



Professional Notes

Vancouver Olympics

Sports chiropractors have served on national teams at the Olympic Games for many years, but the recent Winter Olympic Games in Vancouver was the first Games where they were part of the host medical team for all athletes.

The Canadian Olympic Team had 4 chiropractors on its own medical staff, but besides this the Vancouver Organizing Committee (VANOC), with backing from the IOC Medical Commission, had 24 chiropractors on the host medical team for the Olympics and Paralympics. They served all athletes, working in sports medicine polyclinics in the 2 athletes' villages in Vancouver and Whistler and in treatment facilities at the competition venues.

This impressive achievement was the result of the established high standards and reputation of sports chiropractors who are fellows of the specialty organization for sports chiropractic in Canada, the College of Chiropractic Sports Sciences (CCSS(C)), together with the vision and support of Dr. Jack Taunton, VANOC Chief

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Science and Art in Healthcare

What Claims Of Effectiveness Should Be Made?

A. Introduction

HOW OFTEN WE DISCOVER the pattern in life, both as individuals and communities, that some of our most important advances result from the challenge of adversity – and facing that challenge well.

There have been many examples of this in the history of the chiropractic profession. Now we have one more with the February publication of a major new scientific review titled *Effectiveness of Manual Therapies: The UK Evidence Report¹* by Gert Bronfort, DC, PhD, of Northwestern Health Sciences University in Minnesota and his four co-authors.

This was commissioned and funded by the General Chiropractic Council (GCC), the regulatory body for the profession in the UK, in response to a current media storm concerning what claims chiropractors may legitimately make on their websites and elsewhere with respect to the effectiveness of chiropractic care for various musculoskeletal and non-musculoskeletal disorders.

See more on the origins and current impact of that storm below – but the impact includes disciplinary complaints now filed with the GCC against over 500 chiropractors relative to website claims of the effectiveness of chiropractic treatment.

Published with the new review by Bronfort et al. is a commentary by the US neurologist and leading authority in this field Dr. Scott Haldeman, observing that while it is possible to argue over a few specifics “it is not possible to question the depth and scientific integrity of this work.”² A second commentary, by Dr. Martin Underwood of the University of Warwick Medical School Clinical Trials Unit, one of the principal investigators for the UK BEAM trial

of manipulation and exercise for back pain, applauds the review also.²

So what is the important advance for the chiropractic profession in the face of adversity? It is that the most comprehensive scientific review of the effectiveness of manual treatments:

(a) is by a distinguished team of chiropractic scientists – Dr. Gert Bronfort, Dr. Roni Evans and Dr. Brent Leiniger also of Northwestern University of Health Sciences, Dr. Mitchell Haas of the University of Western States, Portland, Oregon, and Dr. John Triano of the Canadian Memorial Chiropractic College, Toronto and McMaster University, Hamilton, Ontario.

(b) reports that by highest current standards of scientific evidence spinal manipulation/mobilization is effective in adults for:

- Acute, subacute and chronic low-back pain
- Migraine and cervicogenic headache
- Cervicogenic dizziness
- Acute/subacute neck pain
- Several extremity joint conditions

(c) reports that there is inconclusive but favorable evidence for manipulation/mobilization for many other conditions, both musculoskeletal (e.g. ankle sprains, sciatica, coccydynia, TMJ disorders, tension headache) and non-musculoskeletal (e.g. pre-menstrual syndrome, pneumonia in older adults, nocturnal enuresis in children).

(d) reports, however, that spinal manipulation is not more effective than sham manipulation – and therefore not proven effective – for conditions such as asthma and colic/incessant crying in children.

(e) supports the safety and appropriateness of spinal manipulation/mobilization for all these conditions.

