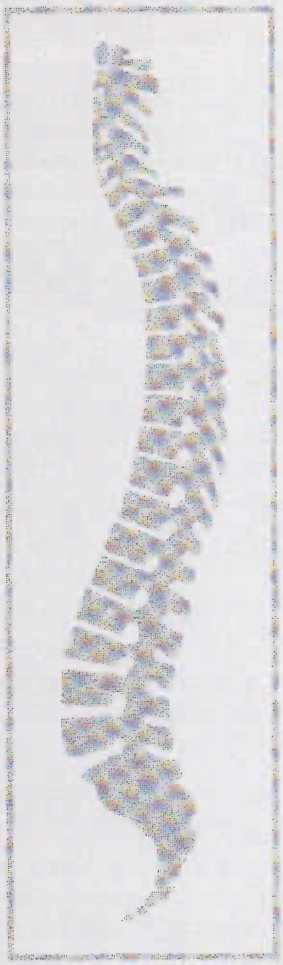

THE CHIROPRACTIC REPORT

An international review of professional and research issues, published bimonthly

Editor: David Chapman-Smith, LL.B. (Hons.), FICC (Hon.) **September 1995 Vol. 9 No. 5**

The Powerful and Mysterious Placebo

A. Introduction

"The placebo effect in general practice is the power of the doctor alone to make the patient feel better, irrespective of medications. It is one of the most important factors in the consultation,yet generally it is neglected, unrecognized, and untaught."
K.B. Thomas MD, England[1]

"The necessity for including a placebo group in drug studies was stimulated in the USA by the October, 1962 Food and Drug Administration regulations, which required for the first time that drugs be proven effective. Subsequently, thousands of drugs - which many patients and physicians thought worked - were removed from the market ... Long live the placebo.

After 40 years of conducting controlled clinical studies on new as well as old drugs, I have concluded that the placebo has made probably the single most important contribution to modern therapeutics of any drug."
F. G. McMahon, MD, U.S.A.[2]

"Perhaps modern doctors have lost the techniques for giving purpose and confidence to their patients ... it's time to put some hope back into the black bag."
N. Swan, MD, Australia.[3]

1. Each healing encounter, and every treatment, has specific and non-specific treatment effects.

For back and leg pain disc surgery removes part of the herniated disc relieving nerve root pressure, an analgesic drug modifies pain perception, and a chiropractic spinal adjustment restores range of joint motion and decreases nerve entrapment and irritation. These are specific treatment effects.

Non-specific effects, or placebo effects, are the benefits felt by the patient because of the nature of the healing encounter - the drama of surgery, the magic potency of pills, the reassurance of the laying on of hands, the definitive 'pop' of the chiropractic adjustment and the presence of a confident health professional.

2. A pure placebo (*Latin: I will please*) may be defined as a treatment or intervention which is believed to lack any specific treatment effect, or a scientifically demonstrable mechanism of action. Placebo interventions used in scientific trials include, for example, a pill with no medication in it and electrotherapy (e.g. ultrasound, laser) with the electricity turned off. (Electrical machines have great appeal to patients, and studies of patients with soft-tissue injuries and tibial fracture show that patients do just as well with the electricity shut off.[4,5])

3. A recent series of seven articles in *The Lancet*[6] takes a thorough look at the non-specific or placebo effects of treatment. Some conclusions are:

a) Placebo effects, which were probably the only effective basis of treatment for thousands of years, remain one of the most important elements of health care. They should be understood, embraced, and enhanced, not rejected. This is particularly so in chronic pain conditions which combine physical and functional disorders.

b) There will be a plausible mechanism of action for all placebos, if we learn enough about them. For this and other reasons, and approaching the matter logically, it is actually impossible to define a placebo effect. In the words of Gøtzsche from Denmark:

"We should divert our focus of interest from the essentially unsolvable problem of whether or not an intervention is a placebo towards the magnitude of the measured effect ... the larger the effect compared with no treatment, the more useful the intervention - whatever its nature ..... the important thing is that treatments are tested, not what we might choose to call them or their practitioners."[7]

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Professional Notes

British Trial - Long Term Results

The three year follow-up results of the British Medical Research Council's trial of chiropractic (Meade TW, Dyer S et al (1990) *Low Back Pain of Mechanical Origin: Randomised Comparison of Chiropractic and Hospital Outpatient Treatment* Br Med J 300:1431-37) were published in the British Medical Journal on August 5, 1995. (Br Med J 311:349-351)

The original multicenter trial compared chiropractic and hospital out-patient management of patients with acute and chronic mechanical low-back pain. It reported much superior results for chiropractic patients in terms of reduction of pain and disability, particularly for those patients with severe or chronic (long-term) pain.

