, nerve root compression and fracture. Severe, but irreversible, complications included dissection or vasospasticity of cervical arteries, causing CVA and death.⁴ Additionally, cases found to be preventable were analyzed to determine the underlying condition for which it was placed in the preventability category.

All data collected from the analysis sheets were input to a spreadsheet and all statistics were performed using PASW 17.0 (SPSS 2009).^{*} Chi square analysis was used to determine if there was a difference in proportion between the six categories: appropriate/preventable, appropriate/unpreventable, appropriate/unknown, inappropriate/preventable, inappropriate/unpreventable and inappropriate/unknown.

^{*} PASW Statistics 2009 PASW statistics version 17.0. Chicago, IL: SPSS, Inc.

Further examination of these categories was done with frequency statistics. Demographic data and remaining data from the case analysis sheet were analyzed using descriptive and frequency statistics.

Results

Demographics

One hundred thirty four (134) cases, reported in 93 articles, were analyzed for this study. Language translation was required in 9% of the cases. The cases involved 73 males and 61 females. The average age was 43.8 years (SD=11.8, Range= 23 to 86 years).

Adverse events were categorized by severity of injury. Most of the injuries (51.5%, n=69) reported were categorized as severe and irreversible, while 41% (n= 55) were severe reversible, 5.2% (n=7) were transient, and 5.2% (n=7) were unknown.

Arterial dissection was the most common adverse event reported, being present in 34.5% of the cases (n=50). Other common adverse reactions included disc herniation (17.2%, n=25), CVA (12.4%, n=18), and vertebral dislocation or fracture (6.2%, n=9). The most common post-manipulation symptoms described were weakness (n=59), paresthesias (n=53), and increased pain (n=43) (Figure 1).

Chiropractic physicians were involved in the majority of injuries following CSM with 69% (n=93) of the cases analyzed (Figure 2). Physical therapists were involved in 4% (n=5) of the cases, while 11% (n=15) did not report the practitioner performing the CSM. Non-clinicians, including bone setters, barbers, and masseurs accounted for 7% (n=9) of the CSMs.

Appropriateness and preventability

Chi-square analysis showed no significant difference in the proportions between appropriateness of the manipulation and preventability of adverse outcomes, $\chi^2(2)=1.556$, $p=.459$. Of the cases analyzed, 19.4% (n=26) of the manipulations were categorized as inappropriate, 44.8% (n=60) of the adverse outcomes were preventable and 9% (n=12) of the cases were both inappropriate and preventable (Table 3).

Many of the cases categorized as preventable (49.2%, n=30) were determined to be so because of the presence of a preexisting condition in the cervical spine. Preexisting conditions present in the preventable cases consisted mostly (70%, n=21) of active bony pathologies including: severe spondylosis, osteoporosis, rheumatoid arthritis, ankylosing spondylitis, and cervical stenosis. Vascular pathologies, such as cardiac infarct and atherosclerosis of the cervical arteries, accounted for 13.3% (n=4) of preexisting conditions. Miscellaneous conditions, consisting of pregnancy, chronic symptoms from a motor vehicle accident 40 years prior and symptomatic disc pathology, accounted for 16.7% (n=5) of adverse events. Continued manipulation with either no change in presenting symptoms or worsening of symptoms occurred with a frequency of 24.6% (n=15) in both conditions.

Cases resulting in death

Seven (5.2%) of the total cases ultimately resulted in death. Of the patients involved, 4 were male and 3 were female between the ages of 25 and 51. Practitioners involved in resulting death included: chiropractic physicians (71.4%, n=5), a naturopath (14.3%, n=1), and an unknown practitioner (14.3%, n=1). Arterial dissection was the cause of 5 deaths and CVA accounted for the remaining two. Four deaths were

determined to be preventable, 1 unpreventable and 2 unknown. Two of these cases resulting in death were categorized as preventable because the practitioner continued to perform manipulations when symptoms were worsening, and in the other 2 cases clinicians performed excessive (deemed greater than 3) manipulations with no change in symptoms.