Haldeman pinpoints the significance of

this. He explains that not long ago there was “little or no evidence to support the practice of manipulation that is the mainstay of chiropractic practice” and there were “widely advertised claims of serious complications”. There has been rapid growth in the number of clinical trials and “chiropractors are extremely fortunate in these times of evidence-based healthcare”, says Haldeman, because:

- “There is now little dispute amongst knowledgeable scientists that manipulation is of value in the management of back pain, neck pain and headaches that make up 90% or more of all patients who seek chiropractic care”.
- New evidence has demonstrated “that the incidence of serious side effects such as stroke following chiropractic care is extremely rare and is probably not related to manipulation in most patients but due to the fact that patients develop neck pain or headaches as a result of a dissection of a vertebral artery that progresses through the natural history of dissection to stroke irrespective of the clinician the patient consults”.

In summary about 90% of chiropractic practice is supported by scientific evidence at the most rigorous RCT level. We wonder if there is any other profession or medical specialty that can claim scientific support at that level.

2. However there have been a few trials and there is less evidence supporting manipulation/mobilization or chiropractic care for what Bronfort et al. call non-musculoskeletal conditions. This is an area in which chiropractors may have some legitimate claims to make, but have often got into difficulty – as in the UK now – for overclaim. An additional and important way in which the international profession will benefit from the current storm in the UK, and the challenges and cost being faced by the British Chiropractic Association (BCA), the GCC and individual chiropractors, is debate on and a move to a modified and more widely agreed approach to what promotional claims can fairly and professionally be made for the effectiveness of chiropractic care for non-musculoskeletal conditions. There is a world of difference between the claim that a certain treatment can cure or help specific conditions, and the statement that patients with those conditions and contributing spinal dys-

function/subluxation may be relieved or helped by chiropractic care. See more on this below.

This report now looks at what generated the current UK situation, the details of the Bronfort et al. study and finally the major issues that arise. In a world where most treatments given by most healthcare professionals do not have even moderate evidence of effectiveness according to the rigorous levels adopted by Bronfort et al., what treatments should be given and what claims should be made?

B. The UK – Background

3. In 2007-2008 Simon Singh, a prominent science writer and journalist with a grounding in mathematics rather than healthcare, teamed up with the outspoken CAM critic Dr. Edzard Ernst to write a book for the general public titled *Trick or Treatment: Alternative Medicine on Trial*. This claimed to be “the world’s most honest examination of alternative medicine” but was in fact a heavily biased attack on CAM in general and chiropractic in particular.

At a time in 2008 when he was promoting sales of his newly published book Singh wrote in *The Guardian* newspaper: “The British Chiropractic Association claims that their members can help treat children with colic, sleeping and feeding problems, frequent ear infections, asthma and prolonged crying, even though there is not a jot of evidence. This organization is the respectable face of the chiropractic profession and yet it happily promotes bogus treatments”.

Accused of being deliberately dishonest the BCA sued for libel and won in a High Court ruling in May 2009. The judge found that the ordinary meaning of Singh’s words comprised “the plainest allegation of dishonesty”. Singh appealed, the appeal was heard last month, and the parties are awaiting the decision.

This case has generated huge media interest because Singh and his media allies have cast this as an attempt by the BCA to stifle scientific debate by use of the libel laws – and are campaigning for reform of the law. They also discovered that the General Chiropractic Council (GCC) is obliged by its rules to undergo an expensive administrative process for each complaint received. The result has been over 500 complaints against

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individual chiropractors for professional misconduct in making website claims of effectiveness in breach of the standards of the UK Advertising Standards Authority and therefore also the GCC. In the past year complaints rose from 40 to 600. It is in preparation for dealing with those complaints that the GCC commissioned the Bronfort et al. report, now available at its website www.gcc-uk.org.

C. Bronfort Study

4. **Purpose.** The purposes of the study were to summarize the scientific evidence for the effectiveness of manual treatments – each of joint manipulation and mobilization, massage and soft-tissue techniques – for musculoskeletal and non-musculoskeletal conditions, and to give guidance on application of this evidence in clinical practice:

- In making individual healthcare decisions with patients

- In making supportable public claims of effectiveness of treatment

5. Evidence and Grading. Evidence accepted and included was 49 systematic reviews of randomized controlled trials (RCTs), 16 evidence-based clinical guidelines that are “widely accepted” internationally and primarily from the UK and the US, and 46 recent RCTs not yet included in systematic reviews. This represented all RCT evidence through to October 2009.

