



Professional Notes

New U.S. Guideline on Low-Back Pain - Strong Endorsement for Chiropractic Practice

On the scientific literature the most effective, safe and appropriate treatments for acute low-back pain in adults are spinal manipulation and non-prescription pain relievers such as acetaminophen (e.g. Tylenol) and NSAIDS (e.g. aspirin).

Prescription medication should be avoided because of side effects. There is "no evidence of benefit" from massage, traction, ultrasound, TENS, biofeedback techniques, ligamentous and facet joint injections and needle acupuncture. Bedrest should be avoided, but "may be an option for patients with severe initial symptoms of sciatica for 2 to 4 days". Surgery is seldom indicated.

These are the dramatic findings of the new, nationally-based, multidisciplinary guideline titled *Acute Low-Back Problems in Adults* released by the US government's Agency for Health Care Policy and Research (AHCPR) at a major press conference in Washington DC on December 8, 1994. This AHCPR Guideline is, to put it simply, the most comprehensive and important document ever published on back pain.

Associated Press began its December 8 wire service article that was duplicated in hundreds of newspapers across the US with the sentence - "Chiropractors get a boost and surgeons a setback in new government-backed guidelines on how to treat low-back pain". The US media has given chiropractic its best exposure ever. Points of significance include:

a) The Guideline relates to *acute* problems (defined as pain for less than 3 months - though new episodes of

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THE CHIROPRACTIC REPORT

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Chiropractic Research in the Centennial Year - Part II

Somatovisceral

A. Introduction

1. This is the second half of a two part review of current chiropractic research. The first, in the November 1994 issue of this Report, dealt with basic science and clinical research relevant to headache, neck pain, back pain and other neuromusculoskeletal disorders. In response the Report has been advised of much other current work in these areas, including for example:

a) **Neck Pain.** Another major interdisciplinary randomized controlled trial (n 120) is underway, at the National University Hospital, University of Copenhagen, Denmark. Principal investigator is Alan Jordan DC MSc. Patients with chronic neck pain (more than 3 months) are being randomly assigned to 1 of 3 treatments being compared in the trial - chiropractic (joint adjustment/manipulation), physiotherapy 1 (modalities and light exercises) and physiotherapy 2 (intensive strength training).

The treatment phase will conclude in March 1995. Results will be assessed following treatment and after one year, and will be measured in terms of pain (30-point scale), function (a rating scale similar to the Neck Disability Index and developed and validated by Jordan) and patient satisfaction (5-point Global Assessment). Funding of \$100,000 is from the National Research Council and Arthritic Foundation in Denmark. To further validate his functional rating scale for the cervical spine, Jordan is soon commencing a separate study involving 150 post-operative patients from Aarhus University Hospital.

b) **Neck Pain.** In Canada Peter Aker DC FCCS BSc and co-authors have just completed the first meta-analysis or pooling of results of the published studies on conservative management of neck pain, and papers have been submitted to *Spine* and the *British Medical Journal*.

c) **Headache and Children.** At the Karl-Franzens University in Graz, Austria, Udo Kastner BSc (Chiro) MD and colleagues are commencing a randomized controlled trial in which children aged 7-14 with chronic tension-type or migraine headache (at least 2 headaches per month for at least 4 months) will be assigned to 1 of 3 treatment groups - chiropractic (6-10 treatments with manipulation), chiropractic-placebo (6-10 sham manipulations) and biofeedback (10 treatments). Children are being recruited from the Graz University Children's Hospital, primary outcome measure is a daily questionnaire on frequency, duration and intensity of headaches, and there will be 2 years follow-up after treatment.

d) **Back Pain.** In the US John Grostic DC is principal investigator at Life College, Atlanta, Georgia for a 3 year randomized controlled trial (n 300) which is looking at two groups of low-back pain patients - chronic (pain for 6 months or more) and sub-acute (pain between 2 and 8 weeks). Management protocols being compared in each of these groups are upper cervical adjustment and back school, and the primary outcome measure is improved function (Oswestry Index, Chronic Disability Index, McGill Pain Questionnaire).

2. This issue of the Report, however, now looks at current *somatovisceral* research - research relevant to chiropractic management of conditions that many people see as unconnected with spinal health, such as infantile colic, childhood asthma, dysmenorrhoea and hypertension. First there is a summary review of basic science issues and research, then comment on several major interdisciplinary clinical trials presently in progress.

