

Informed Consent and Stroke
Brown and Cooperstein

THE CONNECTICUT LAW ON CHIROPRACTIC INFORMED CONSENT TO CERVICAL ARTERY DISSECTION AND STROKE: A NARRATIVE REVIEW

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ABSTRACT

Objective: This paper reviews the evidence considered by the Connecticut Board of Chiropractic Examiners in their 2010 memorandum concluding (a) stroke or cervical artery dissection (CAD) is a not likely to be a risk or side effect of joint mobilization, manipulation, or adjustment of the cervical spine; and (b) chiropractors are not required to address stroke or CAD as a part of securing informed consent by patients for such treatment. The 2010 memorandum contains 5 Findings of Fact. An additional objective of this narrative review was to determine if there is sufficient evidence to support the Board's third and fourth Findings of Fact.

Methods: We analyzed the 2010 memorandum to determine what evidence was considered by the Connecticut Board in arriving at their third and fourth Findings of Fact. Analysis revealed that the Connecticut Board reviewed 3 studies. All 3 studies were acquired and reviewed.

Results: Analysis of the Connecticut Board's 2010 memorandum shows that they relied solely on the first conclusion of the 2008 Cassidy et al. study, Risk of Vertebrobasilar Stroke and Chiropractic Care: Results of a population-based Case-Control and Case-Crossover Study.

Conclusion: We conclude that the third and fourth Findings of Fact in the 2010 memorandum of the Connecticut Board of Chiropractic Examiners are not supported by the evidence. Patients have the right to

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consider whether the clinical benefits they seek are worth the inherent risks. The present authors therefore recommend that chiropractors include the risk of stroke and/or CAD in securing informed consent by patients to manipulation of the cervical spine. This practice would be both evidence-based and patient-centered, and constitute an important element of the chiropractic standard of care. (J Contemporary Chiropr 2025;8:162-169)

Key Indexing Terms: Chiropractic; Stroke; Dissection; Manipulation; Adjustment; Informed Consent; Adverse Consequences

INTRODUCTION

Several high-profile medical stroke malpractice cases following chiropractic cervical spine manipulation (CSM) occurred in Connecticut in the 1980's and 1990's. (1) This led to the formation of 2 patient advocate groups, the Chiropractic Stroke Awareness Group (CSAG) and the Victims of Chiropractic Abuse (VOCA). These groups advocated requiring by law that informed consent for chiropractic care of the cervical spine include warnings related to the risk of stroke or cervical artery dissection (CAD). In response to a June 2009 legal agreement between the Connecticut Chiropractic Association and VOCA, the Connecticut Board of Chiropractic Examiners agreed to issue a declaratory ruling concerning the risk of stroke or CAD related to chiropractic care (2) and informed consent to such risk.

The Connecticut State Board of Chiropractic Examiners took up the matter in 2010, conducting hearings featuring representatives of the Connecticut Chiropractic Association, the Connecticut Chiropractic Council, the American Chiropractic Association, the International Chiropractic Association, the Foundation

for Chiropractic Progress, and several chiropractic colleges; as well as representatives of the CSAG and VOCA. The Connecticut Board concluded informed consent to the risks of chiropractic care is integral to the standard of care for the chiropractic profession. However, the Board also concluded that evidence was insufficient to conclude that stroke or CAD is a risk of chiropractic care, and furthermore concluded chiropractors need not address stroke or CAD as a part of securing informed consent by patients for such treatment. A summary of the Board's memorandum follows.

THE 2010 DECLARATORY RULING MEMORANDUM OF DECISION

On June 10, 2010, the State of Connecticut Board of Chiropractic Examiners issued a Declaratory Ruling Memorandum of Decision (3) concerning whether the risk and/or possibility of the occurrence of a stroke or CAD should be addressed when a chiropractic physician obtains informed consent from a patient prior to the performance of a joint mobilization, manipulation, or adjustment of the cervical spine.

The Board issued the following Findings of Fact:

- 1. The standard of care for chiropractors in Connecticut requires that they obtain informed consent before any procedure and provide post-treatment instructions.
- 2. "Informed consent" requires, in part, disclosure of the risks associated with a medical or chiropractic procedure to patients so they can make an informed decision whether to undergo the procedure. Obtaining informed consent from a patient prior to treatment is a legal duty as well as part of the standard of care.
- The evidence is sufficient to establish that a stroke or CAD is not a risk or side effect of a joint mobilization, manipulation or adjustment of the cervical spine performed by a chiropractor.
- 4. The likelihood of suffering a stroke following an appointment with a chiropractor is no greater than that following an appointment with a primary care physician (PCP).
- 5. Chiropractors are required by the standard of care to perform a history and physical examination and if determined that a patient is having a stroke or CAD, refrain from providing care and refer the patient for medical diagnosis and treatment.

