



The Trials of Evidence

Interpreting Research and the Case for Chiropractic

A. Introduction

IF YOU ARE A CLINICIAN AT work in a typical chiropractic practice you see many patients with acute and chronic back pain, neck pain and headaches.

If you are making best efforts to keep up with the ongoing flood of research and evidence-informed clinical guidelines you can feel confident that the scientific evidence now supports your clinical experience that spinal manipulation specifically, and chiropractic management incorporating manual care generally, are very helpful for most patients with these complaints. Therefore for example:

- For the great majority of patients with both acute and chronic low-back pain, namely those without diagnostic red flags, spinal manipulation is recommended by evidence-informed guidelines from many authoritative sources – whether chiropractic (the UK Evidence Report from Bronfort, Haas et al.¹), medical (the 2007 Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society²) or interdisciplinary (the European Back Pain Guidelines³).

- For the great majority of patients with acute and chronic neck pain, and those with cervicogenic headache, spinal manipulation is similarly recommended, most recently and authoritatively by the Bone and Joint Decade Neck Pain Task Force⁴. For headache, including migraine headaches, see evidence reviews and recommendations from the Evidence-Based Practice Center at Duke University⁵ and Bryans Descarreaux et al. in Canada⁶.

2. What are we to make, then, of a new systematic review for the Cochrane Collaboration, looking at chronic back pain and published last month in *Spine*? This is from Rubenstein, van Middel-

koop et al., an experienced research team at the VU University, Amsterdam which includes noted epidemiologist Dr. Maurits van Tulder, so will attract attention. It concludes that the evidence suggests “there is no clinically relevant difference between spinal manipulative therapy (SMT) and other interventions for reducing pain and improving function in patients with chronic low-back pain”⁷.

What is going on? What is the explanation for such glaring inconsistency? What is a clinician to do? This issue of *The Chiropractic Report* addresses these questions, and discusses:

a) The dispute that exists between researchers concerning two different methods of evaluating research evidence – the Cochrane back pain review method and the best evidence synthesis method. These two methods can, as in the present case, lead to very different conclusions.

b) What can fairly and appropriately be said about the superior effectiveness of skilled manipulation/mobilization for patients with chronic back pain? Even this new Cochrane Review acknowledges better short term results for SMT than any alternative treatment in terms of reduced pain and improved function.

c) Why chiropractic management is and must be much more than skilled manual treatments.

d) The best case to support chiropractic management of patients with both acute and chronic spinal pain and disability – as also for patients with other conditions or seeking preventive/maintenance care. There is a convincing case for chiropractic care but it is not one of markedly superior effectiveness. The evidence does not support that. What it does support, however, is that chiropractic care is:

- At least as effective as any other alter-

Professional Notes

New Primary Care Musculoskeletal Specialists

The times are definitely changing. In May the British Medical Journal published a well-argued short review suggesting that primary care for patients with back pain and other musculoskeletal problems should be transferred from general medical practitioners (GPs) to chiropractors, osteopaths and physiotherapists.

Authors of the review are prominent figures from general medical practice and physiotherapy in the UK, Dr. Peter Croft, Professor of General Practice Epidemiology and Dr. Nadine Foster, Professor of Musculoskeletal Health in Primary Care at the Arthritis Research UK Primary Care Centre, Keele University, and from the chiropractic profession in Denmark, Dr. Jan Hartvigsen, Director of Research for Clinical Biomechanics, Institute for Sports Science and Clinical Biomechanics, Odense, Denmark.

The authors observe that back pain contributes substantially to workload and healthcare costs in primary care

continued on page 4

native treatment approach, better than most with which it has been compared.

- Safer.
- More cost-effective.
- Produces much higher patient satisfaction rates.
- In a number of countries, is more readily accessible than other options.

B. Systematic Reviews

3. Case reports and retrospective reviews of past cases offer valuable ideas for research, but to reach conclusions on the effectiveness of a treatment for a given population of patients one must move to these higher levels of evidence:

a) **Prospective case series.** Patients are managed, and results measured, according to a research protocol planned in advance. With good design and experienced researchers sound evidence can be obtained. A good example of this level of research in the field of chronic low-back pain is the work of Kirkaldy-Willis and Cassidy in Canada.⁸ This reported the effectiveness of 2-3 weeks of daily chiropractic spinal manipulation for patients who had been disabled by mechanical low-back pain for an average period of over 7 years but were now able to return to normal activities of daily living.

b) **Randomized controlled trial (RCT).** This provides superior evidence of effectiveness. A significant advantage of an RCT over a case series is that the treatment being tested for effectiveness can be compared with no treatment and/or a sham/placebo treatment and/or another treatment. Patients are randomly assigned to different groups. The trial can test the effectiveness of one component of care (e.g. spinal manipulation or an exercise protocol) or overall management more representative of daily practice.