B. Basic Science Investigations

3. The practice of chiropractic is based upon neurology more than orthopedics. Mechanical joint and muscle disorders have effects throughout the body, chiro-

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1995 Centennial Celebrations: *Canada:* May 31 to June 4, Toronto, Ontario. **Information:** (416) 781-5656. *United States:* July 5-10, 1995, Washington DC (incorporating the 1995 World Chiropractic Congress) and September 13-17, 1995, Davenport Iowa. **Registrations:** 1-800-324-1995.

practitioners hypothesize, because of their impact on the nervous system. A chiropractic adjustment is given not only to restore range of motion to a joint but also to cause and/or relieve reflex effects in the nervous system. The chiropractor is not only an engineer (correcting joint function) but also a telecommunications specialist (influencing spinal reflexes and nerve function).

Understanding of spinal reflexes is still at a formative stage in the health sciences. With respect to chiropractic principles, leading animal experiments during the past 15 years have come from Akio Sato MD PhD and chiropractic co-investigators at the Tokyo Metropolitan Institute of Gerontology in Japan. Current work by Sato and Brian Budgell DC MSc, funded by the Foundation for Chiropractic Education and Research (FCER), relates to the effect of stimulation of spinal joints in rats on blood flow.

Before describing this, and to clarify its relevance to chiropractic practice, it is perhaps helpful to review the three major forms of spinal reflexes and the two ways in which chiropractic treatment may influence them.

4. Forms of spinal reflexes are:

a) **Somatosomatic** (Greek: soma = body). Stimulus at one level of the soma or musculoskeletal system produces reflex activity or response in the nervous system elsewhere in the musculoskeletal system.

Everyone knows of the knee jerk reflex because it is so visible. This is a spinal somatosomatic reflex. A light tap on the knee tendon activates receptors in muscle associated with the tendon. The nerve fibers fire a message into the spinal cord which, within the spine and without involvement of the brain or any conscious control, fires a reflex response out to the muscle which contracts, jerking the lower limb.

Similarly, stimulus to the spinal structures and nerves, whether from abnormal joint or muscle tension or manipulative treatment to relieve it, causes various spinal reflex responses in the musculoskeletal

system. Somatosomatic reflexes are particularly pronounced in infants.

b) **Somatovisceral** (Latin: viscera = internal organs). Stimulus to the spinal structures and nerves produces reflex responses influencing function in the viscera - for example in the digestive or respiratory systems.

c) **Viscerosomatic**. Opposite of the above. Digestive or respiratory dysfunctions such as colic or asthma, may cause reflex disturbance in the spine leading to muscle tension and joint subluxation or dysfunction).

These reflexes, which are beyond voluntary control, are purposeful - they are not haphazard, *but exist to regulate function*. However they can be altered by spinal subluxation. Korr PhD,¹ did much of the basic clinical research showing that there may be prolonged nerve excitability, or reflex response or barrage, at levels of the spine with movement restriction. This is known as 'facilitation'.

5. Spinal manual care, including techniques of manipulation, mobilization and pressure point, influences spinal reflexes in two ways:

a) Directly, as reflex therapy, similar to acupuncture or electrical stimulation. It introduces a stimulus that produces a reflex response that interferes with and modifies current established reflex activity.

b) Indirectly, by removing spinal joint and muscle dysfunction that produces abnormal levels of spinal reflex activity (facilitation).

To summarize this in the more technical language of Sato:

"Manipulation performed by chiropractors excites somatic afferent fibers in the musculoskeletal structures of the spine. These afferent excitations may, in turn, provoke reflex responses affecting skeletal muscle, autonomic, hormonal, and immunologic functions. An understanding of spinal reflex physiology is, therefore, fundamental to comprehending the effects of manipulation."²

(For a full discussion of reflex physiology and past clinical research on reflex function see chapters by Sato and Swensen DC MD PhD in Haldeman's *Principles and Practice of Chiropractic*²).

6. Returning now to Sato and Budgell's present work:

a) Anesthetized rats are being given spinal joint stimulation by injection of saline into a facet joint in the L4 to L6 region of the lumbar spine. Facet joints in both humans and rats are rich in nerve cells that transmit information on pain (nociceptors) and movement and position (proprioceptors).

b) To see whether the saline stimulation produces somatovisceral reflexes that alter function in the viscera and peripheral nerves in a statistically significant way, blood flow within the sciatic nerve is being measured at mid-thigh by laser Doppler flowmetry. Blood pressure and heart rate are being monitored by a catheter in a common carotid artery.

