The Chiropractic Report

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Professional Notes

Pediatric Back and Neck Pain

There is an important clinical trial underway in Denmark that is led by senior chiropractic researchers and will provide the first high-quality evidence on the management of pediatric back and neck pain by chiropractors, with and without manipulation.

The study protocol has just been published online in Chiropractic and Manual Therapies with free access for all.

The trial is a sub-study of the Childhood Health, Activity and Motor Performance School Study (CHAMPS) which collected data from 2008 to 2014 on approximately 1,200 children aged 9-15 in 13 primary schools in the town of Svenborg, considered representative of Danish children. The main purpose of CHAMPS was to evaluate the influence of extra physical education on the frequency of musculoskeletal injuries and on childhood health in general.

The 237 children in the sub-study are those who experienced back or neck pain as reported by parents in response

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Chiropractic for Non-Musculoskeletal Conditions

A Introduction

MOST PATIENTS CONSULT A chiropractor for musculoskeletal pain, commonly spinal pain or referred pain including headache, which is no longer controversial. This core area of practice is well-supported by research evidence on safety and effectiveness and mechanisms of action. There is routine referral of patients by medical doctors and other health care professionals.

However chiropractic management of patients with non-musculoskeletal (non-MSK) conditions, such as respiratory and digestive disorders, infant colic and childhood asthma, is much less understood by other professionals and the public and remains a source of controversy.

Chiropractors carry considerable responsibility for that. A significant number with misplaced enthusiasm have made inappropriate website and other claims of proven ability to cure specific conditions when no such proof exists. In recent years this has led to highly visible media debate in countries such as Australia and the UK.

But for all those whose main focus is the best interests of patients, the controversy generated by irresponsible claims by some chiropractors should not obscure the great potential of skilled joint manipulation, other manual therapies and chiropractic care for many patients with, or medically diagnosed with, non-MSK conditions.

It should not obscure the growing research during the past generation to understand the mechanisms of action of treatment and clinical results. This has involved researchers from all major professions employing manual therapies – including chiropractic, medicine, osteopathy and physiotherapy – increasingly working together. In this issue of The Chiropractic Report we review:

- Potential mechanisms of action, and evidence in support
- The state of the clinical evidence
- The example of asthma to illustrate main issues that arise in this field – such as design issues in controlled trials; specific and non-specific effects of treatment; and diagnosis/misdiagnosis.
- What claims can fairly be made by chiropractors.

2. First though, and to illustrate the area of health care under discussion, here are examples of early case series conducted by research-minded clinicians from various profession in the 1980s and 1990s. These uncontrolled studies have now been superseded by randomized, controlled trials and systematic reviews which are discussed later below.

- Browning, from his US chiropractic practice, reported 10 cases of improved gynecological/bowel function[2]
- The Australian ophthalmologist Gorman, working with chiropractors, reported on 18 cases where visual field loss was restored following spinal manipulation[2]
- In the Czech Republic Lewit, a neurologist and manual medicine specialist, reported relief from chronic recurring tonsillitis in 37 children given manipulation for upper cervical spine dysfunction[3]
- Chiropractic researchers Fitz-Ritson in Canada and Bracher et al. in Brazil, in studies with 112 and 16 patients respectively, reported excellent results from chiropractic management of patients with vertigo secondary to cervical spine dysfunction[4,5]

3. On one hand these studies are preliminary, do not prove causation, and

merely give direction to priority areas for RCTs in due course. On the other hand they demonstrate that many patients with a variety of non-MSK conditions report improvement associated with spinal manipulation and chiropractic care.

B Mechanisms of Action

4. There are a number of scientific hypotheses explaining the biomechanical, neurological and psychological mechanisms of action of joint manipulation, other manual therapies, and the whole clinical encounter in relieving non-MSK conditions and their symptoms. These are summarized below.

All of these now have evidence in support, which is to say that the mechanisms of action exist. However much further research is needed to determine the clinical significance of each.

i. **Biomechanical Effects**. Manipulation and other manual therapies may influence non-MSK conditions by addressing associated biomechanical factors. For example manipulation and mobilization are used in the management of asthma. There is little evidence yet to suggest that manipulation can alter the pathophysiological course of the underlying asthmatic condition, though see the neural processing effects discussed below.