An example of the latter is the British Medical Research Council Trial of acute and chronic back pain patients by Meade et al.⁹ in which patients were randomly assigned to either chiropractic care or hospital out-patient care. All chiropractic patients received spinal manipulation and as a group did significantly better in terms of reduced pain and disability than those in the hospital out-patient group.

c) **Systematic reviews.** Most treatments are not in fact supported by one or more RCTs. For them best evidence

must still be found in case series and clinical experience. Where there are RCTs for a treatment the quality varies enormously, and there are often conflicting results from different trials. As the volume of research built in the 1980s and 1990s so did the research method of systematic reviews. At first this was known as meta-analysis of research results. Results of different studies were pooled together to present a conclusion from all the relevant research. Efforts were made by individual researchers to measure for quality as well as quantity, but rules had not been developed.

The advent of the Cochrane Collaboration in 1993, a large international network of volunteer researchers presenting the research evidence online for all, led to much development and much greater sophistication of systematic review methods. At first the approaches developed for Cochrane reviews, and appearing in the online Cochrane Handbook for Systematic Reviews, was largely unchallenged. In recent years there has been growing criticism, and there are now many proponents of an alternative approach called best-evidence synthesis.

Cochrane Review Method. The fundamental concept is that the quality of individual studies/RCTs is scored according to a check list of items or criteria. For back pain reviews, for example, there is a check list of 11 items as in Table 1. No one challenges that these criteria are important. The problem is that trials are scored and rated on technical criteria alone. This appeals more to epidemiologists than clinician researchers. It has led to the frequent conclusion in Cochrane reviews that all the evidence is inconclusive – and that more evidence is necessary before clinical recommendations can be made.

Best-evidence Synthesis Method. This is just as rigorous scientifically, but does not use a scoring method or scale. It focuses on whether any design weaknesses in a trial actually led to bias in selection of patients/subjects or the information reported, or in other ways made results unreliable. This was the method of systematic review used by the Bone and Joint Decade Neck Pain Task Force in its widely praised report. The method was chosen as being more likely to lead to clinically relevant conclusions and, in the words of the Task

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Force, was considered “one of our key methodological strengths”.

The practical importance of this is seen in a 2007 study by van der Velde, van Tulder et al.¹⁰ which compares these two methods of systematic review in assessing the studies on whether or not exercise is an effective management strategy for workers with neck pain. It is noted:

- a) Twelve relevant trials were found in a comprehensive literature search.
- b) When scored for quality according to the Cochrane Back Review Group Guidelines, with the 12 trials then all considered at their various levels of quality or strength, “no treatment recommendation could be formulated”.
- c) When assessed by best-evidence synthesis a clear treatment recommendation was possible. Four of the 12 trials were accepted as scientifically sound and with low risk of bias. Synthesis or combination of the results of these 4 tri-

Table 1 Cochrane Back Review Group Guidelines Internal Validity Scale

Question	Response
Was a method used for generating a random allocation sequence?	Yes/No/Unclear
Was the treatment allocation concealed?	Yes/No/Unclear
Was the care provider blinded to the intervention?	Yes/No/Unclear
Were co-interventions avoided or comparable?	Yes/No/Unclear
Was the compliance acceptable in all groups?	Yes/No/Unclear
Was the patient blinded to the intervention?	Yes/No/Unclear
Was the outcome assessor blinded to the intervention?	Yes/No/Unclear
Were outcome measures relevant?	Yes/No/Unclear
Was the withdrawal/dropout rate described and acceptable?	Yes/No/Unclear
Was the timing of the outcome assessment in both groups comparable?	Yes/No/Unclear
Did the analysis include an intention-to-treat analysis?	Yes/No/Unclear

Scoring: Yes = 1; no/unclear = 0; total internal validity score = 11.

als, without the confounding influence of the other 8 weaker trials, supported the recommendation that “workers should be activated with exercise given its beneficial effect on patient-perceived recovery”.

