THE CHIROPRACTIC REPORT

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Clinical Trials, Science, and Chiropractic

A. Introduction

1. The randomized controlled trial (RCT), or double-blind clinical trial, is in theory the most scientific method of testing the effectiveness of any health care treatment.

2. The chiropractic profession, as with all major health care professions today, is actively involved in controlled trials. With respect to chronic low back pain there are currently 4 major trials underway – in Canada, England and the United States (2). Three are comparing chiropractic and medical treatment, one is comparing chiropractic spinal adjustment with no active treatment – just a sham adjustment.

3. Clinical research through trials has obvious importance, not only clinically but also politically. However, the controlled trial was not developed for health care and human subjects and has many scientific limitations, particularly for physical treatments for pain relief. Indeed one prominent medical researcher conlcudes:

"The practical limitations in clinical research impair the techniques of the RCT such that, although a veneer of scientific respectability may result, little new information is likely to emerge".[1]

4. In 1985 orthopedic surgeons Rudicel and Esdaile from Yale University noted that "the orthopedic literature is almost devoid of trials of surgical therapy" and openly argued against the need for clinical trials in orthopedic surgery.[2]

5. Most health care interventions, whether medical, chiropractic or other, have never been proved effective by controlled trials. Where trial evidence suggests ineffectiveness this frequently has little effect on medical practice – for a striking recent surgical example see Professional Notes, first item, at left on this page.

6. This Report now reviews the RCT (comparing it with other research methods), where it came from, its limitations, the chiropractic trials underway at present, and suggests that the huge cost of clinical trials remains justified despite the problems.

B. What is an RCT

7. The classical randomized clinical trial tests the effectiveness of a defined treatment by giving this to one group of patients while a second comparable group receives a sham treatment or 'placebo'. Adding another group with a second treatment allows the trial to show comparative effectiveness as well. For practical reasons, including the welfare of patients with serious disorders, there may be no sham treatment or 'control' group, just different treatment groups (e.g. comparison of medical vs surgical treatment of acute angina). This sacrifices some scientific validity – but, as we shall see, many things do in the best designed trials.

8. Other essential features of an RCT are:
a) **Randomization.** Patients meeting the 'eligibility criteria' for entrance to the trial are randomly assigned to the trial groups. They, and those running the trial, cannot choose.

b) **Double-blindness.** Not only can they not choose a group or treatment, but neither the patient nor the researchers assessing treatment results should know which treatment, if any, was received. Both are 'blind' – the trial is double-blind. The aim of these and other design features in the trial is to rule out all chance effects, as opposed to effects of the therapy under trial – i.e. to eliminate 'bias'.

9. The RCT is costly, time-consuming, Cadillac/Rolls Royce science. It may be compared with these less rigorous research methods:

a) **The descriptive study.** The next best method in theory. With sound methodology you can control bias. This type of study looks at the response of a series of patients to a given treatment, according to a careful

Professional notes:

Surgeons Reject Trial Evidence

EC/IC Bypass Study: Results of an International Randomized Trial, New England Journal of Medicine, November 7, 1985 (1191-1200). 'Extracranial-Intracranial Bypass 1: Clinical Trials, Nil' Dudley H.A.F. Brit Med J (June 13, 1987) 294:1501-1502. **PN1**

Here is a particularly interesting example of the conflict between clinical practice and scientific evidence. Facts are:

i) The surgical procedure of arterial anastemosis, joining the superficial temporal artery to the middle cerebral artery to decrease the rate of stroke and stroke related death in patients with atherosclerotic disease in the carotid and middle cerebral arteries, was first performed in 1967. During the next 10 years the technique was widely used.

ii) To test whether the surgical technique, which resulted in fatalities and other serious side effects, was in fact effective in reducing the rate of subsequent stroke among patients, an international multicentre randomized trial was commenced in 1977.