The most likely mechanism by which manual therapies achieve positive clinical outcomes is by addressing associated musculoskeletal factors, such as spinal and/or costovertebral joint dysfunction. This may be a cause of the laboured mechanical ventilation and overuse of secondary muscles of respiration commonly observed with asthmatics.

ii. **Modulation of Neural Processing and Central Sensitization**. Spinal manipulation has direct effects not only on joint biomechanics and musculoskeletal dysfunction but also on mechanosensory afferent information moving from the peripheral nervous system into the spinal cord and brain. Research suggests that the long-term effect of manipulation may be due to a burst of afferent activity generated by the manipulation that causes long-term changes in synaptic efficacy at the spinal cord and/or supraspinal levels[6].

Many mechanisms of modulated neural processing after manual therapy have been or are being studied including:

- Altered sensorimotor integration and motor control – to reach for and grasp objects, to turn towards an auditory stimulus, to maintain postural stability, etc.
- Altered proprioception
- Altered sensory filtering – the ability of the central nervous system (CNS) to moderate sensory processing when there are multiple peripheral inputs as in feedback generated by movement
- Central sensitization (CS) – the heightened signaling of neurons in the CNS, considered to be a maladaptive and amplified response to peripheral, somatosensory afferent input.

CS is a particularly promising mechanism with respect to non-MSK effects of manipulation. It can have an impact on a broad range of sensory pathways, conveying mechanical pressure and chemical, sound, cold, heat, stress and electrical stimuli[7].

CS has been linked to many musculoskeletal conditions (e.g. fibromyalgia, chronic whiplash, low-back pain, osteoarthritis, headache) but an increasing body of literature links CS also to conditions of visceral hypersensitivity. These include, for example, gastrointestinal disorders such as irritable bowel syndrome[8] and functional dyspepsia[9] and non-cardiac chest pain.

Supraspinal centers can magnify or decrease perception of pain, but magnification is a key feature of CS and related syndromes[10]. There is now clear evidence that joint manipulation and mobilization achieve some of their effects by influencing mechanisms of CS, but there needs to be much more research to identify exact mechanisms, their clinical significance, and to answer specific questions such as whether or not manipulation can reverse chronic, supraspinal CS – the situation where what started as strain in the muscles is now chronic strain in the brain.

iii. **Reduction of Nerve Root Compression**. Spinal manipulation may also impact the nervous system by reducing nerve root compression at both dorsal and ventral nerve root sites of the spine. The dorsal root region within the intervertebral foramen is particularly sensitive to the effects of mechanical compression and/or inflammation because of the higher density of sodium channels in the cells of the soma and the initial segment of the dorsal root ganglia (DRG).

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For this reason low to moderate mechanical pressures in the dorsal root region are sufficient to significantly alter nerve function at dorsal roots and DRG sites, more so than at peripheral nerve sites. Pressure as little as 10mm Hg on the dorsal root segment of an afferent nerve has been shown to increase the discharge of all afferent fibers (Groups I-IV) within that neuron, reduce neuronal nutritional transport by up to 30%, increase edema and hemorrhage within the DRG, and enhance the expression of neuroactive chemicals. Sustained compression of 20mm Hg to the dorsal root region leads to full conduction block[11]. Herniated discs typically exceed these pressure thresholds.

In addition to the mechanical compression, exposing the dorsal root to contents of the nucleus pulposus leads to local inflammatory responses and increased blood flow to DRG. Phospholipase (an inflammatory mediator associated with disc herniations) is neu-

rotoxic to Groups I-IV afferents, causing mechanical hypersensitivity in the dorsal root region and increased discharge from the DRG[12].

The experimental literature consistently demonstrates that manipulation improves clinical outcomes in disc herniation, but further research is needed to better understand these mechanisms and how manipulation may exploit them to restore normal function to peripheral tissues, both musculoskeletal and non-musculoskeletal.

iv. **Somatovisceral Mechanisms.** Somatovisceral effects are changes in the viscera following stimulation of somatic tissues, changes that are mediated by the autonomic nervous system. There is now a considerable body of research demonstrating that spinal manipulation produces somatovisceral effects, and addressing the mechanisms involved. However limitations in this research are that many of the studies involve healthy individuals and measure short-term response only, often just the immediate effects of the sensory stimulus of the manipulation itself.