The authors acknowledge that non-randomized studies (e.g. observational and cohort studies, prospective clinical series and case reports) “can yield important preliminary evidence” of effectiveness, but these were excluded because in strict terms they merely suggest rather than adequately test effectiveness. At the same time Bronfort et al. are concerned to point out that evidence-based healthcare (EBH), and translating scientific evidence to clinical practice, require consideration of a much wider evidence base than RCTs. For most treatments there is not clear RCT evidence of superiority. Even where there is, clinical experience and patient preference are important. Healthcare is not a science – it is a fusion of art and science.

The evidence grading system used, developed by the US Preventive Services Task Force and also used in the 2007 Joint Clinical Practice Guideline on Low-Back Pain from the American College of Physicians and the American Pain Society, produced three overall categories:

(a) High-quality evidence. The evidence is based on at least two consistent higher-quality (low risk of bias) randomized trials. Conclusions drawn are therefore unlikely to be strongly affected by the results of future studies.

(b) Moderate quality evidence. The evidence is sufficient to determine effectiveness, but confidence is limited by one or more factors (e.g. number, size or quality of individual studies; inconsistency of findings across individual studies). As more information becomes available conclusions may well change.

(c) Inconclusive (low-quality) evidence. The available evidence is insufficient to determine effectiveness (e.g. unexplained inconsistency between higher-quality trials; important flaws in study design or methods – only studies available have high risk of bias). Importantly,

in this report a finding was made on whether the inconclusive evidence appeared favorable or non-favorable or simply unclear.

6. Scope of Conditions Reviewed.

RCTs are found for manual treatments for 13 musculoskeletal conditions, 4 types of chronic headache and 9 non-musculoskeletal conditions as set forth in Figure 1. You must go to the full report, available at the websites for the GCC (www.gcc-uk.org) and BioMed Central’s online journal *Chiropractic & Osteopathy* (www.chiroandosteo.com) for full details of the review for each of these conditions, but here are some observations on points of importance.

(a) Key messages. As Underwood explains in his commentary, key messages are that there is now evidence to support the use of manual therapies for a range of primarily musculoskeletal disorders for which it is biologically plausible, but there is not yet sound evidence for their effectiveness for a range of other disorders for which a biologically plausible mechanism for a specific effect remains unclear.

(b) Non-specific low-back pain. This is defined as “soreness, tension and/or stiffness in the lower back region for which it is not possible to identify a specific cause of pain” and commands the largest evidence base. This includes 13 new trials published in 2007 to 2009. One is a trial by Hondras, Long et al. from Palmer College reporting superior effectiveness of both spinal manipulation and lumbar flexion-distraction to minimal medical care for patients with subacute or chronic low-back

pain³. Bronfort et al.’s conclusion is that there is moderate to high evidence of effectiveness of spinal manipulation/mobilization for both acute and chronic low-back pain.

(c) Other spinal conditions. See Figure 2. There is also moderate/good evidence of effectiveness of spinal manipulation/mobilization for acute and chronic neck pain, in the latter case particularly when combined with exercises. (“Positive” is used to indicate evidence in favour of a treatment – elsewhere “negative” is used to indicate that there is evidence, but it supports the finding of ineffectiveness).

Relative to neck pain there is reference to new clinical practice guidelines from the Orthopaedic Section of the American Physical Therapy Association recommending use of “cervical manipulation and mobilization procedures to reduce neck pain based on strong evidence”. This is mentioned here to draw attention to the fact that there is significant inconsistency between the various reviews of the scientific evidence. Bronfort et al.’s review is conservative – here more conservative than the APTA on the value of manipulation/mobilization for neck pain.

The evidence supporting spinal manipulation for sciatica/radiating leg pain, and coccydynia, defined as symptoms of pain in the region of the coccyx, is reported as inconclusive but favorable. With respect to coccydynia the favorable finding is based upon on a recent positive trial from Maigne et al. in France. There is no other manual approach with evidence of effectiveness.