The new study shows that, three years after the trial, chiropractic patients continue to show significant long-term benefits - 29% superior improvement in function as measured by Oswestry Questionnaire to those treated by medical doctors and physiotherapists.

Chronic Back Pain - An Important new Trial

Triano JJ, McGregor M et al (1995) *Manipulative Therapy versus Education Programs in Chronic Low Back Pain*, Spine 20(8):948-955.
In the management of back pain six weeks is identified as a critical time. If there has been

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1995 Centennial Celebrations: *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.

c) Specific and non-specific treatment effects are often interactive (synergistic or antagonistic), with one enhancing or minimizing the other. This is an important fact for clinical practice. It also means that research should not always separate and exclude placebo effects. Treatment effects should often "be assessed more pragmatically, comparing one treatment to another in their own optimum settings of non-specific factors."[8]

In a chiropractic trial this means, for example, that it is ultimately wrong to test a given series of manipulations in a prescribed manner in a setting unlike practice - without office ambience, without patient education, prescription of exercises, and monitoring of these exercises and advice on follow-up visits, and forbidding variation in technique and site of treatment as dictated by physical diagnosis.

The British Medical Research Council trial of chiropractic[9] was designed to be pragmatic in this way, combining specific and non-specific effects. The maximum number of treatments was fixed but beyond that treating practitioners managed patients as they would normally in their own clinics. In this trial patients with acute and chronic mechanical low-back pain were found to achieve much better results under chiropractic care than medical and physiotherapy care in hospital out-patient clinics.

d) The history of surgery shows that much surgery derives its success from placebo effects - arising from the aura of expectations, surroundings, the surgeon's personality, the anesthetic, and the incision.

Thus, for example, in the 1950s ligation to obstruct blood flow in the internal mammary artery was popular for myocardial ischemia. The theory was that this diverted flow of blood to the heart, and results were good. However, experimental evidence later showed the theory to be untrue. A placebo-controlled trial was done - some patients getting ligation, others an incision only (sham operation) - and those getting the sham operation did just as well.[10]

It is particularly important to know if the main effect of surgery is specific or non-specific because of the significant risk rate. If it is non-specific (placebo) a safer method should be used. This is of particular relevance in the area of back and neck pain. If it is assumed that spinal surgery and spinal manipulation are equally effective for a certain condition, and that the main effect of both is non-specific, then the safer method of manipulation should be preferred. The same argument applies to prescription drugs.

4. In a recent U.S. analysis titled *The Importance of Placebo Effects in Pain Treatment and Research*, Turner, Deyo et al[11] identify five commonly held misconceptions with respect to placebo effects:

a) **The administration of a placebo is the same as doing nothing**. It is simply a prejudice to believe this, and to hold that non-specific treatment effects are somehow illegitimate, especially when these are equal or superior to specific treatment effects.

b) **Individuals responding to placebo had nothing wrong with them in the first place**. This assumes that only imaginary conditions respond to placebo effects. This is clearly not the case. Placebo responses have been observed for many 'real conditions' including angina,[10] asthma,[12] ulcer,[13] pain from dental surgery,[14] and hypertension.[15]

c) **Personality type affects the likelihood of being a placebo responder**. It is a myth that people who respond to placebos are peculiar, or different from the rest of us.[16] Anxiety has often been identified as a personality trait of those who respond to placebo. It is essential to differentiate:

i) Anxiety as a personality trait, experienced at relatively high levels as a chronic or stable characteristic of one's life-style;

ii) Situational anxiety, temporarily experienced due to specific high-stress instances.