Heart rate variability studies indicate that manipulation can decrease sympathetic drive and increase parasympathetic drive to the heart in individuals experiencing neck and back pain, whereas in asymptomatic individuals manipulation may increase sympathetic drive. Future work is needed to differentiate the short-term stimulus of manipulation itself, which is thought to be a transient increase in sympathetic drive, and the longer-term effects in individuals with underlying spinal dysfunction and/or pain, where manipulation appears to normalize both sympathetic and parasympathetic drive.

v. **Biochemical and Immunological Effects**. There is emerging evidence that manipulation can modify levels of endogenous anti-oxidants and impact immune function, but this potentially important immunomodulatory effect for the management of patients with a broad profile of non-MSK conditions needs much further investigation before its clinical significance is known.

Endogenous anti-oxidants are known to neutralize the effects of reactive oxygen species (e.g., hydrogen peroxide, nitric oxide, and superoxide species) which are thought to be part of the mechanism by which central sensitization (CS) is maintained in the spinal cord. Preliminary evidence suggests that manipulation may affect levels of endogenous anti-oxidants, therefore the maintenance of CS, and therefore the oxidative stress balance and the function of the immune system.

Kolberg et al. recently demonstrated that manipulation twice weekly for 5 weeks for individuals with non-specific, chronic, neck or back pain increased levels of the antioxidant enzymes superoxidedismutase (SOD), catalase and glutathione peroxidase (GPx) in the systemic blood[13]. Their previous work found that catalase activity increased after 6 interventions of manipulation in individuals with neck pain[14].

vi. **Psychological Effects.** The mechanisms of action discussed so far relate to the specific effects of manual therapies, principally spinal joint manipulation and mobilization. All health care encounters also produce non-specific effects – also known as placebo effects. A number of components contribute to these, for example the setting, the treatments, the empathy of the clinician and the expectations and meaning of it all to the patient.

There is growing evidence that placebo effects have complex underlying biological mechanisms which act through similar pathways to medications, and Finness et al. have summarized this body of work on the mechanisms of action of placebo[15]. They group the mechanisms of the placebo response into the two main areas of psychological and neurobiological.

The main and best-supported psychological mechanisms are expectancy (numerous studies have now manipulated patient expectations and demonstrated that if patients expect to have a response to a placebo they will) and conditioning. Expectancy effects have been demonstrated for manual therapy, with patient expectation of effectiveness being associated with better functional and psychological outcomes[15].

Recent research means that much more is now known about the significance of non-specific effects of health care, the mechanisms of action of these effects, and that they are genuine and important phenomena. (For much more on placebo effects see the November 2015 issue of this Report.)

C State of the Evidence on Effectiveness

5. Fortunately there is a recent, authoritative, systematic review of all of the evidence on the clinical effectiveness of manual therapies for patients with non-MSK conditions. This covers the published research from all professions, principally from chiropractic, osteopathy and physiotherapy, and 'manual therapies' includes joint manipulation, joint mobilization and various soft-tissue techniques (e.g. mobilization, static stretching, muscle energy techniques).

This review, published online in 2014 in Chiropractic and Manual Therapies where it is available for free, is from Christine Clar and colleagues[16], public health researchers at Warwick Evidence which is affiliated with the University of Warwick Medical School in Coventry in the UK. Clar et al. undertake systematic reviews of the evidence relative to various health care interventions for the UK National Institute for Health and Care Excellence (NICE) and other policy makers. That is to say they are recognized as independent and expert.

Their review updates a 2010 systematic review by chiropractic researchers Gert Bronfort and colleagues known as the UK Evidence Report. Both reviews report on evidence with respect to musculoskeletal conditions as well as non-MSK ones. For a summary of Clar et al.'s findings on non-MSK conditions see Table 1. Key points are:

a. **Evidence Ratings**. Evidence was rated either high-quality (more than one RCT with low risk of bias and consistent results – allowing a confident positive or negative conclusion); moderate-quality (at least one RCT with low risk of bias, or two consistent but lower-quality RCTs – meaning that evidence was "sufficient to determine the effectiveness" but that one additional low risk of bias RCT could change conclusions); or low-quality (lower-quality or inconsistent RCTs – meaning that the evidence was "inconclusive", which is the word used in Table 1).