Discussion

There was no significant association between appropriateness of CSM and preventability of adverse events. Contrary to our hypothesis, CSMs that were performed inappropriately were not more likely to be classified as preventable. In fact, while 80.6% of all reviewed CSMs were performed for appropriate conditions, 44.8% of the cases were preventable and apparently not screened for contraindicating signs. These results suggest that simply determining that a CSM may be indicated is not sufficient to prevent adverse events. From a clinical perspective, a thorough examination to rule out all contraindications and 'red flags' may prevent nearly half of all adverse events related to CSM. Additionally, 19.4% of CSMs reviewed were performed for inappropriate conditions, meaning patients were placed at risk for adverse event although they were not likely to benefit from the technique.

Inability of clinicians to recognize signs indicating a patient is at increased risk may be attributed to the lack of reliable and valid screening tools, as well as poor history taking and insufficient clinical reasoning. The most common adverse reaction reported in these cases was arterial dissection. This finding has been well documented and as a result pre-manipulative screening tools have mostly focused on identifying vertebral basilar

insufficiency (VBI) to rule out risk of vertebral artery dissection associated with CSM, although use of these tests remain controversial.^{2,4,5,106-108} The controversy stems from the high rate of false-positive results associated with these tools.¹⁰⁸ Westaway et al (2003) and Haldeman et al (2002) describe cases in which patients had VBI, but screening tools, consisting of end range extension and rotation of the cervical spine to evaluate vertebral artery patency, failed to provoke symptoms that would contraindicate CSM. In cases reviewed that were found to be preventable, clinicians may have excluded VBI testing due to conflicting evidence regarding its efficacy. However, it is also possible that clinicians had no intent to screen for contraindications due to lack of knowledge, poor clinical judgment or carelessness. Childs et al (2005) suggest that, regardless of the evidence, or lack thereof, it is the responsibility of the clinician to perform screening examinations and clearly document their use to reduce legal risk if an adverse event were to occur with CSM.

With uncertainty regarding screening tools, clinicians must use additional strategies (e.g., red flags) for decision making when choosing to use CSM.¹¹ Most of the cases reviewed were classified as preventable due to inability of the clinician to recognize red flag symptoms of preexisting conditions that would contraindicate the use of CSM. The most common preexisting conditions were found to be boney pathologies such as severe osteoporosis, spondylosis and rheumatoid arthritis. These conditions are clear contraindications to CSM and should have been easily identifiable through a detailed patient history. With the lack of accurate screening tools, it is prudent for the clinician to perform a thorough history to ensure patient safety.¹¹ Childs et al (2005) suggest that clinicians should use not only clinical reasoning to determine whether or not CSM is

appropriate and safe, but they should also consider their own skill level, the preferences of the referring provider, as well as the demeanor and goals of the patient.

While most of the cases of adverse events were classified as preventable, 10.4% of cases were found to be unpreventable. Considering reported incidence figures, adverse events following CSM are uncommon at 1 per 50,000, indicating that unpreventable adverse events are even more uncommon. Though millions of CSMs are performed without adverse events, the results suggest a very small but inherent risk associated with CSM even after a thorough examination for contraindications and proper clinical reasoning. The findings are consistent with conclusions made by Haldeman et al (2002), but may also reflect the inability of examination procedures to detect patients at risk for adverse events.

Demographics of the patient population were comparable to those reported in previous literature, with one disparity consisting of gender ratios being skewed more toward male than female.^{2,8,9} In this study, the majority of adverse events were categorized as severe and irreversible. However, according to current literature, transient side effects are more common than severe adverse reactions.¹⁰⁹ In fact, transient side effects are reported to occur in 55% of all CSMs.^{110,111} The discrepancy in representation of severity is likely because transient side effects tend to be under-reported. Severe complications are more likely to require medical attention and, therefore, be documented.¹¹² Additionally, the purpose of this study was to review cases with severe adverse events rather than transient reactions following CSM.