Studies have shown that situational anxiety is related to placebo-induced changes in pain tolerance, but that chronic anxiety is not.[17] The literature also provides no consistent data to suggest that other personality variables such as dependency, dominance, compliance, social desirability, introversion, extroversion, acquiescence or neuroticism predispose individuals to placebo reactions.[18]

However certain traits, *in combination with* specific situations of anxiety, may well predispose some individuals to placebo responses. It is the situation that is the dominant factor - for all of us.

d) **The effects of a placebo are short-lived**. The duration of the placebo response has not been extensively studied, and it is premature to assume that the benefits are temporary in nature. In the Dimond study, for example, sham surgery (skin incision only) was performed for angina pectoris, a condition unlikely to show natural remission of symptoms. 100% of patients reported over 50% improvement in symptoms at one year follow-up.[10]

e) **One third of subjects in any clinical trial will have a placebo response**. This is a widely held misconception based on Beecher's landmark paper *The Powerful Placebo* published in JAMA in 1955.[19] From a review of 15 studies he concluded that the placebo effect was produced in 33% to 37% of individuals over a wide variety of conditions.

Turner, Deyo et al now conclude that placebo response rates "vary considerably across studies" and "are strikingly high on average". A recent analysis of evidence on treatments originally thought to be effective, but later abandoned because it was found they had no specific effects, has revealed an impressive average of 70% of patients experiencing positive outcomes from these treatments.[11]

5. As these introductory remarks indicate, a major re-thinking of the role and power of placebo effects is presently underway. This Report now looks at three aspects of placebo effects:

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i) The mechanisms by which placebos are thought to work.

ii) Placebos in chiropractic practice. What can and should be done to enhance non-specific treatment effects?

iii) The placebo in research.

B. Placebo Mechanisms

6. The exact mechanisms of action of the placebo response remain largely unknown. Three theories are widely discussed in the current literature.

i) **Classical Conditioning**. The first report of a conditioned placebo effect was by Pavlov who observed experimental dogs displaying morphine-like effects when placed in the same chamber in which they had previously experienced morphine administration.[20]

Studies since then have suggested that the placebo response can be conditioned in humans as well. Voudouris et al observed placebo effects of reduced pain in response to a neutral cream following conditioning trials in which the cream had been associated with pain reduction.[21] Wickramasekera analyzes this conditioning mechanism in detail.[22]

Therefore, for example, a person who has experienced relief from a spinal adjustment in the past will most likely experience positive placebo effects during subsequent chiropractic treatment. However, another person who experienced pain and aggravation of symptoms after chiropractic treatment will probably have a negative placebo response if he/she pursues further treatment. On the conditioning model of placebo effects a patient's health history and previous health care experiences play a vital role in shaping the outcome of subsequent health-care encounters, and should not therefore be ignored or underestimated.

ii) **Expectations**. Expectancy models of placebo hold that both the patient's and the clinician's expectations regarding treatment will influence the changes that take place. It has been well documented that placebo effects in drug trials are especially strong, and that it is patient expectancies rather than the drug's pharmacological effect which tend to prevail.[20]

It is a matter of debate as to how exactly patient expectations produce a response. One theory is that the expectation of successful treatment increases perception of control, and thus relieves the stress, anxiety and loss of control associated with illness. Another explanation of the expectancy model is that changes in expectations may cause behavioral changes, which in turn alter the patient's report of symptoms.[23] An example is the neck or back pain patient who, anticipating that chiropractic treatment will be helpful, is now confident enough to resume normal activities which he/she had come to fear. Patients are distracted from their illnesses, improve their moods, and even enhance their physical states (i.e. increased muscle tone, increased motion) - quite apart from the specific or non-placebo effects of treatment.

The expectations of the clinician, not just the patient, are also important. In a double-blind study of dental patients[24] dentists were informed that patients in Group 1 would receive only a placebo (naloxone - a narcotic antagonist), whereas those in Group 2 would receive either a narcotic or the placebo. The only difference between those patients in both groups who received the placebo was the clinicians' knowledge. Dentists knew Group 1 patients received no active treatment, with Group 2 patients there was a known chance of active treatment. Interestingly pain reduction for those who received the placebo in Group 2 was significantly greater than in Group 1. It was concluded that the dentist's expectations influenced placebo analgesic effects.

iii) **Endogenous Opiates**. There is experimental evidence to suggest that production of the body's natural or endogenous opiates might mediate placebo responses to pain. Levine et al were the first to study this using naloxone, an opioid antagonist, in dental surgery patients. Patients were first given a placebo 'analgesic' for pain after dental surgery. Some responded experiencing pain reduction (placebo responders), some did not (placebo non-responders).