) The trial involved 1377 randomized patients, recruited in 71 centres in 10 countries, cost $9 million and was finally reported in the New England Journal of Medicine in late 1985. The report flows with jargon, statistical analysis and learned discussion and can fairly be described as the paragon of scientific medicine.

continued on insert page 1.

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methodology worked out in advance – i.e. it is a prospective study. However, it does not compare the treatment under study with a control group or alternative treatment. Additionally the patients are usually self-selected – they chose the treatment themselves rather than being randomly assigned to it by a trial administrator.

The fundamental criticism of a descriptive study, scientifically speaking, is that patients may have got better at the same rate without any treatment – how do you know, since there was no control group. However, in practice this criticism may carry little weight for a good descriptive study. See for example the work of Kirfkaldy-Willis, M.D. and Cassidy, D.C. with chiropractic treatment of a hospital population of patients with chronic low back pain.[3] Given that these patients had suffered for many years, the variety of prior treatments, the calibre of the researchers, the thoroughness of the design and reporting, and the excellent treatment results achieved, this descriptive study is the equal in science and importance of any controlled trial of manipulation yet performed.

b) **The case control study.** Sometimes called 'a case history' or 'retrospective' study, this is commenced after treatment is over. This makes it weaker in design and science than the descriptive study. Fewer factors are controlled, there is much more chance, results are less reliable.

An example is the well-known study by Kane et al comparing the effectiveness of medical and chiropractic treatment of low back pain published in 1974 in Lancet.[4]

c) **Observational study.** Similar to the case control study, except that there is no contact between the researchers and patients. Examples are the various studies of WCB records in the United States comparing the cost of medical and chiropractic treatment of injured workers.

d) **Case study.** Scientifically weaker again, and really amounts just to a starting point for further research. Reports on one or more individual cases.

10. It is important to appreciate that work may range from excellent to useless in all of the above categories. In JMPT in 1984, David Brunarski, D.C. reviewed the 50 studies of effectiveness of spinal manipulation published in the literature to 1983 – 12 involved chiropractic researchers. He concluded that, scientifically, an RCT evidencing "the true effectiveness of spinal manipulative therapy has yet to be performed".[5] He lists the minimum necessary requirements. Other chiropractic and medical researchers agree. Why have there been these difficulties?

C. Where did the RCT come from?

11. You may be surprised that the first RCT in health care research was not done until 1946. (This was a streptomycin trial designed by Bradford Hill for the British Medical Research Council.)[1]

12. This form of research came from agriculture. The methodology was developed in England in the 1920s and 1930s, and was being used routinely in agricultural research worldwide by the mid-1930s.

13. The aim of this research method is to assess which observed differences result from the trial intervention and which merely from the chance fluctuations inherent in all living matter. You can see immediately that it is much easier to control variation in agriculture than in humans.

Agricultural investigators can exercise a high degree of control over environment, and have the benefit of being able to dissect in vivo if necessary. Given the economic and strategic importance of their work, they have had the sort of consistent government and private funding for research of which health care researchers can only dream.

14. The fact that research using clinical trials is so new to health care has two results:

a) Contrary to popular belief, the effectiveness of most health care treatments has never been established by clinical trial. In the April 1987 issue of the British journal Physiotherapy Cecily Partridge, PT, Ph.D., observes:

"The basis on which efficacy has been judged in the past in physiotherapy, and on which it is still mainly based today, is clinical experience and personal opinion".[6]

The same can be said of chiropractic and medicine and all health care.

b) The great majority of the clinical trials published are, as scientific evidence of effectiveness, worthless. This is because of flaws in research methods that are only now becoming apparent with growing experience.

D. RCT – Limitations in Evaluation of Health Care

15. There has been a noticeable increase in recent years in the number of articles criticizing clinical trials as currently performed in health care. Some criticism goes to central principles of the clinical trial. Thus, for example, Kramer and Shapiro[7] challenge the concept of randomization.

