THE CHIROPRACTIC REPORT

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PROFESSIONAL NOTES

Cervical Disc Degeneration - Not a Contraindication for Manipulation

Elliott v Richmond, Supreme Court of British Columbia No. C937034. Judgement dated December 3, 1996.

In this recent Canadian case the plaintiff, a 47 year old woman, sued for damages for pain and disability from cervical herniations at C5-C6 and C6-C7 which she alleged were caused by cervical manipulation given by the defendant chiropractor. X-rays provided objective evidence that the plaintiff suffered from pre-existing degenerative change.

The plaintiff's expert evidence was that there was a greater than 50% chance that the manipulation could have caused the injury to the discs or nerve roots. On the facts the court rejected this and the plaintiff's claim, holding that the defendant's treatment did not cause the herniations. The court expressly preferred and accepted this expert evidence from Scott Haldeman DC MD PhD:

"Cervical disc degeneration is not a contraindication for cervical rotary manipulation. By far the majority of the population over the age of 40 have cervical degenerative changes, and by age 60 approximately 80 percent of the population have degenera-

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MANAGING PATIENTS WITH LOW-BACK PAIN

Evidence-based Guidelines Create New Partnerships

A. INTRODUCTION

Recent issues of this Report have focused on the cervical spine. This issue returns to the low back because:

a) New management guidelines just published by the Royal College of General Practitioners in England, and based on an updated literature review to April 1996, reaffirm the findings of other recent government-sponsored reports in the United States, Canada and Britain in saying that manipulation "by a properly trained practitioner" and early activation have an important role in the management of most back pain patients.[1]

b) Back pain remains a dominant problem for individuals and society. 85% of people will be disabled by back pain at some point in their lives.[2] In the US disability from back pain is growing at a rate 14 times faster than the population growth,[3] and the direct and indirect costs are estimated to be at least $60 billion per year.[4] In Britain there are similar statistics.[5] In the 30-50 age group low-back pain is the single most expensive health care problem.[6]

2. Experts acknowledge that traditional management of patients has been disastrous[7,8] and warn that the costs of low-back pain are "a unique liability to the business community" and represent "the single greatest and most inefficient expenditure of health care resources in our society today."[9]

These new guidelines are particularly significant because:

a) They are published by a professional medical association, the Royal College of General Practitioners.

b) They were developed in consultation with the British National Health Service, the British Chiropractic Association, and other professional groups. Senior members of the Guideline Development Panel were Professor Gordon Waddell of Glasgow, the orthopaedic surgeon and researcher who was a consultant to the US Agency for Health Care Policy and Research (AHCPR) Back Pain Guidelines Panel, and Dr. Alan Breen, Research Director, Anglo-European College of Chiropractic, Bournemouth.

c) They accept the AHCPR literature review as a starting point, but update this from 1992 to April 1996.

d) In essence the AHCPR management guidelines are endorsed and refined for easy clinical use. The Royal College advises general practitioners (family physicians):

i) *Assessment*: Avoid routine use of x-rays. Perform a differential diagnosis (diagnostic triage) between simple backache, nerve root pain, and possibly serious spinal pathology.

ii) *Management*: For most patients, being those with simple backache and many with nerve root pain, avoid bed rest and referral to medical specialists. Advise patients to stay active, prescribe over-the-counter analgesics and "consider manipulative treatment within the first six weeks" because of its effectiveness in terms of pain relief, better activity levels and higher patient satisfaction. "The risks of manipulation are very low in skilled hands."

e) All of this shows a fusion of literature, clinical wisdom and interprofessional co-operation that is an example to the rest of the world. Much credit must be given to the Royal College and Professor Waddell whose trenchant analysis of the disastrous state of back care 10 years ago[10,11] triggered many of the major developments since.

3. The Royal College's *Clinical Guidelines for the Management of Acute Low Back Pain* appear in two documents, the *Clinical Guidelines and Evidence Review* (35 pages) and a summary pamphlet (2 pages, 6 panels). A copy of the pamphlet is enclosed with this Report and may be photocopied freely. Copies

of the *Clinical Guidelines and Evidence Review* are available for £10 inclusive of shipping costs from the Royal College of General Practitioners, Sales Office, 14 Princess Gate, Hyde Park, London SW7 1PU, England, Tel 44-171-823-9698 Fax: 44-171-225-0629.

