



Professional Notes

RCTs and Quality

It is widely recognized that a randomized controlled trial (RCT), comparing one treatment with a placebo or others, is a stronger research design for proof of safety and effectiveness than a case series or observational study where there is no comparison group of patients.

Less well-known is that RCTs can be everything from convincing to worthless, and that a poorly-designed RCT may provide much less evidence than a well-designed case series, depending upon methodological quality.

In healthcare research much more has been learned about research design in recent years – how to avoid the risk of biased results, and what is and is not a good quality RCT. Systematic reviews of RCTs for a specific treatment rate the quality of each RCT according to established research design criteria.

An excellent new review of these matters in the field of spinal manipulative therapy (SMT) for neck and back pain has just been published in JMPT. It is from Sidney

continued on page 4

Cervical Manipulation Revisited

The New AHA Scientific Statement

“Current biomechanical evidence is insufficient to establish the claim that spinal manipulation causes CD.”

—American Heart Association¹

A. Introduction

THIS REPORT HAS PREVIOUSLY reviewed in depth the scientific and professional issues arising from the extremely rare but now well-researched association between cervical manipulative therapy (CMT) and stroke, most recently last January, and did not anticipate returning to the subject soon.

However we now do because a landmark new paper represents an historic turning point in this field. It was published on August 7 in the American Heart Association’s journal *Stroke* and is endorsed by the American Association of Neurological Surgeons.

Until now, and despite accumulating evidence to the contrary, many individual neurologists, other critics and their professional organizations have felt free to claim that cervical manipulation may cause cervical artery dissection (CD) and stroke, has little or no proven benefit, is therefore unacceptable, and that the public should be warned of these things.

The new “Scientific Statement for Healthcare Professionals” from Biller, Sacco et al. on behalf of the American Heart Association, its Stroke Council and the American Stroke Association, changes all that. It exposes such critics as unscientific and irresponsible and strips away the professional solidarity they have relied upon. This clearly has major significance for the chiropractic profession and patients – as we say, represents an historic change.

In a comprehensive review titled *Cervical Arterial Dissections and Association with Cervical Manipulative Therapy*¹ Biller, Sacco et al., a writing group of 13 experts appointed by the AHA Stroke

Council’s Scientific Statements Oversight Committee, report:

- **Definition.** *Spinal manipulation* is defined as “a therapeutic intervention in which a high- or low-velocity, low-amplitude thrust is applied to the spine.” It is performed in North America and internationally not only by chiropractors but also “members of the allopathic, osteopathic and physical therapy/physiotherapy professions.” *Cervical Manipulative Therapy (CMT)* “is a broad term that encompasses cervical spine manipulation by any health-care professional.”

- **Effectiveness.** A number of controlled trials provide evidence that CMT is effective for patients with neck pain, and more effective than non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, muscle relaxants, and narcotics. A recent multi-center, randomized, controlled trial by Dunning, Cleland et al.² suggests that manipulation is superior to mobilization. It “compared cervical and thoracic thrust manipulation with cervical and thoracic non-thrust mobilization for patients with neck pain and found an improvement in the manipulation (vs mobilization) group at 48 hours.”

- **Causation.** “Current biomechanical evidence is insufficient to establish the claim that spinal manipulation causes CD.” In other words no one can make an evidence-based claim that CMT generally, including spinal manipulation specifically, may cause CD – the injury to the vertebral arteries or internal carotid artery that may lead to stroke.

- **Association.** There is a statistical association in time between CD and CMT in that the percentage of those consulting a health professional for CMT during the week or month before ischemic stroke from vertebral artery dissection (VAD) is slightly higher than for matched control patients with stroke

who did not receive CMT. However the only study that evaluated association not only with CMT but also primary medical care not involving CMT, found the same increase and association in patients receiving medical care.

This was the Bone and Joint Decade Neck Pain Task Force study by Cassidy, Boyle, Côté et al.³ These authors, as Biller, Sacco et al. note, concluded that CMT (in that study chiropractic care) “does not appear to pose an excess risk of VA stroke” and that headache and/or neck pain from already existing VAD causes people to seek care from a chiropractor or physician. That explains the increased association.

During the last generation the American neurologists Dr Walter Carlini et al., the Canadian neurologist Dr John Norris, the UK-based critic of complementary medicine Dr Edzard Ernst and many others have relied upon retrospective opinion surveys, case reports and other invalid and anecdotal evidence to claim that CMT, including specifically chiropractic adjustment, causes VAD and stroke, is unacceptably dangerous and should be banned. Just last year there was a concerted effort by medical specialists in the Netherlands to have upper cervical manipulation banned. The world being what it is critics will remain. But this comprehensive new scientific statement from the heart of American neurology will render them exposed and toothless at last. That is the historic significance of this new scientific statement.