Cranial Adjustment

1. Which defendant settled just before the recent re-trial of the Wilk suit?
2. Where and what was the Big Debate on July 3, 1987
3. Give one of the 2 major design differences between a controlled trial and a descriptive study.
4. Dr. Ron Harris, ACA Exec. VP, Dr. Roger Naef, Director, Swiss Chiropractors Association, and Dr. Jay Triano, Dean of Research, NCC, are graduates of which chiropractic college?
5. Ronald Sim, D.C. of Oamaru is the new president of which national chiropractic association?
6. What was the former name of the New York College of Chiropractic?
7. Springer Verlag of Heidelberg, West Germany publishes the one medical journal in the specialty of manual medicine – in German and English editions – what's its name?
8. In which Asian country is the traditional bone setter and herbalist known as a sensay?
9. What do the initials DACBR stand for?
10. What diagnostic method of value to chiropractic was recently approved by the American Medical Association?

Answers

1. American Hospital Association – freeing its members to make their own decisions concerning relationships with chiropractors.
2. Las Vegas, at the first joint ACA/ICA Convention. About one united association in the U.S.
3. Patients entering a study are not randomized, and a study has no control group. (See main article, this Report).
4. Logan.
5. The New Zealand Chiropractors Association.
6. Columbia Institute.
7. Manuelle Medizin/Manual Medicine.
8. Singapore.
9. Diplomate of the American Chiropractic Board of Roentgenologists.
10. Thermography.

While this is found appropriate for the classic drug efficacy trial, where patients are treated individually and treatment groups remain apart, "random assignment by individuals can actually be detrimental" because in reality there is subsequent communication between patients which leads to 'contamination' and 'bias' which "directly threatens the internal validity of the trial". Where interaction between patients after treatment but before measurement of outcome is likely, "treatment allocation by . . . region may be preferable to randomization by individuals".

16. Then there are general problems facing all trials including:

a) **Hawthorn effect** (or the effect of participation). Simply stated this means that mere participation in a trial means that patients experience results which may be significantly better than if they received the same treatment or placebo in the normal course of health care. This may mean that patients in the control group receiving no

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iv) The study showed that this surgical technique, now widely performed internationally for approximately 20 years, was not effective. Patients assigned to the best medical care did better overall. The British Medical Journal reported that this trial "was widely regarded as having put the ultimate scientific boot into what seemed an elegant and rational procedure".

v) Would surgeons with long experience of this operation, convinced that it was effective for them, accept this evidence? For many the answer has been no. The British Medical Journal reports that the American Association of Neurological Surgeons, after "a strenuous round of telephoning, writing and interviewing", has established that about 50-70% of eligible patients were not included in the trial. Because of this flaw the trial is being rejected.

This raises 2 immediate points. Firstly scientific limitations can be found in all clinical trials, usually much more serious than the failure to include a number of eligible patients. If this massive trial is rejected, it provides a clear and visible reminder of the reluctance of the medical profession to accept 'scientific evidence' when it conflicts with established patterns of clinical practice.

Secondly, you can safely bet your home and fortune that surgeons continuing with this procedure, which has no controlled trial evidence of effectiveness, and trial evidence strongly suggesting ineffectiveness, will never initiate a trial more thorough than the one already performed. It will be interesting to see if they do a trial at all.

Chiropractic and Research – Observations of an Australian Government Committee

Second Report (June 1986) Australian Government Medicare Benefits Review Committee, Commonwealth Government Printer, Canberra, Australia, 74-75 and 387. **PN2**

For detailed analysis of this Australian study see the July 1987 issue of this Report. In assessing the effectiveness of health care the Australian Committee was quite prepared to rely on clinical as well as scientific trial evidence in assessing the effectiveness of health care. The following passages explain why, and answer the inappropriate criticism sometimes heard about lack of research by various professions including chiropractic.