4. There are now seven major evidence-based reviews in North America and Britain in the 1990s that offer compelling support for chiropractic management of patients with low-back pain. These are summarized in Table 1 (see page 3).

Some of the reviews have been sponsored by government, some by professional associations. Some have looked at the overall management of low-back pain, some at chiropractic management. The US government sponsored AHCPR Guideline, and the new updated guideline from the Royal College, focus on patients with acute pain - defined as a current episode of pain for up to three months.

The balance of this Report now looks at the Royal College Guideline, and then comments on the area it does not cover - management of patients with chronic low-back pain.

B. Royal College Guideline

5. The goal was to start with the US AHCPR evidence review, update this, and produce current guidelines. All of the major findings in the AHCPR Guideline were endorsed and found not to be changed by trials that have been reported in the period 1992 to 1996. For the essential findings in terms of triage (differential diagnosis), recommendations and strength of evidence in support, see the summary pamphlet. Other points of interest include:

a) **Psychosocial factors**. It is found that there is now a great deal of evidence on the relevance of psychosocial factors in *chronic* low-back pain but that "there are not at present any RCTs (*randomized controlled trials)* which demonstrate whether psychosocial assessment or interventions in *acute* low-back pain affect clinical outcomes."

b) **Drug therapy**. Findings remain consistent with the AHCPR Guideline - simple over-the-counter medications are equally effective as, but avoid the significant adverse affects of, muscle relaxants and opioids. "There is no evidence available on the use of anti-depressants in acute low-back pain."

c) **Bed rest**. There are now 9 randomized controlled trials (RCTs) of bed rest for acute or recurrent low-back pain with or without referred leg pain and "these show consistently that bed rest is not effective." These guidelines say that bed rest should not be used as a treatment.

d) **Early activation.** 8 RCTs show that advice to continue with daily activities of living will give better results than traditional medical treatment with analgesics and advice to rest.

e) **Manipulation**. There are now 36 RCTs of manipulation for low-back pain, including another two since the AHCPR evidence review, and these show early patient benefits in terms of pain relief, improved activity levels and patient satisfaction. Chiropractors will approve of the emphasis on manipulation only being provided by those with proper formal training. The guideline emphasizes:

"..... the risks of manipulation for low-back pain are very low provided patients are selected and assessed properly and it is carried out by a trained therapist or practitioner."

From a chiropractic perspective it is disappointing to see manipulation discussed in the context of *pain relief* only, and thus as an alternative or supplement to medication, rather than as a treatment approach that restores joint and muscle *function*. Chiropractic manipulation is successful because it addresses the underlying problem, restricted function, rather than symptoms only.

As demonstrated by the British Medical Research Council trial of chiropractic[12,13] this means not only earlier results but also fewer recurrences of back pain, less disability and long term benefit. In the words of Prof. Vert Mooney, Past-President of the International Society for the Study of the Lumbar Spine, orthopaedic surgeon and researcher, San Diego:

"We have not been honest with ourselves in the past when we have supported months of passive modality care that can offer no long-term benefit. We have not been fair to our patients when we have focused on *pain* rather than *function* as medical clinicians, and have relied only on the science available to us for the care of *structural* disorders and not for *functional deficits* ... The time has come to develop rational principles of care".[7]

f) **Back exercises**. Findings are interesting and cut right through the common perception that there is good evidence in support of back exercises. This guideline indicates there are now 28 RCTs of specific back exercises for back pain, but many are of poor quality and "on the evidence available at present it is doubtful that specific back exercises produce clinically significant improvement in acute low-back pain, or that it is possible to select which patients will respond to exercises."