b. **High-Quality.** There was no high-quality evidence, as defined, either for or against the effectiveness of spinal manipulation or other manual therapies for any non-MSK condition. (This does not mean there are no individual high-quality/low risk of bias RCTs in this field of research – there are many, one recent one on colic mentioned below, but just

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Pediatric Back and Neck Pain

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to weekly text messages (SMS) and were ruled eligible for the trial. They have been randomly assigned to one of two groups, both of which received care from 5 chiropractors with at least 3 years clinical experience:

Non-Manipulative Group – pragmatic advice (e.g. suitable activities; use of hot and cold packs; taping; ergonomics), exercises (self-strengthening and/or stretching), soft-tissue treatment (trigger point therapy and/or massage) but no assisted stretching because this was considered too close to mobilization.

Manipulative Group – joint manipulation and/or mobilization to the spine and/or extremities "where indicated based on movement restriction and/or pain response during movement palpation".

In both groups frequency and exact content of care were determined pragmatically by the treating chiropractor. Primary outcome measure is the number of recurrences (positive report of pain on the weekly SMS, after at least one pain free week and with pain in the same area) during the 3 to 27 months follow-up period. Secondary outcomes are duration of complaint time; change in pain intensity after 2 weeks; global perceived effect after 2 weeks.

Additional information collected at baseline included expectations of treatment and future course of pain. See the paper for much more of interest, but including these referenced comments:

"Complaints in the musculoskeletal system often start during childhood and adolescence and back and neck pain in children and young people are well-established predictors for similar problems in adulthood".

"It has been shown that back and neck pain in children may progress; both to more locations in the spine, to higher frequency of pain, and to a higher pain intensity"– the reference is to earlier chiropractic research by this same team.

For traumatic injuries in children there are specific treatment strategies, but " for most common non-traumatic musculoskeletal complaints no standardized and evidence-based treatment strategy exists".

(Dissing BD, Hartvigsen J, Wedderkopp N, Hestbaek L (2016) *Conservative care with or without manipulative therapy in the management of back and neck pain in Danish children aged 9-15. Study protocol for a randomized controlled trial* Chiropractic & Manual Therapies 24:5 DOI 10.1186/s12998-916-0086-y)

Acute Neck Pain – Importance of Psychological Factors

Psychological factors are well-studied and known to be important in chronic neck pain and whiplash, but there is very little known with respect to acute, non-specific neck pain. A new study from Wirth et al. in Switzerland, in which subjects were 103 chiropractic patients with a first episode of acute (less than 4 weeks) neck pain, reports significant new findings.

These are that psychological factors in the early phase of acute, non-specific neck pain are important, and that persistent anxiety and depression at baseline may be risk factors for chronicity and therefore should be addressed in early management of neck pain patients.

Patients completed two outcome measures before their first treatment and then after 1 week, and 1 and 3 months – the Bournemouth Questionnaire (BQ) and the Patient Global Impression of Change (PGIC). The BQ has questions on psychological factors – 4 (anxiety), 5 (depression), 6 (fear avoidance) and 7 (pain locus of control). Changes in these, and associated changes in PGIC, were followed.

Results included:

a. After one week of standard chiropractic care 3 of 4 patients (75.6%) reported "clinically significant improvement", with that percentage rising to 83.3% after one month and 86.6% after 3 months.

b. All psychological parameters showed significant reduction within the first month.

c. Baseline depression – but not anxiety –"was a predictor of poor outcome."

d. Anxiety was clearly associated with outcome at 1 and 3 months – "A high reduction in anxiety within the first month was a significant predictor for favorable outcome after 1 month".

Wirth et al. conclude: "In order to prevent an acute neck pain episode from developing into a chronic problem, the reduction of anxiety at the beginning seems to be a key point in treatment…."). See the good Discussion of anxiety and depression in neck pain in this paper, available free online.

(Wirth B, Humphreys BK, Peterson C (2016*) Importance of psychological factors for the recovery from a first episode of acute non-specific neck pain – a longitudinal observational study*, Chiropractic & Manual Therapies 24:9 DOI 10.1186/s12998-016-0090-2.)