Results will be presented by Sato and Budgell at the Chiropractic Centennial Foundation meeting in Washington DC next July.

Intervertebral Foramen

7. Sato and Budgell's work assumes, and simulates experimentally, continuous mechanical irritation of nerve fibers in the capsules of spinal facet joints. Can spinal nerve roots and ganglia be compressed or irritated by abnormal mechanics at the intervertebral foramen (IVF)? A simplistic view of anatomy would suggest that there is sufficient room for the spinal nerve as it passes through the IVF, especially in the lumbar spine where the IVF is normally approximately 3 times as large as the exiting spinal nerve. Crelin, in his study 20 years ago titled *A Scientific Test of the Chiropractic Theory*,³ argued that the nerve roots in the lumbar spine passed through a "spacious lumbar intervertebral foramen" and could not be restricted by chiropractic subluxation. However sophisticated current chiropractic research is showing Crelin was

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back pain for patients with a recurring problem fall within the Guideline also), and relates to *adults* (over age 18).

- b) The 23 AHCPR panel members who established the Guideline comprised a consumer representative and 22 health providers representing the various disciplines involved in the management of low-back pain. The two chiropractors, who obviously did an impressive job, were Scott Haldeman DC MD PhD and John Triano DC MA.
- c) The new Guideline comprises three documents:
- Acute Low-Back Problems in Adults (*Clinical Practice Guideline*). The full guideline, 160 pages.
 - Acute Low-Back Problems in Adults: Assessment and Treatment (*Quick Reference Guide for Clinicians*). A summary available free to all clinicians.
 - Understanding Acute Low-Back Problems (*Patient Guide*). A consumer version of the Guideline that is available free to everyone.

(To order Guideline documents: Call (in US toll free 1-800-358-9295; from other countries (410)381-3150 or write to AHCPR Publications Clearing House, P.O. Box 8547, Silver Spring, MD 20907. Single copies of the Quick Reference Guide and Patient Guide are sent free. The Clinical Practice Guideline has a price, not yet established as this Report goes to press. Discounts are available for bulk orders. Call AHCPR for prices and ordering information).

- d) The overview in the Guideline gives the 4 reasons why guidelines on acute LBP were developed:
- **Prevalence.** Acute low-back pain is extremely common and "the most common cause of disability for persons under age 45".
 - **Cost.** It is enormously expensive. Low-back problems are "the second most common reason for visits to primary care physicians", "the most common reason for visits to orthopedic surgeons, neuro-

surgeons and occupational medicine physicians", and "the third most common reason for surgical procedures". Annual cost to society in the US may be \$50 billion.

- **Inappropriate Care.** It had become apparent that much treatment for low-back pain was ineffective, wasteful and inappropriate.
 - **New Scientific Literature.** The point had now been reached where there was sufficient literature to make decisions on which treatments were effective and which were not.
- e) Manipulation is defined as "manual loading of the spine using short or long lever methods" and the course of treatment recommended is initially up to four weeks. If there is symptomatic and functional improvement, treatment may be continued, if not it should be stopped. This adopts the findings of the RAND Study sponsored by the chiropractic profession, and rejects the traditional medical approach to manipulation which involves trial of 2 or 3 treatments only.

The strongest recommendation for manipulation is for patients with symptoms for less than one month. Patients with symptoms for longer than one month or with radiculopathy should also be considered for manipulation - for them it has as much research-based evidence as, for example, back school or exercise. (*Quick Reference Guide, Table 5*). There are recommendations against "manipulation for patients with undiagnosed neurologic deficits" or "a prolonged course of manipulation".

- f) 'Red flags' such as fracture, tumour and infection lead to alternative management. However, in the absence of these, most patients should be "treated similarly during the first month" of care and the AHCPR recommends "non-prescription medication and/or spinal manipulation". (*Guideline, Abstract*).
- g) In the Patient Guide, manipulation is described as "using the hands to apply force to the back to 'adjust'

the spine", and there is warning that "manipulation should only be done by a professional with experience in manipulation".

- h) There is a strong emphasis throughout on low-tech management and keeping the patient on normal activities of daily living as much as possible. Costly imaging and other investigations should only be considered "if the patient continues to be limited by back symptoms for more than one month without improvement" under care.
- i) It is noteworthy that the Guideline documents use inclusive language throughout - they talk to consumers about "your health care provider" or "health professionals". There may be no mention of "chiropractor" but similarly there is no mention of "medical doctor" or "physician" or any other category of professional.

