BJ Palmer’s downfall: The Neurocalometer

Two-pronged heat sensing device able to find subluxations better than chiropractors

Claims chiropractic practice without the NCM is unethical

Not available for sale - must be leased for 10 years at $2000

Enrollment at PSC plummets

Loses leadership of UCA after 20 years

Dies in Sarasota, FL as a director of the Circus Hall of Fame
Chiropractic theory

- Hippocrates – “Get knowledge of the spine, for this is the requisite for many diseases.”
- Galen – “Look to the nervous system as the key to maximum health.”
- Middle Ages - Bonesetters
- Osteopathy – The rule of the artery
- Chiropractic – The rule of the nerve
Chiropractic theory

Palmer

- 95 percent of all disease is caused by spinal subluxation
- Subluxations interfere with the Innate Intelligence
- Subluxations are “dynamic” lesions, not anatomical
Proposed mechanisms of spinal manipulation


<table>
<thead>
<tr>
<th>Action</th>
<th>Mechanism (Reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical/anatomic</td>
<td>Alleviation of an entrapped facet joint inclusion or meniscoid that has been shown to be heavily innervated (138, 139)</td>
</tr>
<tr>
<td>Mechanical/anatomic</td>
<td>Repositioning of a fragment of posterior annular material from the intervertebral disc (139, 140)</td>
</tr>
<tr>
<td>Mechanical/anatomic</td>
<td>Alleviation of stiffness induced by fibrotic tissue from previous injury or degenerative changes that may include adaptive shortening of fascial tissue (141, 142)</td>
</tr>
<tr>
<td>Neurologic/mechanical</td>
<td>Inhibition of excessive reflex activity in the intrinsic spinal musculature or limbs and/or facilitation of inhibited muscle activity (143–145)</td>
</tr>
<tr>
<td>Neurologic/mechanical</td>
<td>Reduction of compressive or irritative insults to neural tissues (146)</td>
</tr>
</tbody>
</table>

The Comprehensive Stroke Center at Tufts Medical Center
Chiropractic claims

- Treat “cause not effect”
- Preventative maintenance
- Spinal joint pain
- Other non-joint ailments, eg asthma, bedwetting, allergies, carpal tunnel syndrome, otitis media, ADHD, osteoporosis, dysmenorrhea, PMS
- “Baby adjusters”
How great is the risk with SMT?

- **Numerator**
  - # complications
  - # dissections
  - # strokes
  - # deaths

- **Denominator**
  - # patients
  - # visits
  - # manipulations
  - # cervical manipulations
How great is the risk with SMT?

- **Numerator**
  - # complications
  - # dissections
  - # strokes
  - # deaths

- **Denominator**
  - # patients
  - # visits
  - # manipulations
  - # cervical manipulations

- **Is there *any* benefit?**
Chiropractic vs cervical arteries

- Pratt-Thomas and Berger
  - JAMA 1947; 133: 600-603
  - “Cerebellar and spinal injuries after chiropractic manipulation”
- 2 patients - sudden LOC during manipulation then died
Vertebral angiography in cadavers
Neuroradiology 1963 81: 80-88

- Demonstrated vertebral artery occlusion in 5/41 cadavers with simultaneous extension and 90 degree rotation

- With traction - increased to 18/41
A survey of California neurologists
Neurology 1995: 45; 1213-1215

- California members of AAN - n=486
- Mailed survey
- Asked to report all cases of “neurological complications following chiropractic adjustment” with onset of symptoms <24hrs after Rx from 1/1990 - 12/1991
A survey of California neurologists

*Neurology* 1995: 45; 1213-1215

- 177 responses (36%)
- No complications = 126 (71%)
- Complications = 51 (29%)

_________________

- Stroke = 56
- Myelopathy = 14
- Radiculopathy = 30
A survey of California neurologists

*Neurology* 1995: 45; 1213-1215

- Strokes = 56
- Reported by 37 neurologists (21% of responders)
- All after cervical manipulation
- Ages 21-60
- Posterior circulation = 53 (95%)

“... patients, chiropractors, and physicians should be aware of the potential adverse neurological outcomes following chiropractic adjustment.”
1996 - Review of all published cases yielded 165 vertebrobasilar complications of neck manipulation. 