The Board issued the following order based on these

Findings of Fact:

- 1. Evidence is insufficient to conclude that stroke or CAD is a risk or side effect of joint mobilization, manipulation, or adjustment of the cervical spine.
- Chiropractors are not required to address stroke or CAD as a part of securing informed consent by patients to such treatment.

Terminology and Abbreviations

For ease of reference, at the risk of oversimplifying some important distinctions, we will refer to "joint mobilization, manipulation, or adjustment of the cervical spine" as "cervical spine manipulation" or CSM, so that the word "manipulation" simply means treatment by hand.

Cervical artery dissection (CAD) includes both vertebral artery dissection (VAD) and internal carotid artery dissection (ICAD). It should be noted that the 2010 memorandum references CAD, yet the only studies the Connecticut Board reviewed were studies of VAD. We will use the term CAD to be consistent with the 2010 memorandum.

OBJECTIVE

The objective of this study was to perform a narrative review of the evidence considered by the Connecticut Board of Chiropractic Examiners in their 2010 memorandum to determine if such evidence supports their third and fourth Findings of Fact.

METHODS

We analyzed the 2010 memorandum to determine what evidence was considered by the Connecticut Board in arrival at their third and fourth Findings of Fact. Analysis revealed that the Connecticut Board reviewed three studies. All three studies were acquired and reviewed.

RESULTS

Table 1 summarizes the 3 studies presented to the Connecticut Board for their consideration. The Board only weighed the evidence presented by the constituencies invited to its hearings. The State of Connecticut did not charge the Board to search the biomedical literature for additional evidence. It was the responsibility of the persons petitioning for a declaratory ruling to submit such evidence. (4)

Table 1: Evidence reviewed by the Connecticut Board						
Year	Study	Author(s)	Design	Publisher		
2001	Chiropractic Manipulation & Stroke: A Population-Based Case-Control Study (5)	Rothwell et al.	Case Control	Stroke		
2003	Spinal manipulative therapy is an independent risk factor for vertebral artery dissection (6)	Smith et al.	Case Control	Neurology		
2008	Risk of vertebrobasilar stroke & chiropractic care: results of a population-based case-control & case- crossover study (7)	Cassidy et al.	Case Control	Spine		

It was the Connecticut Board's opinion that the most compelling evidence was generated by the 2008 Cassidy study. As regards the research, the Board's conclusions were based entirely on the evidence provided by this single study. No other evidence was reviewed by the Board. Table 2 summarizes the multiple relevant studies on this topic published prior to 2010 that were not considered by the Board.

Table 2: Relevant Evidence not reviewed by the Connecticut Board							
Year	Study	Author(s)	Design	Publisher			
1980	Vertebral-basilar distribution infarction following chiropractic cervical manipulation (8)	Krueger et al.	Case Series	Mayo Clinic Proceedings			
1989	Dissecting aneurysm of the vertebral artery & cervical manipulation: a case report with autopsy (9)	Mas et al.	Case Report	Neurology			
1991	Standards of practice relative to complications of and contraindications to spinal manipulative therapy (10)	Gatterman	Narrative Review	Journal of the Canadian Chiropractic Association			
1999	Risk factors and precipitating neck movements causing vertebrobasilar artery dissection after cervical trauma and spinal manipulation (11)	Haldeman et al.	Case Series	Spine			
2000	Sudden neck movement and cervical artery dissection (12)	Norris et a.	Case Series	Canadian Medical Association Journal			
2002	Unpredictability of cerebrovascular ischemia associated with cervical spine manipulation therapy: a review of sixty-four cases after cervical spine manipulation (13)	Haldeman et al.	Case Series	Spine			
2002	Stroke, cerebral artery dissection and cervical spine manipulation therapy (14)	Haldeman et al.	Case Series	Journal of Neurology			