In summary the new AHCPR Guideline represents a dramatic milestone in the history of the management of patients with low-back pain, and a powerful endorsement for chiropractic practice. All chiropractors will wish to study and be familiar with all 3 documents. The Guideline is, however, a twin-edged sword. On one hand it brings new recognition to the chiropractic profession, on the other it provides strong motivation to other health providers to claim ownership of and perform spinal manipulation. In addition, competing providers will be forced to improve. Accordingly, chiropractors must also continue to improve quality of care.

Stop Press: United Kingdom - Further Low-Back Pain Guidelines

As this Report goes to press the Report of a UK Clinical Standards Advisory Group Committee on back pain released December 7, 1994 has been received. This is based on the AHCPR literature review in the US and has similar recommendations for care. See the next issue of this Report for further comment.

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wrong and why, and offers new support for chiropractic hypotheses concerning the effects of joint subluxation.

8. **The Interpedicular Zone.** The IVF is not a two-dimensional hole, but a tunnel or canal through which the spinal nerve passes. In Australia Lynton Giles DC PhD has been looking at the dimensions of the interpedicular zone of this canal in the lumbar spine. In an impressive recent paper in JMPT⁴ he concludes that "neural and associated vascular structures within the important interpedicular zone may well be compromised due to vertebral joint subluxation. This may result in chronic compression." The precise clinical significance "is yet to be determined". With respect to this study:

- a) 9 randomly chosen blocks of adult lumbosacral spinal tissue were subjected

to histological examination for measurement of the L4-L5 and L5-S1 IVF canals.

- b) The region or zone of these canals that lies between the pedicles of the adjacent vertebrae was found to have a horizontal length of 8.2-12.2 mm. The minimum distance between the nerve structures and side of the IVF canal was 0.4-0.8 mm at L4-L5, and 0.4-0.6 mm at L5-S1.
- c) Giles concludes that Crelin's study was "meaningless as a basis for considering the possible physiological and/or pathophysiological functions of spinal nerves beyond the intervertebral canal as he did not examine the important interpedicular zone" which contains the spinal nerve root and ganglion, but only examined "the relatively insignificant lateral border".

9. **Transforaminal Ligaments.** At the National College of Chiropractic in

Chicago, Barclay Bakkum DC PhD is studying transforaminal ligaments (TF ligaments) which cross the lateral opening of the intervertebral foramen (IVF). In a paper just published⁵ he has shown that TF ligaments, once thought to be an abnormality, are normal and greatly reduce the functional compartment or space available for the spinal nerve. With respect to his most recent study:

- a) 4 adult lumbosacral spines without visible pathology or significant degenerative changes were sectioned.
- b) 35 of the 49 IVFs examined (71%) had at least one TF ligament. More than 1 in 4 (27%) had 2 TF ligaments, and 8% had 3 or 4.
- c) The height (superior-to-inferior dimension) of the functional compartment containing the ventral ramus of the spinal nerve was "significantly

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decreased". Average height reduction was about one-third (31.5%). However reduction was by at least 50% in 12% of IVFs with a TF ligament, and in one case the reduction was by over two-thirds (67.8%).

d) Bakkum et al also measured the effect of TF ligaments on the anterior-to-posterior dimension of the IVF. Here, on average, there was not a statistically significant decrease but in individual cases there was up to 18% decrease in dimension.

10. In summary, contemporary basic science research is supporting fundamental chiropractic hypotheses concerning spinal nerve irritation, facilitation, somatovisceral reflexes and altered function in systems generally thought to be unconnected with spinal mechanical dysfunction.

Basic science research sets the stage, but doesn't address clinical significance. Clinical trials are needed for that - and these are now considered.

C. Clinical Trials

Asthma

11. Asthma, variable limitation in air flow and breathing that causes episodes of wheezing and breathlessness, is the most common chronic disease of childhood. From 1980 to 1987 the US National Health Survey showed a trend of significantly increasing prevalence, morbidity and mortality in spite of increasingly aggressive medical approaches to the disorder. US health care costs for asthma exceeded \$4 billion in 1988.⁶ There is a similar picture in many parts of the world - more children suffering worse consequences from asthma.