There is only moderate evidence (2 star) that McKenzie exercises "may produce some short term symptomatic improvement". Early commencement of exercise programs is based on "strong theoretical arguments" rather than evidence.

g) **Physical agents and modalities**. The recent evidence continues to support AHCPR conclusions - although ice, heat, short wave diathermy, massage and ultrasound are commonly used for symptomatic relief "these passive modalities do not appear to have any effect on clinical outcomes".

h) **Traction and TENS**. As with physical agents and modalities, the studies

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Table 1

EVIDENCE-BASED REPORTS RECOMMENDING APPROPRIATENESS OF MANIPULATION FOR PATIENTS WITH BACK PAIN

STUDY/REPORT	AUTHORS	SPONSORSHIP	METHOD	FINDINGS
1. RAND (1991)[1]	9 member multi-disciplinary expert panel	Private research institute	Literature review and modified Delphi consensus process	Spinal manipulation is appropriate for patients with many categories of back pain. Initial course of treatment to produce documented improvement is 4 weeks, with reassessment and change of technique at 2 weeks if no improvement at that time.
2. Mercy Center (1993)[2]	35 member chiropractic panel	The US chiropractic profession including all professional and educational organizations	Literature review and modified Delphi consensus process	As in 1 above. In addition chiropractic manipulation is given an *established* rating on Class I and II evidence for patients with acute and chronic mechanical back pain, and an *established* rating on Class II and III evidence for patients with mechanical back and leg pain, and various other forms of back pain.
3. Manga (1993)[3]	University-based health economists and faculty	Government of Ontario, Canada	Literature review and report	Chiropractic manipulation and management is superior to other treatments for most acute and chronic back pain patients in terms of effectiveness, cost-effectiveness and patient satisfaction.
4. Glenerin (1994)[4]	35 member chiropractic panel with one lay member	Canadian Chiropractic Association	Literature review and modified Delphi consensus process	As in Mercy Center Report (2 above)
5. Agency for Health Care Policy and Research (1994)[5]	23 member multi-disciplinary expert panel with one lay member	US government	Literature review and modified Delphi consensus process	Spinal manipulation is appropriate as a first line approach to treatment of most patients with acute low-back pain (defined as a present episode of pain for up to 3 months). In the absence of certain red flag conditions patients should be encouraged to remain active and receive manipulation and/or over-the-counter medications.
6. Clinical Standards Advisory Group (1994)[6]	10 member multi-disciplinary expert panel	UK government	Literature review and consensus report	As in AHCPR Report (5 above)
7. Royal College of General Practitioners (1996)[7]	10 member multi-disciplinary guideline development group	Professional association for general medical practitioners	Update of AHCPR and CSAG literature reviews to April 1996 and consensus report	As in AHCPR Report (5 above)

For notes and references see next page

Notes to Table 1

1. **Standard of Evidence**. Some reports (e.g. AHCPR, CSAG, RCGP) considered only randomized controlled trial (Class I) evidence. Others (e.g. Mercy, Manga and Glenerin) gave predominant weight to Class I studies but considered all the evidence. What weight to give strong Class II evidence (well-designed prospective studies e.g. Kirkaldy-Willis and Cassidy[8]) is a matter of considerable debate. Judging the evidence without including them at all is felt by many people to be like judging the effectiveness of the English language by the standards of dictionaries but excluding Shakespeare.

2. **Scientific Meta-analysis**. There have been a number of straight scientific overviews (meta-analyses) of the literature on spinal manipulation.[9,10,11] These were part of the evidence base considered in the above-mentioned studies. The present table lists reports that make recommendations or guidelines based on the scientific evidence and representative professional consensus. It does not list individual scientific papers, whether single trials (of which there have now been 36) or meta-analysis of them.

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show that these do not have any effect on clinical outcomes.

i) **Trigger point and ligamentous injections**. Again, there is no strong evidence of effectiveness and "ligamentous and sclerosant injections are invasive and can expose patients to serious potential complications."

j) **Manipulation under general anaesthesia**. This is mentioned along with bed rest with traction, systemic steroids and other treatments as having negative evidence. It is concluded that "there is no evidence that these treatments are of any benefit for low-back pain or sciatica. In every case there are simpler and safer alternatives, and they are all associated with potential hazards or complications." Manipulation under general anaesthesia "is associated with an increased risk of serious neurological damage."