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Figure 1

Musculoskeletal

- Spinal Pain
 - low back
 - thoracic
 - neck
 - coccyx
- Extremity pain
 - shoulder
 - elbow
 - wrist
 - hip
 - knee
 - foot/ankle
- Other
 - temporomandibular disorders
 - fibromyalgia
 - myofascial pain syndrome

Headache

- migraine
- tension type
- cervicogenic
- miscellaneous headache

Non-Musculoskeletal

- asthma
- pneumonia
- vertigo
- infant colic
- hypertension
- enuresis
- dysmenorrhea
- premenstrual syndrome
- otitis media

The Chiropractic World

Vancouver Olympics

continued from page 1

Medical Officer. It was Dr. Taunton who negotiated the inclusion of chiropractors with the IOC Medical Commission.

All chiropractors on the host medical team were fellows of the CCSS(C) and were fully integrated with other healthcare professionals in the collaborative team of health professionals available to all athletes. Manager of Chiropractic Services was Dr. Robert Armitage (right) of Vancouver.



Dr. Gregory Uchacz (left) of Calgary, President, CCSS(C), was one of the 4 chiropractors with the Canadian team. He works throughout the year with Canadian skeleton luge and bobsled athletes and was seen rejoicing on television when Canadian Jon Montgomery captured the Gold medal in skeleton.

Robin McKenzie – Autobiography

The last issue reviewed a new biography of the chiropractic leader Dr. Scott Haldeman. *Against the Tide* (www.spinalpublications.co.nz) is a new autobiography by physiotherapy leader Robin McKenzie of New Zealand. McKenzie is the founder of McKenzie Methods, the biomechanical method of diagnosis and treatment that is now well established internationally and is included in chiropractic undergraduate and postgraduate education programs.

There are some interesting parallels between the barriers faced by McKenzie and the chiropractic profession in advancing their principles and services within spinal care. McKenzie was promoting the value of spinal extension when that was the opposite of orthodox thinking and treatment. The Foreword to McKenzie's book is written by prominent US orthopaedic surgeon Dr. Vert Mooney, since deceased. He praises McKenzie and explains how the history of McKenzie Methods "draws attention to the many and diverse barriers in modern medicine to effective, non-operative musculoskeletal care".

McKenzie acknowledges his former longstanding opposition to chiropractors, but explains how and why that changed in the early 1990s. He has high praise for the leader of his chiropractic seminars division in North America – Dr. Gary Jacob of Los Angeles.

Research Notes

1. Backpacks and the Pediatric Spine. The correlation between back pain and backpack load in schoolchildren is well documented in the literature but now we have the first radiographic study of schoolchildren showing the response of the spine to backpack loads. It uses standing weight bearing MRI studies for 8 children aged between 9 and 13 and showed that typical backpack loads significantly compresses lumbar disc heights and significantly increase lumbar asymmetry – measured by the coronal Cobb angle from the superior endplates of S1 and L1.

The children, healthy and with no history of back pain or scoliosis, underwent sagittal T2 scans of the lumbar spine standing without load, then with a 500g backpack loaded with 4, 8 and finally 12 kgs. These loads represented about 10%, 20% and 30% of bodyweight. Previous studies showed that over 90% of US students carry back packs "typically loaded with 10 to 22% of bodyweight".

All discs from T12-L1 to L5-S1 compressed, but most compression was at L4-5 and L5-S1. These latter discs were significantly compressed with a 4kgs load, whereas other required 8 or 12 kgs for significant compression. Overall the L5-S1 disc was about twice as compressible as the T12-L1 disc. Heavier loads brought significant pain

(Neuschwander TB, Cutrone J, Macias BR et al. *The Effect of Backpack on the Lumbar Spine in Children: A Standing Magnetic Resonance Imaging Study* (2009) *Spine* 35(1):83-88).