When naloxone was then given to all patients it caused a significantly greater increase in pain in the placebo responders, apparently neutralizing the natural opiates that had caused pain reduction. Levine et al concluded that endogenous opiates mediate placebo analgesia for post-operative dental pain.[14] This result was not replicated in a subsequent study and more evidence is required before definite conclusions can be made on the role of endogenous opiates.[25]

7. Placebo effects are not without their dangers. Patients with chronic illnesses, particularly chronic pain, may experience what is called an 'extinction response' to placebo effects. In this case:

- A patient improves after a treatment that has only non-specific or placebo effects (e.g. electrotherapy for chronic back pain principally caused by an untreated joint subluxation). However over time the placebo effects diminish or disappear because the underlying organic problem remains unaffected by the placebo treatment.
- This cycle is repeated on a few occasions. The patient becomes so conditioned to the non-response that he fails to respond to any future treatments, including those with a demonstrated specific treatment effect (e.g. chiropractic adjustment to correct the joint subluxation).

8. Finally, a word on natural regression. Generally when patients seek care they have symptoms - they are sick. During any period of treatment there is a natural tendency to get better. Even chronic illnesses such as multiple sclerosis that do not resolve spontaneously tend to regress over the short term, and it is over the short term that most clinical observations are made.

Analysis of the reasons for a patient's improvement must therefore not only consider specific and non-specific treatment effects but also natural remission. The extreme view, expressed by a few, is that most of the improvements attributed to placebo can really be explained by natural regression.[26]

C. Placebo in Chiropractic Practice

9. In order to understand the role of placebo (non-specific treatment effects) in clinical practice, it is necessary to remind ourselves of the difference between organic and functional illness.

An organic illness is one in which there is an identifiable biological lesion. This might be an infection or a tumor, or something more subtle such as a metabolic disorder or subluxation. An organic or biological illness begs for a biological solution. A functional illness is anything else, and affects function not structure. Psychological disturbances, such as anxiety, are considered to be functional disorders.

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The reality is, of course, that almost every illness or disease contains elements of both organic and functional disorders. The functional component of an illness may be viewed as the patient's reaction to the organic illness - anxiety, fear, depression, loss of control, etc. These functional reactions can, in turn, adversely affect the underlying organic disorder. Cause and effect become blurred. A positive feedback cycle can be established -the organic disorder occasions the functional disorder which exacerbates the organic disorder.

Loeser, a leading pain researcher, presents the organic/functional model of chronic pain seen in Figure 1.[27] Nociception (perception of noxious stimuli) leads to pain (the central nervous system's processing of the painful stimuli), then to suffering (the interaction of the psyche with the physical pain), and finally pain behavior (changes in actual behavior resulting from the suffering). An injury (source of nociception) may be the initial cause of the pain and suffering and pain behavior, but the healing of the injury may be insufficient to change the pain behavior that has been established.

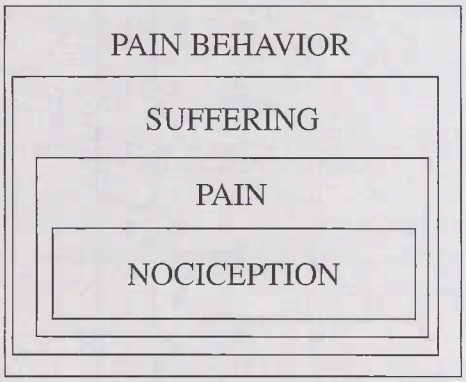
10. Most chiropractic patients have neuromusculoskeletal pain syndromes, often recurring or chronic. These are organic and functional problems. From the above discussion it is clear these patients need a management approach which:

a) Has specific (active) treatment effects. Manual treatment, including spinal manipulation, has these for mechanical problems - restoring joint motion, releasing muscle spasm and trigger points, and altering neurophysiological effects.

b) Provides the greatest non-specific (placebo) effects. Chiropractic practice is clearly strong in this area. This is reflected in the studies showing high patient satisfaction compared with medical care.[28,29]

Figure 1

Loeser Pain Heirarchy



11. What elements of chiropractic practice encourage these non-specific benefits, and what should a chiropractor do to enhance these? On the basis of practice observation and evaluation,[30,31] and patient studies,[28,32] these factors can be identified:

a) **Confidence and commitment**. Perhaps the most influential and remarkable aspect of most chiropractic encounters is the practitioner's commitment to chiropractic philosophy or theory.[31,32] This is an important source of non-specific effects for several reasons - the chiropractor is more comfortable and confident, there is a real cause (subluxation) amenable to a tangible treatment (adjustment), there is a plan of treatment rather than "let's wait and see", and these factors give the patient confidence and expectation of success - especially if the problem was previously dealt with ineffectively by another practitioner.[31]