4. New Cochrane Review. The new systematic review by Rubenstein et al. relates to the effectiveness of “spinal manipulative therapy (SMT)” for chronic back pain (more than 12 weeks). SMT is defined as “any hands-on treatment, including both manipulation and mobilization of the spine”. As the authors themselves note “there are likely to be objections” to this leveling of the field – putting all SMT by all practitioners regardless of professional training and skill and for all chronic back pain patients into the same pool and then judging effectiveness.

Here are two illustrations of the problems with that. In the Meade et al. trial already mentioned all patients in the chiropractic treatment group received chiropractic manipulation, and did significantly better than patients in the hospital outpatient group – 84% of whom received physiotherapy manipulation and/or mobilization techniques according to Cyriax and Maitland. In this Cochrane review such distinctions are gone.

In a study by Khan, Cook et al.¹¹ patients with chronic neck pain from road traffic whiplash injuries who were referred for chiropractic manipulation from a UK hospital orthopedic department were classified in three sub groups – Group 1 with restricted range of neck movement but no neurological deficit, Group 2 with restricted movement but also neurological signs and/or symptoms, and Group 3 with no restricted neck movement or neurological signs or symptoms but disabling neck pain – indicating psychosocial factors.

There was significant improvement in patients in Groups 1 and 2 – patients with objective signs including restricted ROM – but not those in Group 3. Sorting out those with and without physical signs is clearly important. Most trials have made no such distinctions and submitted all chronic pain patients to the treatment being tested. To be fair to Rubenstein et al. they acknowledge this concern. They comment that “identifying subgroups seems important”, and that some studies do suggest that “clinically important effects are observed when treatment is matched to the patient’s signs and symptoms rather than provided to all patients with low-back pain”. However their review does not allow for that.

5. With respect to other features and conclusions of the review:

a) Only randomized studies/trials (published up to June 2009) were included, which is quite normal in a systematic review but excludes a significant part of the evidence used in evidence-based care – including case series, clinical experience, and patient preferences.

b) Over 30 RCTs were excluded, and their results therefore not considered, for what was seen as fatal design flaws, such as patients had either acute or chronic back pain and the number with chronic pain was unclear or under 50%; the contribution of SMT to treatment effect could not be discerned; and a high drop out rate at first assessment of treatment. This excluded many of the trials of chiropractic treatment from experienced and highly regarded researchers such as Meade et al.⁹, Triano, McGregor et al.¹², Bronfort¹³, Haas, Group et al.¹⁴ and Muller and Giles¹⁵.

c) This degree of scientific rigor meant that only 26 RCTs survived for inclusion in the review, with only 9 of these scored as having low risk of bias. These 26 were further subdivided into SMT vs. sham SMT (3), SMT vs. other treatment interventions (15), and SMT plus another intervention vs. the other intervention alone (5). This meant, for example, that conclusions on the effectiveness of SMT against sham SMT were made on the basis of 3 studies “all with a high RoB (risk of bias)”. Such conclusions must be regarded as extremely tentative and unreliable.

d) With respect to conclusions on the effectiveness of SMT vs. other interventions (e.g. exercises, education, psychosocial interventions):

- For pain, Rubenstein et al. report “there is high-quality evidence that SMT provides statistically significantly better pain relief than other interventions at 1 and 6 months” but also high-quality evidence against that at 12 months.
- For functional status, “there is high-quality evidence that SMT provides statistically significantly better functional improvement at 1 month than the other interventions”, but not at 6 and 12 months.
- For recovery as perceived by patients, there is moderate-quality evidence “that SMT provides a significantly better chance of recovery than the contrast interventions” at 1 month, but low-quality evidence that that difference is lost at 6 and 12 months.

e) Similarly, when SMT is added to another treatment intervention there is evidence that it has a statistically significant short-term effect on pain relief and functional status. However the size of all beneficial effects mentioned is assessed as small and, as mentioned at the beginning of this article, not clinically relevant.

f) SMT is reported as safe – in all the studies considered “no serious complications were observed”.