". . . there seems to us to have been a significant shift in the last decade in the attitude of some complementary (professions) towards the issue of scientific research. *This is particularly true of chiropractic*. Previously, it was too often claimed that some professions relied upon an alternative paradigm of health knowledge to that of Western scientific medical knowledge and therefore could not be evaluated according to the canons of Western scientific knowledge. In recent years, however, with the emergence and the refinement of clinical trials of various sorts, there appears to us to be a greater acceptance of scientific evaluations. . ."

"(Chiropractic and other complementary health care professions) might reasonably have been expected to support some research, but *it is unreasonable, in our view, to expect that they should engage in large-scale programs from their own resources.*"

continued on insert page 2.

AN ORTHOPAEDIC SURGEON ASSESSES CHIROPRACTIC

This special item for the Report is from Emeritus Professor William H. Kirkaldy-Willis, M.A., M.D., F.R.C.S.(Edin)(C) Department of Orthopaedic Surgery, University Hospital, Saskatoon, Canada, an internationally respected orthopaedic surgeon and senior researcher in the field of low back pain. Prof. Kirkaldy-Willis has published a number of texts and numerous articles in leading medical journals. 'Managing Low Back Pain' (1983) Churchill Livingston, New York and London, of which Prof. Kirkaldy-Willis is editor and principal author, deals in detail with the 3 phases of degeneration referred to below. (A second edition of this prominent text is due for release in Fall, 1987). See also 'Recognizing Specific Characteristics of Non-specific Low Back Pain' Bernard and Kirkaldy-Willis, published in the April 1987 issue of Clinical Orthopaedics and Related Research (217:266-280) and referred to in the July 1987 issue of this Report.

Introduction

In my practice I have found, over 35 years, that manipulation is a valuable modality of treatment for low back pain. Over the past 10 years in Saskatoon I have worked closely with chiropractors. One of them comes regularly to my out-patient clinics. We examine patients together and decide what treatment will help the patient most. Manipulation and allied therapy, when indicated, is given by the chiropractor in his office. Often I see the patient again at the end of treatment.

Dysfunction

We are of the opinion that the main indication for manipulation is 'dysfunction', a phase in the spectrum of the degenerative process in the spine. By 'dysfunction' we mean the functional changes seen during the first of three phases, the others being 'instability' and 'restabilisation'. During this first phase the three-joint complex of two facet joints and the disc does not function normally, but the anatomical changes are minimal.

Our Low Back Clinic

In the Low Back Clinic of the University Hospital in Saskatoon 1293 patients were seen over a 12 year period from 1972 to 1984. This clinic only sees patients on referral, and thus consists of those who have not responded to primary care. Of this selective group:

a) 22.08% had a Posterior Facet Syndrome; and
b) 22.55% a Sacroiliac Syndrome.

These two syndromes are examples of 'dysfunction' and comprise the most commonly encountered types.

Overall 49.98% (1 in 2) of patients entering the low back clinic had dysfunction alone (without any other concomitant lesion), were considered candidates for chiropractic treatment, and were given daily manipulations for 2-3 weeks. This produced a successful result (good or excellent results) with 87% of these patients.

Other Types of Lesions

Other conditions, such as a disc herniation, lateral stenosis and central stenosis, are frequently accompanied by a concomitant dysfunction at an adjacent level. The dysfunction may be the cause of pain rather than the anatomical lesion seen on radiographic or CT examination. Manipulation, when advisable, may relieve the pain. We then say that the pain was due to the dysfunction.

A misconception that often creeps into any debate on the subject is that the chiropractor is treating the anatomical pathology. We do not pretend that manipulation affects this – rather it is relieving the dysfunction which proves to be the cause of pain in these cases.

In 38 patients with spondylolisthesis there was a concomitant sacroiliac syndrome, with pain over the sacroiliac joint. In 89% of these patients manipulation produced a good or excellent result. In these instances the pain was due to dysfunction of the sacroiliac joint, not the spondylolisthesis. Once again we are careful to make it clear that we do not believe that manipulation can change anatomical pathology. It is, however, always wise to exclude sacroiliac syndrome before prescribing treatment for spondylolisthesis.

