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Editor: David Chapman-Smith LL.B. (Hons.)

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Professional Notes

Spinal Manipulation – German Medical Training

A paper just published in the European Spine Journal gives fascinating insight into the teaching of spinal manipulation

- called chiropractic spinal manipulation
- to medical students in Germany.

Knobe et al., orthopedic surgeons from Aachen University in Aachen, Germany, report a controlled trial to see if "the demanding bimanual tasks of complex spinal manipulation motor skills" can be taught as successfully by studentteachers as by orthopedic surgeons experienced in the practice of manipulation. Not surprisingly, they find studentteachers less effective. However their conclusion is not that students should therefore not be teachers, which we suggest would be the obvious conclusion, but that "medical educators should invest time and resources in programs designed to educate the student-teachers and to improve their confidence in the field of demanding manipulative skills."

However of real interest in this paper is

continued on page 4

BMJ Demonstrates its Class

Addressing the Critics of Cervical Spine Manipulation

A. Introduction

To the chiropractic profession, and the many medical doctors, osteopaths, physical therapists, practitioners of Chinese traditional medicine and others throughout the world who include cervical spine or neck manipulation in their practices daily for patients with mechanical neck pain and related headache, it is astonishing to see the ongoing complaints from medical critics concerning the potential risks of neck manipulation – and the sustained attention the media is willing to give this.

Astonishing because all informed and impartial persons accept that on best current research and scientific knowledge:

- Cervical spine manipulation is one of the appropriate and recommended treatments for patients with the most common forms of troubling neck pain and related headache.
- It is as effective as any other treatment.
- It has less risk of harm than common medical treatments, specifically including the use of non-steroidal anti-inflammatory drugs (NSAIDS) or paracetamol.
- It is sought after and preferred by many patients, and delivers consistently high patient satisfaction rates.

Astonishing, but perhaps not surprising. Most health professionals, including medical doctors, are far from scientific in their approach to practice, conscious and unconscious bias are pervasive, and for most media the fundamental interests are promoting controversy and attention. Newspapers and television are much more interested in a fight between professions and a victim in a wheelchair than a balanced assessment of treatment alternatives or the merits of a profession.

2. The British Medical Journal (BMJ)

is one of the health sciences journals with a reputation for higher standards. It is the official journal of the British Medical Association which, chiropractic readers should recall, is the one national medical association that has a record of actively supporting the legal recognition and regulation of developed complementary health care professions, specifically including chiropractic and osteopathy.¹

In an impressive new display of impartiality the BMJ has taken the bull by the horns. Faced with lesser voices creating media controversy and public concern about the potential risk of serious harm from "chiropractic manipulation" the BMJ:

- Correctly identifies the issue as cervical spine manipulation, as delivered by many health professionals, not chiropractic manipulation.
- Has drilled down to the fundamental challenge made by critics should cervical spine manipulation from mechanical neck pain be continued or abandoned?
- Has commissioned true experts to debate the issue.
- In June has published that debate. ^{2,3}
- 3. Arguing in the affirmative for the proposition "should we abandon cervical spine manipulation for mechanical neck pain?" are:
- Associate Professor Benedict Wand, School of Physiotherapy, University of Notre Dame Australia, Fremantle, Western Australia.
- Peter Heine, Research Fellow, Warwick Clinical Trials Unit, Division of Health Sciences, University of Warwick, Coventry, UK.
- Neil O'Connell, Lecturer, Centre for Research in Rehabilitation, Brunel University, Uxbridge, UK.

Arguing against the proposition and abandonment are:

- Professor David Cassidy, Division of Epidemiology, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada.
- Professor Gert Bronfort, Department of Research, Northwestern Health Sciences University, Bloomington, Minnesota, USA.
- Professor Jan Hartvigsen, Institute of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark.

Chiropractors will immediately note two things about this. First, that the three experts chosen to speak in support of cervical spine manipulation are chiropractors, and second that they are foremost scientific leaders on the subiect. In other words the BMI has chosen well and fairly.

So, what arguments and evidence are presented, who delivers the more compelling argument?

B. BMJ Debate

4. Since they support the proposition to abandon cervical spine manipulation, Wand, Heine and O'Connell go first. They begin with definition. Joint manipulation comprises "a high-velocity, low-amplitude, end-range thrust maneuver," whereas joint mobilisation involves manual techniques without thrust or sudden movement. (Figure 1 is a commonly used illustration showing the different ranges of joint motion involved in manipulation and mobilization.)