g) Rubenstein et al. conclude that the decision to use or refer patients for SMT, which is as good as but not markedly better than other treatments, should be based on costs, preferences of the patient and providers, and relative safety. Implications for research are that subgroups suitable for SMT should be identified, SMT should be evaluated as an additional or adjunct therapy in a multimodal package, and there is a need for cost-effectiveness studies. SMT may be more cost-effective

continued on page 6

The Chiropractic World

New Primary Care Musculoskeletal Specialists

continued from page 1

but is not well managed by GPs. They receive little training in common musculoskeletal problems. Surveys indicate they feel ill-equipped in examining and treating patients with back pain, having to rely on pharmacological management or referring patients to those with special qualifications. The authors note:

- When GPs manage conditions such as angina or diabetes they have toolboxes of diagnostic and practical management skills acquired in training that allow them to provide interventions that make a difference. This is not so with back pain.
- Data from the UK, elsewhere in Europe and the US demonstrate that patients are now comfortable with choosing chiropractors, osteopaths and physical therapists as points of entry into the healthcare system. "The main interests of such professional groups are in musculoskeletal health and back pain, and they drive much research and professional development in these disciplines".
- Non-medical professionals are well accepted as primary care providers of oral and dental health, visual health and many aspects of mental health. Why not musculoskeletal health? (Hartvigsen J, Foster NE, Croft PR (2011) *Views and Reviews: We Need to Rethink Front Line Care for Back Pain* BMJ:342:d3260 doi:10.1136/bmj.d3260.

Other Research Notes

1. Infantile colic – Europe. Trials of chiropractic management of infants with colic/irritable baby syndrome have produced conflicting results. One criticism of good results has been that these are reported from observations by caregivers who may be biased because they are aware of whether or not active treatments have been received. In the first of two new pediatric randomized controlled trials presented at the World Federation of Chiropractic's 11th Biennial Congress in Rio de Janeiro in April, Bjelkarøy, Miller et al. from Europe address that issue and reported:

- a) A study population of 102 infants with average age of five weeks was randomized into three groups:
 - A routine treatment group (33) receiving spinal manipulation on an average of four visits.
 - A similar treatment group (34) but with caregivers blinded.
 - An untreated control group (34) with caregivers blinded.
- b) The validated, gold-standard, 24-hour crying diary was used to detect results. There was statistically significantly greater improvement in the first two groups (reduction of 70.2% in daily crying from 4.6 hours to 1.4 hours, and 54% from 5.1. hours to 2.3 hours respectively) compared with the untreated control group (9.4% reduction from 5.7 hours to 5.1 hours).
- c) Bjelkarøy, Miller et al. conclude that "chiropractic manual therapy was found to be beneficial in the treatment of infant colic regardless of the caregivers knowledge of actual treatment". (Bjelkarøy MT, Miller J et al. (2011) *Chiropractic Manual Therapy*

for Infant Colic: A Double-Blinded Placebo-Controlled Randomized Trial Proceedings of WFC's 11th Biennial Congress, 101-102. Abstract)

2. Neuro-Emotional Technique (NET) for AD/HD – Australia.

This is the second pediatric RCT from the WFC Congress. In a well-designed trial Karpouzis, Bonello et al. reported:

- a) The objective of this study was to determine whether the addition of the emotional component of NET therapy to existing treatment protocols of psychosocial treatment and/or pharmacological treatments for pediatric AD/HD could improve clinical outcomes (i.e. reduce inattention, hyperactivity and impulsivity).
- b) Subjects were 121 children aged 5-12 years randomized into three groups – Group A receiving a sham NET protocol, Group B receiving a NET protocol, and Group C which was the control group just maintaining current treatments.
- c) Only the NET therapy group achieved the chosen measure of minimal clinically important difference (MCID) after 14 interventions over 7 months – significant changes in five or more sub-scale points on the Conners ADHD Index.

(Karpouzis F, Bonello R et al. (2011) *Final Data of the Effects of the Neuro-Emotional Technique for Pediatric Attention – Deficit/Hyperactivity Disorder: A Randomized Controlled Trial* Proceedings of WFC's Congress 112. Abstract.