2. This is a moment when everyone in the chiropractic profession should pause to acknowledge and give profound thanks to the researchers inside and outside the profession, and those who have funded their work, who have brought about this change. It is the research of the current generation of researchers that has fashioned the new scientific statement, evidence that appears in its 236 references. Prominent chiropractic research scientists with significant papers referenced include:

- Scott Haldeman DC, MD, PhD, consulting neurologist and chiropractor of Los Angeles and David Cassidy DC, PhD, DrMedSci, epidemiologist and chiropractor of Toronto, the profession's foremost leaders in this field.
- Greg Kawchuk DC, PhD and Walter Hertzog PhD, biomechanics experts and their research teams in Alberta, Canada

– studies on exact forces reaching the vertebral arteries during manipulation.

- Eric Hurwitz DC, PhD of Hawaii, Pierre Côté DC, PhD of Toronto, epidemiologists, and other members of the Bone and Joint Decade Neck Pain Task Force – studies on safety and effectiveness.
- Gert Bronfort DC, PhD, Roni Evans DC, PhD, clinical science researchers from Minnesota – evidence on effectiveness.
- Alan Breen DC, PhD, and Haymo Thiel DC, PhD of the UK – studies on safety and effectiveness.
- As to funding, Dr Louis Sportelli, President, NCMIC Group in the USA, and Dr Paul Carey, now Past-President, Canadian Chiropractic Protective Association in Canada.

3. Having emphasized the overall positive impact of the AHA's Scientific Statement, it must be said that there are still substantial concerns. These are reflected by the fact that, even though the American Chiropractic Association accepted the offer to participate in development of the paper – clearly a wise decision given its importance to the profession, its representative elected not to be named as an author. Significant concerns include:

- The singular focus on CMT, only one of many factors associated with CD. Why was this not a statement on *CAD and Association with Trivial Trauma*, or even more appropriately *CAD and Association with Minor Movements and Forces*?
- Failure to emphasize how very rare CD and ischemic stroke from all causes are, how extremely rare the association between CMT, CD and stroke is, and how the issue of stroke following CMT is not a significant public health issue. The AHA must have known that this paper for health professionals would lead to media articles and warnings against CMT, discouraging patients from seeking a treatment option as appropriate as any other for many patients. It has led to such media articles – see more on this below.
- From the evidence of a mechanical cause of CD from major trauma (e.g. high-impact vehicle accidents or sports), assuming there is likely a mechanical cause from trivial or minor trauma (e.g. sneezing, coughing, various sports, turning to back the car, CMT).
- A pervasive medical bias throughout,

The Chiropractic Report is an international review of professional and research issues published six times annually. You are welcome to use extracts from this Report. Kindly acknowledge the source. Subscribers may photocopy the Report or order additional copies (.80 cents each, plus shipping – minimum of 20 copies) for personal, non-commercial use in association with their practices. However, neither the complete Report nor the majority or whole of the leading article may be reproduced in any other form without written permission.

The opinions and statements in this publication are those of the individual authors alone, not the Editorial Board, World Federation of Chiropractic or any other organization.

Subscription: for rates and order form, see page 8.

- Visit www.chiropracticreport.com
- Call 416.484.9601
- Email us at TCR@chiropracticreport.com

Editorial Board

Alan Breen DC, PhD, *England*
Raul Cadagan DC, PT, *Argentina*
Ricardo Fujikawa DC, MD, *Brazil*
Scott Haldeman DC, MD, PhD, *United States*
Donald Henderson DC, *Canada*
Nari Hong DC, *South Korea*
Gary Jacob DC, MPH, LAc, *United States*
Dana Lawrence DC, *United States*
Charlotte Leboeuf-Yde DC, PhD, *Denmark*
Craig Morris DC, *United States*
Lindsay Rowe DC, MD, DACBR, *Australia*
Hossein Sabbagh DC, *Iran*
Louis Sportelli DC, *United States*
Aubrey Swartz MD, *United States*
Yasunobu Takeyachi DC, MD, *Japan*

Changes of mailing instructions should be sent to The Chiropractic Report, 203–1246 Yonge Street, Toronto, Ontario, Canada M4T 1W5, telephone 416.484.9601, fax 416.484.9665. Printed by Harmony Printing Limited, 416.232.1472. Copyright © 2014 Chiropractic Report Inc.

ISBN 0836-144

quite revealing given the efforts by the AHA and these neurologists to be purely scientific. This is seen for example in describing the evidence of effectiveness of CMT as “sparse and questionable” when according to standard evidence ratings in systematic reviews and clinical guidelines it is either “positive” or “moderate” – and stronger than the evidence supporting the medical interventions after stroke that Biller, Sacco et al. review and recommend.^{4,5}

As another example it is also seen in calling potentially severe complications including stroke from a medical diagnostic procedure for imaging the arteries, digital subtraction angiography, “rare” at “up to 1%”, but the much more rare association between CMT and CD as “probably low”.

4. This report now discusses in more detail the content of the AHA paper, the above and other concerns, the paper's public impact, and how chiropractors

and others employing CMT should respond, if at all, to media comment. The World Federation of Chiropractic (WFC) has already distributed talking points which may be found at www.wfc.org under News, as have some larger national associations.