In the environment of the BMJ, and confronted by others with real scientific expertise on the subject, Wand et al. advance rather different arguments than run-of-the-mill, outspoken medical critics such as Ernst who claim no benefit and established serious harm from neck manipulation. 4 Therefore:

- a. Effectiveness. They acknowledge that manipulation has proven effectiveness but argue that it is not superior to other physical interventions, such as cervical spine mobilisation and use of exercises.
- b. Risk of Harm. The one suggested source of significant harm from cervical spine manipulation is vertical artery dissection (VAD) leading to vertebrobasilar stroke (VBS). They acknowledge that there is no proven link between manipulation and VAD – "causality is not proven" - and that such adverse events associated in time with manipulation are rare. This is so even though "cervical spine manipulation is a common treatment for mechanical neck pain."

Their concern, exactly as they express it, is that such manipulation "may carry the potential for ... vertical artery dissection and subsequent vertebrobasilar stoke."

Wand et al. assert that mobilisation is safer, implying - but interestingly not saying expressly – that it has no potential for VAD and harm.

c. Conclusion. Wand et al. argue that "neck manipulation should only be used if there is substantial and unique benefit associated with this technique." "The potential of catastrophic events and the clear absence of unique benefit lead to the inevitable conclusion that manipulation of the cervical spine should be abandoned as part of conservative care for neck pain."

Further comment on that appears below in paragraphs 7-11.

5. Cassidy, Bronfort and Hartvigsen disagree, and argue that cervical spine manipulation is a valuable addition to patient care.

> Cassidy et al. The best evidence, Decade 2000-2010

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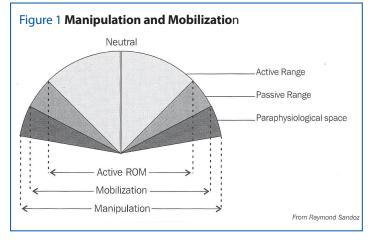
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manipulation "as one of several firstline treatments for neck pain, whiplash and related headaches based on a systematic review of randomized clinical trials of interventions and research on adverse events."

- b. Risk of Harm. Cassidy et al. discuss the "one concern about manipulation... the risk of stroke", and conclude that the evidence "raises doubt about any causal relationship between manipulation and stroke." Points made include:
- i. The main evidence leading to concerns has been from case reports. However these are "the lowest level of evidence. They raise hypotheses to be tested in analytical designs that include control groups but cannot be used to infer causation."
- ii. For rare events such as a vertebrobasilar stroke (VBS) the best research design is the case-control study (with this design you compare persons suffering an adverse event with age and sex-matched control persons from



essentially agree with Wand et al. including the recent report of an international, multi-disciplinary task force (the Bone and Joint Task Force on Neck Pain and its Associated Disorders.5,6) endorses

a. Effectiveness.

the general population). The three such studies published all involve chiropractic care. They suggest an association between VBS and chiropractic care within the previous day, week and month, but exactly the same association between VBS and family physician care during the same time frames. Associations increased when the analysis was limited to neck-related diagnoses by chiropractors and family physicians (eg. cervical pain, strain, sprain, head ache). These are common reasons for seeking care and the most common presenting complaints of people with CAD.

This suggests that the association between manipulation and stroke is "confounded b" indication". What this means is that some patients presenting with neck pain have a CAD, which is the cause of the neck pain and the fundamental cause of an ensuing stroke. The stroke is associated in time with, rather than caused by, the manipulative or medical care.

- iii. VBS has been reported in association with many other activities and trivial movements that include rotation or extension of the neck, such as yoga, looking up, and hair washing at a salon.
- iv. Cassidy et al. note that "a recent high quality trial found spinal manipulation more effective for acute and subacute neck pain, over both the short and long term" than NSAIDS or paracetamol. They pointedly observe "The authors did not advocate abandoning these drugs, even though their harms are well documented."
- v. "There is no evidence that mobilisation is safer... than manipulation". (On this see paragraphs 7-8 below.)
- c. Patient Preference. With respect to this, a subject not addressed by Wand et al., Cassidy et al. explain that "Manipulation is one of the most common treatments for neck pain and is clearly preferred by many patients given that 6-12% of the population receives it annually."
- d. **Conclusion.** Cassidy et al. say "the evidence clearly suggests that manipulation benefits patients with neck pain." "We say no to abandoning manipulation and yes to more rigorous research on the benefits and harms of this and other common interventions for neck pain."
- 6. From the perspective of logical and reasonable persons Wand et al. are advocating an untenable position that a widely used treatment of proven benefit be abandoned because of unproven potential for harm. The logical course in this situation, as suggested by Cassidy et al., is further research into benefits and risks of harm not abandonment. Thank you to the BMJ for providing the forum in which this has been made clear.