2003	Risk management for chiropractors and osteopaths: neck manipulation and vertebrobasilar stroke (15)	Reggars et al.	Review	Australasian Chiropractic & Osteopathy
2004	Identification of internal carotid artery dissection in chiropractic practice (16)	Haneline et al.	Review	Journal of the Canadian Chiropractic Association
2007	Association of Chiropractic Colleges Informed Consent Guideline (17)	Association of Chiropractic Colleges	Practice Guideline	Association of Chiropractic Colleges
2008	Should the chiropractic profession embrace the doctrine of informed consent? (18)	Lehman, et al.	Narrative Review	Journal of Chiropractic Medicine
2009	Clinical and radiographic natural history of cervical artery dissections (19)	Schwartz et al.	Case Series	Journal of Stroke & Cere- brovascular Diseases

DISCUSSION

The 2008 Cassidy study was entitled Risk of Vertebrobasilar Stroke and Chiropractic Care: Results of a population-based Case-Control and Case-Crossover Study. (7) The study's objective was to investigate associations between chiropractic (DC) visits and vertebrobasilar artery (VBA) stroke and to contrast this with PCP visits and VBA stroke over a 30-day exposure period. The authors came to these conclusions:

- 1. There is an increased risk of VBA stroke associated with DC and PCP visits in the 30-day period after those visits.
- 2. This increased association is likely due to patients with neck pain and headaches from an existing undiagnosed VBA dissection seeking chiropractic and medical care before their stroke.

An Implausible Mechanism of Causation of Stroke

The 2008 Cassidy study design evaluates the hypothesis that CSM could cause VAD, which could then progress to stroke sometime during the next 30 days. (5)(20) The study did not find any evidence to support this mechanism of causation; however, evaluation of this mechanism was unnecessary due to the following:

 Biomechanical research performed in 2002 on healthy cadaveric vertebral arteries had already shown CSM is not likely to cause VAD. (21) Subsequent research also supports this conclusion. (22-25) 2. Even if CSM did directly cause VAD, however uncommonly, VAD is not destined to inevitably progress to thromboembolic VBA stroke. Most dissections generally have a good prognosis and heal spontaneously when treated in routine clinical fashion. (26,27) Multiple asymptomatic healed dissections that did not cause a stroke have been noted on imaging done for unrelated reasons. (28,29)

A Plausible Mechanism of Causation of Stroke

Cassidy did not rule out CSM as a potential cause of some VBA strokes (7) and proposed a plausible mechanism of causation by which it could happen. The authors state, "It might also be possible that chiropractic manipulation, or even simple range-of-motion examination by any practitioner, could result in a thromboembolic event in a patient with a pre-existing vertebral artery dissection." (7)

The authors acknowledged that CSM can precipitate stroke by this mechanism in the very design of the study: "For the chiropractic analysis, the index date was included in the hazard period, since chiropractic treatment might cause immediate stroke and patients would not normally consult a chiropractor after having a stroke." (7)

Thus, Cassidy supports the view that stroke can be caused by performing CSM in the presence of an undiagnosed VAD, via a thromboembolic mechanism. The sudden head and neck movement of CSM performed in the presence of existing VAD may dislodge a loosely adherent thrombus, enabling it to embolize to the brain and cause a stroke. (12) Multiple peer reviewed studies support the view that CSM can cause thromboembolic VBA stroke when performed in the presence of undiagnosed VAD. (16,30) Many of these were studies published prior to the Connecticut Board's 2010 decision, see Table 2.

In the thromboembolic mechanism, symptoms of VBA stroke would likely be immediate, occurring within seconds or minutes of CSM. (31-33) Multiple case reports and case series document an immediate temporality between CSM and stroke consistent with this causal mechanism. (9,34-36) In fact, Cassidy's Table 3 reports that the highest odds ratio for CSM-stroke, 12, occurs on the very day of exposure. (7)

Third Finding of Fact

In their third Finding of Fact, the Connecticut Board

found: "The evidence is sufficient to establish that a stroke or CAD is not a risk or side effect of a joint mobilization, manipulation or adjustment of the cervical spine performed by a chiropractor." (3) We will consider stroke and CAD separately.

Causation of Stroke

The evidence is sufficient to establish that stroke is not a risk or side effect of CSM in the presence of healthy cervical arteries. However, Cassidy's second conclusion was that patients with unhealthy cervical arteries suffering from undiagnosed VAD may present to chiropractors. (7) Subsequent studies concur with their conclusion. (37,38) This is consistent with the thromboembolic mechanism of causation of immediate stroke supported by the present authors.

Therefore, notwithstanding the opinion of the Connecticut Board, there is indeed sufficient evidence to establish stroke as plausible risk and adverse consequence of CSM.