As Shapiro explains, commitment to a treatment approach also tends to make a clinician more tolerant of the patient's idiosyncrasies. The patient is accepted without criticism or rejection. As an additional bonus, the commitment is often interpreted by patients as an interest in them.[33]

In a British study demonstrating the importance of confidence[34] 200 patients reporting to a general medical practice with a variety of complaints (cough, sore throat, back pain, fatigue, headache, etc.) were divided into two groups. One received what was termed a 'positive consultation.' This consisted of giving the patients a firm diagnosis and reassurance that they would recover in a few days. The other group received a 'non-positive consultation.' No firm diagnosis or reassurance was given. Patients in each group were then either given a 'treatment', which was actually a placebo pill, or no treatment. Thus, there were a total of four different groups.

The researchers discovered that it made very little difference whether or not a 'treatment' was administered. Two weeks after the initial consultation 50% of those not treated showed improvement compared to 53% of those who were treated. However what kind of consultation they received made a big difference - 64% of those receiving a positive consultation reported improvement compared to 39% of those who received a non-positive consultation. This study suggests that the personal attributes of the clinician have a bigger impact on placebo effects than the therapy provided. The attitude of the doctor was more important than the presence or absence of a pill. For a chiropractor, attitude is more important than the fact of manual treatment.

b) **Information and advice**. The information patients are given regarding their conditions, content and form, is reported by them as a strong point in the chiropractic encounter.[28] Patients are typically given an explanation in a context they can understand which meets patient expectations.[31] Explanations are often supplemented by visual aids such as models, charts and radiographs which assist understanding and serve as conditioning stimuli which can promote placebo response.[22] (Depending upon the patient's previous experiences other objects such as white coats, stethoscopes and xray machines may have a positive or negative effect on placebo response.)

c) **The laying on of hands**. Chiropractic practice involves "the laying on of hands", both in examination and treatment, and this is generally regarded as having stronger non-specific effects than medication, machines or surgery. In addition the actual adjustment or manipulation typically produces a 'pop' or audible release. To most patients this provides obvious and tangible evidence of value. Something that was previously 'out' is now 'in'. (The noise is, of course, merely the collapse of a nitrogen gas bubble released from the synovial joint during gapping).

12. In summary, to generate non-specific effects and enhance the specific effects of treatment in chiropractic practice, it is important for chiropractors to appear confident and enthusiastic, to emphasize manual contact and low technology in diagnosis and treatment, and through information and advice and otherwise to give patients confidence, expectation of success and a new sense of control over their problems.

D. Placebos in Research

13. For researchers placebo effects are generally a nuisance. They distort the specific effect of a treatment being studied, and create a bias that should be excluded. This negative attitude has

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tended to permeate clinical practice. As can be seen that should change and is now changing.

14. An important issue for researchers is to see whether the improvement rate in a group of patients receiving the active treatment being studied is significantly better than in the group receiving a placebo treatment. For this a placebo is necessary. There are major problems in finding a valid placebo or sham treatment for any of the manual therapies, and it is currently a high priority in chiropractic research to develop and standardize effective placebo procedures. A good sham should simultaneously:

a) superficially resemble the active therapy,

b) be consistent with the patient's expectations as to what the active therapy consists of, and

c) have no intrinsic therapeutic value beyond the non-specific treatment effects.

With spinal manipulation, if you satisfy components a) and b) the placebo or sham manipulation is likely to have a specific therapeutic effect. Conversely, if you satisfy component c) the sham treatment is likely to be accurately seen by patients as being of no value - thereby making it worthless as a placebo.

15. Mobilization and massage were formerly proposed as placebos for spinal manipulation. However they are unsuitable for various reasons, including the fact that they undoubtedly have specific therapeutic effects for certain conditions. During the past 10 years chiropractic researchers have used the following different methods to provide a credible sham for manipulation.:

a) Treatment tables with releasable drop sections adjusted so that a very light downward force would cause the drop piece to release and the patient to experience a rapid momentary change in position.[35]

b) The above, together with leg length checks and light soft-tissue massage to simulate a complete treatment.[36,37]

c) Passive rotation of the neck with very slight oscillatory pressure to the contact point.[38]

d) Light-force, low-amplitude thrust on the thoracic spine.[39]

e) Palpation of the cervical spine, then performance of a setup procedure bringing the patient "to tension", with the clinician backing off just prior to point of thrusting.[40,41]

f) Same as the above but with delivery of a very low-force thrust by thumb to contacts such as the transverse process of the thoracic spine or the lateral masses of C1.[42]