In advancing their arguments large considerations for Wand et al. are that:

- Joint mobilisation is safer than joint manipulation.
- "Numerous case studies report neurovascular complications immediately after cervical manipulation."

Let's explore these views.

C. Safety - Manipulation vs. Mobilisation

7. It was once thought that manipulation, particularly manipulation with rotation and extension, might carry higher risk of vertebrobasilar stroke (VBS) than mobilisation. However that view, although still asserted by some, is now contradicted by research. When Michaeli surveyed complications follow-

ing manipulation and mobilisation by physiotherapists in South Africa the one reported case of VBS was associated with mobilisation not manipulation. ⁷

A foremost expert in this field is Los Angeles neurologist Scott Haldeman MD, DC, PhD. As he and colleagues report in a leading study VBS is an extremely rare form of stroke, and one that must be seen and accepted as "a rare, random, unpredictable complication" of all neck movements. These include both manipulation and mobilisation, ordinary range of motion tests in health care, and normal activities of daily living such as turning the head while driving or kneeling at prayer. See Table 1 for more examples from Haldeman et al. No manipulative or mobilisation technique can be said to have more risk than any other.

A perception of critics of cervical spine manipulation is that a sudden movement as in neck manipulation may produce forces that injure one of the two vertebral arteries in the upper cervical spine. A Canadian study by Symons, Leonard and Herzog from the University of Calgary, using sophisticated measurements with fresh cadavers, reports:

- i. The maximum forces/strains on a vertebral artery (VA) from chiropractic manipulation are no greater than those recorded during common diagnostic range of motion (ROM) tests regularly performed by chiropractors, medical doctors and physical therapists.
- ii. The forces are "within the range of strains produced during normal, physiologic motion of the cervical spine."
- iii. Maximum strains during chiropractic manipulation provide only "approximately one ninth of the strain" required to produce first mechanical failure in the tissues of a VA.

Accordingly forces are not remotely close to causing physi-

Table 1 Normal Neck Movements and Trivial Trauma Associated with Vertebrobasilar Artery Dissection/ Occlusion and Stroke (VBS)

Type of Trial Trauma	Examples	No. of Cases
Sporting activities	Basketball, tennis, softball, swimming, calisthenics	18
Leisure activities	Walking, kneeling at prayer, household chores, sexual intercourse	8
Sustained rotation and/or extension	Wall papering, washing walls and ceilings, archery, yoga	10
Short-lived rotation and/or extension	Turning head while driving, backing out of driveway, looking up	7
Sudden head movements	Sneezing, fair ride, violent coughing, sudden head flexion	7
Miscellaneous minor trauma	Minor fall, "banging" head	2
Miscellaneous	Atlantoaxial instability, postpartum,	
	post-gastrectomy	6
Total		58

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The Chiropractic World

Spinal Manipulation - German Medical Training

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what we learn about the content of medical training for spinal manipulation in Germany. On one hand there is recognition that spinal manipulation is demanding – chiropractic authors referenced on this include Triano et al., Peterson and Bergmann, and Descarreaux and Dugas. On the other hand this is what German medical students receive:

- a) Eight 120-minute lessons over eight weeks to learn the theoretical and practical aspects of "complex chiropractic techniques."
- b) Each lesson begins with 30 minutes of theory and there is then a 90 minute practical session.
- c) This is according to a defined curriculum from the German Society for Manual Medicine (DGMM) which leaves students with three techniques for the cervical spine, two for each of the thoracic and lumbar spine, and three for the sacroiliac joint.

In Knobe et al.'s trial students asked to be teachers received an enhanced ten week program. None had any previous experience of spinal manipulation. They had two weeks of literature review and theoretical preparation, then the eight week course as already described, but in addition the opportunity to assist experienced manipulators in treatment daily. Unbelievable.