Garbutt is New FICS President

Dr Peter Garbutt (*right*) of Canberra, Australia is the new president of the Fédération Internationale de Chiropratique du Sport (FICS) from May 1, 2016. He succeeds Dr Sheila Wilson of Indianapolis, USA, FICS President for the past six years, who now moves to lead the FICS Foundation.

FICS was formed in 1987 to promote the international organization, growth and recognition of sports chiropractic. Its voting members are national sports chiropractic councils in all world regions. Major programs include the ICCSP postgraduate education course and qualification, a requirement for participation on a FICS team at international games events.

Through its relationships with international sports federations it assists in providing teams of sports chiropractors for world and regional championships for many sports, and for multisports games up to and including the Olympic Games. The chiropractic services in the host medical team at this year's Rio de Janeiro

Olympic Games in August will be led by FICS First Vice-President Dr Marcelo Botelho of Brazil.

Dr Garbutt has been in private practice in Sydney and then Canberra, Australia since graduating in 1996 from Macquarie University in Sydney. From 2007-2013 he was the Chairperson of Sports Chiropractic Australia, and from 2010-2016 he served as President of the Australian Capital Territory (ACT) Branch of Sports Medicine Australia. He represents the Pacific Region on the FICS Council, and has served as a FICS Vice-President for the past two years.

Dr Garbutt holds two postgraduate qualifications in sports chiropractic, a master of chiropractic sports science degree from Macquarie University (2000) and the FICS ICCSP postgraduate certification (2006). He is the founder and director of Enhance Running, which teaches running technique in Australia, Europe and the USA.

With sports chiropractic experience spanning sports such as beach volleyball, water polo, triathlon, soccer and pole dancing, Dr Garbutt lectures both locally and internationally on topics in sports injury management and running technique. In 2015 he became the first chiropractor to be admitted into Fellowship in the Australian Sports Medicine Federation.

"I am standing on the shoulders of many giants of sports chiropractic who have gone before me in FICS," said Dr Garbutt while chairing the FICS Council Annual Meeting held in Oslo, Norway on Friday May 6. "These include Dr Sheila Wilson, who has given FICS strong and invaluable leadership through a period of impressive growth of FICS and sports chiropractic during her six years as president."

Other sports chiropractic news from the FICS meeting in Oslo includes:

SportAccord. This is the most powerful annual meeting in the sports world. SportAccord members are the international federations (IFs) for each sport, from FIFA for football to the smallest such as TWIF for tug-of-war, and multisports organizations up to and including the International Olympic Committee (IOC). FICS is an associate member.

At this year's meeting, held in Lausanne, Switzerland in April, FICS had an exhibit booth and a team of six representatives led by President Dr Sheila Wilson and Secretary-General Dr Phil Santiago. Several new agreements for sports chiropractic services at world championships were signed with IFs – example events are the International Powerlifting Federation's World Bench Press Championships in South Africa May 15-22 and the Ju Jitsu European Championships in Belgium June 3-5. FICS teams will service 20 championships this year.

ICCSP Program Expands. The FICS Internationally Certified Chiropractic Sports Practitioner (ICCSP) certification program is open to all chiropractors as an online course plus two hands-on seminars offered in all world regions. Details are at the website.

Because the online course is in English only, special seminar courses have been offered and completed in France (French), Brazil (Portuguese) and Japan (Japanese). Current plans, worked on in Oslo with Latin American representatives Dr Mercedes D'Acosta of Mexico and Dr Aleisha Serrano of Puerto Rico, are for a course in Spanish in Mexico and Chile.

*Tim Ray, USA, Chair, FICS Games Commission (*left*) with Tim Stark, USA, Co Chair FICS Education Commission and Mercedes D'Acosta, President, Mexican Sports Chiropractic Federation.*

FICS Council members Angela Salcedo (left) and Kelly Lange (right), USA, with Aleisha Serrano, President, Puerto Rico Sports Chiropractic Council.

FICS Foundation. One of the three disabled powerlifters in the Philippines receiving financial support for training and competitions and chiropractic care from the FICS Foundation, Adeline Dumapong-Ancheta, has been selected for the Rio Paralympics. Read about Adeline's impressive life story in an interview in the March FICS News, found at www.fics-sport.org.