2. Herniated Disc, Radiculopathy and a New Approach. In a new study Murphy et al. from the Rhode Island Spine Center report clinical success with challenging patients with persistent back pain and lumbar radiculopathy secondary to confirmed herniated disc. They adopt what they call a diagnosis-based clinical decision rule (DBCDR) summarized as follows:

a. The 3 essential questions of diagnosis are first, are the symptoms with which the patient is presenting reflective of a visceral disorder or serious disease (red flags for referral); second, from where is the patient's pain arising; and third, what has gone wrong with this person as a whole that would cause the pain experienced to develop and persist?

b. On the second question, acknowledging that the precise origins of pain cannot be determined for most patients, the four signs of greatest importance are:

- Centralization signs – detected by end-range loading examinations first developed by McKenzie Methods
- Segmental pain provocation signs, - detected through palpation and pain provocation tests
- Neurodynamic signs – neurodynamic test
- Muscle palpation signs – palpation

Murphy et al. report on 49 consecutive patients with disk herniation confirmed on imaging, pain and disability for an average of 60.5 weeks, then chiropractic management based on the above DPCDR and it is noted:

a. Treatment was individualized but patients were generally seen 2 to 3 times per week for 3 weeks initially. Treatment was one or more of distraction manipulation, neurodynamic techniques, end-range loading manoeuvres, joint manipulation, myofascial techniques and exercise begun "well before pain resolution" and "from the beginning in most cases" to make the "important educational point that movement and activity should be pursued even in the presence of pain".

b. At baseline, end of treatment, and an average of 14.5 months after treatment there were assessments of disability (Bournemouth Disability Questionnaire), pain (Numerical Rating Scale),

News and Views

fear beliefs (Fear Avoidance Beliefs Questionnaire) and self-rated improvement.

c. "Clinically meaningful improvements in pain and disability were seen in 79% and 70% of patients respectively at the end of treatment, and 79% and 73% respectively at the end of long-term follow-up at 14.5 months.

(Murphy DR, Hurwitz EL, McGovern EE *A Nonsurgical Approach to the Management of Patients with Lumbar Radiculopathy Secondary to Herniated Disk: A Prospective Observational Cohort Study with Follow-Up.* (2009) *J Manipulative Physiol Ther* 32 (9):723-733).

The West Hartford Group – www.westhartfordgroup.com

The West Hartford Group (WHG) is a new chiropractic organization in the US describing itself as a think-tank rather than a political or service organization, and with a mission of seeing doctors of chiropractic integrated and serving within the mainstream health delivery system as patient-centered, evidence-based, non-surgical spine specialists.

President is Dr. Michael Schneider (*right*) of Pittsburgh, a 1982 Palmer graduate who holds a PhD in rehabilitation science from the University of Pittsburgh, where he is an Assistant Professor in the School of Health and Rehabilitation Sciences. Vice-President is Dr. Richard Vincent, a widely respected senior member of the profession from Cape Cod who is a former President of the Massachusetts Chiropractic Society. The other members of the Board of Directors include Drs. Christopher Coulis, Alfred Furtado, Gary Ierna, Brian Justice, Brett Kinsler, Donald Murphy and Stephen Perle.



The WHG publishes these values at its website:

- Chiropractors are healthcare providers who provide non-surgical clinical management of spine and other musculoskeletal conditions.
- Chiropractic clinical management includes diagnosis and treatment, with an emphasis on prevention, rehabilitation, wellness and holism.
- Objective measurable treatment effectiveness must be demonstrated.
- A bio-psycho-social (BPS) approach is essential for the management of musculoskeletal pain and dysfunction.
- Treatment must focus on active care that empowers the patient toward management of his/her own healthcare.
- Treatment goals must be functional, and focused on return to normal activities of daily living (ADL) and improved quality of life.
- Treatment must be based upon the best evidence available.

The WHG seeks to promote scholarship, research and practice leading to general adoption of the above values by the profession. For articles by WHG members illustrating these values go to the "Publications" link at the WHG website. Information on

members and membership – which is currently by invitation following application – is at the website.

Dr. Schneider who is widely published, currently has two US federal funding and a NIH research grant for conducting a randomized clinical trial, comparing mechanical and manual manipulation for patients with low-back pain. He states that two key WHG initiatives are 1) to stimulate the chiropractic profession toward acceptance of the non-surgical spine care identity, thereby increasing the numbers of patients seen by chiropractors and 2) to assist chiropractic colleges with preparation of a curriculum for a chiropractic residency in non-surgical spine/orthopedic care.