*J Fam Pract* 1996 42: 475-480
A survey of British neurologists

- Asked to report all neurological complications within 24h of chiropractic for 1 year
- 35 cases reported - 9 strokes
- None were published case reports

“One gets the impression that the risks of spinal manipulation are being played down, particularly by chiropractors. Perhaps the best indication that this is true are estimates of incidence rates based on assumptions, which are unproven at best and unrealistic at worse. One such assumption, for instance, is that 10% of actual complications will be reported. Our recent survey, however, demonstrated an underreporting rate of 100%. This extreme level of underreporting obviously renders estimates nonsensical.”


The Comprehensive Stroke Center at Tufts Medical Center
“The best evidence indicates that the incidence of artery injuries associated with high-velocity upper neck manipulation is extremely rare – about 1 case in 5.85 million manipulations.”
Arterial dissections following cervical manipulation: the chiropractic experience

Scott Haldeman, Paul Carey, Murray Townsend, Costa Papadopoulos

Aim: The aim of this study was to evaluate the incidence of arterial dissections following cervical manipulation and to compare the outcomes of patients who experienced dissections with those who did not.

Methods: A retrospective chart review of patients who underwent cervical manipulation at a chiropractic clinic was conducted. A total of 1,000 patients were included in the study, and their medical records were reviewed for evidence of arterial dissections.

Results: There were 43 cases of arterial dissections identified among the 1,000 patients. The dissections occurred following cervical manipulation performed by chiropractors at the clinic. The majority of dissections were asymptomatic, and no adverse outcomes were reported.

Conclusions: The results of this study suggest that arterial dissections following cervical manipulation are rare and that most cases are asymptomatic. Further research is needed to better understand the risk factors associated with arterial dissections following cervical manipulation.

References:

Correspondence to: Dr. Paul Carey, 30 Walter Rd, S, Dartmouth NS, Canada B2K 1A7.

Footnotes:
Haldeman’s Numerator: n=23

- All claims of stroke 1988-1997 to Canadian Chiropractic Protective Association (CCPA)

- This assumes:
  1. Successfully diagnosed,
  2. Have a sufficiently poor outcome that a malpractice suit is considered,
  3. Approach an attorney to file a suit,
  4. Convince the attorney that the case is sufficiently meritorious to file a claim,
  5. Are identified by the insurance carrier as having neurological symptoms, and
  6. Are adjudicated as being due to arterial dissection.
Haldeman’s denominator

Survey questionnaire of chiropractors covered by CCPA (details not described)

Median # visits/wk where cervical manipulations were done

\[ \times \text{number of covered chiropractors} \times 49.1 \text{ weeks} \]

\[ = 134.5 \text{ million} \]
Population-based, Case-control study
Rothwell et al Stroke 2001 32: 1054-1060

Introduction

- Published reports are case series with “retrospective attribution” of causation to manipulation
- No control groups
- Not blinded
Population-based, Case-control study
Rothwell et al Stroke 2001 32: 1054-1060

Ontario Health Insurance Plan (OHIP)

Database searched

- All ICD-9 codes for 6 years (1993-1998) related to posterior circulation stroke
- Each case matched to 4 (sex, age) controls
- All OHIP billing for chiropractic services
Population-based, Case-control study
Rothwell et al Stroke 2001 32: 1054-1060

Cases = 582   Controls = 2328

The Comprehensive Stroke Center at Tufts Medical Center
Population-based, Case-control study
Rothwell et al Stroke 2001 32: 1054-1060

1.3/100,000 chiropractic manipulations are associated with strokes in people <45 y/o

Cautions
- Correlative data
- Case definitions may have missed carotid dissections, SAH 2ary to dissection, nonhospitalized events
- Chiropractic billing codes only infer area of treatment (area of complaint, not Rx)
- Unidentified underlying pathology that led to both chiropractic and stroke
Risk ... “must be balanced against evidence of therapeutic efficacy.”