The distribution of clinicians in our study mirrors those described by both Di Fabio (1999) and Ernst (2007). Chiropractors were found to be involved with the

majority of severe adverse events resulting from CSM. This result may be because CSM is the most common treatment modality used in Chiropractics and is performed more frequently by chiropractors than any other clinician. Osteopaths and physical therapists were also involved in 11% and 4%, respectively, of the adverse events associated with CSM in the current study. Presumably, osteopaths and physical therapists may be involved in a lower percentage since both professions have a wide range of practices not only in orthopedic spinal conditions (e.g., neurological, cardiac, respiratory, acute care) where CSM may not be appropriate.

The incidences of severe injuries resulting from CSM have been estimated to be uncommon, with injuries resulting in death even less common.^{6,7} Of the cases analyzed, death occurred in only 5.2% compared to 18% as reported by Di Fabio (1999). This discrepancy may be attributed to differences in the results of the literature search. The most recent case of death included in the present study was reported in 1995, which may indicate either a lower incidence of death resulting from CSM or a lack of reporting of such incidences in recent years. Other factors that may have contributed include: a paucity of reports written by clinicians regarding death after CSM, search methods may not have been sufficient to identify more recent cases of death, and stipulations of settlements on litigated cases may have not allowed information regarding the case to be made public. Most deaths were related to CSM by chiropractors, which reflected the percentage of chiropractors involved in total CSMs. Chiropractors were involved in 71% of the deaths which mirrors the 70% of the total adverse events that were associated with chiropractors performing the CSM. As stated previously, this finding is likely because CSM and spinal manipulation are the foundation of chiropractic treatment.

All deaths were related to either arterial dissection or CVA. It is well known that CVA and arterial dissection are closely related and it is possible that the cases of CVA may have also been caused by arterial dissection that was missed upon examination.¹¹³ Although many factors may lead to serious complications, arterial dissection is potentially the most serious and life threatening complication resulting from CSM.

Four cases of death were found to be preventable. Of these cases, two patients received multiple manipulations with no improvement in symptoms.^{64,88} The first patient received at least 19 CSMs in four months without change in presenting headache symptoms, while the second patient was receiving CSM maintenance therapy over multiple years with no improvement of symptoms.^{64,88} These cases indicate that repeated CSMs may cause damage to the vessels over time. While no human studies have been conducted, Austin et al (2010) was unable to refute or support the idea that micro-damage occurs to arterial vessels with repeated CSM in his animal model study.¹¹⁴ The third patient experienced symptoms of vertebrobasilar ischemia following CSM including dizziness, severe headache, and nausea, but was treated with another CSM one hour later resulting in loss of consciousness and cessation of breathing.⁴⁸ The final patient was noted to have a red flag symptom of vertigo, prior to receiving CSM.⁷³ In these cases, the clinician ignored symptoms indicating the patient was at risk for serious injury. Although evidence for VBI testing and related symptoms are lacking, it is unwise for clinicians to disregard these symptoms and continue to perform CSM in their presence.¹¹

One limitation of our study was that the definitions of the categories for appropriateness and preventability were not standardized and the interpretations of case reports, as well as the placement of them into suitable categories, were areas of

subjectivity. Also, the search for relevant case reports may not have been exhaustive. There may have been discrepancies between what was reported in the case report and what actually occurred, as physicians, rather than the clinician performing the CSM, published many of the cases. Missing information needed for the analysis of cases resulted in the exclusion or placement of a large proportion (44.8%) of cases into an unknown category, which may have had an influence on the results of the statistical analyses. When the term ‘chiropractic manipulation’ was used in the case reports, it was assumed that the clinician performing CSM was a chiropractor. However, Di Fabio (1999) stated that the term ‘chiropractic manipulation’ was occasionally used when other clinicians were performing the CSM.² Additionally, relying on secondary sources for translation of non-English articles may have led to misinterpretation by the translators as well as the reviewers.

This study presented initial definitions for appropriateness of CSM and preventability of adverse events. Future research should standardize these definitions, as well as definitions regarding manipulation. Additionally, an objective recording system should be developed to determine the true incidence of adverse events related to CSM.^{109,115} By utilizing standardized definitions and an objective recording system, stronger evidence can be produced, with a reduction in limitations.

