Safety and Efficacy of Cervical HVLA

American Academy of Osteopathy at
American Osteopathic Association

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Learning Objectives:

After viewing the slides and participating in the presentation the osteopathic physician or student will be able to:

1. Describe the history of cervical HVLA in manual medicine and manual therapy

2. Evaluate the reports of vertebral artery dissection and neurological disorders attributed to cervical HVLA

3. Provide ideas for the next steps by the osteopathic profession in evaluating the use of cervical HVLA in clinical practice
Safety concerns have been raised before in the osteopathic literature

Concluded that OMT was safe and complications were a very rare. However, we should do a thorough structural evaluation and know what we are treating in order to avoid adverse effects.

Many osteopathic medical students and physicians have an inherent fear of injuring patients when they perform osteopathic manipulative treatment (OMT). Based on the estimated several hundred million treatments performed each year in the United States as well as a review of the literature over the past six decades, only 185 reports of injury were found. However, besides good training in these techniques, the key to the safety of OMT is the taking of a thorough patient history and performing a thorough physical examination before the application of any manipulative procedure.
C-Spine Manipulation Adverse Effects Examined


Examined 582 cases of vertebral artery accidents in Ontario, CA.1993-1998. For those <45 years old were 5 times more likely to have had a cervical diagnosis. This is somehow associated with spinal manipulation because of case of Laurie Jean Mathiason – a death after chiropractic upper neck manipulation,


Found 117 cases of post manipulation cerebrovascular ischemia in the English language literature. Examined 64 for which records were found. Concluded that CV accidents appeared to be unpredictable and rare.
Cervical Manipulation: Serious Adverse Events

- Several case reports worldwide
- Over 400 cases reported in the literature
- 1 in 50,000 to 1 in 5 million manipulations

Most Common Events

<table>
<thead>
<tr>
<th>Event</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial dissection</td>
<td>20</td>
</tr>
<tr>
<td>Brain stem injury</td>
<td>18</td>
</tr>
<tr>
<td>Wallenberg syndrome</td>
<td>12</td>
</tr>
<tr>
<td>Cerebellar injury</td>
<td>10</td>
</tr>
<tr>
<td>Spinal cord injury</td>
<td>9</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>8</td>
</tr>
<tr>
<td>Locked in syndrome</td>
<td>5</td>
</tr>
<tr>
<td>Horner’s syndrome</td>
<td>3</td>
</tr>
<tr>
<td>Joint dislocation</td>
<td>2</td>
</tr>
<tr>
<td>Brain death</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>14</td>
</tr>
</tbody>
</table>

http://neck911.com/

NECK911USA.com

The Problem:
There are over 20 different kinds of stroke pathology that can happen as a result of neck manipulation.

Our Mission:
Neck911USA is a volunteer group of individuals who provide consultations on complications due to neck manipulation. Although most cases are due to chiropractic manipulation, Neck911USA is equally concerned about cases that arise from physical therapists or medical doctors.

Watch the shocking video aired on RTE News
Click here to view and sign an international online petition to demand that chiropractors warn patients of the risk of stroke following neck manipulation

Send this site to a friend...
Name Email Send Site

What Chiropractors are saying...
Abdelmotis, Joanne Marie
Ahmed, Shabbir
Aiken, Terrance
Andrew
Ajala, Godwin
Akrassi-Minkah, Nana

Database of victims...
27 Forest Hi
45 Brooklyn
30 Staten Is
33 Jamaica
48 New York

Video...

Send Site
Victims
Laurie Jean Mathiason
Laurie Jean Mathiason was born on April 23, 1977. Laurie Jean died needlessly, on February 7, 1998. The cause of her death, at age 20, was a stroke caused by the dangerous practice of a chiropractic upper neck manipulation. This useless twisting of the upper neck is performed on everyone from newborn babies to senior citizens as a panacea for all disease. In Laurie's case she suffered from pain in the lowest part of her back, and yet the chiropractor "treated" her by twisting the upper part of her neck, an area where she never had any pain. Chiropractors have been successful in convincing politicians in North America that they are "doctors". Laurie and others have been misled because of this classification of chiropractors as doctors. It is the hope of Laurie's family and the families of the many other victims that these useless and dangerous "procedures" will be banned so that others do not have to suffer death or permanent severe disability.