3. Subclinical Neck Pain and Neuroplastic Change – New Zealand.

Heidi Haavik, PhD, BSc (Chiro), Director of Research, New Zealand College of Chiropractic and Bernadette Murphy, PhD, DC, formerly of New Zealand but now back in Canada, have authored an impressive line of papers on neuroplastic changes and whether manipulating dysfunctional spinal segments can alter central neural function. In their latest paper recently published in JMPT:

- a) They observe that Knox and Hodges, Australian PTs, have demonstrated that changes in head and neck position in individuals without any history of neck pain or injury led to impaired proprioception in the upper limb – in the form of reduced accuracy of elbow joint position sense (JPS).
- b) Accordingly they designed this study to investigate whether JPS accuracy differs between individuals with subclinical neck pain (SCNP) and those with no history of any neck symptoms or injury, and to determine whether manipulating dysfunctional cervical segments in the SCNP group can improve the accuracy of their elbow JPS.
- c) In a population of 25 SCNP participants and 18 control participants JPS accuracy improved significantly for those in the SCNP group after cervical adjustment, but not in the control group.
- d) These results suggest that asymptomatic people with a history of SCNP have maladaptive neuroplastic changes to CNS function which cause altered proprioception and reduced elbow JPS accuracy. Furthermore, correcting cervical dysfunction in those with SCNP can improve their proprioception and upper limb JPS accuracy.

(Haavik H, Murphy B (2011) *Subclinical Neck Pain and the Effects of Cervical Manipulation on Elbow Joint Position Sense* J Manipulative Physiol Ther (34)2:88-97.)

Prosecutions in South Korea – Appeal for Support and Donations

Source: World Federation of Chiropractic

This is a special report on the prosecution of chiropractors in South Korea, and a request that all chiropractors and chiropractic organizations donate funds as you are able to the Korean Chiropractic Association (KCA), the World Federation of Chiropractic's (WFC) member association in South Korea.

Background. In South Korea chiropractors, and other health professionals not recognized by law such as acupuncturists, face two major opponents. The first is the Korean Medical Association (KMA) representing the medical profession. However a powerful second group is the Oriental Medical Doctors' Association (OMDA), representing a large and powerful group of regulated OMDs who provide chuna (manipulation techniques – taught with translated versions of chiropractic text books) and herbal remedies and acupuncture.

The KMA and the OMDA have been reporting chiropractors to the police, leading to multiple prosecutions against chiropractors since the first Korean chiropractor Dr. Yong Serb Song returned from Palmer College in the early 1990s. Dr. Song, the first President and founder of the KCA, was convicted three times before he passed away in 2001. His son and daughter, Dr. Joonn-Han (Steven) Song and Dr. Su-Hie (Katrina) Song, are also Palmer graduates and have also faced prosecutions.

Over the years many chiropractors, most prominently anyone brave enough to become KCA President, have faced prosecutions and convictions. Several have had second and third convictions and not only large fines but suspended prison sentences, forcing them to leave their homes and country for new lives in Australia, Malaysia, Singapore, the USA and elsewhere.

Some convicted chiropractors, including Dr. Katrina Song, have appealed to the Constitutional Court. Their argument has been that Koreans have a constitutional right to choose and receive natural forms of healthcare that relieve pain and suffering, and chiropractors have a constitutional right to offer their services. The current medical law is too wide and unconstitutional in restricting those rights.

In early cases the panel of nine judges all supported the medical law. When Dr. Katrina Song appealed in 2001 two of nine judges found in her favour, and all said that the government should be reviewing the situation. However facing the threat of a one year suspended term of imprisonment Dr. Song had to abandon chiropractic practice.

Each year the Constitutional Court has become more supportive as brave KCA leaders and others have continued in practice, faced prosecution and conviction, and then appealed. A majority of six of nine judges is required for success. Acupuncturists have also continued fighting appeals. In an acupuncture appeal last July the Constitutional Court had five of nine judges ruling the medical law was unconstitutional – one short of victory.

Current Situation. The current President of the KCA is Dr. Taeg Su Choi, a 1998 graduate of Life Chiropractic College who practices in Changwon City in South Korea. He has been KCA Presi-

dent since December 2003 and has been an inspirational leader. Working with Congressman Kim he arranged KCA/WFC symposia at the Korean National Assembly in Seoul in 2005, 2006 and 2007. He has written policy documents on chiropractic for legislators and an impressive book on chiropractic for the general public titled *No Surgery, No Drugs, Chiropractic Medicine*.

Dr. Choi has faced five prosecutions since 2004 – in other words since becoming KCA President. The most recent began on a complaint from the OMDA. He was convicted and fined \$3,000. On legal advice he appealed to both the Constitutional Court and within the general court system. In the general court appeal he received probation.

Dr. Choi has now launched a further appeal in the general court system and is waiting for hearings there and in the Constitutional Court.