B. AHA Statement – Contents

6. The full text of this statement, approved by the AHA Science Advisory and Coordinating Committee on November 29, 2013, is available free online at www.myamericanheart.org/statements under the By Publication Date link.

Chair and Co-Chair respectively of the writing group of 13 authors are José Biller MD, Professor of Neurology and Neurological Surgery at the Stritch School of Medicine, Loyola University, Chicago, and Ralph Sacco MS, MD, Professor and Chairman of Neurology at the Miller School of Medicine, University of Miami, and formerly of Columbia University and a recent AHA President (2010-2011). As mentioned the Statement is written specifically for health professionals, and it therefore includes:

a) Sections relative to cervical manipulative therapy (CMT):

- Definition, utilization, effectiveness.
- Association of CD and CMT.
- Cervical spine biomechanics and CMT.
- Postulated mechanisms of vessel (artery) injury.
- Locations of arterial injury – for each of the internal carotid artery (ICA) and the vertebral artery (VA).

b) Extensive sections relative to all cervical artery dissection (CD):

- Clinical presentation.
- Pathology.
- Diagnosis and investigations – including initial and follow-up duplex ultra-sonography, CT and CTA, MRI/MRA, and digital subtraction angiography (DSA).
- Treatment – including acute management (e.g. endovascular treatment to re-establish blood flow; thrombolysis to reduce local thrombus formation and secondary embolism) and prevention of recurrences.
- Outcomes and prognosis – including clinical outcomes and risk of recurrence of CD or stroke.

7. Much of this is familiar information to chiropractors, given their specialized field of education and practice, but there is valuable reference to recent research findings in many areas. The paper, available free online, should be read directly and in full. Points of clinical interest include:

a) **Causation of CD.** The cause of most CD is “unknown”. The exception is severe trauma, as in a high-speed motor vehicle crash, where the cause is mechanical force. However even with “blunt cervical trauma” the prevalence of CD is only 1-2% of patients. In all other circumstances, and for the great majority of patients with CD, the cause and etiology are unclear. Biller, Sacco et al. list 25 factors identified in research and propose a model consistent with the multi-factorial model of CD and stroke that has been advanced by Rubinstein, Haldeman, and van Tulder⁶. Four necessary elements found in these rare but troubling stroke patients are:

- Genetic predisposition – e.g. connective tissue disorders

(“ultra-structural aberrations of dermal collagen fibrils and elastic fibres, hereditary hemochromatosis”)

- Environmental exposure – e.g. increased CD in autumn/winter “believed to be a result of increased occurrence of infection or weather-related changes in blood pressure”; current use of oral contraceptives.
- Common risk factors associated with atherosclerosis, e.g. hypertension, diabetes mellitus, smoking.
- Trivial trauma characterized by hyperextension, rotation or lateroversion of the neck – e.g. CMT and “coughing, sneezing or countless sporting activities such as heavy lifting, golf, tennis and yoga”.

Biller, Sacco et al. acknowledge “confusion” about the distinction that has been made between spontaneous CD, where the patient and health professional cannot identify any precipitating trivial trauma, and CD following trivial trauma – identified in an estimated 12-34% of patients. They say that “the relationship, *if any*, of CD to any of these minor cervical traumas is often difficult to discern in an individual patient.” (Emphasis added.)

On this issue of whether CMT or other everyday movements that have been called “trivial trauma” can ever *cause* CD or stroke Biller, Sacco et al. review much important new evidence including:

- The line of research by Hertzog and others demonstrating that spinal manipulation produces less force on the vertebral arteries than passive range of motion testing, and insufficient force to strain the arteries to the level of potential injury.⁷⁻⁹
- The research by Kawchuk, Wynd and Anderson using a canine model and showing “no significant change in VA lesions before and after cervical manipulation”.^{10,11}
- Case control studies investigating the association between VAD and CMT, including that by Cassidy, Boyle, Côté et al.³ As already mentioned, this was the first and is currently the only one to look at increased risk of stroke after both chiropractic and medical primary care visits, and it reports that the slightly increased incidence of stroke for those who had visited a chiropractor in the past 7 or 30 days compared with those in the general population, was exactly the same for those who had visited a primary care physician during the past 7 or 30 days.

Biller, Sacco et al. present these conclusions:

- i. There is no evidence to support the claim that CMT causes CD.
- ii. There is evidence of association. “Because patients with VAD commonly present with neck-pain, it is possible that they seek therapy for this symptom from providers, including CMT practitioners, and that the VAD occurs spontaneously, implying that the association between CMT and VAD/vertebrobasilar artery stroke is not causal.”
- iii. It is “plausible CMT could exacerbate the symptoms or the VAD and possibly increase the risk of stroke.” In this sense CMT, as with many other usual neck movements, may represent a “mechanical trigger event.”
- iv. This association suggests that there should be “increased education of providers, including CMT providers, in diagnosing CD.”
- v. “Patients with neck pain and without neurological symp-

continued on page 6

The Chiropractic World

RCTs and Quality

continued from page 1

Rubinstein DC, PhD and others from the Department of Health Sciences, VU University, Amsterdam in The Netherlands.