(Knobe M, Holschen M et al. (2012) *Knowledge Transfer of Spinal Manipulation Skills by Student-Teachers: A Randomised Controlled Trial.* Eur Spine J (2012); 21:992-998.)

Other Research

1. Norway – Pregnancy, LBP, Pelvic Pain and Spinal Manipulation

The purpose of a new study from Malmqvist et al., chiropractors and medical specialists from the Stavanger University Hospital in Norway, was to investigate the prevalence of low-back pain and/or pelvic pain (LBPP) during pregnancy in a general and representative sample of Norwegian women giving birth in a busy maternity hospital during a four month period. As with studies in other countries that the authors quote, LBPP was found to be very common. Key points are:

- a) After exclusions and dropouts (failure to complete questionnaires) the study group comprised 569 women.
- b) 57.4% or a majority reported "moderate and severe (LBPP) pain during pregnancy." "Nearly 50%" had moderate and severe pelvic pain, half of them pelvic pain only and the other half combined pelvic pain and LBP. Approximately 10% had moderate and severe LBP only.
- c) Of those with moderate and severe pelvic pain only, 55% or more than half experienced pain at the symphysis, 40% had pain at all three pelvic joints, 20% experienced pain only at the symphysis, 20% experienced pain only at one sacroiliac joint.
- d) Average amount of sick-leave during pregnancy was 9.6 weeks. This was "2 to 3 times more sick-leave days than women without or with only mild pain."

This study included measurement and reporting on pain (numerical rating scale and pain drawings), disability (Oswestry Disability Index) and exercising. The ODI results showed that the pain complaints reported "have major impacts on the functioning of pregnant women. These findings underline the importance of pelvic pain in pregnancy for women and society."

Malmqvist et al. review earlier studies showing that "pelvic pain in pregnancy does not vary according to geography or socioeconomy, and that pelvic pain has a prevalence of 49% in Sweden, 66% in Tanzania, 77% in Finland and 81% in Zanzibar, with overall similarity in symptoms and degree in pain. In the US two-thirds of pregnant women report low-back pain and "most women report their first episode ever of LBP to occur during pregnancy."

This Norwegian study does not report on treatment or risk factors for pain. It reviews past literature on risk factors for pelvic pain during pregnancy concluding:

- Studies "have not yet been able to reveal one single dominant causative factor"
- There are various different physical and psychosocial factors correlating with self-reported pain including "increased abdominal diameter, higher body mass index, muscle dysfunction and fetal weight." The literature also shows "a general increase in mobility of joints during pregnancy."

(Malmqvist S, Kjaermann I et al. (2012) *Prevalence of Low-Back and Pelvic Pain During Pregnancy in a Norwegian Population.* J Manipulative Physiol Ther 2012;35:4)

Canadian and US chiropractic researchers Stuber et al. have provided the first literature review regarding adverse events from spinal manipulation during pregnancy and postpartum – adverse events are very rare, with seven cases in the 30 year period from 1978-2009 and none with significant residual harm. (Stuber K, Wynd S et al. (2012) Adverse events from Spinal Manipulation in the Pregnant and Postpartum Periods: A Critical Review of the Literature. J Manipulative Physiol Ther 2012;20:8)

2. New Zealand - Balance, Falls and Manual Therapy

A new literature review by Dr Kelly Holt, and Dr Heidi Haavik, respectively Assistant Director and Director of Research at the New Zealand College of Chiropractic, and Raina Elley MD, PhD on the effects of manual therapy on balance and falls notes that in New Zealand and Australia falls are the leading cause of injury-related hospital admissions and death in older adults. "Up to 30% of all reported falls result in a serious injury or death, with crude injury rates associated with falls rising sharply as the population ages." In 2004 it was estimated that direct health care costs associated with falls were approximately US \$30 billion per annum in the United States. Points are:

- a) Eleven relevant randomized controlled trials were found. Most had "poor to fair methodological quality".
- b) All trials reported outcomes of functional balance tests or

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tests that used a computerized balance platform. Nine of the 11 trials reported some statistically significant improvements relating to balance after an intervention that included a manual therapy component.

c) No firm conclusions can be drawn because of the quality and number of studies. More and better ones are needed.