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Figure 2

Spinal Conditions	Intervention	Evidence		
		Inconclusive	Moderate	High
Acute Low Back Pain	Spinal manipulation/mobilization		Positive	
Chronic Low Back Pain	Spinal manipulation/mobilization			Positive
Chronic Low Back Pain	Massage		Positive	
Chronic Low Back Pain	Foot reflexology added to usual medical care	Non-favorable		
Sciatica/Radiating Leg Pain	Spinal manipulation/mobilization	Favorable		
Coccydynia	Spinal manipulation/mobilization	Favorable		
Mid Back Pain	Spinal manipulation	Favorable		
Acute/subacute Neck Pain	Thoracic spinal manipulation/mobilization		Positive	
Acute Whiplash				
–Associated Disorders	Mobilization with exercise		Positive	
Chronic Neck Pain	Spinal manipulation/mobilization with exercise		Positive	
Neck Pain of any duration	Cervical spinal manipulation/mobilization alone	Favorable		
Chronic Neck Pain	Massage		Positive	

(d) **Headaches.** After back and neck pain the condition most commonly seen in chiropractic practice is headache. It is encouraging therefore to see a report of moderate evidence of effectiveness of spinal manipulation – a higher rating than that achieved for any other manual therapy – for both migraine (defined as recurrent/episodic, moderate or severe headaches which are usually unilateral, aggravated by routine physical activity and are associated with either nausea, vomiting, photophobia or phonophobia) and cervicogenic headache (defined as unilateral or bilateral pain localized to the neck and occipital region which may project to regions on the head and/or face. Head pain is precipitated by neck movement, sustained awkward head positioning, or external pressure over the upper cervical or occipital region on the symptomatic side).

The evidence for spinal manipulation for tension-type headache (defined as a headache that is pressing/tightening in quality, mild/moderate in intensity, bilateral in location and does not worsen with routine physical activity) remains unclear.

(e) **Extremity conditions.** Moderate evidence supporting manipulation/mobilization exists for shoulder-girdle pain/dysfunction, adhesive capsulitis, hip osteoarthritis, knee osteoarthritis, patellofemoral pain syndrome and plantar fasciitis. Evidence is rated inconclusive but favorable for manipulation/mobilization for rotator cuff pain, carpal tunnel syndrome and ankle sprains.

(f) **Non-musculoskeletal conditions.** In this field the review finds little RCT evidence and most frequently rates the evidence as inconclusive. For most individual conditions there is only one RCT with adequate methodology in all the international literature. Rating the evidence under these circumstances leads to some apparently inconsistent results such as:

- Spinal manipulation alone is found to have inconclusive but favorable evidence of effectiveness for Stage 1 hypertension, but moderate evidence of ineffectiveness for the same condition when it is added to diet.
- Osteopathic manipulative therapy (OMT), not isolated from spinal manipulation elsewhere in the review, has inconclusive but favorable evidence of effectiveness for asthma, but spinal manipulation generally has moderate evidence of ineffectiveness.

- For infantile colic two manual therapies used by chiropractors – cranial OMT and massage – are found to have inconclusive but favorable evidence of effectiveness, but spinal manipulation is rated negative on the basis of moderate evidence.

7. Based upon gold standard, RCT evidence Bronfort et al. suggest what public claims can be made and what advice should be given to patients. See Figure 3. Public claims of effectiveness may be made where there is moderate positive evidence, for example for spinal manipulation – and therefore chiropractic care - for cervicogenic and migraine headaches. However, the evidence “does not support any public claims regarding effectiveness” where the evidence is favorable but inconclusive – such as manipulation for ankle sprains, carpal tunnel syndrome and nocturnal enuresis. Further, patients should be advised against a treatment where there is moderate quality negative evidence. This is the rating Bronfort et al. give to infantile colic – the example we now explore.