Supplementing Chiropractic with Other Modalities

Chiropractors have a great advantage – that their treatment is done on an out-patient basis. They might well profit from using other types of therapy more than they do. Some suggestions are:

1. A light elastic supporting garment gives the patient much relief without restricting movement or leading to muscle atrophy.
2. Back School. We have found this so effective that chiropractors should invest widely in this form of patient education.
3. We read that from 75%-90% of physical lesions stem from an emotional problem. There is good evidence that this applies as much to backache as to other problems. The chiropractor who takes the trouble to understand the emotional and psychological aspects of the patient's problem will score on all counts on every occasion. The same of course applies to the physician or surgeon!

Conclusion

Our experience over 12 years in a hospital low back clinic is that chiropractic manipulative therapy is cost-effective and of very great value in the treatment of many patients with chronic low back pain.

William H. Kirkaldy-Willis, M.D., F.R.C.S.(C),
Saskatoon.

". . . There are several reasons (for little research conducted on the issue of effectiveness of different treatments), the major one being that medical research has generally been accepted as being of more importance and that the resources available have overwhelmingly been directed to that end. At least partly this is the result of the composition of fund allocating bodies being established researchers working in conventional medical areas. The Webb Report (*an Australian Federal Government report on chiropractic in 1976*), for instance, recommended that an annual sum of $200,000 be made available for research into chiropractic treatment. As far as we have been able to ascertain, none has been forthcoming."

"The situation is complicated further by the conventional opposition of the medical profession to at least some complementary (health care professions) on the grounds of the lack of a scientific basis to their services. In some respects this may be seen as unfair since incomplete research has been performed in all areas including some areas of orthodox medical treatment. Most of the treatments themselves are performed by some members of the medical profession, and the placebo effect is also well documented in conventional medical treatment. *Indeed we are inclined to regard this criticism of (chiropractic and some other professions) as something of a 'red herring', as did the New Zealand Report into chiropractic."*

See lead article for detailed comment on clinical trials and chiropractic.

Meeting MDs Over An Odontoid Fracture

Giving his key impressions after two years as ACA President, Dr. Weldon L. Odom says "chiropractic can no longer play the martyr's role and isolate itself from the rest of the health care community. Whatever the wrongs perpetrated against us, we must talk them out and work them out. We must build bridges, not barriers, with all health care and ancillary groups." (ACA J of Chiropractic, June 1987.)

There can be little doubt that the best way to 'build bridges' is by displaying professional competence with patients who have sought both medical and chiropractic care. Dr. Donald Henderson of Toronto doesn't want his patients to have odontoid fractures, but often when they do another medical specialist drops his/her reservations about chiropractic and begins to correspond and refer.

One orthopaedic surgeon particularly resistant to chiropractic for years is no longer. The following orthopaedic consultation note explains why:

12 May, 1987

PATIENT: A.B.

This 67-year-old man was involved in a motor vehicle accident in early April. He hit his head in the collision. 'He was hit broadside by another car. He may have been unconscious for a period. He went to the hospital in Brampton and had x-rays of his neck which were interpreted as normal. He went home.

After three weeks at home he continued to have a lot of pain and stiffness in his neck. He thought he needed some more treatment and he consulted Dr. Henderson, the chiropractor. Dr. Henderson took some x-rays in his office and observed that the patient had a fracture of the base of his odontoid and sent him down to the Emergency at the Queensway where I saw him with Dr. H. Tomograms were done which revealed clearly that there was an undisplaced fracture of the base of the odontoid which was now three or four weeks old.

The patient certainly has a lot of stiffness in his neck and this is not surprising. He has no neurological abnormalities of any kind.

He had a cloth collar and I arranged for him to get a plastic collar made, and advised him of his problem, and told him how to look after himself. I believe this fracture will heal with treatment in a collar, and I do not think that we need to do anything more radical than that. However, I will watch him closely and be sure that things are coming along well.