Holt, Haavik et al. explain that manual therapy may have a positive influence on fall risk if it improves one or more of the components of the nervous system important for the maintenance of balance, including the cerebellum, the vestibular system, and the somatosensory system. They explain:

"If articular or other lesions interfere with mechanoreceptors within the joints or associated muscle spindles, they may result in reduced postural control and balance. If manual therapy results in correction or improvement of these lesions, it may lead to improved integration of neurologic information in the central nervous system that is important for the maintenance of balance and, therefore, the prevention of falls."

(Holt K, Haavik, H, Elley R, et al. (2012) *The Effects of Manual Therapy on Balance and Falls: A Systematic Review.* J Manipulative Physiol Ther 2012;35:3)

3. Denmark - Hip Osteoarthiritis in Chiropractic Practice

A new study on the prevalence of hip osteoarthritis (OA) in chiropractic patients in Denmark involves excellent practice-based research. There was retrospective review of 2000 patient records, including 1000 radiographs, in 20 chiropractic clinics throughout Denmark, together with a two-week prospective survey of new patients at the same clinics.

The study shows that hip OA is quite common. In patients aged 40 or older 19.2% demonstrated radiographic signs of hip OA. In the prospective arm of the study 3.4% of patients overall had signs of hip OA, and 70% of these had no previous medical diagnosis of OA. The study demonstrates how hip OA is managed in chiropractic practice – chiefly through manual treatments and advice on over-the-counter pain medications and/or supplements.

(Poulsen E, Christensen H, et al. (2012) *Prevalence of Hip Osteo-arthritis in Chiropractic Practice in Denmark: A Descriptive Cross-Sectional and Prospective Study.* J Manipulative Physiol Ther 2012;35:4)

4. USA - Complications in Spine Surgery

- 1. Lee et al. from the University of Washington have a new and improved and rather dramatic analysis of complications after spine surgery, based on all patients receiving such surgery over one year in two hospitals in Seattle. There were 1,591 eligible patients. Key points are:
- a) This was a carefully designed prospective study to capture all complications within a two year period, representing "the most exhaustive effort" published yet.
- b) It reports complications in 42% of patients or almost one in two. This is far higher than the rate of 7 8% reported in most studies, because of the more thorough design and is "more reflective of reality" according to Dr Raja Rampersaud, who was

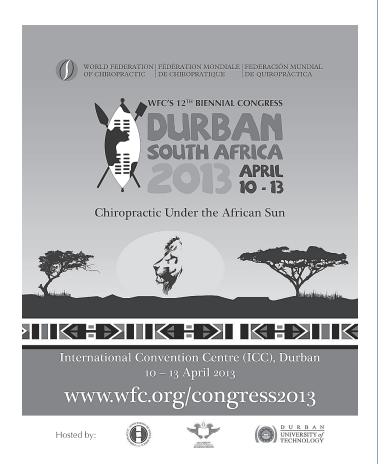
chosen by The Spine Journal to provide expert commentary on the paper.

- c) Various patients had more than one complication complications per organ system were cardiac, 8.4%; pulmonary, 13%; gastrointestinal, 3.9%; neurological, 7.35%; hematological, 10.75%; and urological complications, 9.18%.
- d) The number of deaths is not given but the study "significantly associated cardiac and pulmonary complication to a fourfold and tenfold increased risk of death" within two years of the complication.

The purpose of the study by Lee et al. was to assess risk factors for complications. Those of most importance were age (non-modifiable) and severity of surgery (modifiable).

Patients received lumbar, thoracic, or cervical spine surgery, many following trauma but most being non-trauma and elective. Lee et al. state that "surgical invasiveness has been poorly evaluated in prior studies" and Rampersaud admits that "we have a long way to go" in "this crucial area of quality improvement in spinal surgery."

(Lee M, Konodi M et al. (2012) *Risk Factors for Medical Complication After Spine Surgery: A Mulitvariate Analysis of 1,591 Patients* (2012); The Spine Journal (2012)12:197-206. Rampersaud R (2012) *Commentary: Complications in Spine Surgery: "The Devil is in the Details"*. The Spine Journal (2012); 207-208.)



cal harm to a normal artery, and this study sweeps away the hypothesized injury mechanism most commonly given to link manipulation to stroke.⁹

Walter Herzog PhD, a human biomechanics researcher who is Professor and Associate Dean of Research in the Faculty of Kinesiology at the University of Calgary promoted the above study because he had heard, as he explains in an earlier paper¹⁰, the claim that manipulation could cause stress and injury to a vertebral artery. He wondered if this was actually possible as a matter of biomechanics given the depth and location of the vertebral arteries. There was not "a shred of scientific evidence" to support the injury hypothesis and he wanted to investigate.