We propose that case reports regarding adverse reactions to CSM provide standardized information. This should include detailed information regarding the manipulation technique, as proposed by Mintken et al (2008).¹¹⁶ The six categories suggested include: rate of force application, location in range of available movement, direction of force, target of force, relative structural movement, and patient position.¹¹⁶

Additionally, case reports should include: number of CSMs performed for the present condition, for what condition the CSM was performed, which clinician performed the CSM, and a description of examination procedures to rule out contraindications and red flags. These details would provide a comprehensive description of the adverse event, which would reduce assumptions during analysis of cases for future research.

With VBI testing being unreliable, it is necessary for future research to develop reliable and valid screening tools to better help clinicians identify red flags and contraindications when present.^{10,108,117} These tools should be accessible and efficient so that they may be incorporated easily into an examination scheme. Future research should also look for an association between CSM and micro-trauma to the cervical arteries, to determine if multiple manipulations cause damage to the arterial vessels, which may put one at greater risk for arterial dissection. This may assist in identifying a maximum number of CSMs that a clinician should perform without change in symptoms before choosing an alternative treatment technique.

Conclusion

If all contraindications and red flags have been ruled out, there is potential for a clinician to prevent 44.8% of adverse events associated with CSM. Additionally, 10.4% of the events were unpreventable, suggesting some inherent risk associated with CSM even after a thorough exam and proper clinical reasoning. By performing a thorough examination and using sound clinical reasoning, clinicians may be able to prevent a majority of adverse events, further reducing risks associated with CSM and improving patient safety.

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Table 1.

Absolute contraindications to performing CSM	
Acute fracture	Acute soft tissue injury
Dislocation	Osteoporosis
Ligamentous rupture	Ankylosing spondylitis
Instability	Rheumatoid arthritis
Tumor	Vascular disease
Infection	Vertebral artery abnormalities
Acute myelopathy	Connective tissue disease
Recent surgery	Anitcoagulant therapy

Table 2.

Red Flags
Previous diagnosis of vertebrobasilar insufficiency
Facial/intra-oral anaesthesia or paresthesia
Visual disturbances
Dizziness/vertigo
Blurred vision
Diplopia
Nausea
Tinnitus
Drop attacks
Dysarthria
Dysphagia
Any symptom listed above aggravated by position or movement of the neck
No change or worsening of symptoms after multiple manipulations

Table 3. Distribution of cases categorized by appropriateness and preventability

	Appropriate	Inappropriate	Total
Preventable	48 35.8%	12 9.0%	60 44.8%
Unpreventable	13 9.7%	1 0.7%	14 10.4%
Unknown	47 35.1%	13 9.7%	60 44.8%
Total	108 80.6%	26 19.4%	134 100.0%