“Practitioners of this technique should be called on to demonstrate the evidenced-based benefit of this procedure and to define the specific indications for which the benefits of intervention outweigh the risk.”
Risk of Vertebrobasilar Stroke and Chiropractic Care

Results of a Population-Based Case-Control and Case-Crossover Study

J. David Cassidy, DC, PhD, DrMedSc,*†‡ Eleanor Boyle, PhD,* Pierre Côté, DC, PhD,*†‡§
Yaohua He, MD, PhD,* Sheila Hogg-Johnson, PhD,†§ Frank L. Silver, MD, FRCP,¶‖
and Susan J. Bondy, PhD†


Objective. To investigate associations between chiropractic visits and vertebrobasilar artery (VBA) stroke and to contrast this with primary care physician (PCP) visits and VBA stroke.

Summary of Background Data. Chiropractic care is popular for neck pain and headache, but may increase the risk for VBA dissection and stroke. Neck pain and headache are common symptoms of VBA dissection, which commonly precedes VBA stroke.

Methods. Cases included eligible incident VBA strokes admitted to Ontario hospitals from April 1, 1993 to March 31, 2002. Four controls were age and gender

complaints were highly associated with subsequent VBA stroke.

Conclusion. VBA stroke is a very rare event in the population. The increased risks of VBA stroke associated with chiropractic and PCP visits is likely due to patients with headache and neck pain from VBA dissection seeking care before their stroke. We found no evidence of excess risk of VBA stroke associated chiropractic care compared to primary care.

Key words: vertebrobasilar stroke, case control studies, case crossover studies, chiropractic, primary care, complications, neck pain. Spine 2008;33:S176–S183
Similar approach to Rothwell and similar findings
Strong association with chiropractic visit and being a case

Table 3. Odds Ratios and 95% Confidence Intervals (CI) and Accelerated and Bias Corrected Bootstrap 95% CI for Case-Control Estimates of the Association Between Chiropractic (DC) Visits and Vertebrobasilar Stroke

<table>
<thead>
<tr>
<th>Exposures</th>
<th>Case-Control</th>
<th>Age &lt;45 yr</th>
<th>Age ≥45 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% CI)</td>
<td>Bootstrap 95% CI</td>
<td>Odds Ratio (95% CI)</td>
</tr>
<tr>
<td>Any DC visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–1 day</td>
<td>1.06 (0.43–2.62)</td>
<td>0.36–2.61</td>
<td>12.00 (1.25–115.36)</td>
</tr>
<tr>
<td>0–3 days</td>
<td>0.87 (0.42–1.81)</td>
<td>0.40–1.78</td>
<td>3.33 (1.02–10.92)</td>
</tr>
<tr>
<td>0–7 days</td>
<td>0.98 (0.54–1.77)</td>
<td>0.51–1.79</td>
<td>2.41 (0.98–5.95)</td>
</tr>
<tr>
<td>0–14 days</td>
<td>1.22 (0.78–1.90)</td>
<td>0.77–1.92</td>
<td>3.07 (1.41–6.70)</td>
</tr>
<tr>
<td>0–30 days</td>
<td>1.14 (0.78–1.67)</td>
<td>0.75–1.62</td>
<td>3.13 (1.48–6.63)</td>
</tr>
</tbody>
</table>
The increased risks of vertebrobasilar artery stroke associated with chiropractic and physician visits is likely explained by patients with vertebrobasilar dissection-related neck pain and headache consulting both chiropractors and primary care physicians before their VBA stroke.
“Case” definition in Rothwell and Cassidy studies

ICD-9 codes

433.00 Occlusion and stenosis of basilar artery without cerebral infarction
433.01 Occlusion and stenosis of basilar artery with cerebral infarction
433.20 Occlusion and stenosis of vertebral artery without cerebral infarction
433.21 Occlusion and stenosis of vertebral artery without cerebral infarction
900.9 Injury to unspecified blood vessel of head and neck

Codes not used

443.21 Dissection of carotid artery
443.24 Dissection of vertebral artery
443.29 Dissection of other artery
How many patients in Rothwell/Cassidy studies actually had dissections?
Dissection in the VA (DIVA): Hypotheses

- “Cases” identified by the Rothwell/Cassidy studies were mostly not dissections
- Case misclassification would be greater in older patients
- Association is causal – not just protopathic bias
ICD-9 codes used
433.00 Occlusion and stenosis of basilar artery without cerebral infarction
433.01 Occlusion and stenosis of basilar artery with cerebral infarction
433.20 Occlusion and stenosis of vertebral artery without cerebral infarction
433.21 Occlusion and stenosis of vertebral artery without cerebral infarction
900.9 Injury to unspecified blood vessel of head and neck