Rubinstein et al. asked if the quality of RCTs in this field had increased over time, giving a reduced risk of bias. The answer was yes. Therefore, for example, the UK trial of SMT for back pain by Doran and Newell published in the British Medical Journal in 1975, and reporting that SMT was not effective, was poorly designed and had a high risk of bias. This was so for most RCTs published before the late 1990s.

The UK BEAM trial published in the BMJ in 2004, reporting that SMT was both effective and cost-effective for back pain patients, was much larger, much better designed, had a low risk of bias, and represents convincing evidence. So does the recent trial of SMT and exercise for neck pain by Bronfort, Evans et al. (2012).

How are quality and risk of bias assessed? Rubinstein et al.'s new paper provides excellent information on this. Points are:

- Through the Cochrane Collaboration there has been an international effort to establish criteria for evaluation of risk of bias in RCTs.
- These criteria have been modified specifically for neck and back pain RCTs by Furlan, Pennick, Bombardier, and van Tulder on behalf of the Cochrane Back Review Group.
- These criteria, appearing in Table 1, were used by Rubinstein et al. for their new review. See the paper for individual ratings for each of 105 RCTs.

Table 1

A 12-Item Criteria List Used to Evaluate Risk of Bias

Randomization and allocation of Patients

- Was the method of sequence generation adequate?
- Was the treatment allocation concealed?

Blinding patient/provider/outcomes assessor

- Was the patient blinded to the intervention?
- Was the care provider blinded to the intervention?
- Was the outcome assessor blinded to the intervention?

Reporting of the data

- Was the drop-out rate described and acceptable?
- Were all randomized participants analyzed in the group to which they were allocated?

Selective reporting

- Are reports of the study free of suggestion of selective outcome reporting?

Other potential sources of bias

- Were the groups similar at baseline regarding the most important prognostic indicators?
- Were co-interventions avoided or similar?
- Was the compliance acceptable in all groups?
- Was the timing of the outcome assessment similar in all groups?

Adapted from Rubinstein SM et al, JMPT, 2014

- The bottom line practical point is that you need to be aware of the quality of the research you are relying upon as evidence of safety and effectiveness – not just whether or not the method used was an RCT.

Rubinstein et al. made various recommendations for further improvement in the future, including increase in the number of patients enrolled in trials.

(Rubinstein SM, Eekelen R, Oosterhuis T et al. (2014) *The Risk of Bias and Sample Size of Trials of Spinal Manipulative Therapy for Low-Back and Neck Pain: Analysis and Recommendations*. J Manipulative Physiol Ther. xx:1-19).

World Notes

Canada – Wickes is CMCC President



Following the retirement on June 30 of Dr Jean Moss, President of the Canadian Memorial Chiropractic College (CMCC) in Toronto since 1991, new President is Dr David Wickes.

Dr Wickes, a 1977 graduate of the National College of Chiropractic who also holds a Master of Arts in Education and Human Development from George Washington University (2009), comes to CMCC from his previous position as Dean of the College of Chiropractic at the University of Bridgeport. He formerly held senior academic positions at both the National University of Health Sciences and the University of Western States.

Malaysia – First Graduates from IMU



For years while on faculty at Palmer West in the USA Dr Michael Haneline (*left*) imagined the day when he might be part of a future program at a high-quality institution where chiropractic and medical students could learn together. In his words:

“That dream came true for me when the International Medical University (IMU) in Kuala Lumpur, Malaysia decided to start a chiropractic program and I was invited to be its first Head. That is why I was willing to give up a great position at Palmer West and move half way around the world to be a part of it, serving as Head for four years until 2013.”

In June I was IMU's guest at the convocation of the first cohort of 28 chiropractic students. The Convocation Proceedings record graduates from medical, dental, chiropractic, and other disciplines all receiving their diplomas together. I wish you could have seen the beaming faces of the graduates and their proud parents after the ceremony. Sights I will never forget! They were without exception wonderful students to work with... now they are the first home-grown chiropractors in all of Southeast Asia.



News and Views

Chiropractic and Primary Spine Care – Hearing the Experts on New Opportunities

Many recent developments in Europe, North America and elsewhere at last show a new era of widespread, practical, health-care opportunities for chiropractors in mainstream primary spine care. Wouldn't it be nice to hear an informed discussion of this by true experts from the various professions involved?

Such a discussion will occur at next year's WFC/ECU Congress May 13-16 in Athens, Greece. Keynote medical, chiropractic and physiotherapy speakers for three sessions of lectures and discussion on this topic and titled *Opportunities in Spinal Healthcare* are:



Anthony Woolf MD (left), Professor of Rheumatology, Universities of Exeter and Plymouth, UK, Consultant Rheumatologist at the Royal Cornwall Hospital, and Chairman of the International Coordinating Committee of the Bone and Joint Decade and International Alliance for Musculoskeletal Health. He is leading the European Musculoskeletal

Surveillance and Information Network – a new initiative supported by the European Community to promote a comprehensive strategy to minimize the impact of musculoskeletal conditions across Europe.