Figure 1. Frequency of symptoms associated with adverse events following CSM

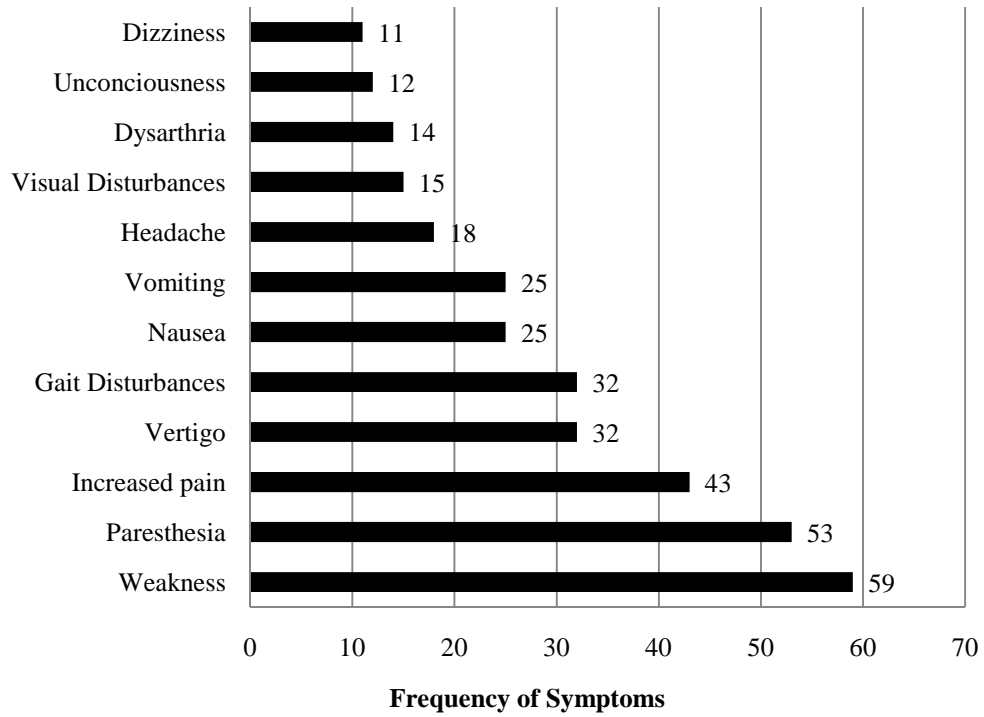
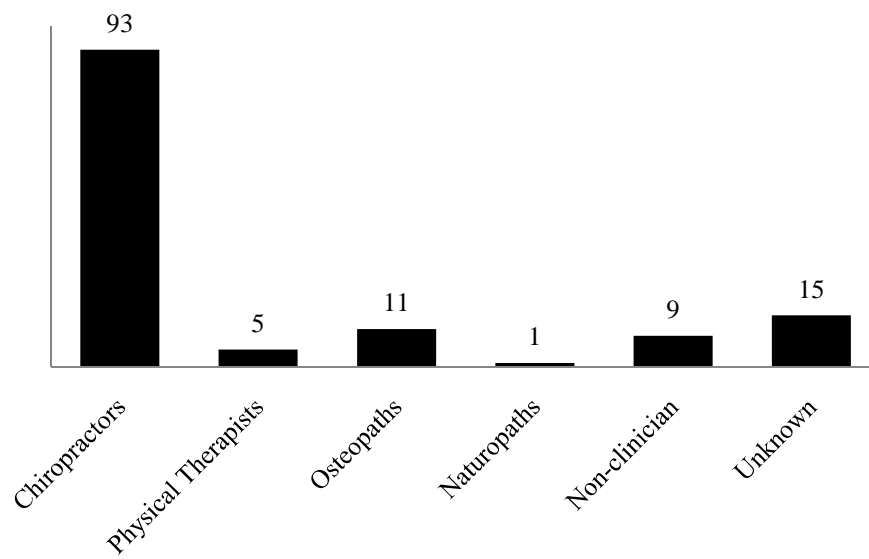


Figure 2. Frequency of practitioners performing CSM in cases of adverse events





Biomedical IRB –Review Notice of Excluded Activity

DATE: June 9, 2009

TO: Dr. Louie Puentedura, Physical Therapy

FROM: Office for the Protection of Research Subjects

RE: Notification of IRB Action by Dr. John Mercer, Chair
Protocol Title: **The Safety of Cervical Spine Manipulation: Are Adverse Events Predictable and/or Preventable?**
OPRS# 0905-3116

This memorandum is notification that the project referenced above has been reviewed by the UNLV Biomedical Institutional Review Board (IRB) as indicated in Federal regulatory statutes 45CFR46.

The protocol has been reviewed and deemed excluded from IRB review. It is not in need of further review or approval by the IRB.

Any changes to the excluded activity may cause this project to require a different level of IRB review. Should any changes need to be made, please submit a Modification Form.

If you have questions or require any assistance, please contact the Office for the Protection of Research Subjects at OPRSHumanSubjects@unlv.edu or call 895-2794.

VITA

Graduate College
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Amber Perez

Degrees:

Bachelor of Science, Kinesiology 2008
University of Nevada-Las Vegas

Dissertation Title: Safety of Cervical Manipulation: Are Adverse Events Preventable and Are Manipulations Being Performed Appropriately?

Dissertation Examination Committee:

Research Advisor, Louie Puentedura, PT, DPT, GDMT, OCS, FAAOMPT
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