Symptoms arise, it is thought, from an over-response to stimuli which triggers an allergic reaction. This reaction produces an inflammatory response - epithelial swelling and secretion of mucous - which narrows the airways. If allergic trigger factors are identifiable, avoidance of these is recommended. However trigger factors are numerous, including various drugs, foods, food additives, air pollution, infection, exercise and psychosocial factors.

Medical management is directed principally at the inflammation (oral or inhaled steroids) and the constriction (bronchodilators). There is increasing evidence that aggressive, preventive drug therapy is, over the long term, increasing levels of morbidity and mortality.⁷

In Australia 30% of asthmatic families use chiropractic for the treatment of asthma, and report a satisfaction rate of 86.5%.⁶ However, although there has always been quite widespread chiropractic management of asthma, there have never been good controlled clinical trials to establish a firm scientific basis for treatment. What has been required is a climate of cooperation between chiropractic and medicine that would allow interdisciplinary research. Happily that is now here.

12. Canadian Memorial Chiropractic College and McMaster University, Ontario, Canada. (*Principal*

Investigators: Jeff Balon DC MD BSc, CMCC and Malcolm Sears MB ChB FRACP FRCPC, McMaster). Dr. Balon is a graduate of both CMCC and the Department of Medicine, McMaster University, and Dr. Sears, Professor of Medicine, Director of Respiratory Services, Firestone Unit, St. Joseph's Hospital, McMaster University, is an internationally recognized expert in pediatric respiratory disorders. Prominent chiropractic co-investigators include Dr. Peter Aker and Dr. Edward Crowther at CMCC and Dr. Clark Danielson at LACC.

Titled *Chiropractic Care of Children with Asthma*, this controlled trial funded by the Consortium for Chiropractic Research (CCR - \$300,000) commenced in October 1994. 100 mild to moderately severe asthmatics (ages 8-16) who are under continuing medical treatment will be randomly assigned to:

- a) Chiropractic treatment - up to 28 treatments over a 4 month period by experienced chiropractors.
- b) Simulated adjustment or manipulation.

Primary outcomes (peak expiratory flow rates) and secondary outcomes (spirometry results, patient symptoms, medication use, inflammatory reaction, hospital admissions and emergency department visits) are being assessed in a blinded fashion. Other aspects of the study include analysis of the demographic, palpatory and historical profiles of patients, as well as inter-examiner agreement on palpatory findings. Results should be available in early 1996.

13. Northwestern College of Chiropractic, Minneapolis and Children's Hospital, St. Paul.

(*Principal Investigators:* Gert Brontford DC Northwestern, and Paul Kubic MD PhD Children's Hospital. FCER/NCMIC - \$85,000). This is a pilot study titled *The*

Role of Chiropractic Treatment in Chronic Childhood Asthma which, if it proves feasible, will lead to a full-scale interdisciplinary trial similar to that in Canada.

In the pilot study, a prospective clinical series with 39 patients which commences in January 1995, patients under standard medical treatment are receiving 12 weeks of chiropractic management with spinal adjustment/manipulation as indicated. The five primary outcomes measures are:

- a) Morning peak expiratory flow rates (PEFL)
- b) Evening PEFL
- c) Patient reported asthma severity
- d) Use of inhaled bronchodilators
- e) Non-specific bronchial reactivity.

A 15% improvement will be seen as a positive outcome. The proposed randomized clinical trial (n 130) will compare two groups - both receiving standard medical therapy, but one adding active chiropractic care and the other sham manipulative procedures.

Dysmenorrhoea

14. **National College of Chiropractic, Chicago.** (*Principal Investigator:* Pat Brennan PhD.) Primary dysmenorrhoea (PD) affects 50% of all women of child-bearing age. In a 1992 pilot study involving 45 women those in the chiropractic treatment group had a significant improvement in reduced pain and distress, and in reduced plasma levels of the prostaglandins that cause primary PD.⁸

Brennan et al are now completing the main trial in which 150 women (ages 18-45) with PD are being randomly assigned to either a treatment group (chiropractic manipulation) or a controlled group (sham manipulation). The study is designed to indicate not only whether manipulation reduces pain in PD but also whether it might correct the underlying cause altogether. Outcome measures are:

- Changes in pain - measured by visual analog scale.
- Changes in menstrual distress - measured by an independent questionnaire (MDQ).
- Biochemical analysis - measurement of the levels of a prostaglandin metabolite KDPGF₂. (Prostaglandins have been implicated as the agents responsible for uterine contraction and resulting pain during menstruation.)