Dr Woolf, whose special interests and expertise include disability from, and the best management of, musculoskeletal conditions, will explain the need for a new approach to the management of spinal disorders and disability – and the important role that chiropractors should have in this. It will be fascinating to hear this from one of the world's leading medical authorities on musculoskeletal health.



Jan Hartvigsen DC, PhD (left), Professor and Head of the Research Unit for Clinical Biomechanics, University of Southern Denmark, and **Nadine Foster PT, PhD**

(right), Professor of Musculoskeletal Health in Primary Care at Keele University in the UK. Drs Hartvigsen



and Foster, both in much demand internationally as experts and speakers in this field, are joint authors of two articles published in the British Medical Journal arguing for the re-organization of primary musculoskeletal and spinal health care so that patients have direct access to the health professionals most qualified to address their needs – often chiropractors and physiotherapists rather than primary or specialist medical practitioners.

Dr Hartvigsen, also Head of the Graduate Program for Physical Activity and Musculoskeletal Health at the Faculty of Health Sciences, USD, has a research focus on spinal and musculoskeletal pain. He has published randomized clinical trials in the area of conservative treatment of back and neck pain, musculoskeletal chest pain, and osteoarthritis of the hip. He has been active in national and international task forces and health technology

assessment groups in the areas of spine pain, traumatic brain injury, and evaluation of musculoskeletal research.

Dr Foster moved full time into the Arthritis Research UK Primary Care Centre in December 2004 supported by a five year Primary Care Career Scientist Award from the National Institute of Health Research (NIHR), and was made Professor of Musculoskeletal Health in Primary Care in March 2010. She is the Honorary Secretary of the Society of Back Pain Research in the UK, as well as serving on the International Organising Committee for the International Forum for Back Pain Research in Primary Care.

The theme of the Athens Congress is *The Alpha and Omega of Spinal Healthcare*. The theme of the three Friday sessions featuring Drs Woolf, Hartvigsen, and Foster is *Opportunities in Spinal Healthcare: Rules vs Real Life Practice*. Other speakers on this subject are:

- Deliver Value – Rick Branson, USA
- Listen to your Patient – A patient representative, Greece
- Motivate Health Behaviour Change – Gary Jacob, USA
- Follow Protocols – Mark Gurden, UK
- Be Evidence-Based – Charlotte Leboeuf-Yde, Denmark
- Summary and Comment – Scott Haldeman, USA

For the full academic and social programs, all information and to register for this conference go to www.wfc.org/Congress2015.

The Alpha and Omega of Spinal Healthcare
ATHENS HILTON AND MEGARON INTERNATIONAL CONVENTION CENTRE

www.wfc.org/congress2015

WORLD FEDERATION OF CHIROPRACTIC | FEDERATION MONDIALE DE CHIROPRAQUE | FEDERACION MUNDIAL DE QUIROPRAXIA

toms after any trauma should be informed about the potential risks and benefits of receiving CMT, and practitioners should carefully consider CD prior to performing CMT.”

In practice and for legal reasons, which are rather different than scientific ones, chiropractors in many jurisdictions do advise patients of the remote risk of CMT as they obtain informed consent for treatment. However this final recommendation from Biller, Sacco et al. is scientifically controversial. To be consistent all health professionals would need to advise patients of risk of stroke from passive cervical range of motion tests, which is never done. Primary care medical doctors would need to give similar advice before prescribing non-steroidal anti-inflammatory drugs (NSAIDs) – again, never done.

Here are the comparisons. Patient groups are not exactly equivalent but this gives meaningful context.

- The generally accepted risk rate of association of stroke with CMT is about 1 in 1 million treatments.¹² Fortunately, as Biller, Sacco et al. note, 70 – 92% or the great majority of these and all patients with stroke following CD have good outcomes with minimal or no permanent disability.
- Use of NSAIDs cause 153 stroke deaths per million patients.¹³
- Cervical spine surgery causes 500 stroke deaths per million patients.¹⁴

b) Clinical Presentation. To assist primary care professionals in early recognition of CD and prevention of stroke, Biller, Sacco et al. give detailed advice on symptoms of internal carotid artery dissection (ICAD) and vertebral artery dissection (VAD). Typical presentations by patients with ICAD are:

- The “classic triad” of pain on one side of the head, face or neck, accompanied by a partial Horner’s Syndrome and followed hours or days later by cerebral or retinal ischemia. However only about a third of ICAD patients have this.
- Wherever the extracranial pain, “usually there is an ipsilateral headache ... most commonly in the frontotemporal area.” This is usually of gradual onset but may be sudden. It is “most commonly described as a constant steady aching” but may be “throbbing or steady and sharp.”
- “Most patients consider the headache or facial pain to be unlike any other pain”.
- “After the onset of pain the median time to appearance of neural symptoms is an average 9 days (range 1-90 days)”.
- Unilateral Horner’s Syndrome “should be considered to be caused by an ICAD until proven otherwise.”