A Surgeon
MD., F.R.C.S.(C)

cc. Dr. S.D.K. (*Family Physician*)
Dr. D. Henderson

The hospital Department of Diagnostic Imaging Report dated April 14, 1987, and signed by a radiologist, reports as follows on the cervical and thoracic spine:

"Bone texture is normal. Alignment is normal. Disc spaces are normally maintained."

Odontoid fractures are not uncommon, as you will know. For a previous case report part authored by Dr. Henderson, see 'Fracture Dislocation at the Atlanto-Axial Junction: A Case Report to Demonstrate the Importance of Radiographic Examination in Chiropractic Practice" Korbelas P.A. and Henderson D.J., J Can Chiro Assn (December 1980) 24(4): 157-160 **PN3**

Next Issue: Cost Effectiveness of Chiropractic – The Evidence.

Main Article – *continued from page 4.*

F. Conclusion

23. With the exception of drug trials, published clinical trials provide little evidence concerning the effectiveness of health care interventions. This is partly because RCT methodology with human beings is comparatively new – there is only 40 years experience – and is still being learnt.

However, the trials performed have provided the means for continually refining methodology, and have given much information of importance. Most health care professionals agree that, limitations and all, it is essential to perform trials.

24. In all this talk of science it is necessary to remember that, in the majority of clinical situations, treatment decisions cannot be based on clinical trials. The great majority of health care has no such evidence. Where there is a trial with a positive result this may not apply to the individual patient because of the trial eligibility criteria; and even in successful trials the experimental therapy does not benefit many patients.

Many will feel there is wisdom in these words of Feinstein in Lancet in 1972 quoted with approval by Sir James Howie in the British Medical Journal in December, 1984:

"Until the methods of science are made satisfactory for all the important distinctions of human phenomena, our best approach to many problems in therapy will be to rely on the judgements of thoughtful people who are familiar with the total realities of human ailments."[20]

25. In reality health care is probably no more scientific than music. Chiropractors, family physicians and surgeons, like Bach, are artists assisted by scientific method.

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active treatment get better more frequently than in the ordinary world, hiding a true beneficial effect of the treatment(s) under trial.

b) **Treatment compliance.** This has an effect the opposite way. The patient knows – because of what was explained to get his/her consent to enter the trial – that he/she may be getting the placebo or less effective treatment, and therefore does not react as well as in normal practice, where he/she believes the best treatment is being received.

c) **Selective participation.** Patients are generally less willing to participate in randomized trials than in observational studies. Thus there is a tendency to get a certain type of patient, and even if the trial is superbly designed to control chance factors or bias (i.e. has good internal validity) it may bear little relation to what happens in practice (i.e. have no external validity).

Many more examples could be given. The point is that all the above illustrate problems of using an RCT with humans. None of these uncertainties exist with agriculture where one deals with plants whose heredity and environment is under much more absolute control.

17. Turning to particular problems of trial method with respect to chiropractic/manipulation/low back pain, perhaps the best recent reviews are those by Grahame (England, 1980),[8] Greenland, Haldeman et al (U.S. 1980)[9] and Deyo (U.S. 1982).[10] Grahame identifies these 5 areas that "make drug trials look easy by comparison with clinical trials in the back pain field".

a) **Diagnosis.** The first requirement of a clinical trial is to select an identifiable clinical entity – there is much debate about accurate diagnosis of back pain.

b) **Trial design.** Grahame explains why the two major types of design, parallel and crossover, pose difficulties. He explains how double-blinding, regarded as vital, is a major difficulty since you cannot keep a patient unaware of whether or not he is receiving manipulation or exercises or bed rest.

c) **Standardization of therapy.** You can standardize a pill or an injection, but not the skill of a chiropractor – or for that matter a surgeon. Furthermore treatment of individuals is tailored to their needs, both initially and as care proceeds.

d) **Assessment of outcome.** An essential feature of any clinical trial is the ability to gauge response to treatment. Most assessments of improvement with back pain "are crude measures of outcome" only.

e) **Problem of limited yield.** This is a numbers problem – and is most important in assessing many of the published trials of manipulation. "A very minimum of 100 pairs is needed", says Grahame, and Greenwood, Haldeman et alagree. This means a trial with a treatment group and a control group should have at the very least 200 patients.