Laurie Jean Mathiason
Osteopathic Medical Profession Response

1. Raised the issue at the July 2003 AOA House of Delegates.
2. AAO commissioned and approved in 2004 a position paper, “Osteopathic Manipulative Treatment of the Cervical Spine.” The authors were Kenneth Johnson, DO and George Pasquarello, DO.

“Osteopathic manipulative treatment of the cervical spine, including but not limited to High Velocity/Low Amplitude treatment, is effective for neck pain and is safe, especially in comparison to other common treatments. Because of the very small risk of adverse outcomes, trainees should be provided with sufficient information so they are advised of the potential risks… Therefore, it is the position of the American Osteopathic Association that all modalities of osteopathic manipulative treatment of the cervical spine, including High Velocity/Low Amplitude, should continue to be taught at all levels of education, and that osteopathic physicians should continue to offer this form of treatment to their patients.
Focused Research Forum - I
Cervical Spine Manipulation:
Safety and Efficacy

January 13-14, 2006

Sponsored by AOA

Commissioned by AOA House of Delegates
Resolution # 315  July 17, 2004 and
Supplemental Resolution # 316.
Participants and Organizations Represented

Boyd R. Buser, DO – BOCER
John K. Lynch, DO, MPH – CSA
Michael A. Seffinger, DO – AAO
Michael M. Patterson, PhD – COR
Scott T. Stoll, DO, PhD – ORC
Hollis H. King, DO, PhD – ORC
John C. Licciardone, DO, MS, MBA – ORC
Eric L. Hurwitz, DC, PhD – Consultant
Sharon McGill, MPH – AOA
Susan Friedman - AOA
Summary of Proceedings

• There are no clinical trials involving CSM by osteopathic physicians in the USA

• A review of available literature supported the conclusion that CSM was beneficial for chronic next pain as contrasted with acute neck pain.

• The literature on CSM safety revealed that worldwide there have been 300 to 400 cases reports of SAEs.
FRF-CSM Recommendations

**Efficacy**

- Prepare a RFP to AOA for efficacy study of OMT for somatic dysfunction of C-spine
- Examine possibility of CAP measure set for C-spine somatic dysfunction
- Examine potential for observational, retrospective, or descriptive studies of the use of C-spine OMT.
FRF-CSM Recommendations

**Safety**

- Search data bases related to any association between OMT and CSM SAEs
- Examine reports of patient death from CSM by osteopathic practitioners, USA-DOs and/or International osteopaths
- Further delineate differences in HVLA of cervical spine from other forms of manual therapy
- Consider formation of OMT SAE registry
# Manipulation related arterial dissection cases by practitioner

<table>
<thead>
<tr>
<th>Practitioners</th>
<th>Cases reported</th>
<th>Deaths reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chiropractors</td>
<td>158</td>
<td>24</td>
</tr>
<tr>
<td>Other or not specified</td>
<td>55</td>
<td>6</td>
</tr>
<tr>
<td>Physicians NOS</td>
<td>32</td>
<td>9</td>
</tr>
<tr>
<td>Osteopathic physicians</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Physical therapists</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>254</strong></td>
<td><strong>42</strong></td>
</tr>
</tbody>
</table>

Sources: Website - NECK911USA.com; MEDLINE; Haldeman S. et al. Spine. 2002
Reports of Osteopathic Cervical Spinal Manipulation Injuries


Pathophysiology

- Lumen
- Tunica intima (Location of tear)
- Tunica media
- Tunica externa
- Intramural hematoma
- Embolus

Safety and Efficacy of Cervical HVLA - King
Manipulation related arterial dissection – pathophysiology
Cerebral angiogram of the right vertebral artery revealed arterial dissection with a pseudo-aneurysm
• Observations from first FRF-CSM