These important appeals are naturally supported and made on behalf of the KCA. The legal team of three lawyers is led by Taewon Park, a leading lawyer in the field who has won many cases relative to massage therapy and acupuncture. He was involved in the acupuncture appeal before the constitutional court last year.

Another current conviction and appeal relates to Dr. Junyong Ahn, a 2006 Palmer College graduate who has practiced in the capital Seoul for the past 5 years. In the Lower Court he was convicted and fined US\$5,000. His case is now on appeal before the Supreme Court.

“Last month four more chiropractic clinics were investigated by local health officers and one new prosecution has begun,” reports Dr. Taeg Su Choi. “This is from complaints from the KMA and OMDA which continue to try to get rid of the chiropractic profession in South Korea.”

The KCA, which once had approximately 60 members, is currently reduced to 17 members because of the hostile environment to chiropractic practice in Korea. Most of these 17 already have at least one conviction. The WFC, which will itself be making a donation, asks you to be generous in supporting the KCA at this pivotal time for the survival and success of the chiropractic profession in South Korea.

Please support the KCA with your donation at www.chiro.or.kr/index_eng.html



KCA President, Dr. Taeg Su Choi at his local police station during the current prosecution.

“because the therapy is typically provided in a limited number of treatment sessions”, more limited than for example exercise therapy or behavioral treatments – but more studies are required on this.

C. Chronic Pain – The Case for Chiropractic

5. Effectiveness. Rubenstein et al. report that SMT has a significantly better effect on pain and function and a patient's self-assessment of recovery than all other treatments during the first month of follow-up after treatment, but not at 12 months. That should surprise no-one, says Dr. Scott Haldeman, the US neurologist and research leader who chaired the BJD Task Force on Neck Pain and its Associated Disorders. Chronic or persistent back pain, neck pain and headaches are biopsychosocial problems – they have physical and psychosocial causes. No medical or surgical treatment has long-term effects, observes Haldeman, with the only exception being any intervention that succeeds in causing psychosocial change in the patient leading to altered exercise, life style and coping strategies.¹⁶

What can be said on effectiveness about chiropractic practice for acute and chronic back and neck pain, and cervicogenic headaches including migraine, is:

- a) Chiropractic manipulation is at least as effective as any other treatment, with better results than any treatment with which it has been compared.
- b) With chronic pain it provides patients with a period of relief from pain and disability that represents a window of opportunity for long-term relief.
- c) If chiropractic management is multimodal, including patient education and motivation, prescription and monitoring of exercises, and the use of supportive modalities and therapies such as massage and acupuncture as may be needed in individual cases, and other psychosocial interventions, this can bring long-term relief.

6. Safety. A strong part of the case for chiropractic treatment is safety, avoiding the much more frequent and serious complications of medications and surgery. This publication has reported at length on safety in the past and key points are:

- a) **Diagnosis – Red flags.** One aspect of safety is early and appropriate diagnosis of serious pathology. On one hand there has never been evidence to suggest that there is greater risk of misdiagnosis in chiropractic practice than medical practice. On the other hand chiropractic educational practice is on the basis of an ability and duty to diagnose, which greatly adds to the safety of patients who choose or are referred to chiropractors for management that includes spinal manipulation.
- b) **Spinal manipulation – back pain.** One of the central reasons that national and multi-disciplinary, evidence-based clinical guidelines have recommended spinal manipulation as a first line treatment option is its safety in comparison with use of medications, especially prescription medications. As Rubenstein et al. report, in all the RCTs of SMT they reviewed there was not a single serious adverse event.
- c) **Cervical spine manipulation.** There is a perception by some, fuelled by media campaigns by critics of the chiropractic profession in North America and the UK in recent years, that neck manipulation has significant risk of harm. The evidence is that it does not. Key points and evidence are:

- i. The only area of concern is potential vertebral artery injury leading to vertebrobasilar stroke. This complication associated with neck manipulation is extremely rare, with an accepted risk rate of approximately 1 in 1 million treatments^{17,18}

- ii. Over years of study many expert panels, including those from the RAND Corporation (1996)¹⁹ the Evidence-Based Practice Center at Duke University (2001)⁵ and the Bone and Joint Decade Neck Pain Task Force (2008)⁴ have recommended neck manipulation as appropriate for patients with neck pain and/or headaches after assessing the evidence on risks and benefits.