8. The human body is rather well designed, and a little common sense helps here. If there is a true causative relationship between neck manipulation or mobilisation and vertebral artery injury why is injury so rare? It is generally accepted that the incidence of cases where there is an association between neck manipulation and stroke is about 1 in 1 million. As Herzog has suggested in expert testimony, with a true causative relationship one would expect about 100 cases of VBS a week in Canada alone. Canada alone.

Why do we not see frequent CAD and stroke following much more forceful neck movements as in boxing, skiing accidents and football? The answer is that the body is well-designed. There is flexibility in these arteries, they are at a protected site and safe depth and, as Symons et al. have shown, only a modest fraction of external forces are transmitted to them through the various intervening tissues. Similarly, a storm at sea is of no concern to a scuba diver swimming 10 feet below the wind and the waves. Other than in exceptional circumstances, forceful movements of the head and neck are of no concern to the vertebral arteries.

Why is it then that there are rare incidents of VAD and VBS associated with a variety of apparently mild neck movements? Where a patient cannot remember any precipitating movement these incidents are sometimes reported in the literature as "spontaneous". There is growing evidence that those few individuals who prove vulnerable to stroke from VA injury have rare forms of underlying pathology that make the artery wall fragile and susceptible to injury (e.g. genetic collagen and other connective tissue disorders). Recent work suggests that such patients become especially vulnerable after a complicating factor such as an upper respiratory tract infection and that this, therefore, is a multifactorial problem. McDermaid in Canada¹³ and Terrett in Australia¹⁴ discuss much of this new evidence in greater detail in excellent reviews.

A model of CAD by Rubenstein, Haldeman and van Tulder published in 2006, presents current knowledge and concludes that dissection following neck movements is extremely unlikely unless a patient has both an underlying predisposition and one or more necessary triggers. ¹⁵ In this model the four necessary elements for risk of CAD are:

- Genetic predisposition/underlying familial disorder (e.g. connective tissue disease, hyperhomocysteinemia, migraine, vessel abnormalities)
- Environmental exposure (e.g. infection, oral contraceptive use)
- Trivial trauma (e.g. common neck movements, sporting activities, manipulative therapy to the neck)

- Common risk factors associated with atherosclerosis (e.g. hypertension, diabetes mellitus, and smoking).
- 9. An interesting 'near miss' case from Kier and McCarthy at the Welsh Institute of Chiropractic, University of Glamorgan, illustrates this and shows the value of good diagnosis. ¹⁶ They tell this tale concerning one of their patients:
- 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 CAD and stroke leaving him hemiplegic and with speech impairment.

As noted, a near miss. If the patient had received cervical spine manipulation from the chiropractor a week before, this would likely have been recorded in a neurologist's case report as the cause of the following CAD and stroke, and a further example of the dangers of chiropractic care.

D. The Case Studies

10. In asserting that there may be potential for serious risks from cervical spine manipulation Wand et al. rely on two sources of evidence, "numerous case studies" and three case-control studies. The fundamental problem with respect to their reliance on case-control studies is that the only one to compare associations between VAD and stroke for both chiropractors and family physicians, by Cassidy et al. and the most comprehensive in covering 109 million person years at risk, reports exactly the same association. As already discussed, the key factor appears to be that these patients have neck pain suggesting a stroke in progress, not which type of health professional they consult and what treatment they receive.

Turning now to consider the case studies, even if they are well documented, they represent no scientific evidence of causation at all. As Cassidy et al. observe they simply raise hypotheses which must be tested in properly designed studies. And the case studies, and series of them presented in surveys, are generally poorly documented. Here is a prominent example.