D. What to do, and say – the example of infantile colic

8. Simon Singh claims that “there is not a jot of evidence” that chiropractors “can help treat children with colic . . . and prolonged crying”. Is this so? What is “evidence”? As the word “evidence” is used in evidence-based healthcare there is a significant amount of evidence supporting the appropriateness and effectiveness of chiropractic management of infants with signs of spinal dysfunction/subluxation and given the medical diagnosis of infantile colic, a poorly defined condition characterized by excessive, uncontrollable crying in otherwise healthy infants. Thus:

- In Denmark in 1989 a prospective, multicentre study of 316 infants with colic, but also having spinal functional disturbances and motoric unrest (253 who did not meet these inclusion criteria were excluded), the infants were given an average of 3 spinal manipulative treatments over 2 weeks. There was a 94% success rate (colic stopped – 60%; significantly improved – 34%) and Klougart Nilsson et al. reported that standard chiropractic treatment seemed to be effective for this population.⁴ Responsibly, they called for a RCT to confirm these results.
- That trial was duly performed by Wiberg, Nordsteen and

Figure 3

Level of Evidence*

High and Moderate quality POSITIVE evidence

INCONCLUSIVE, but favorable evidence

INCONCLUSIVE, and unclear direction of evidence

INCONCLUSIVE, but non-favorable evidence

High and Moderate quality NEGATIVE evidence

Actions Supported

- Supports public favorable claims regarding effectiveness
- Advise patients that this is an effective treatment choice
- Does not support any public claims regarding effectiveness
- Recommend effective alternative if available
- Advise patients that this is a treatment option in the absence of an effective alternative
- Recommend effective alternative if available
- Advise patients that the effectiveness of this treatment option has not been established
- Advise patients that this treatment option is unlikely to be effective
- Recommend effective alternative if available
- Advise patients AGAINST this as a treatment option
- Recommend effective alternative if available

* See definitions for levels of evidence within the methods section.

Nilsson⁵, chiropractic and medical researchers affiliated with the University of Southern Denmark, and published in 1999. Fifty infants diagnosed with colic by National Health Service visiting nurses were randomly allocated to:

- A medical treatment group – where they were given dimethicone daily for 2 weeks in accordance with Danish guidelines for medical practice.
- A chiropractic treatment group – where they were referred to a local chiropractor for physical examination and spinal manipulation where indicated for a 2 week period. Treatment comprised light manipulation/mobilization for an average of 3-4 sessions (range 1 to 6) until normal mobility was found in restricted spinal and pelvic joints.

The main outcome measure was average number of hours of infantile colic behaviour per day as recorded in parental diaries and read by a blinded observer. Infants in the chiropractic treatment group had superior results from Day 2. At Day 12, when final trial results were measured, the medical treatment group had a 38% reduction in colic behaviour (from 3.4 hours daily to 2.4 hours) and the chiropractic treatment group an average reduction of 67% (from 3.9 hours daily to 1.2 hours).

c. Bronfort et al. included the RCT but not the prospective study in their evidence base. They also included another trial of chiropractic management from Mercer and Nook reporting excellent results from South Africa⁶, but gave it no weight because of design weaknesses - it was a small pilot study (n 30) and was only published in abstract form. They rely upon systematic reviews giving greater weight to a third trial by Olafsdottir et al. in Norway.⁷ The Norwegian trial, in which manipulation was compared with no treatment and there was no significant difference in outcome, had the admitted design strength that parents were blinded to whether or not their infants were in the treatment group.

Bronfort et al. acknowledge another recent evidence review by Hawk et al.⁸ that conflicts with their conclusions in finding that chiropractic care, as opposed to manipulation, is effective for infantile colic. This is based upon an alternative “whole systems research” perspective that has gained more prominence in recent years and looks at the therapeutically beneficial effects of the whole “healthcare encounter” or consultation, regardless of the specific medication, surgery, manual

treatments or exercises given. These non-specific or placebo effects are entirely legitimate and are frequently the major source of patient improvement.

d. Wiberg, the principal investigator in the Danish trial, has looked at plausible reasons for the different result in the Danish and Norwegian trials⁹. One possibility is that parents were unblinded and aware of the treatment given in the Danish trial, leading to bias. However there are other possible explanations. First, a different and more standard form of chiropractic treatment was given in the Danish trial. This was a light manipulation with an audible joint release in the majority of infants, whereas in the Norwegian trial there was a “modified finger tip mobilization” in which audible joint releases “were not heard in any of the infants”. Second is the question of dose response – in the Norwegian study there was a maximum number of 3 treatments, whereas in the Danish study there were up to 6 treatments as needed to restore normal joint motion. Bronfort et al. do not analyse these trials, but rely upon systematic reviews by others who did.