- iii. The most thorough study investigating the association between chiropractic manipulation and stroke was by Cassidy, Boyle et al. for the BJD Neck Pain Task Force²⁰. Using a large government database in Canada that captured all strokes in Ontario over 8 years to March 2002, representing 109 million person years, they found:

- Only 818 VBA strokes from all causes – 7.5 cases per million person years. In other words this is a very rare form of stroke from any cause.
- The increased risk of stroke amongst those who had seen a chiropractor in the past 7 days was exactly the same as for those who had seen a family physician in that time.
- This suggests that strokes are “associated with” chiropractic or medical visits in time rather than “caused by” such visits. Cassidy, Boyle et al. explain that an estimated 80% of VBA stroke patients have neck pain from artery dissection during the days before their stroke. From that point any neck movement can precipitate the stroke. Where there has already been damage to a vertebral artery and formation of a blood clot “a chiropractic manipulation or even simple range of motion examination by any practitioner could result in a thromboembolic event in a patient with pre-existing vertebral dissection” – in other words release of an embolus and stroke.

- iv. Finally, the forces actually reaching the vertebral artery (VA) during neck manipulation have now been measured in sophisticated biomechanical research at the University of Calgary in Canada. Symons, Leonard and Herzog found that the maximum forces on a vertebral artery from chiropractic manipulation are no greater than those recorded during common diagnostic range of motion tests regularly performed by many health professionals, and provide only “approximately one ninth of the strain” required to produce first mechanical failure in the tissues of the VA.²¹

7. Cost-effectiveness. In the Mercer Report leading US health economists at Mercer Health and Benefits and Harvard University assessed the cost-effectiveness of chiropractic management of patients with neck and back pain. They noted that “low-back and neck pain are extremely common conditions that consume large amounts of healthcare resources” and conclude that “when considering effectiveness and cost together, chiropractic physician care for low-back and neck pain is highly cost-effective, and represents a good value in comparison to medical physician care and to widely accepted cost-effectiveness thresholds”.²²

The question of cost-effectiveness, both from the points of view of the individual patient and third party payors, is complex and no field for amateurs. Many studies by health sciences researchers without expertise in economics are inconsistent because of problems such as poor matching of patients, failure

to include all costs, invalid attribution of costs and inadequate sample size. Relevant costs that must be incorporated are direct costs of care, costs arising from harm from treatments, compensation costs for disability and time of work, and other indirect costs incurred by patients, families and employers.

For a full discussion of cost-effectiveness, and the research evidence including the Mercer Report, see the November 2009 issue of *The Chiropractic Report* available at www.chiropracticreport.com under Past Issues. Some key points include:

a) With chiropractic care the chiropractors' fees represent 80% of total healthcare costs – only 20% is secondary costs from other diagnostic tests and therapy/specialist/in-hospital services. With medical care the situation is reversed. Physicians' fees represent 23% of total healthcare costs – the other 77% is secondary healthcare cost. These were the findings of Canadian health economists Manga and Angus when they reviewed all the international evidence from workers compensation, employer and other data in 1998 relative to back pain.²³ They conclude that there is 20 to 60% total cost saving when a matched group of patients receive chiropractic care rather than medical care for back pain, depending upon jurisdiction and healthcare system.

b) A major issue for third party payors is substitution. Even if chiropractic care is cost-effective for patients with back and neck pain, headaches and other neuromusculoskeletal disorders, will a chiropractic benefit given to patients be an add-on cost similar for example to a dental benefit and most other benefits, and therefore increasing overall costs even though cost-effective in itself, or will chiropractic services given under the benefit truly “substitute” for more expensive medical care? The first large study, on that issue, based on data from 1.7 million members of a managed-care network in California, confirms that virtually all chiropractic services used by plan members were used in direct substitution for medical services. This was for all conditions seen by chiropractors – a range of 654 ICD-9 Codes covering neuromusculoskeletal disorders such as spinal pain, rib disorders, headache, extremity problems and myalgias or arthralgias.²⁴

8. Patient satisfaction. Level of patient satisfaction, always important to patients, is becoming an increasingly important research area and outcome of care for third party payors. There may be debate about the comparative effectiveness and cost-effectiveness of chiropractic care for the prevention and management of various conditions, but no one can dispute the extensive research findings showing that chiropractic patients are generally very satisfied with their care and that patient satisfaction rates are consistently higher than for medical and other forms of care with which comparisons have been made.