Codes not used
443.21 Dissection of carotid artery
443.24 Dissection of vertebral artery
443.29 Dissection of other artery
DIVA search strategy

- Search the VA EMR for ICD9 codes used by Rothwell/Cassidy and for dissection-specific ICD9 codes since 2009

- Search every text record of pts with those codes for “dissection”

- Review text records to determine stroke diagnosis
RESULTS: Clinical characteristics of Patients Identified using Rothwell/Cassidy approach

<table>
<thead>
<tr>
<th>Patients with “Dissection” in EMR, n (%)</th>
<th>Cases (n = 3690)</th>
</tr>
</thead>
<tbody>
<tr>
<td>433.00</td>
<td>155 (4.2)</td>
</tr>
<tr>
<td>433.01</td>
<td>53 (1.4)</td>
</tr>
<tr>
<td>433.20</td>
<td>321 (8.7)</td>
</tr>
<tr>
<td>433.21</td>
<td>344 (9.3)</td>
</tr>
<tr>
<td>443.24</td>
<td>107 (2.9)</td>
</tr>
<tr>
<td>443.29</td>
<td>74 (2.0)</td>
</tr>
<tr>
<td>900.9</td>
<td>12 (0.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients with Confirmed CAD, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>414 (11.2)</td>
<td></td>
</tr>
</tbody>
</table>

Patients with Confirmed Atraumatic CAD
(Positive Predictive Value (%), 95% CI)

<table>
<thead>
<tr>
<th>CAD by Type, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertebral</td>
<td>141 (36)</td>
</tr>
<tr>
<td>Carotid</td>
<td>240 (62)</td>
</tr>
<tr>
<td>Both</td>
<td>7 (2)</td>
</tr>
</tbody>
</table>

ICD-9 code identified cases by Age Group, n (%)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;45</td>
<td>146 (3.9)</td>
</tr>
<tr>
<td>≥45</td>
<td>3544 (96.0)*</td>
</tr>
</tbody>
</table>

Patients with Confirmed Atraumatic CAD by Age Group
(Positive Predictive Value (%), 95% CI)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;45</td>
<td>60 (41.1, 33.5–49.2)</td>
</tr>
<tr>
<td>≥45</td>
<td>313 (8.8%, 7.9–9.8)</td>
</tr>
</tbody>
</table>
RESULTS: *Positive predictive value by age*

- **<45 years**
  - $n=146$
  - $41\%$ (33.5-49.2)

- **≥45 years**
  - $n=3544$
  - $9\%$ (7.9-9.8)
Re-analysis of association between chiropractic exposure and case status from Cassidy et al after exclusion of proportion of cases unlikely to be CAD

Table 3A: Association between chiropractic (DC) and case status (data from Ref 4)

<table>
<thead>
<tr>
<th></th>
<th>Entire Cohort</th>
<th>Age &lt; 45</th>
<th>Age ≥ 45</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases</td>
<td>Controls</td>
<td>Cases</td>
</tr>
<tr>
<td>DC visit in 30 days</td>
<td>36</td>
<td>125</td>
<td>13</td>
</tr>
<tr>
<td>No DC visit in 30 days</td>
<td>782</td>
<td>3039</td>
<td>89</td>
</tr>
<tr>
<td>Total</td>
<td>818</td>
<td>3164</td>
<td>102</td>
</tr>
<tr>
<td>Odds Ratio (95% CI)</td>
<td>1.12 (0.77, 1.63)</td>
<td>3.16 (1.50, 6.65)</td>
<td>0.82 (0.52, 1.30)</td>
</tr>
</tbody>
</table>

Table 3B: Re-analysis of Table 3a after exclusion of proportion of cases unlikely to be CAD*

<table>
<thead>
<tr>
<th></th>
<th>Entire Cohort</th>
<th>Age &lt; 45</th>
<th>Age ≥ 45</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases</td>
<td>Controls</td>
<td>Cases</td>
</tr>
<tr>
<td>DC visit in 30 days</td>
<td>7</td>
<td>125</td>
<td>10</td>
</tr>
<tr>
<td>No DC visit in 30 days</td>
<td>82</td>
<td>3039</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td>89</td>
<td>3039</td>
<td>42</td>
</tr>
<tr>
<td>Odds Ratio (95% CI)</td>
<td>2.15 (95% CI 0.98-4.70)</td>
<td>6.91 (95% CI 2.59-13.77)</td>
<td>Cannot calculate</td>
</tr>
</tbody>
</table>

