Randomised comparison of chiropractic and hospital outpatient management for low back pain: results from extended follow up

T W Meade, Sandra Dyer, Wendy Browne, A O Frank

Abstract

***Objective*—To compare the effectiveness over three years of chiropractic and hospital outpatient management for low back pain.**

***Design*—Randomised allocation of patients to chiropractic or hospital outpatient management.**

***Setting*—Chiropractic clinics and hospital outpatient departments within reasonable travelling distance of each other in 11 centres.**

***Subjects*—741 men and women aged 18-64 years with low back pain in whom manipulation was not contraindicated.**

***Outcome measures*—Change in total Oswestry questionnaire score and in score for pain and patient satisfaction with allocated treatment.**

***Results*—According to total Oswestry scores improvement in all patients at three years was about 29% more in those treated by chiropractors than in those treated by the hospitals. The beneficial effect of chiropractic on pain was particularly clear. Those treated by chiropractors had more further treatments for back pain after the completion of trial treatment. Among both those initially referred from chiropractors and from hospitals more rated chiropractic helpful at three years than hospital management.**

***Conclusions*—At three years the results confirm the findings of an earlier report that when chiropractic or hospital therapists treat patients with low back pain as they would in day to day practice those treated by chiropractic derive more benefit and long term satisfaction than those treated by hospitals.**

Introduction

In 1990 we reported greater improvement in patients with low back pain treated by chiropractic compared with those receiving hospital outpatient management.[1] The trial was "pragmatic" in allowing the therapists to treat patients as they would in day to day practice. At the time of our first report not all patients had been in the trial for more than six months. This paper presents the full results up to three years for all patients for whom follow up information from Oswestry questionnaires[2] and for other outcomes was available for analysis. We also present data on pain from the questionnaire, which is by definition the main complaint prompting referral or self referral.

Methods

Methods were fully described in our first report.[1] Patients initially referred or presenting either to a chiropractic clinic or in hospital were randomly allocated to be treated either by chiropractic or in hospital. A total of 741 patients started treatment. Progress was measured with the Oswestry questionnaire on back pain, which gives scores for 10 sections —for example, intensity of pain and difficulty with lifting, walking, and travelling.[2] The result is expressed on a scale ranging from 0 (no pain or difficulties) to 100 (highest score for pain and greatest difficulty on all items). For an individual item, such as pain, scores range from 0 to 10. The main outcome measures are the changes in Oswestry score from before treatment to each follow up. At one, two, and three years patients were also asked about further treatment since the completion of their trial treatment or since the previous annual questionnaire. At the three year follow up patients were asked whether they thought their allocated trial treatment had helped their back pain.

In the random allocation of treatment minimisation[3] was used within each centre to establish groups for the analysis of results according to initial referral clinic, length of current episode (more or less than a month), presence or absence of a history of back pain, and an Oswestry score at entry of >40 or $\leq 40\%$.

Results were analysed on an intention to treat basis (subject to the availability of data at follow up as well as at entry for individual patients). Differences between mean changes were tested by unpaired t tests, and χ^2 tests were used to test for differences in proportions between the two treatment groups.

Results

Follow up Oswestry questionnaires were returned by a consistently higher proportion of patients allocated to chiropractic than to hospital treatment. At six weeks, for example, they were returned by 95% and 89% of chiropractic and hospital patients, respectively and at three years by 77% and 70%.

Mean (SD) scores before treatment were 29·8 (14·2) and 28·5 (14·1) in the chiropractic and hospital treatment groups, respectively. Table I shows the differences between the mean changes in total Oswestry scores according to randomly allocated treatment group. The difference at each follow up is the mean change for the chiropractic group minus the mean change for the hospital group. Positive differences

TABLE I—*Differences (95% confidence intervals) between mean changes in Oswestry scores**

Time of follow up	Difference	No of patients undergoing chiropractic	No of patients undergoing hospital treatment
Six weeks	1·69 (−0·74 to 4·12)	357	309
Six months	3·31† (0·51 to 6·11)	325	282
One year	2·04 (−0·71 to 4·79)	314	265
Two years	3·02‡ (0·08 to 5·96)	285	256
Three years	3·18‡ (0·16 to 6·20)	290	239

*Positive differences indicate greater improvement in patients treated with chiropractic.
†$P<0·02$; ‡$P<0·05$.