Causation of Cervical Artery Dissection

The evidence is sufficient to establish that CAD is a not risk or side effect of CSM in the presence of healthy cervical arteries. (21,23,24) However, patients with unhealthy cervical arteries susceptible to dissection may present to chiropractors. (22) It is plausible that minor neck movements, such as CSM, are likely initiating events for spontaneous CAD in the presence of a susceptible cervical artery. (23)

A susceptible artery would be one predisposed to dissection by an existing arterial wall weakness. Examples of inherited risk factors for CAD would be an arterial anomaly, such as fibromuscular dysplasia, or a connective tissue disorder, such as Ehlers-Danlos syndrome type IV. (24) Examples of environmental risk factors for CAD include hyperhomocysteinemia and migraine. (39,41) Migraine has been associated with mutations in the MTHFR (methylenetetrahydrofolate reductase) gene, which may cause elevated homocysteine levels and endothelial dysfunction making cervical arteries susceptible to dissection. (25)

Therefore, notwithstanding the opinion of the Connecticut Board, there is sufficient evidence establishing CAD is a plausible risk and adverse consequence of CSM, as CSM may be performed in the presence of an undiagnosed arterial wall weakness.

Fourth Finding of Fact

In their fourth Finding of Fact, the Connecticut Board found: "The likelihood of suffering a stroke following an appointment with a chiropractor is no greater than that following an appointment with a primary care physician." (3)

Cassidy's First Conclusion: 30-Day Exposure Period Odds

In arriving at their fourth Finding of Fact, the Board relied on the first conclusion of the Cassidy study, that the likelihood of suffering a stroke in the 30-day period following an appointment with a DC is no greater than that in the 30-day period following an appointment with a PCP.

The authors of the study excluded the 0-1-day PCP visit exposure period, which allegedly strengthens the conclusion of the study in the 30-day exposure period. Despite the exclusion in favor of PCPs, the 30-day PCP visit exposure period odds ratio is statistically the same as the 30-day DC visit exposure period odds ratio.

0-1-Day Exposure Period Odds

The 0-1-day PCP exposure period (i.e., day of treatment) had zero cases because the authors excluded the index day from analysis, having justifiably assumed the first day PCP visit had occurred after the stroke. However, excluding by design the first-day PCP visit prevents comparing outcomes for DC and PCP visits within this critical time frame immediately following treatment. (26) This high odds ratio in the first day DC exposure period could not be compared to the odds ratio in the first day PCP exposure period. The odds ratio for stroke following a DC visit (6 visits) compared to a PCP visit (0 visits) within one day were theoretically infinite. In the first day exposure period, the odds ratio for stroke following a DC visit compared to controls was 12, 4 times the odds in any other DC exposure period.

There were 6 instances of DC visits on the day of a stroke event. This suggests that the patients who self-selected to visit a PCP, presumably with severe symptoms, were already stroking; whereas those who self-selected to visit a DC, most likely with lesser symptoms related to incipient VAD, suffered conversion of pre-existing VAD to stroke on day one. Patients with more severe symptoms tend to self-refer more frequently to PCPs rather than DCs. The fact that the Cassidy study implicitly assumed the diagnostic codes used by DCs and PCPs, in admitting patients with headache and cervical symptoms were somehow equivalent, led to the unjustified assumption that these self-selected patients

were suffering from identical pathologies.

Excluding the zero cases in the 0-1-day PCP data had no effect on the 30-day PCP visit exposure period odds ratio. However, it compromised the ability to assess immediate risks post-treatment. This methodological choice resulted in the Connecticut Board not considering any data on the odds of stroke within one day of a chiropractic visit when making their fourth Finding of Fact. Consequently, the Board's decision was based on incomplete data, as it did not account for the potentially significant immediate risk of stroke post-CSM, which could skew perceptions of comparative risk.

Cassidy on Informed Consent

Cassidy concluded that the association between chiropractic care and VBA stroke was likely due to pre-existing VAD prior to CSM, with the neck pain and/or headache from VAD causing the patient to seek chiropractic care. (7) They also opined that CSM could result in a thromboembolic event in a patient with existing VAD; and that there was no acceptable screening procedure to identify neck pain patients at risk of VBA stroke.