Have you donated to this Foundation, which has such impressive goals for sports chiropractic voluntary service and support of athletes and the advancement of sports chiropractic? To learn more and donate – a one-time donation or better still a small monthly continuing donation - go to the donate button at the FICS website homepage.

Adeline Dumapong-Ancheta with her chiropractor and FICS Foundation Board member Dr Martin Camara.

not more than one with consistent results for a specific treatment for a specific non-MSK condition.)

c. **Moderate-Quality.** For the conditions listed in Table 1 there was moderate-quality, positive evidence for specific manual therapies for two:

• Cervicogenic vertigo – manipulation and mobilization were supported by evidence from five RCTs. The mechanism given is "perturbation in the information from sensory afferents in the cervical spine."

• Cancer care- combinations of massage, myofascial release, manipulation and /or exercise brought improvements in pain, fatique and mood in cancer patients. Here positive results are from relief of symptoms associated with cancer rather than influence on the underlying disease.

Clar et al. report moderate-quality, negative evidence for manipulation for 3 conditions – osteosarcoma/cancer, dysmenorrhea and hypertension. For the latter, however, there is favourable, inconclusive evidence supporting upper cervical spinal manipulation. For dysmenorrhea there have been five RCTs of manipulative care (four chiropractic, one osteopathic). They have reported that manipulation is not superior to sham manipulation for primary dysmenorrhea. On this see the below discussion of asthma and RCT design problems with respect to sham/placebo comparison treatments.

d. **Low-Quality but Favourable.** For 12 of the 17 conditions there was low-quality, and therefore inconclusive, evidence as to effectiveness. 'Low-quality' does not mean poor research. All of the research evaluated by Clar et al. comprised RCTs, the highest form of clinical research for effectiveness. All RCTs have design or methodology problems. 'Low-quality' here combines two factors – a very low number of RCTs, and with design limitations that give significant risk of scientific bias to their reported outcomes.

It is noteworthy, though, that for all conditions with inconclusive evidence it was found that such evidence as there is was either "favourable" (see those ratings in Table 1) or "unclear". There was no condition for which inconclusive evidence was "unfavourable", in other words tending to be negative.

e. **Changes in the Evidence Base.** Because there are still relatively few RCTs reporting the effectiveness of specific manual therapies for individual non-MSK conditions, new good quality RCTs can quickly change the state of the evidence. An example of this from Clar et al. relates to infantile colic. The 2010 systematic review by Bronfort et al. concluded that there was moderate-quality but negative evidence for the effectiveness of spinal manipulation.

Clar et al. change the rating to inconclusive but favourable. This is because of "a new, high-quality RCT of chiropractic manual therapy that found reduced crying time in the treated infants, irrespective of parent blinding." That is the trial from Miller et al. at the Anglo-European Chiropractic College[17].

f. **Conclusion.** In summary there is an established research effort underway to assess the effectiveness of spinal manipulation and other manual therapies in the management of patients with non-MSK conditions and the chiropractic profession is playing a major role in this. At this point the better quality evidence from RCTs tends to be inconclusive but favourable for most conditions represented in the trials, but much more evidence is required before any claims of proven effectiveness can be made.

This summary review necessarily leaves many questions unanswered – about design challenges in research in this field, the roles of specific and non-specific treatment effects, and diagnosis. On diagnosis for example, do patients medically diagnosed with asthma, cardiac pain and infantile colic have these conditions – or do they have pain and other signs and symptoms mimicking them? These questions are now addressed by taking the example of asthma, the presenting condition of many chiropractic patients.

D Management of Asthma

6. Clar et al. provide three evidence ratings for the management of asthma. These are inconclusive but favourable for each of osteopathic manipulative therapy and cranio-sacral therapy as shown in Table I, and inconclusive and unclear for spinal manipulation. Discussing the basis for the latter they note that in three RCTs of chiropractic treatment "no significant differences between comparison groups were seen in respiratory parameters, symptoms or subjective measures."

Is that correct? If so and there were no differences, did patients in both the active treatment and comparison groups report significant clinical improvement? If so, might this mean that a benefit of chiropractic treatment was hidden by having an inappropriate comparison group, a benefit that would have been seen with a true placebo or no-intervention group? It is

Table 1. Evidence for Effectiveness of Manual Therapies for Non-Musculoskeletal Conditions
Adapted from Clar et al., 2014. Consult article for references.