Check the size of the next one you read. Without these minimum numbers statistical analysis, which is used to work out whether improved results in a treated group are 'significant' or just within the range of chance, is unable to identify significant improvements that do occur. Two examples:

i) In the journal Spine in 1982 Sloop et al[11] reported a medical trial of manipulation for chronic neck pain and concluded that manipulation was ineffective. The total patient population was 38 - 20 in the treatment group, 18 in the control group. This study was a waste of time, and the firm conclusions made cannot be justified.

ii) Again in Spine, in 1984, Godfrey et al [12] reported a trial of manipulation for low back pain. Treatment was by a chiropractor and in the 2-3 week observation period "treated patients improved rapidly". However, so did control patients. There was thus no statistically significant difference between patient groups, and the trial reported that manipulation was ineffective for acute low back pain. But, the trial conclusion is surely ethically indefensible since there were only 81 subjects in the trial. At a very minimum there should have been 200. The researchers even acknowledge that "no consideration has been given to the numbers of cases necessary to rule out (statistical) error".

18. So far (paras 15-17) we have discussed scientific limitations. These pale to insignificance compared with practical limitations in the real world. Central problems are:

a) The reality of research conditions – lack of funds, pressure from institutional or corporate sponsors to demonstrate the success of a product or treatment, and insufficient training and experience. Modern health science research has become enormously complex. Health care training and practice qualifies one to treat patients in a trial, not administer a trial.

Fyfe has compelling criticism here, and complains that many trials "are run just long enough to establish benefits".[1] Godfrey et al and Sloop et al (see para 17e) probably ran small trials because that was all the research grants would cover.

b) Correlation with practice. As an illustration, look at chymopapain therapy to treat back and leg pain by dissolving the herniated nucleus of the disc. This procedure, withdrawn from general use in the U.S. by the Food and Drug Administration in July 1975 because of fatal shock reactions and lack of evidence of effectiveness, was reintroduced in 1982 following a multicenter RCT by Javid et al reporting a 73% success rate.[13]

Thousands of surgeons turned to chemonucleolysis with chymopapain, but then found that the trial results bore no resemblance to clinical practice. At the Annual Meeting of the American Association of Neurological Surgeons only 6 out of 300 who had performed chemonucleolysis were continuing with its use. [14] Success rates of only 40% were reported. The surprisingly high failure rate was put down partly to the fact that the Javed et al trial only followed patients for 6 months. Follow-up for 2 years or more showed that many originally thought to benefit from chemonucleolysis were ultimately no better off. (A 1986 review of 61 Oregon WCB cases reports a projected success rate of 70% – but an actual success rate of only 28%).[15]

Javed et al may argue that their multicentre controlled trial was thorough science – sadly it had little external value for patients.

c) Acceptance by health professionals. It may be thought that the evidence of a good clinical trial influences subsequent health care practice. It is on this basis that medicine claims to be scientific. However, this is often not the case. When British trials in the early 1970s showed that the use of corsets was not effective in the treatment of low back pain physicians kept prescribing corsets. Trial evidence currently says that bedrest is ineffective – physicians continue to prescribe it.

Perhaps the ultimate example is the non-acceptance by many surgeons of the recent $9 million international multi-centre trial indicating that vertebral artery bypass surgery was ineffective[16] (See professional Notes, this Report, P.1).

Who's to say who is right? On one hand there is impressive evidence for medical not surgical management of arterial disease to decrease the rate of stroke. It is most unlikely there will ever be a more impressive trial. On the other hand, as with all trials, design weaknesses can be found and those with 20 years experience of good surgical results may have evidence as valuable in reality (if not theory) as the trial.