Patients are to be treated 3 times in the week prior to menstruation, with results measured on first day of menstruation. Each patient will be followed for 3 consecutive menstrual cycles.

Hypertension

15. Primary or essential hypertension, persistently high arterial blood pressure not associated with other disease, has no known cause. Clinical experience shows that chiropractic treatment can produce striking results in individual cases, such as the one investigated and reported by the New Zealand Commission of Inquiry into Chiropractic in which a middle-aged woman on medication for over 15 years for moderate hypertension received complete and lasting relief following a series of cervical adjustments.⁹ However the studies to date indicate that results are unpredictable, and there has been no properly controlled clinical trial.

16. **Palmer College of Chiropractic West, San Jose and Palmer College of Chiropractic, Davenport, Iowa.** (*Principal Investigator:* Gregory Plaugher DC). With funding of \$85,000 from NCMIC and FCER, investigators from the Palmer Colleges have commenced a pilot study to lay the groundwork for a full scale controlled trial. In the pilot study 30 patients seen at the Palmer Clinics in Davenport will be randomly assigned to chiropractic management (spinal adjustive procedures) or a placebo group (massage) for a maximum of 2 months.

Patients will be evaluated immediately (before and following each therapeutic intervention for both systolic and diastolic pressure), and at long-term follow-up. In addition there will be baseline and subsequent patient questionnaires on health status (SF-36) and exercise and dietary habits, which will be controlled during the study.

Infantile Colic

17. 'Infantile colic' is persistent, often violent, crying for no apparent reason in otherwise healthy and thriving young infants. It is different from normal crying because distress does not stop when the infant's physiological needs are met.

Colic begins at 1-4 weeks of age and usually ends spontaneously at 3-4 months of age. In the meantime, especially in moderate to severe cases which may involve uncontrollable crying for many hours by day and night every day, it is destructive to both infant and family and is a cause of parental violence to infants.

Because the source of the irritability and pain in infantile colic has been and remains unknown, because onset follows the trauma of birth and change to a weight-bearing environment, and because they have found a high incidence of abnormal cervical and thoracic spinal joint function in colicky infants, chiropractors have postulated that a significant cause of infantile colic may often be spinal dysfunction.

18. In 1989 Klougart DC, Nilsson DC MD and Jacobson DC reported a multicentre prospective study coordinated by the Danish Chiropractors' Association and involving 316 infants of median age 5.7 weeks.¹⁰ For these infants, who had to meet strict criteria for entrance into the study including no other illness, normal weight gain and presence upon examination of spinal dysfunction, there was a 94% success rate following a maximum of 6 treatments over 2 weeks. The investigators called for a randomized controlled trial to further test the validity of the excellent results they reported.

Two trials are now underway.

19. **Nordic Institute for Chiropractic and Clinical Biomechanics, Odense, Denmark.** (*Principal Investigators:* Jesper Wiberg DC and Niels Nilsson DC MD). Funding of \$35,000 is from the Health Foundation, affiliated with the Danish National Health Service, and infants are being recruited by nurses working as health visitors for the NHS. Approximately 50 infants aged 2-6 weeks and with severe colic are being randomly assigned to one of two treatment groups:

- a) Chiropractic management - a course of spinal manipulation for up to 3 weeks, with a maximum of 5 treatments.
- b) Medical management - the usual drug therapy for infantile colic in Denmark, which is Mylicon. The active ingredient is dimethicone, which lowers surface tension of the GI contents.

Entry criteria are similar to those in the Klougart et al study - no symptoms suggestive of any other disease apart from the colic; at least one violent crying spell lasting a minimum 1.5 hours during 5 of the 7 preceding days, and normal behaviour outside colicky periods; weight gain of at least 150 grams per week; motoric unrest during colic; and inability to be comforted by various normal means, including cradling, change of diaper, offer of food or other comfort.

The treatment phase is presently underway and preliminary results will be available in the second half of 1995. Parents are keeping nutrition, defecation and distress diaries, the last of which will form the primary outcome measure.