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therefore reflect more improvement (due to a greater change in score) in those treated by chiropractic than in hospital (negative differences the reverse). The 3·18 percentage point difference at three years in table I represents a 29% greater improvement in patients treated with chiropractic compared with hospital treatment, the absolute improvement in the two groups at this time being 14·1 and 10·9 percentage points, respectively. As in the first report those with short current episodes, a history of back pain, and initially high Oswestry scores tended to derive most benefit from chiropractic. Those referred by chiropractors consistently derived more benefit from chiropractic than those referred by hospitals.

Table II shows changes between the scores on pain intensity before treatment and the corresponding scores at the various follow up intervals. All these changes were positive—that is, indicated improvement—but were all significantly greater in those treated by chiropractic, including the changes early on—that is, at six weeks and six months, when the proportions returning questionnaires were high. As with the results based on the full Oswestry score the improvement due to chiropractic was greatest in those initially referred by chiropractors, although there was also a non-significant improvement (ranging from 9% at six months to 34% at three years) due to chiropractic at each follow up interval in those referred by hospitals.

Other scores for individual items on the Oswestry index to show significant improvement attributable to chiropractic were ability to sit for more than a short time and sleeping (P=0·004 and 0·03, respectively, at three years), though the differences were not as consistent as for pain. Other scores (personal care, lifting, walking, standing, sex life, social life, and travelling) also nearly all improved more in the patients treated with chiropractic, though most of the differences were small compared with the differences for pain.

Higher proportions of patients allocated to chiropractic sought further treatment (of any kind) for back pain after completion of trial treatment than those managed in hospital. For example, between one and two years after trial entry 122/292 (42%) patients treated with chiropractic compared with 80/258 (31%) of hospital treated patients did so (χ_1^2=6·8, P=0·01).

Table III shows the proportions of patients at three years who thought their allocated trial treatment had helped their back pain. Among those initially referred by hospitals as well as among those initially referred by chiropractors higher proportions treated by chiropractic considered that treatment had helped compared with those treated in hospital.

TABLE II—*Changes in scores from section on pain intensity in Oswestry questionnaire between score before treatment and score at follow up intervals according to method of treatment and difference between changes*

Interval and method of treatment	No of patients	Mean change in score	Difference (SE) between changes	P value
Six weeks:				
Chiropractic	357	0·99	0·28 (0·08)	0·0006
Hospital	309	0·71		
Six months:				
Chiropractic	324	1·03	0·36 (0·10)	0·0002
Hospital	282	0·67		
One year:				
Chiropractic	314	0·94	0·21 (0·10)	0·03
Hospital	265	0·73		
Two years:				
Chiropractic	285	0·98	0·35 (0·11)	0·001
Hospital	256	0·63		
Three years:				
Chiropractic	290	0·90	0·31 (0·11)	0·004
Hospital	239	0·59		

TABLE III—*Number (percentage) of patients at three year follow up who considered allocated trial treatment had helped their back pain*

	Hospital treatment		Chiropractic treatment	
Referral	Help	No help	Help	No help
Hospital	71 (60·2)	47 (39·8)	103 (79·2)	27 (20·8)
Chiropractic	76 (65·5)	40 (34·5)	127 (84·7)	23 (15·3)

For hospital referrals: χ^2=10·7; P=0·001.
For chiropractic referrals: χ^2=13·3; P<0·0001.