Condition	*Intervention*	*No. of studies*	*Evidence*	
			Inconclusive	*Moderate*
Asthma	Osteopathic manipulative therapy; cranio-sacral therapy	1	Favourable	
Cancer care	Massage, myofascial release, manipulation and/or exercise	4		Positive
Cancer care, osteosarcoma	Manipulation	1		Negative
Cervicogenic vertigo	Spinal manipulation/mobilization	5		Positive
Chronic fatigue syndrome	Osteopathic manipulative therapy	1	Favourable	
Chronic pelvic pain/ interstitial cystitis	Osteopathic manual therapy/ myofascial physical therapy/ pelvic floor distension	3	Favourable	
COPD/pneumonia, elderly	Osteopathic manipulative therapy	3	Favourable	
Dysmenorrhea	Spinal manipulation	5		Negative
GERD	Chiropractic spinal manipulation and ischemic compression	1	Favourable	
Hypertension	Spinal manipulation, high-velocity, low-amplitude	2		Negative
	Upper cervical spinal manipulation	1	Favourable	
Infantile colic	Spinal manipulation	3	Favourable	
Intermittent claudication	Osteopathic manipulative therapy	1	Favourable	
Irritable bowel syndrome	Osteopathic manipulative therapy	1	Favourable	
Parkinson's disease	Osteopathic manipulative therapy	1	Favourable	
Pediatric dysfunctional voiding/nocturnal enuresis	Osteopathic manipulation therapy	3	Favourable	
Venous insufficiency	Myofascial release/kinesiotherapy	1	Favourable	

suggested that the answer to all questions is yes. Let us look at the most prominent trial to test that.

7. An RCT from Balon, Aker et al.[18], published in the New England Journal of Medicine (NEJM)in 1998 and from a joint chiropractic and medical research team from McMaster University and the Canadian Memorial Chiropractic College in Ontario, Canada, studied the effectiveness of chiropractic management of children and adolescents with asthma. Details are:

a. Patients were 91 children aged 7-16 with continuing symptoms of mild to moderate asthma (for more than one year, using a bronchodilator at least 3 times daily) despite continuing medical treatments.

b. They chose a treating chiropractor from a panel of 11 experienced clinicians, but were randomly assigned to receive one of two treatment protocols from the chiropractors, who had been trained in both for the trial:

• Active treatment group. Manipulation/adjustment as described in the paper (HVLA, Diversified but otherwise as determined by the treating chiropractor) and "soft-tissue therapy to the overlying tissues". This was three times weekly for 4 weeks, then twice weekly for 4 weeks, then weekly for 8 weeks over the 4 months of the study period.

• Simulated treatment group. Over the same number and duration of visits, no manipulation but "soft-tissue massage and gentle palpation applied to the spine, paraspinal muscles and shoulders" and distraction and low-velocity manual procedures as more fully described. All of this was deemed "non-therapeutic". In both groups "all medical treatment…. was maintained during the study, including the use of inhaled corticosteroids or cromolyn, at the dose used before randomization."

Accordingly, the comparison or control group also received a chiropractic treatment encounter with hands-on manual care. There was no other control group – for example receiving just medical care as usual, or medical care plus other non-chiropractic or non-manual care.

c. The primary outcome was change from baseline in the morning peak expiratory flow measured at two and four months before the use of a bronchodilator. Secondary outcomes included changes in each of airway responsiveness, forced expiratory volume, symptoms of asthma, the need for inhaled β-agonists, the use of oral corticosteroids, quality of life and overall satisfaction with treatment.

d. Results included:

• Primary outcomes: There were small increases in morning and evening peak expiratory flow in both groups, but these spirometric changes were "neither statistically significant or clinically important", and there were no significant differences between the two groups.

• Secondary outcomes:

i. There was "substantial improvement in symptoms and quality of life" at two and four months, again in both groups."

ii. The use of β-agonists declined in both groups at both two months and four months, with no significant differences between groups.

iii. Mean satisfaction scores were very high for each of the active treatment (6.22 out of a maximum of 7) and simulated treatment (6.44) groups. A majority of patients (63%) "were uncertain whether they had received active or simulated treatment".