20. **Northwestern College of Chiropractic, Minnesota and the Nordic Institute for Chiropractic and Clinical Biomechanics, Odense, Denmark.** (*Principal Investigators:* Gert Brontfort DC and Niels Nilsson DC MD). A second randomized controlled trial to be performed in Denmark (n 120), with funding of \$90,000 from NCMIC and FCER, will assign infants aged 2 to 6 weeks to 1 of 3 comparison groups:

- a) Chiropractic treatment with spinal manipulation
- b) Parental use of written systematic guidelines for responding to persistent infant crying (Taubman's Method), and
- c) A control group in which infants will receive sham chiropractic manipulations.

Infants will again be recruited through the central nurse visitation system of the Danish NHS. The two primary outcome measures are parental 24 hour diaries of the hours of infant crying, and daily parent-rated distress scores. Secondary outcome measures are parent-rated weekly scores for severity and distress. The treatment phase in this trial commences soon and preliminary results should be available in early 1996.

Otitis Media

21. **Northwestern College of Chiropractic, Minneapolis.** (*Principal Investigator:* Kassem Kassak PhD MPH). Otitis media (OM) is inflammation of the middle ear, commonly seen in young children. Aggressive medical management is often unsuccessful, and is attracting widespread criticism. Chiropractic management obviously cannot address acute infection, but can it break a chronic cycle of repeated infections? Clinical experience suggests that it can,¹¹ perhaps because relief of cervical dysfunction/subluxation may alter the tone of muscles that affects the diameter and/or inclination of the eustachian tubes.

In this retrospective and prospective study, Kassak is reviewing the results of management at chiropractic offices in Florida and New York where there is an established pattern of medical referral of children with OM for chiropractic care. Tympanometry is being used to provide objective measurement of pressure within the ear before and after chiropractic adjustment. If feasible a related study will be commenced using digitised MRI or CT scan data to measure diameter and/or inclination of the eustachian tubes before and after treatment.

This is a further research initiative funded by NCMIC/FCER and first results will be available in mid-1995.

CD4 Cell Count - Immune Response

22. Life College, Atlanta. (*Principal Investigator: John Grostic DC, Director of Research*). Tractional effects of an atlas subluxation may be transmitted by the dentate ligament to the brainstem. This controlled trial investigates whether or not this potential source of neurological interference at the brainstem influences immune response in HIV-positive patients. Specifically, the study will evaluate the effects of upper cervical adjustments on CD4 cell counts.

Two groups of 100 HIV-positive patients from Grady Hospital, one group with CD4 counts below 250 and the other with counts between 250 and 500, are being randomly assigned to a chiropractic treatment group (Grostic orthogonal upper cervical technique) and a control group (sham adjustment). Treatment will be for a period of 12 months (10 times in the first month then decreasing to once a month during the final 9 months).

CD4 count and other blood chemistry will be measured by an independent laboratory at 6 months, at the conclusion of treatment and 1 year follow-up. This trial has partial funding from the National Institutes for Health, follows a pilot study which suggests

that CD4 cell counts may be significantly raised following chiropractic care¹², and is part of a wider move to research alternative forms of care for HIV-positive patients.

Conclusion

23. Several other clinical trials of somatovisceral effects of chiropractic care are in the formative stage. One of particular interest is a proposed first controlled trial comparing chiropractic and medical management of patients with duodenal ulcer, to be performed in Kansas City by Andrei Pikalov MD PhD, principal investigator, and colleagues at Cleveland Chiropractic College.

In Australia the Australian Spinal Research Foundation has just funded two trials - one on premenstrual syndrome ('A Randomised Placebo-controlled Cross-Over Clinical Trial on the Efficacy of Chiropractic Manipulative Therapy for Premenstrual Syndrome', School of Chiropractic, RMIT University, Melbourne, *Max Walsh*) and the other on blood pressure ('Long-Term Effect of Chiropractic Adjustments on Blood Pressure: A Controlled Trial', School of Chiropractic, Macquarie University, Sydney, *Henry Pollard*).

24. Can chiropractic correction of a spinal dysfunction or subluxation relieve colic, asthma, hypertension, and other disorders apparently remote from the spine? There are logical hypotheses and extensive clinical evidence to support such claims. Presently there is too little scientific evidence to answer yes or no with certainty. Clinical experience suggests that the answer is "yes in many cases, in some with dramatic success," and that many patients will benefit from collaborative chiropractic and medical care. That was the conclusion of the New Zealand Commission of Inquiry into Chiropractic after lengthy investigation and deliberation.¹³

As the profession enters its centennial year it is exciting to see that there is a new openness of mind to these issues in the health science community, and that much important basic science and clinical research is proceeding.

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