9. In evidence-based healthcare (EBH) evidence is not restricted to RCTs. It is acknowledged that healthcare practice is both a science and an art, and that “evidence” properly includes everything from RCTs to other research evidence to clinical observations and experience. Accordingly, in line with this normal usage of the word evidence in healthcare there clearly is evidence suggesting that chiropractic management may be effective for many infants with spinal disturbances and uncontrollable crying who are medically diagnosed as having colic. This gives rise to the question – should the rules of professional conduct and society’s standards restrict professionals from making any claims of potential benefit with respect to a generally safe, commonly used, but as yet unproven treatment protocol – as is the case for colic in both medical and chiropractic practice? Let us review the claims of effectiveness that might be made by chiropractors, from the most outspoken to the more restrained. These are:

- a. Spinal manipulation is proven effective for the cure of infantile colic
- b. Spinal manipulation may be effective in reducing the symptoms of infantile colic
- c. Manual treatments may be effective in reducing the symptoms of infantile colic

- d. Chiropractic care may be effective in reducing the symptoms of infantile colic
- e. Where spinal joint dysfunction/subluxation is found, chiropractic care may be effective in reducing abnormal and incessant crying in infants medically diagnosed as having infantile colic
- f. Chiropractic care has a central focus of assessing and correcting spinal joint dysfunction/subluxation and its biomechanical and physiological effects, and where these are addressed many symptoms may be reduced for example back pain, neck pain, headache, colic, digestive and respiratory symptoms.

Presenting the matter in this way shows that the issue is much more complex than simply a black and white question of whether or not a claim of effectiveness can be made. There are many qualifiers and shades of grey. The fundamental rationale and explanation for chiropractic care is given in para f. above, but in the practical world it is plainly reasonable and necessary to explain to potential patients what symptoms and conditions may respond to care. The enemy is absolute claims as in para a. above, not measured claims as in paras d. to f.

And one must always remember the difference between the effectiveness of a specific treatment technique and the whole clinical encounter. To quote Underwood in his commentary:

- “Any consideration of the effectiveness of manual therapies also needs to recognize that non-specific factors such as the interaction between the (clinician) and the patient may have a therapeutic effect, in addition to any specific effect resulting from the manual treatment itself”.
- “From an academic perspective it is of considerable interest to be able to quantify the specific and non-specific effects of any particular treatment. From a patient perspective, however,

knowing whether an overall package of care, which includes manual therapy, has shown to be effective is probably of greater relevance”.

- Many negative trials of manual therapy are too small to be sure that “an important therapeutic effect has not been overlooked. Thus, it is important when reading this report to remember that absence of evidence of effectiveness is not the same as evidence of absence of effectiveness”.

E. Conclusion

10. The General Chiropractic Council faces a challenging task as it now adjudicates hundreds of complaints filed in such a challenging atmosphere. The British Chiropractic Association is in an equally challenging position as it defends the rights of its members.

In the words of the BCA President, Dr Richard Brown, in the most recent issue of the BCA's Newsletter *Contact*, “the recognition that health and healing are dependant on the judicious application of (both science and art) is essential if we are to continue to help our patients. It is right, therefore, that we resist the interventions of pure scientists to determine our scope of practice just as we should be wary of pure evangelists who proceed regardless of best evidence”.

Chiropractors everywhere should review the claims of effectiveness they make – both to the general public via website or otherwise and to their patients when offering care.

On one hand science and EBM require compelling evidence for unqualified claims of proven effectiveness. On the other hand the art of healthcare and EBM allow that patients and the public should be given appropriately qualified claims of effectiveness – and hope of benefit – where all of the evidence base supports that. **TCR**

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