• It is the neurologists who see the patients with the SAEs from CSM, and they are against any CSM

• However, there may be “referral bias”


The problem of nomenclature!!
OMT – Osteopathic Manipulative Treatment
everything we do is “manipulation”

HOWEVER

In the broader world of manual therapies, there are other sets of nomenclature

A good reference:
# Grades of Mobilization

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Small amplitude movement performed at the beginning of the passive range of motion.</td>
</tr>
<tr>
<td>II</td>
<td>Large amplitude movement performed within the passive range of motion.</td>
</tr>
<tr>
<td>III</td>
<td>Large amplitude movement performed up to the point of limitation in the passive range of motion.</td>
</tr>
<tr>
<td>IV</td>
<td>Small amplitude movement performed at the limit of the passive range of motion.</td>
</tr>
<tr>
<td>V</td>
<td>Small amplitude, high-velocity thrust performed at the end of the passive range of motion (manipulation).</td>
</tr>
</tbody>
</table>
We contrasted chiropractic cervical technique with OMT.
But then found some classic OMT AAO Yearbook. 1945:7-12.
More Becker technique
Second Focused Research Forum
Cervical Spine Manipulation
January 19-20, 2007

Sponsored by AOA

Recommended by Bureau of Scientific Affairs (BSA) and AOA House of Delegates after receipt of first FRF-CSM report and request to continue research
FRF-CSM-II Participants

Boyd R. Buser, DO – BOCER
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Michael A. Seffinger, DO – AAO
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Scott T. Stoll, DO, PhD – ORC
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John C. Licciardone, DO, MS, MBA – ORC
Eric L. Hurwitz, DC, PhD – Consultant
Krista Gordon, MPH - ORC
Issues - Again

1. Safety

2. Efficacy
Safety

No really new research, though John Lynch, DO says the evidence is growing that manipulation related arterial dissection (MRAD) is a real problem, there is still no definitive proof.

We are still looking for population studies to do “data mining” but we are finding that in the ongoing studies that the kind of data we want was not collected systematically.
# CAD: Risk Factors

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Odd Ratios</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic root diameter &gt;34 mm</td>
<td>14.2 (3.2-63.6)</td>
</tr>
<tr>
<td>Migraine</td>
<td>3.6 (1.5-8.6)</td>
</tr>
<tr>
<td>Common carotid changes</td>
<td>10.0 (1.8-54.2)</td>
</tr>
<tr>
<td>Trivial trauma (manipulation)</td>
<td>3.8 (1.3-11)</td>
</tr>
<tr>
<td>Recent infection</td>
<td>1.6 (0.67-3.8)</td>
</tr>
</tbody>
</table>

Other factors – age, oral contraceptives, connective tissue disorders, hypercholesterolemia, homocysteine, alpha-1 anti-trypsin

Summary of Findings:
Neck Associated Disorders

- Compared with placebo or sham interventions, medications, percutaneous neuromuscular therapy, mobilization and LLLT were found efficacious in the short term; evidence from placebo-controlled trials for acupuncture was inconsistent.
- Compared with primary medical care or care involving unspecified interventions, strength or endurance training with dynamic exercises, and acupuncture, appear beneficial in the short term.
- Passive modalities, ergonomic interventions, and physical and stress management programs have not been proven effective.
- Active exercises in combination with education emphasizing self management and return to normal function appear more beneficial than manual therapy, TENS, neck collar, or simple advice (singly or as part of a multimodal intervention).
- There are little if any differences between the effectiveness of endurance vs. strength training, manipulation vs. mobilization, one type of manipulation vs. another, manual therapies vs. acupuncture, and various passive multimodal approaches without active exercise components.
- There is no information to suggest that one medication is superior to any other medication or other non-medication interventions.
- There is no evidence that a longer vs. shorter duration of care or particular course of care with any intervention improves prognosis of neck disorders.
FRF-CSM-II Recommendations