There has been impressive sophistication in recent trials, and much more thorough description of the sham/placebo procedures employed. In a trial of chiropractic manipulation for chronic back pain by Triano, McGregor et al just published in *Spine*,[43] the sham manipulation is described in detail and illustrated by diagram. A high-speed low-force placebo manipulation is used. Treating chiropractors were trained to stay below a force load of 400N. Patients were positioned on the treatment table in a standard manner to reduce risk of any specific treatment effect. The search for a standard, effective placebo continues.

16. Honesty and science demand that the chiropractic profession, as it is doing, and all health professions learn as much as possible about the specific effects of their treatments through controlled trials.

However chiropractors must also, in the words of Basmajian and Nyberg, "learn to harness and drive the powerful tool of the placebo response." If a chiropractor, or anyone else providing a form of manual therapy, "is knowledgeable about the procedures employed, is confident, and above all comes in close contact of with the patient, success of almost any treatment occurs in 30-50% of patients".

These factors are "at least as important as the specific effect of the treatment ... It is the human being, surrounded by the mystique of a profession, that has the strongest influence."[44]

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no substantial improvement this is when acute problems threaten to become truly chronic, disabling and expensive. There should now be aggressive multidisciplinary intervention.

Assuming it has not yet been used, what is the role of chiropractic manipulation at this point? It has an important role according to the above trial just published in *Spine* in which:

a) 209 patients with chronic low-back pain as defined by the Quebec Task Force (7 weeks or longer, or more than 6 episodes in the past year) and with palpatory tenderness over one or more of the lumbar facets were randomly assigned to three treatment groups - chiropractic manipulation, sham manipulation and back education.

b) Subjects received 7-12 treatments over a 2 week period.

c) Results were assessed at the end of the 2 week treatment period, and at 2 weeks follow-up, primarily by Visual Analog Scale (patient pain perception), the Oswestry Low Back Pain Disability Questionnaire (limitations in function or activities of daily living) and the modified Zung Depression Index (relative level of psychologic depression). The two main findings were:

- Patients in all three groups improved over time - confirming "a strong time-based recovery effect" regardless of exact treatment.
- The patients in the manipulation group did significantly better.

d) The authors conclude that spinal manipulation is clinically useful in chronic pain patients who have been suffering for 7 weeks or more, "a critical time during which many patients begin to evince signs of inappropriate illness behavior and other signs of chronicity and pending chronicity."

Spinal manipulation combined with exercise should be used at the acute stage. Failing that it should be used as soon as possible in the sub-acute or chronic stage. This is more appropriate and much more cost-effective than going to leading alternative approaches such as functional restoration, behavioral modification and chronic pain programs - "all of these methods while beneficial in their own right, are high cost approaches that focus on late stage cases where nearly heroic effort is required."

Risk of Stroke - Misrepresentation

Terrett AGJ (1995) *Misuse of the Literature by Medical Authors in Discussing Spinal Manipulative Therapy Injury*, J Manipulative Physiol Ther 18(4):203-210.

In this article Terrett, an Australian chiropractic researcher, documents widespread negligent and intentional misrepresentation by medical authors on the subject of stroke following 'chiropractic' manipulation. Terrett has not only reviewed the literature but has corresponded with many of the authors and this article vindicates the suspicions of many in the chiropractic profession.

As one example only take the paper by Frisoni and Anzola published in the medical journal *Stroke* in 1991. This refers to many past examples of stroke following chiropractic manipulation where the practitioner was not in fact a chiropractor, and then reports on three new cases of stroke following chiropractic manipulation. But the practitioners in those cases were actually a medical practitioner and two physiotherapists.

Many subsequent medical publications quote Frisoni and Anzola, compounding the misrepresentation. In the 1993 Yearbook of Neurology and Neurosurgery, for example, Chapter 15 is titled *Chiropractic Manipulation Risks* and is based on a review of the Frisoni and Anzola paper. After review of numerous cases where complications of neck manipulation were wrongly described as chiropractic, Terrett makes this pointed observation:

" ... No example was found in the medical literature where a case of manipulation iatrogenesis involving a chiropractor had been incorrectly ascribed to a medical or other practitioner."