In 2000 a Canadian Stroke Consortium of neurologists led by Dr John Norris, Professor of Neurology, University of Toronto, produced a much-publicized SPONTADS study that was quoted by him and others in the media internationally as demonstrating established risks of CAD and VBS from neck manipulation. This study comprised a retrospective questionnaire completed by neurologists who were asked to record cases of VBS where they understood there had been recent chiropractic manipulation. Under cross-examination at a subsequent inquest Dr Norris acknowledged that his study had not in fact produced a single case documenting stroke caused by manipulation and that his comments in the media were wrong.¹⁷

At the same inquest Dr David Sackett, founding chair of the Clinic in Epidemiology at Oxford University in the UK and known as one of the fathers of evidence-based medicine, rejected the SPONTADS study as a weakly-designed, retrospective case series that was of no scientific value whatsoever on the subject of manipulation and stroke. Dr Norris had been "scientifically irresponsible" in making any claims on causation based on this study.¹⁸

The one reference Wand et al. provide with respect to case studies is a review by Ernst. That is unfortunate for the persuasiveness of their argument. Dr Edzard Ernst, formerly a Professor of Complementary Medicine at Exeter University in the UK, is a long-term advocate of the dangers of cervical spine manipulation – specifically manipulation as performed by chiropractors but not others. Problems with Ernst's publications in this field have been carefully analyzed in a recent article by Joseph Morley DC, PhD, Assistant Professor, University of Bridgeport College of Chiropractic, Connecticut, USA and Neils Grunnet-Nilsson DC, MD, PhD, Emeritus Professor, Faculty of Health Sciences, University of Southern Denmark and colleagues published in the Journal of the American Chiropractic Association.¹⁹ Problems include using cases where the patient's medical/chiropractic records have almost never been obtained for verification of rather important matters

- Date and time of onset of symptoms.
- Type of manual treatment, if any, given.
- Whether the treating practitioner was a duly qualified chiropractor. It has been well-documented and is generally acknowledged, including by Wand et al., that various of these rare incidents attributed to chiropractic treatment in fact involved other practitioners.

Morley, Grunnet-Nilsson et al., charge Ernst with bias and research misconduct on an analysis of his published research,

Table 2 Near-Miss Cases

Case 1 A 40-year-old man had experienced neck pain with some diffuse dizziness, nausea and a stiff, painful neck. A CT scan of the head, ordered by his medical doctor, showed no positive findings. The man kept on working but the stiffness of the neck remained. Two weeks after the onset of symptoms and 20 minutes before his first appointment with the chiropractor, he died from a massive stroke while still at work.¹

Case 2 A chiropractor worked for a couple of weeks as a locum in a busy practice. Because he was unused to the patients and the clinic procedures, he was running late. Patients waited in cubicles to be called in for treatment. As the chiropractor was treating a patient, he heard a loud thump on the cubicle wall. It was a middle-aged man who was the patient next in line for treatment. He had died from a stroke.¹

Case 3 A 44-year-old male first developed problems while bowling during a cricket match. As the left neck and shoulder pain persisted, he saw a chiropractor, who manipulated his neck using rotational manipulation, with some apparent benefit. About five days later, he suddenly developed vertigo that lasted for about four days before resolving spontaneously. The vertigo recurred the following day, became more severe, and was associated with double vision, tinnitus, left orbital headache, vomiting and weakness of the left arm. He returned to the chiropractor, who immediately referred him to the local hospital. The patient died before investigations could be completed. This was 15 days after the neck manipulation and 18 days since the game of cricket. Post mortem examination revealed cystic mucoid degeneration (medial cystic necrosis), which is an accepted predisposing cause of arterial dissection.²

1 Leboeuf-Yde C, Rasmussen LR et al. (1996) The Risk of Over-reporting Spinal Manipulative Therapy-Induced Injuries: A Description of Some Cases that Failed to Burden the Statistics, J Manipulative Physiol Ther 19:36-38.

2 Johnson CP, Lawler W, Burns J. Use Of Histomorphometry In The Assessment Of Fatal Vertebral Artery Dissection. J Clin Pathol 1993; 46:1000-3. for traits that include frequent misuse of references, omission of highly relevant studies, altering critical text by omitting parts of quotations, inappropriate research methodology and publication of a fabricated datum. Ernst, the one reference given by Wand et al. on case studies, is not an authority to be relied upon to influence scientific opinion. And apart from that, these are only case studies, unable to prove causation and risk.

11. To underline the difference between association in time on one hand, and causation on the other, near-miss cases are most instructive. We have already quoted one. See others in Table 2.