C. Chronic Low-Back Pain

6. The Royal College Guideline, like the AHCPR guideline, doesn't deal with chronic pain patients. It does, however, include the comment, based on moderate or two-star evidence only, that "the evidence in inconclusive that manipulation produces clinically significant improvement in chronic low-back pain." This is a comment which invites misinterpretation, and which gives rise to a number of important points about evidence generally. It is noted:

a) This does not mean that the evidence shows that manipulation is ineffective for patients with chronic back pain. There is similar RCT evidence for manipulation as for exercise and physical reconditioning programs. It means there is not strong RCT evidence.

b) However many scientists and clinicians have an important question for those producing new evidence-based guidelines - is it fair and appropriate to exclude other classes of evidence where there are only a few randomized controlled trials (RCTs), and these RCTs give no clear message?

It is one thing to exclude prospective studies (i.e. research based on treatment of a series of patients, but with no comparison group as in a randomized controlled trial) when RCTs contradict them and show ineffectiveness. But it is quite another matter, and one is on much more fragile ground, to exclude them when the RCTs are equivocal and the prospective studies are strong. With chiropractic manipulation for patients with chronic back pain consider for example this prospective study by the respected researchers Kirkaldy-Willis and Cassidy published in the Canadian Family Physician in 1985:[14]

i) The aim was to determine the effectiveness of chiropractic treatment for a population of patients who:

- Had experienced low-back and leg pain for a period of several years;
- Were totally disabled by this pain (scaled as *Grade 4* on a scale where *Grade 1* was symptom free, *Grade 2* mild, constant or intermittent pain but with no restrictions for work or other activities, *Grade 3* pain-restricting activities, and *Grade 4* disabled from work or other activities by constant severe pain).
- Had been referred to a specialized hospital clinic after not responding to conservative and/or operative treatment.

ii) Following referral for chiropractic examination, 171 of 283 patients were diagnosed as having posterior joint syndrome and/or sacroiliac joint syndrome. *They had experienced Grade*

4 disability for over 7 years on average.

iii) Following a 2-3 week regime of daily chiropractic adjustment, combined with back school and advice on exercise, 87% returned to full function with no restrictions for work or other activities. (Grades 1 and 2).

iv) No patient was made worse.

v) The 87% success rate was maintained when the patients were reviewed after 12 months.

In this research the patients, in a very real measure, provided their own control group because they had been fully disabled for a period of years despite various conservative treatment approaches. These excellent results led to an interdisciplinary program at the hospital and a new model of care most fully described in Kirkaldy-Willis' widely read text *Managing Low-Back Pain*.[15] Yet work such as this is completely ignored because it is not an RCT.

c) For scientists another problem with the work of Kirkaldy-Willis and Cassidy is that it does not involve only one intervention - chiropractic manipulation - but a combination of interventions including back school and exercise. But this is what happens in rational practice - and there is an inherent absurdity in judging manipulation only on studies that have this as the sole intervention, discounting other research that has combination management as in practice.

Although the Royal College Guideline, adopting a narrow evidence-base of RCTs only (*Class I* evidence), suggests that the evidence on manipulation for patients with chronic back pain is inconclusive, a good case can be made that on a broader evidence base there is quite compelling support in the literature.

Perhaps the strongest single piece of evidence, the large (n 741) multicenter randomized controlled trial by Meade et al for the British Medical Research Council,[12] is also often discounted by scientists because it is said to be a trial of chiropractic management - not chiropractic manipulation. Virtually all patients (99%) received joint manipulation but many also received back education, specific exercises and physical therapy modalities. In this trial by independent investigators:

i) The aim was to compare chiropractic and hospital out-patient treatment for low-back pain of mechanical origin.

ii) Treatment was at the discretion of the participants subject to limitations on frequency (10 visits) and duration of care ("concentrated in the first three months").

iii) Virtually all chiropractic patients received joint manipulation, and received basic advice and back education. Some also received specific exercises and/or physical therapy modalities.