High satisfaction rates were confirmed in a 2006 literature review and report of a new US national survey by Gary Gaumer, PhD, an independent health services researcher from the Department of Health Care Administration, Simmons College, Boston.²⁵ Gaumer concludes that “overall satisfaction levels amongst persons using chiropractic is very high” and that “this is remarkable given the fact that much of the financial burden of the care is borne by patients and that the preponderance of care is for the difficult chronic problems of the back and neck”.

Again, a previous issue of this Report available at www.chiropracticreport.com – the January 2007 issue – reviews the evidence and the reasons for patient satisfaction. A 1986 study

by Cherkin and MacCornack comparing satisfaction with chiropractic and medical treatments for patients with low-back pain in 457 patients in a Washington State health maintenance organization (HMO) has always been regarded as a landmark study. It found:

- a) The percentage of chiropractic patients who were “very satisfied” with the care they received for low-back pain was 3 times that of patients of MDs – 66% vs. 22%.
- b) Common reasons for higher satisfaction given by chiropractic patients included more information received about the back problems, including the cause of pain, recovery from pain, content of care and instructions on exercise, posture and lifting; the amount of time the DC spent listening to the patient's description of pain; the DC's belief that the pain was real and expression of concern; and doctor confidence in the diagnosis and effectiveness of the proposed treatment.

The Cherkin and MacCornack study was in an HMO, an environment not well suited to high patient satisfaction rates. Many studies report much higher satisfaction. Recent survey results from the Jordon Hospital Spine Care Program in Massachusetts, led by a chiropractor and with most patients managed by chiropractors (78%) has 95% of patients rating their overall satisfaction with care as “excellent”.²⁶

Research findings are one important way of describing patient satisfaction. Here is another – an explanation of chiropractic management from Meeker and Haldeman, writing for a series on CAM for physicians in the *Annals of Internal Medicine*:²⁷

“The clinical encounter tends toward a high-touch, low-technology health model with more concern for the person than the disease. Chiropractors believe in the inherent healing ability of the body and communicate the hope of healing to patients. Spinal manipulation and other forms of touching care require that a level of trust develop between the patient and the chiropractor. Repeated visits allow a relationship to flourish that is often used to communicate on a social and psychological level as well as about biological implications of care.

One recent essay opined that much of chiropractic's success and perhaps its most important contribution to health care might concern this patient-physician relationship. Analyses from anthropologic and sociologic perspectives have suggested that treatment by a chiropractor, especially for many patients with chronic pain, can generate a sense of understanding and meaning, an experience of comfort, an expectation of change, and a feeling of empowerment. The hands-on and compassionate “can do” clinical behavior of the typical chiropractor seems to be concrete, reassuring, and immediately satisfying. Observational studies and randomized trials leave little doubt that chiropractic patients are very satisfied with their management.”

D. Conclusion

9. From all these facts and numbers and observations, from all the challenges of interpreting evidence on which even the research experts cannot reach agreement, there are perhaps two fundamentally important messages. The first is that there is a strong case for inclusion of chiropractic services in primary healthcare for neuromusculoskeletal problems. With respect to joint adjustment and skilled manual care, this case cannot be based upon much greater effectiveness than other

treatments – it is based upon at least equal effectiveness, safety, cost-effectiveness and patient choice and satisfaction. In a number of countries it is also based on ready availability of services without delay.

The second message is that skilled manual treatments, central as they are and must remain to chiropractic care, are not enough to secure the future success of the profession. Various other interventions have similar effectiveness. Combination of treatments, such as spinal manipulation and exercise for chronic back and neck pain, sometimes brings superior results. Patient preferences and choice need to be accommodated, particularly since preferred treatments are usually more successful.

If doctors of chiropractic are to remain spine care or musculoskeletal specialists in primary care they, themselves and in collaboration with others, must offer what is now described as multi-modal care. This means a range of effective treatments including manual care, rehabilitative exercises, patient education and motivation concerning musculoskeletal pain, counseling on nutrition, exercise and healthy living, provision of orthopedic and orthotic supports, and availability of physical therapy modalities, acupuncture and massage therapy. There must be understanding, management and referral as necessary for psychosocial factors. As Meeker and Haldeman explain in the quote above the chiropractic clinical encounter has always involved much more than joint adjustment or manipulation. This formula for success must be built upon and expanded.



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