Typical presentations by patients with VAD are:

- “Pain in the back of the neck or head followed by posterior circulation ischemia,” but first manifestations are less distinct than for ICAD “and usually interpreted as musculoskeletal in nature.”
- Pain develops in the back of the neck in half of patients, and a headache occurs in two thirds of patients.
- The pain can be unilateral or bilateral, but when unilateral is always ipsilateral to the dissected VA.
- Headache may be throbbing or steady and sharp.
- Only half of the patients consider the neck pain or headache “to be unlike any other”, but it is rarely mistaken for migraine by those with a history of migraine.

- The median interval between the onset of neck pain and the appearance of other symptoms is two weeks.

This final fact demonstrates the challenge for all in recognizing these rare patients with VAD, presenting with neck/head pain and likely to progress to stroke unless preventive steps are taken. It also explains why any minor neck movement including CMT in this two week period may trigger release of an embolus and stroke. Here is a chiropractic case report illustrating the time sequence:¹⁵

- a) The patient was a 49-year-old farmer with chronic, episodic head and neck pain since the age of 19, not in severe pain, with unremarkable imaging and many things suggesting a mechanical origin for his problem and suitability for chiropractic adjustment.
- b) However a careful examination revealed various risk factors and signs suggesting potential for cardiovascular disease – elevated blood pressure, family history of cardiovascular disease including stroke, bilateral tinnitus and nausea during severe attacks of pain, reduced cervical range of motion in all directions during severe attack, and inability of the chiropractor to reproduce the patient’s head pain during examination.
- c) He was referred to his general practitioner for further assessment prior to commencement of any chiropractic care, and the following week had a stroke leaving him hemiplegic and with speech impairment.

As this case indicates there may be cases where, based upon presenting symptoms, predisposing factors for stroke in the patient’s history and examination findings, it is appropriate to delay CMT until more than two weeks have passed since pain symptoms began. (It also illustrates why there is slightly increased incidence of stroke after a patient consults either a primary care medical practitioner or chiropractor, but why that stroke is not caused by either. It also illustrates why case reports cannot prove causation, and why those criticizing CMT based on case reports have been scientifically naïve or irresponsible.)

d) Treatment of CDs. See the paper for review of the strengths and limitations of the current imaging modalities being used for better detection of the site and exact nature of CD in individual patients. All treatments for CD, however caused, are based on case reports or series or clinical experience since none is yet supported by a randomized controlled trial. They include:

- Acute Management. This is focused on re-establishment of blood flow to brain tissue at risk. Thrombolysis with tissue-type plasminogen activator is a primary option, but worsens the dissection in rare cases. Other endovascular treatments involve stenting of the artery, and are used to re-establish blood flow in patients with severe occlusion/stenosis at the site of CD.
- Prevention of Re-Occurrences – Anti-Thrombotic Therapy. Anticoagulants and antiplatelet agents are widely used to prevent both early and late stroke recurrence. They are used to prevent local thrombus formation at the site of the CD and secondary embolism. Preliminary observational studies show that neither of these two alternative approaches is superior to the other in terms of subsequent rates of stroke. The best choice of anticoagulant (e.g. intravenous or oral warfarin) or antiplatelet agent (aspirin being the most common in antiplatelet-naïve patients), and the optimal duration of treatment

are not known. If anticoagulant therapy is used it is generally discontinued after 3-6 months “since arterial remodeling, if it is to occur, is generally complete by 6 months”. Long-term antiplatelet therapy is thought to be less warranted for most patients.

Other risk factors (e.g. hypertension, use of oral contraceptives or hormone replacement therapy) should be managed.

e) Clinical Outcomes. As already mentioned 70-92% of patients with strokes following CD from any cause have a good final outcome/result, defined as 0-2 (no or slight residual disability) on the modified Rankin Scale (mRS). “Generally neurobiological outcome depends upon lesion location and the presence of adequate collaterals”.

Estimates of overall recovery of arterial patency range from 55-78%. “Factors associated with increased chances of recanalization include spontaneous (versus traumatic) dissections, stenotic vessels (versus occluded vessels), dissections in women, and VADs versus ICADs.”

C. Further Concerns with the AHA Statement

8. As previously commented the singular focus on CMT in this article, without making it clear that the association with stroke is extremely rare and that CMT is overall a safe and appropriate treatment, seems irresponsible. Furthermore, maintaining the concept that CMT involves trauma seems illegitimate. Surely Biller, Sacco et al. should have at least questioned that concept given the evidence they reviewed, which includes:

- Basic science research showing that direct forces on the vertebral arteries from CMT are far less than those generated during normal range of motion testing and are similar to those from many activities of daily living – none of which are described as “traumatic”.
- Compelling new evidence showing that stroke is equally associated with healthcare visits to primary care medical doctors who do not use CMT.