E. Related Issues

- 12. **Best Evidence.** The best evidence supporting manipulation as an appropriate treatment for patients with mechanical neck pain, whiplash and related headache is the report of the BJD Neck Pain Task Force already referred to, specifically the best evidence synthesis by Hurwitz, Carragee et al. Important high-quality, randomized controlled trials since that report are:
- For acute and subacute neck pain, a trial by Bronfort, Evans et al. reporting manipulation to be more effective than management with NSAIDS or paracetamol. ²⁰ This trial, which included subjects treated with exercises, also found exercises superior to medication. It builds on earlier evidence suggesting that patients should receive a combination of manipulative therapy and exercises mechanical treatments for a mechanical problem.
- For cervicogenic headache, a trial by Haas, Spegman et al. which reports a clinically significant benefit of chiropractic manipulation over the placebo intervention of light massage for patients with consistent, moderately severe, disabling headaches, both during the eight week treatment phase and after a further 16 weeks follow up.²¹
- 13. Science and Law and Informed Consent. Whatever the science may say, legal risk remains. There may be no scientific proof that manipulation or mobilisation can cause CAD and VBS but, especially where first symptoms of VBS occur exactly following manipulative treatment, a specific judge or jury may decide there is causation faced with competing expert testimony and an injured plaintiff.

It is known that VBS may be associated with cervical manipulation in rare patients with underlying disorders currently incapable of diagnosis. In terms of patient rights, ethics and the law of informed consent in many jurisdictions that means that practitioners using manual methods of treatment have a duty to disclose the risk. Failure to obtain informed consent is likely to lead to a finding of negligence and liability for damages in the event a patient experiencing VBS contemporaneous with chiropractic treatment. With appropriate consent, however, liability for negligence is most unlikely.

- 14. Addressing the Subject in the Media. Key points are:
- i. Sympathy first. If you are asked to discuss the safety of cervical spine manipulation in circumstances where, whatever the actual cause may be, a person has experienced significant harm, it is obviously important to express sympathy for the patient. There is a personal tragedy involved for the person and his/her family. Ultimately that is more important to most people than any professional issue.

- ii. Appropriateness is the Issue. At the outset, establish that the issue for any healthcare intervention is appropriateness, and that this involves consideration of two balancing factors - effectiveness and safety, or risk/benefit ratio. Anyone who wants to talk about risk only is demonstrating that he or she is biased or doesn't understand the issues. Stay with the issue of appropriateness until the persons you are talking to acknowledge, or at least give you ample opportunity to explain, that any discussion of the merits of neck manipulation is meaningless unless you are looking at both benefits and risks - at what is technically called appropriateness. Challenge a critic with the question "Did you know that several reviews of the scientific literature from leading authorities have agreed that neck manipulation is safe, effective and appropriate for patients with a number of very common complaints – for example common forms of neck pain and headache?
- iii. Case Reports Cannot Prove Causation. If, as is likely, you are presented with one or more case reports as evidence ask a critic if (s)he accepts as a matter of scientific fact that case reports cannot prove causation. Quote Dr David Sackett, the father of evidence-based medicine. Illustrate the point with one of the near-miss case examples given in this report.
- iv. Focus on Chiropractic Responsibility not Medical Risk. Although it is true that medical and surgical treatments for the patients in question involve considerably more risk of harm it is not productive to dwell on this. To most people it seems defensive, beside the point, and escaping the issue. Focus on how well these concerns are understood in chiropractic education, research and practice, and what is done in practice to minimize any risk of harm.
- v. *Make the Remoteness of the Risk Real*. VBS following manipulation or mobilisation is extremely rare at about 1 in

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1 million treatments – a risk rate of .0001%. How can that be better illustrated? To adapt an example from Terrett, this represents one incident every 20 years in a group of 25 chiropractors maintaining average practices. In other words most chiropractors never experience a single case of VBS in their careers. In the medical malpractice world a risk rate of one in 1 million is not even regarded as a legal risk, or worthy of mention.

In many situations the wisest advice is to avoid media debate. The media are interested in generating conflict and emotion, not considered discussion, and you have no guarantees of fairness or reasonable control of the situation. The BMJ debate, the impetus for this issue of the *Report*, is a refreshing exception. It is a shining example of a planned and fair scientific forum. Our congratulations to the British Medical Journal and its editorial staff.

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