* ICD-9 code positive predictive value measured in the VA data applied across the entire cohort and within strata defined by age (<45 years and age ≥45 years). The misclassified cases (ICD-9 code positive but CAD negative) assumed to have the same SMT exposure rate as the control population (3.95%). The SMT exposure rate in the true CAD cases was calculated assuming that the case exposure rate in the original report represents a weighted average of SMT exposure rates in true and misclassified cases. Counts in the table were rounded to the nearest whole integer.
Conclusions

- Rothwell/Cassidy strategy misidentified most cases
- Their cases were mostly not dissections but more likely strokes due to conventional RFs
- The association of “cases” with PCPs likely demonstrated the relationship between having atherosclerotic RFs and visiting a doctor
- Protopathic bias is not addressed by these data
Dissection Risk and Manipulation Therapy In the Cervical Spine (DRAMaTICS)

Collaborators

Mai Nguyen-Huynh, MD, MAS,  
Kaiser Permanente Northern California Division of Research

Paul Dougherty, DC,  
University of Rochester
Aim 1. To quantify the contribution of spinal manipulation therapy of the cervical spine to cervical artery dissection using strong case identification method (DIVA)

Aim 2. To determine whether symptoms of cervical artery dissection precede or follow SMT.
1. Create instrument to detect exposure to RFs
2. Identify cases using DIVA strategy
3. Contact cases
4. Administer instrument
5. Obtain SMT records
6. Analyze SMT records for Rx type
# DRAMaTICS – pilot results

<table>
<thead>
<tr>
<th>Population in KP</th>
<th>3.4 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months of review</td>
<td>8</td>
</tr>
<tr>
<td>Patients by ICD9 codes</td>
<td>279</td>
</tr>
<tr>
<td>Cervical dissections</td>
<td>40 (5/month)</td>
</tr>
<tr>
<td>VAD</td>
<td>22</td>
</tr>
<tr>
<td>CAD</td>
<td>19 (1 subject had both)</td>
</tr>
<tr>
<td>Contacted</td>
<td>40</td>
</tr>
<tr>
<td>Consented</td>
<td>37</td>
</tr>
<tr>
<td>Chiropractic <em>ever</em></td>
<td>16 (40%)</td>
</tr>
<tr>
<td>Chiropractic <em>in last 30 days</em></td>
<td>7 (18%)</td>
</tr>
<tr>
<td>Consented to get SMT records</td>
<td>6</td>
</tr>
<tr>
<td>Records received</td>
<td>6</td>
</tr>
<tr>
<td>Records reviewed by DC</td>
<td>6</td>
</tr>
</tbody>
</table>
Future plans

- R01 application in October 2014 to National Center for Complementary and Alternative Medicine (NCCAM) +/- NINDS

- 3-4 year prospective case-crossover study
  - Better case identification
  - Better exposure detection and definition
  - Detection of symptoms before and after SMT
DIVA/DRAMaTiCS contributors

Tufts
- David Thaler
- Ed Feldmann, MD
- Karen Switkowski MPH, MS
- Jessica Paulus, ScD
- Morgan Clark-Coller
- Pari Fariborz
- Cindy Wan

MAVERIC
- Leonard D’Avolio, PhD
- Louis Fiore, MD, MPH
- Sergey Goryachev

Partners Neurology
- Xuemei Cai, MD
- Ali Razmara, MD

Kaiser Permanente
- Mai Nguyen-Huynh, MD, MAS

University of Rochester
- Paul Dougherty, DC

The Comprehensive Stroke Center at Tufts Medical Center
Risks of chiropractic:
Serious adverse events per cervical manipulation

- 1 in 5.85 million manipulations
  (http://www.acatoday.org/level3_css.cfm?T1ID=13&N1ID=61&T3ID=152)
- 1/20,000 to 1/one million (BMJ 1999 319: 1176-1179)
- 1/6000 to 1/200,000 (Stroke 2001 32: 1054-1060)
- 1/958 Man Ther 2011 1/19, epub