In defense Biller, Sacco et al. and the AHA may assert that they didn’t need to put CMT in context and review the established concept of ‘trivial trauma’ because this statement was written for health professionals rather than the public. But they must have known that this new AHA Scientific Statement would lead to media misinterpretation, and comment warning the public that CMT was dangerous. The Statement was published on Thursday, August 7. We can illustrate the above concerns with an article in Europe on Monday, August 11. This followed an interview with and quoted Dr José Biller, the AHA’s primary author.

9. On August 11 the Times of Malta, the national paper in that country, published a prominent article titled *Experts Warn over Neck Treatment Risks: Techniques to ease pain, including extending and rotating the neck can cause serious injury*. This is reproduced in full as Figure 1. Points to note are:

- Already in the title the distinction between *association* and *cause* is lost.
- The article begins with a “new warning”, later refers to other medical warnings about “unnecessary and inadvisable” treatments that are “provided by chiropractors and osteopaths”.

Figure 1

Times of Malta, Monday, August 11, 2014
John von Radowitz, PA

Experts warn over neck treatment risks



Techniques to ease pain, including extending and rotating the neck, can cause serious injury.

Patients should seek emergency help if they develop neurological symptoms after neck manipulation, such as pain, dizziness, double vision, unsteadiness, slurred speech, nausea and jerky eye movements.

Experts have issued a new warning about the risk of strokes associated with neck manipulation to treat back pain.

Scientists highlighted a type of neck injury called a cervical artery dissection (CD) that can cause small tears in the walls of blood vessels in the neck.

This could result in clots blocking the flow of blood to the brain, leading to a stroke.

US neurologist José Biller, from the Loyola University, Chicago, who led a group of physicians writing in the journal *Stroke*, said: “Most dissections involve some trauma, stretch or mechanical stress.

“Sudden movements that can hyper-extend or rotate the neck – such as whiplash, certain sports movements, or even violent coughing or vomiting – can result in CD, even if they are deemed inconsequential by the patient.”

He pointed out that some manipulation techniques used to correct spinal misalignments and ease back pain involved extending, rotating and jarring the neck.

“Although a cause-and-effect relationship between these therapies and CD has not been established and the risk is probably low, CD can result in serious neurological injury,” he added. “Patients should be informed of this association before undergoing neck manipulation.”

Last year doctors writing on the British Medical Journal website also warned about the possible side effects of the treatments provided by chiropractors and osteopaths. They argued that the therapies were “unnecessary and inadvisable”.

Cervical artery dissection can result in serious neurological injury.

Although case control studies had shown a link between CD and neck manipulation, they were not designed to prove cause and effect, Biller’s team said.

But the experts said patients should seek emergency help if they developed neurological symptoms after neck manipulation, including pain, dizziness, double vision, unsteadiness, slurred speech, nausea and jerky eye movements.

“Tell the physician if you have recently had a neck trauma or neck manipulation,” said Biller. “Some symptoms, such as dizziness or vertigo, are very common and can be due to minor conditions rather than stroke, but giving the information about recent neck manipulation can raise a red flag that you may have a CD rather than a less serious problem, particularly in the presence of neck pain.”

and ends with Biller's advice concerning the "red flag" of "neck trauma or neck manipulation".

Unsurprisingly Dr Nicolo Orlando, President of the Malta Chiropractic Association, reports that he and other MCA members were approached by existing patients with serious concerns. The wider concern is that many people with neck pain and headache and other conditions for which skilled CMT is an appropriate treatment will be deterred from receiving it.

D. Conclusion

10. Publication of the AHA Scientific Statement represents the end of the era in which individual neurologists can claim that CMT causes CD and stroke, present case reports as evidence, and rely on their colleagues for professional and scientific support. The AHA Statement, notwithstanding the concerns mentioned, is therefore a truly important milestone in the ongoing documentation of the appropriateness and value of CMT for many patients.

How should health professionals practicing CMT, specifically including chiropractors, respond to future media reports of patients allegedly suffering CD/stroke as a result of CMT? There must be an expression of sympathy for any patient suffering a stroke whatever the cause, but the AHA statement, with its evidence and conclusions, can be relied upon to explain that leading neurologists, other medical experts and their organizations including the Stroke Council of the American Heart Association agree that there is no evidence to support the claim that CMT causes CD or stroke.

How should chiropractors and their associations respond if asked about the AHA statement itself? There should be a focus on its positive features, including those summarized at the

beginning of this article. That is consistent with the advice of the World Federation of Chiropractic and its Talking Points published under News at www.wfc.org.