The great majority of hospital out-patients (84%) received manipulation or mobilization from physiotherapists according to the techniques of Maitland or Cyriax. Some also received, singly or in addition, traction, corsets, exercises, and physical therapy modalities.

iv) Measurement of results was subjective (Oswestry Pain Disability Questionnaire) and objective (degrees of straight leg raise and lumbar flexion).

v) The chiropractic patients did significantly better, especially those with severe or chronic pain. These superior results were maintained at 1 and 2 year follow-up.

vi) The investigators identified three likely reasons for the superiority of chiropractic treatment - diagnostic and treatment skill, frequency of treatment (medical/PT patients received 6.3 treatments on average, chiropractic patients 9.1) and duration of treatment (79% of medical/PT patients had completed treatment within 6 weeks, only 29% of chiropractic patients).

vii) Meade et al concluded that chiropractic manipulation has long-term success in the management of severe and chronic mechanical back pain, is highly cost-efficient, and recommended introduction of chiropractic services into the British National Health System.

They referred to an editorial by Jayson[16] in the British Medical Journal in the mid-1980s suggesting that manipulation was of benefit for acute pain but may not be of benefit for severe problems or in reducing long term complications and concluded that "for chiropractic our findings suggest otherwise."

D. Conclusion

7. Modern evidence-based management of patients with acute low-back pain, as the new Royal College Guideline confirms, requires a multidisciplinary approach with medical doctors, chiropractors, physiotherapists and others working together. Most patients have biomechanical or functional pathology, rather than structural pathology. Obviously relief from pain is important to the patient, but the primary goal must be restoration of function.

The importance of effective early management of patients is underlined by the fact that 85% of the overall cost of back pain to society comes from the 5-10% of patients who progress to chronic pain and disability.[14] Early results are important and cost-effective. The traditional 'wait and see' approach has in fact promoted disability and, paradoxically, has been far more expensive than early active management as in chiropractic practice. In the words of health economists Manga and Angus, commissioned by and reporting to the Ontario government in Canada in 1993:

"In our view, the constellation of the evidence of:

(a) the effectiveness and cost-effectiveness of chiropractic management of low-back pain.
(b) the untested, questionable or harmful nature of many current medical therapies.
(c) the economic efficiency of chiropractic care for low-back pain compared with medical care.
(d) the safety of chiropractic care.
(e) the higher satisfaction levels expressed by patients of chiropractors,

together offers an overwhelming case in favour of much greater use of chiropractic."[17] TCR

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tive changes of the cervical spine. These people, for the most part, can safely receive cervical rotatory manipulation without complication".

Points

- ***Mechanical Neck Pain*:** The British Medical Journal has just published a new review of conservative management of mechanical neck pain. Lead author is Dr. Peter Aker, Assistant Professor, Canadian Memorial Chiropractic College (Aker PD, Gross AR et al (November 23, 1996) *Conservative Management of Mechanical Neck Pain: Systematic Overview and Meta-Analysis*, Br Med J 313:1291-6).

As with the Quebec Task Force Report it is concluded that there is little evidence supporting many common treatments. In particular:

- A 1994 survey of British physicians reported that they perceived active exercise, traction, TENS and ultrasound to be the best methods for treatment of neck pain. "The results of this overview clearly do not support these approaches."

- Best evidence, though still not strong, is for manual treatments in combination with early activation and modalities for pain relief.

- ***Headache:*** Two new randomized controlled trials supporting the effectiveness of chiropractic manipulation for cervicogenic headache (Nilsson N et al, Denmark) and migraine (Whittingham W et al, Australia) were reported at the recent International Conference on Spinal Manipulation held by the Foundation for Chiropractic Education and Research at the Anglo-European College of Chiropractic in England. Both have been submitted for publication and will be reviewed further in due course.

- ***A New Journal*:** *Evidence-Based Medicine*, published by the British Medical Journal in association with the American College of Physicians, is an exciting new form of journal for the 1990s that started in 1996. Principal editors are epidemiologists Dr. Brian Haynes from Canada and Dr. David Sackett from England and the journal is published in Philadelphia.

Nothing is more than one page in length. Trials newly published in other journals are summarized on one half page under the subheadings *Objective, Design, Setting, Patients, Intervention, Main Outcome Measures, Main Results, Conclusion.* The other half of the page carries a short expert commentary.

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