The trial reported that "the addition of chiropractic spinal manipulation to usual medical care provided no benefit." Today, after new research methods and evidence, the limitations of that conclusion are apparent. The comparison/simulated treatment was clearly inappropriate.

8. That may be illustrated by a more recent asthma trial from Wechsler, Kelley et al.[19] from Harvard University published in the NEJM in 2011. This had a more advanced design with respect to comparison groups. Its main purpose was to compare the effects of active and placebo treatments, and the effects of placebo treatments with natural history by using a no-intervention group. Patients were 46 adults with stable asthma. They were assigned to four groups – inhaled albuterol (active treatment), placebo inhaler (placebo one), sham acupuncture with retracting needle (placebo two) and no intervention (control group).

All patients received all four interventions but on separate visits 3-7 days apart and in random order. This was repeated twice, meaning a total of 12 visits/interventions for each patient.

Although patients receiving the active treatment had greater improvement on the objective measurement/outcome of forced expiratory volume in one second (measured every 20 minutes for 2 hours on each treatment visit), there was no significant difference between them and the two placebo groups on all subjective outcomes. These included patient-assessed percent improvement in asthma symptoms during the 2 hours (patients completed a visual analogue scale (VAS) from 0-10, and the score was multiplied by 10) and reduction of medication use.

Patients reported substantial and similar improvement in symptoms with each of the inhaled albuterol (50%), inhaled placebo (45%) and sham acupuncture (46%) – but not the no-intervention (21%). In other words all of the active treatment and placebo groups did significantly and equally better than the no treatment group.

Wechsler Kelley et al. conclude that '"albuterol provided no incremental benefit with respect to the self-reported outcomes. Placebo effects can be clinically meaningful and can rival the effects of active medication in patients with asthma". Further, "patients could not reliably detect the difference" between the active drug with its objective effect and the two placebo treatments, and "the effect of the active medication did not exceed that of the ritual of the treatment itself".

A trial like this confirms the need to review the conclusions made in the Balon, Aker et al. trial. It also demonstrates the challenges faced by those undertaking systematic reviews. Should the Balon et al. trial still be regarded as evidence against the effectiveness of chiropractic care and/or manipulation for childhood asthma?

9. Why do many asthma patients experience relief of symptoms and high satisfaction under chiropractic care as seen in the Balon et al. trial? All health care and healing is complex. There will be a combination of factors including:

• Specific effects of treatment. These will include biomechanical effects (e.g. release of tension in the rib musculature from joint and soft-tissue manipulation) and may include central neurological mechanisms of action, though current evidence

suggests minimal impact on the underlying condition/inflammation of the airways.

• Non-specific/placebo effects from the whole clinical encounter, now understood to be legitimate and potentially as important as direct effects from medications and other treatments.

• Reduced use of medication and the complications they bring

• It should be mentioned that some patients will have been medically misdiagnosed as asthmatic and have no underlying disease. As this Report is being prepared there has been national news in Canada on a new Canadian study showing that approximately 30% – yes, 1 in 3 – of those diagnosed with asthma in general practice and put on long-term use of inhaled medication do not have the disease.

E Conclusion

10. At present there is no body of high or moderate quality evidence to support the claim that chiropractic or other forms of manual healthcare are effective in the management of specific non-MSK conditions, the one exception being manipulation and mobilization for cervicogenic vertigo. Such absolute claims should not be made. The problem is a lack of sufficient, quality RCTs, not trials reporting ineffectiveness.

On the other hand Clar et al. report that the evidence, though inconclusive, is favourable for the effectiveness of various manual therapies for a variety of non-MSK disorders including asthma, chronic obstructive pulmonary disease, hypertension, infantile colic, irritable bowel syndrome and nocturnal enuresis. Evidence-based practice combines the best available research, clinician experience and patient preference. It is clearly evidence-based and appropriate for chiropractors to offer a course or trial of treatment to patients with many non-MSK conditions. Often, as with non-cardiac chest pain for example, chiropractic and medical co-management will be ideal.

What claims should the chiropractic profession make? That is for individual chiropractors and their associations to decide but, given the history of misunderstanding and controversy, erring on the side of conservative claims sounds wise. TCR

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