Plainly, any possible association between CD and CMT is an important professional issue, warranting careful understanding, diagnosis and all reasonable steps to prevent harm to patients. On the other hand any such association is extremely rare and is not a significant public health issue. It doesn't warrant more attention and debate than many other everyday neck movements or than medical interventions for similar patients that have less benefit and far higher risk of serious harm. The AHA Statement should be read and received in this context. **TCR**

For relevant past issues of The Chiropractic Report, available online at www.chiropracticreport.com, see March 2008 (BJD Neck Pain Task Force); March 2012 (Best Treatments for Neck Pain); July 2012 (BMJ Debate on CMT) and January 2014 (CMT – Safety and Effectiveness – embargoed until January 2015).

References

- (2014) Biller J, Sacco RL et al. On behalf of the American Heart Association Stroke Council *Cervical Arterial Dissections and Association with Cervical Manipulative Therapy*. Stroke 45:xxx-xxx doi:10.1161/STR.000000000000016.
- (2012) Dunning JR, Cleland JA et al. *Upper Cervical and Upper Thoracic Thrust Manipulation versus Nonthrust Mobilization in Patients with Mechanical Neck Pain: A Multicenter Randomized Clinical Trial*. J Orthop Sports Phys Ther. 42:5-18.
- Cassidy JD, Boyle E, Côté et al. (2008) *Risk of Vertebrobasilar Stroke and Chiropractic Care: Results of a Population-Based Case-Control and Case-Crossover Study*. Spine 33(4S):S176-183.
- Bronfort G, Haas M et al. (2010) *Effectiveness of Manual Therapies: The UK Evidence Report*. Chiropractic & Osteopathy 18:3 (25 February 2010). Doi: 10.1186/174601340018-3.
- Bryans R, Decina P et al. (2014) *Evidence-Based Guidelines for the Chiropractic Treatment of Adults with Neck Pain*. J Manipulative Physiol Ther 37:42-63.
- Rubinstein SM, Haldeman S, van Tulder MW (2006) *An Etiologic Model to Help Explain the Pathogenesis of Cervical Artery Dissection: Implications for Cervical Manipulation*. J Manipulative Physiol Ther 29:336-338. (#15 July 2012)
- Herzog W, Leonard TR, Symons B et al. (2012) *Vertebral Artery Strains During High-Speed, Low amplitude Cervical Spinal Manipulation*. J Electromyogr Kinesiol. 22:740-746.
- Symons BP, Leonard T, Herzog W. et al. (2002) *Internal Forces Sustained by the Vertebral Artery During Spinal Manipulative Therapy*. J Manipulative Physiol Ther. 25:504-510.
- Wuest S, Symons B, Leonard T et al. (2010) *Preliminary Report: Biomechanics of Vertebral Artery Segments C1-C6 During Cervical Spinal Manipulation*. J Manipulative Physiol Ther. 33:273-278.
- Kawchuk GN, Wynd S, Anderson T (2004) *Defining the Effect of Cervical Manipulation on Vertebral Artery Integrity: Establishment of an animal model*. J Manipulative Physiol Ther. 27:539-546.
- Wynd S, Anderson T, Kawchuk G (2008) *Effect of Cervical Spine Manipulation on a Pre-Existing Vascular Lesion Within the Canine Vertebral Artery.. Cerebrovasc. Dis. 26:304-309.*
- Haldeman S, Kohlbeck FJ, McGregor M (2001) *Unpredictability of Cerebrovascular Ischemia Associated with Cervical Spine Manipulation Therapy: A Review of Sixty-Four Cases After Cervical Spine Manipulation*. Spine 27(1):49-55.
- (2005) Lanas A et al. *A Nationwide Study of Mortality Associated with Hospital Admission due to Severe Gastrointestinal Events and Those Associated with Nonsteroidal Anti-inflammatory Drug Use*. Am J Gastroenterology 100(8):1685-93.
- (2014) Marquez-Lara A, Nandyala SV et al. *Sentinel Events in Cervical Spine Surgery*. Spine Jan 29 [Epub ahead of print], <http://www.ncbi.nlm.nih.gov/pubmed/24480955>.
- Kier AL, McCarthy PW (2006) *Cerebrovascular Accident without Chiropractic Manipulation: A Case Report*. J Manipulative Physiol Ther 29:330-335.

SUBSCRIPTION AND ORDER FORM

(6 bi-monthly issues) Year commences January

Check one

US and Canada (your currency)	1 year	\$145.00	<input type="checkbox"/>
	2 years	\$270.00	<input type="checkbox"/>
Australia	1 year	A\$165.00	<input type="checkbox"/>
	2 years	A\$290.00	<input type="checkbox"/>
Europe/elsewhere	1 year	US\$155.00	<input type="checkbox"/>
	2 years	US\$280.00	<input type="checkbox"/>

Name _____

Address _____

City _____ Province/State _____

Country _____ Postal Code/Zip _____

Telephone (_____) _____

PLEASE CHECK ONE

Visa Card number _____

MasterCard Expiration date _____

Cheque/Check enclosed

Payable to: The Chiropractic Report

203-1246 Yonge Street

Toronto, Ontario, Canada M4T 1W5

Tel: 416.484.9601 Fax: 416.484.9665

E-mail: TCR@chiropracticreport.com

Website: www.chiropracticreport.com