Given this potentially life-threatening clinical setting, the authors recommended that the treatment of patients with neck pain and/or headache should be driven by effectiveness and patient preference. It should also be driven by safety. This emphasis on patient preference implies a need for informed decision-making, in our opinion mandating discussion of potential risks like stroke. Doing so would be consistent with Cassidy's admission that they had not ruled out CSM as a potential cause of some VBA strokes. Multiple chiropractic researchers that have recommended informed consent include discussion of the risk of stroke following CSM. (27)

Evidence-Based Informed Consent

The evidence supporting adding the risk of stroke following CSM to informed consent documents is chiefly based on case reports, (9) case series, (12) and case control studies, (6) which are considered low levels of evidence. (28) However, the purpose of informed consent laws is to protect the public. Thus, the threshold is low for the type of evidence required to justify inclusion in informed consent.

A comparable situation arises in the setting of insurance premiums. These not only consider the likelihood of severe injury, but the severity of accidents and severe injury in different scenarios. However rare instances

of VAD stroke following CSM may be, the possibility of catastrophic outcomes, up to and including death, inevitably lead to the conclusion that the patient must consent to the risk. (17,18)

A Comment on Plausibility

Our use of the term "plausible" to describe the risks of stroke and CAD following CSM stems from reliance on case reports, case series, and case-control studies, which are considered low-level evidence in the scientific hierarchy. (28) While these studies support a thromboembolic mechanism in patients with pre-existing CAD or arterial vulnerabilities, their observational nature limits the ability to establish causality, potentially weakening the argument for readers expecting higher-level evidence, such as randomized controlled trials (RCTs) or large cohort studies. However, RCTs are impractical for studying rare adverse events like stroke or CAD due to ethical concerns and the extremely large sample sizes needed to detect such low-incidence outcomes. (29) Similarly, large cohort studies struggle to account for confounders like undiagnosed arterial conditions. We acknowledge the limitations of case-based evidence and emphasize that, despite the lack of definitive causal proof, the consistent findings across multiple case reports and series justify including stroke and CAD risks in informed consent to prioritize patient safety and autonomy.

In medicolegal contexts, establishing causation relies on demonstrating plausibility (a feasible mechanism), temporality (proximity between CSM and stroke onset), and the absence of a more likely alternative cause, (30) without requiring high-level evidence like RCTs or cohort studies. The consistent reports of stroke following CSM in case studies, combined with the plausible thromboembolic mechanism, satisfy these criteria. Chiropractors should recognize that acknowledging this plausibility supports the inclusion of stroke and CAD risks in informed consent, enhances patient trust, and reduces malpractice liability. This approach ensures patients are informed of rare but serious risks, aligning with both legal standards and ethical practice.

A Further Concern

Apart from the relevance of our review of the Connecticut Board of Chiropractic Examiners position on including the risk of stroke in informed consent, the larger issue is whether chiropractors and other manual therapists will practice more carefully when patients present with incipient VAD symptoms. We fear many

of them have been lulled into a sense of false security by crudely interpreting the Cassidy study to imply CSM simply cannot result in a stroke.

CONCLUSION

It is recommended that the Connecticut Board of Chiropractic Examiners re-examine the issues we have raised, considering all the available evidence and issue guidance on the topic. Multiple studies on this topic have been published since the Board's 2010 decision. (33,27-29,44,48-50)

Studies on the frequency of stroke or CAD following chiropractic care of the cervical spine have come to very disparate estimates. (31) It is beyond our scope to address this problem, except to conclude drawing statistical conclusions about the true incidence of very uncommon clinical outcomes faces inherent challenges due to limitations in study design, interpretation, and the nature of rare events. In the absence of incontrovertible data on the true incidence of stroke and CAD related to manual therapy of the cervical spine, it is reasonable to inform patients that these outcomes can occur, although the likelihood is small. Patients have the right to consider whether the clinical benefits they seek are worth the inherent risks. Adopting this position as a standard of chiropractic care would be both evidencebased and patient-centered. (18)

The third and fourth Findings of Fact in the 2010 Declaratory Ruling Memorandum of Decision are not supported by the evidence; therefore, the conclusions based on these Findings of Fact are not. Based on the analysis and references provided in this paper, the following Order by the Connecticut Board of Chiropractic Examiners would be supported by the evidence:

- Evidence is sufficient to establish that immediate thromboembolic stroke is a plausible adverse consequence of joint mobilization, manipulation, or adjustment of the cervical spine in a patient with a pre-existing CAD or identifiable risk factors for such.
- 2. Evidence is sufficient to establish that CAD is a plausible adverse consequence of joint mobilization, manipulation, or adjustment of the cervical spine in a patient susceptible to dissection or identifiable risk factors for such.
- Chiropractors are required to address stroke as part of securing informed consent by patients to such treatment.

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