Safety

1. Continue the “data mining” efforts.

2. Evaluate the results of the Neck Pain Task Force as relates to OMT of cervical spine.

3. Consider convening a “consensus forum” of all the stakeholders in the CSM-SAE debate.
   A. Neurologists
   B. DOs
   C. DCs
   D. PTs
   E. Insurance companies
FRF-CSM-II Recommendations

**Efficacy**

1. ORC to develop an R21, pilot study grant on OMT of the cervical spine efficacy.

2. May need to work with AOA to develop a request for proposals (RFP) on OMT cervical spine efficacy in order to generate preliminary data for an NIH grant proposal.
Finally osteopathic research related to cervical spine


Muscle energy technique is an established osteopathic manipulative intervention often used to treat somatic dysfunctions of the spine. There are little objective data to demonstrate its efficacy, however. To determine the efficacy of this osteopathic manipulative technique, the authors compared active cervical range of motion among asymptomatic young and middle-aged adults (n=18) before and after this treatment protocol, comparing those results against matched control subjects (n=14) who received sham manipulative treatment. Range of motion was measured in three planes (flexion/extension, lateral bending, rotation) on all subjects (N=32) using a motion-analysis system. Multiplanar gross cervical motion restrictions were diagnosed in this asymptomatic population. In the treatment group, cervical long restrictor muscles were treated with the muscle energy technique in the sagittal, frontal, and horizontal planes. The control group had relative restrictions addressed by means of a sham manipulative treatment protocol in which the barriers to motion were not challenged therapeutically. The muscle energy technique produced a significant increase in overall regional cervical range of motion in the treatment group (approximately 4 degrees) when compared with control subjects (*P*<.001). Significant differences were also observed in the magnitude of change in the three planes of movement (rotation, *P*<.002; lateral bending, *P*<.01), with flexion/extension being the least affected (*P*=.2). These data demonstrate that the application of the muscle energy technique can produce acute increases in the active cervical range of motion in asymptomatic subjects.
FRF-CSM-II Recommendations

OMT Issues

1. FRF on Osteopathic Physicians Practice Patterns as relates to treatment of neck pain.

2. Develop a “consensus conference” on manual therapies nomenclature.

3. Prepare article for JAOA on these CSM-OMT issues.
The Bone and Joint Decade 2000-2010 Task Force on Neck Pain & Its Associated Disorders

Scott Haldeman, DC, MD, PhD (President)
J. David Cassidy, DC, PhD, DrMedSc (Scientific Secretary)
Linda Carroll, PhD (Scientific Secretary)

Scientific Secretariat and Advisory Committee
Task Force Objectives

• To complete a systematic search and critical review of the scientific literature on neck pain and its associated disorders, including the epidemiology, diagnosis, prognosis and treatment of neck pain.
• To complete original research on the risks associated with the treatment of neck pain and its associated disorders.
• To complete original research using decision analysis to examine cost-effectiveness and patient preference for various treatment options.
• To reach a formalized consensus of experts in topic areas where there is no evidence.
• To combine the above results in a Best Evidence Synthesis, which addresses risk and prevention, diagnosis, prognosis and treatment risks and benefits, based on the best available scientific evidence.
Literature Screening

- Number of citations screened: 31,878
- Number of articles relevant to Task Force mandate: 1,207
- Number of reviewed intervention articles: 312
- Number of intervention articles included in best-evidence synthesis (as of December 31, 2006):
  - 155 articles (49.7%)
  - 110 separate intervention studies
  - 77 primary intervention studies (93 articles)
Summary of All Intervention Studies

- **19** studies of whiplash-associated disorders (WAD)
  - 13 randomized clinical trials (RCTs)
  - 4 non-randomized intervention studies
  - 2 cohort studies of patterns of care
- **58** studies of neck-pain-associated disorders (NAD)
  - 54 parallel-group RCTs
  - 2 randomized cross-over trials
  - 2 cohort studies
- **3** complication studies
  - 1 case-control study
  - 2 large case series
- **28** systematic reviews of intervention studies
  - 27 systematic reviews
  - 1 systematic review of systematic reviews of intervention studies