E. Chiropractic RCT's

19. Clinical trials require enormous resources of time and money and the cooperation of many professionals with different expertise. For these reasons, together with enormous design difficulties in the area of physical treatments, there has been no significant trial evidence generated by chiropractors, osteopaths, physical therapists, physical medicine specialists, or surgeons until the last 10 years.

20. In Australia in 1975 the government requested and funded an RCT to assess whether chiropractic adjustment was effective in the treatment of migraine. With government direction and funding practical barriers were removed. Medical specialists, chiropractors, physiotherapists and statisticians cooperated and the research was done – providing evidence of effectiveness.[17]

(The Australian government committee recommended that $200,000 per annum be made available for chiropractic clinical research – a fraction of the public funds committed to medical research. The money was never advanced, and major trial research stopped).

21. Criticism of the efforts of the chiropractic profession to prove the effectiveness of its treatments has been rejected by informed independent observers as no longer justified and a "red herring". (For relevant quotes see this Report, Insert, p.1).

22. Presently there are 4 chiropractic controlled trials underway in the area of greatest patient suffering and socio-economic importance, chronic low back pain. All involve substantial resources, complexity, advanced and impressive interprofessional cooperation, and will take 10 years from instigation to published results. They are:

a) **Palmer College Trial** (Davenport, Iowa). This trial is comparing spinal adjustive therapy with no active treatment for patients with mild chronic low back pain, with treatment being given in the PCC clinics.

It is well-advanced. The pilot study was published in 1986,[18] and patients are now being received in the main trial. The pilot study probably has the best design of any trial of manipulation yet published. Important new features are the refinement of a sham adjustment (to better 'blind' the patient) and allowing treating chiropractors to adjust full spine as felt necessary. This means the trial has relevance to clinical practice. Many medical trials have used untrained manipulators, ill-defined techniques, and a single or quite insufficient number of treatments.

The pilot study reports preliminary evidence of effectiveness.

b) **British trial** (Harrow, England). This trial is comparing chiropractic and hospital outpatient management of patients with low back pain of mechanical origin. Chiropractic treatment is in a private clinic, hospital treatment in many centres. 2000 patients are being recruited for the trial. This is also well-advanced with the pilot study reported in the Journal of Epidemiology and Community Health in 1986.[19]

The trial illustrates the sophistication and complexity of modern clinical trials. Initial work commenced in 1979 following publication of the Cochrane Report on Back Pain which noted the "urgent need for rigorous comparative therapeutic trials, particularly of manipulation". Participating organizations are the British Chiropractors Association, and Northwick Park Hospital, and principal investigators are Breen, DC and Meade MD, both prominent researchers in their professions. Notwithstanding their seniority it has taken 7 years to reach the main trial – to get necessary consents, approved proposal and funding, to perform the pilot study, and make administrative arrangements for a large multi-centre trial.

c) **Canadian Trial** (Toronto, Ontario). This is also a comparison of chiropractic and medical treatment of chronic low back pain, but with medical treatment given in private practice. Chiropractic treatment will be at a Canadian Memorial Chiropractic College satellite clinic.

Unlike the Palmer trial adjustive therapy is supplemented with a range of modalities. Similarly the private medical treatment will involve a range of therapy, but no manipulation.

The principal chiropractic investigator, Dr. David Brunarski, has been working on trial protocol with various medical investigators since 1980. No pilot study is being performed and first patients will enter the trial during Fall 1987. Results should be available for publication in early 1989. Funding is from the Foundation for Chiropractic Education and Research (FCER).

d) **Vermont Trial.** This, also comparing chiropractic and medical management of chronic low back pain, is the most recent of the trials and holds considerable promise. Participating organizations are the Los Angeles College of Chiropractic and the University of Vermont. Senior principal researchers are Phillips DC, Adams DC, Haldeman DC MD, and Frymoyer MD. Funding is from the FCER and University of Vermont, and first patients enter a pilot study during September, 1987.

References: *see insert page 2.*

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