Key messages

- Back pain often remits spontaneously
- Effective treatments for non-remitting episodes need to be more clearly identified
- Chiropractic seems to be more effective than hospital management, possibly because more treatments are spread over longer time periods
- A growing number of NHS purchasers are making complementary treatments, including chiropractic, available
- Further trials to identify the effective components of chiropractic are needed

Discussion

The results at six weeks and six months shown in table I are identical with those in our first report,[1] as all patients had then been followed up for six months. The findings at one year are similar as many patients had also been followed up then. The considerably larger numbers of patients with data now available at two and three years show smaller benefits at these intervals than previously,[1] though these still significantly favour chiropractic. The substantial benefit of chiropractic on intensity of pain is evident early on and then persists. The consistently larger proportions lost to follow up throughout the trial in those treated in hospital than in those treated by chiropractic suggests greater satisfaction with chiropractic. This conclusion is supported (table III) by the higher proportions in each referral group considering chiropractic helpful by comparison with hospital treatment.

The main criticism of the trial after our first report centred on its "pragmatic" nature, particularly the larger number of chiropractic than hospital treatments and the longer period over which the chiropractic treatments were spread and which were deliberately allowed. These considerations and any consequences of the higher proportions of patients allocated to chiropractic who received further treatment in the later stages of follow up, however, do not apply to the results at six weeks and only apply to a limited extent at six months, when the proportions followed up were high and extra treatment had either not occurred at all or was not yet extensive. Benefits atributable to chiropractic were already evident (especially on pain, table II) at these shorter intervals.

We believe there is now more support for the need for "fastidious" trials focusing on specific components of management and on their feasibility. Meanwhile, the results of our trial show that chiropractic has a valuable part to play in the management of low back pain.

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Conflict of interest: None.

1 Meade TW, Dyer S, Browne W, Townsend J, Frank AO. Low back pain of mechanical origin: randomised comparison of chiropractic and hospital outpatient treatment. *BMJ* 1990;300:1431-7.
2 Fairbank J, Davies J, Coupar J, O'Brien JP. Oswestry low back pain disability questionnaire. *Physiotherapy* 1980;66:271-3.
3 Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics* 1975;31:103-15.

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Using decision analysis to compare policies for antenatal screening for Down's syndrome

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Abstract

***Objective*—To compare different screening policies for Down's syndrome across a broad range of outcomes, using decision analysis, with particular reference to the role of maternal serum testing.**

***Design*—A decision tree was used to combine data from local sources and the medical literature to predict the likely frequency of several outcomes. Sensitivity analyses were used to test the robustness of the conclusions drawn.**

***Setting*—Oxfordshire Health Authority.**

***Main outcome measures*—Live births with and without Down's syndrome; miscarriages with Down's syndrome; cases of Down's syndrome detected antenatally; amniocenteses performed (and associated miscarriages); direct NHS screening costs; number of women offered screening.**

***Results*—Screening policies for Down's syndrome that include serum testing can produce better population outcomes than programmes that do not. Each option for screening for Down's syndrome that we considered had significant drawbacks. In Oxfordshire, offering serum testing to women of all ages would prevent the birth of approximately one more baby with Down's syndrome per year than would a policy of screening for women aged 30 years or more. The cost of preventing this one extra Down's birth would be one or two normal babies lost after amniocentesis, 4500 blood tests for young women (with the associated anxiety and counselling), approximately 200 false positive serum test results and amniocenteses (with the associated anxiety and distress), and £90 000 for the extra tests, counselling, and amniocenteses. Opinions are divided as to which policy is the better option for the population.**

***Conclusions*—Decision analysis is a useful tool for determining the likely consequences of different policy options across a broad range of outcomes. This focuses debate and decision making on outcomes of care, which in turn makes it clear that the choice of screening programme for Down's syndrome depends on the relative importance ascribed to the different outcomes. If individuals' values vary widely it may be impossible to find one screening policy that meets the needs of all pregnant women.**

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Introduction

Maternal serum concentrations of various analytes including α fetoprotein, oestriol, and human chorionic gonadotrophin can be used to estimate the probability of a fetus having Down's syndrome. Wald and colleagues have predicted and subsequently shown that information derived from measurements of various combinations of such analytes, when interpreted in the knowledge of a woman's age and the gestational age of the fetus, allows a more accurate estimation of the risk of a fetus being affected with Down's syndrome than does risk estimation based on maternal age alone.[1 2] This has raised the possibility of introducing biochemical testing as a screening test for Down's syndrome for some or all pregnant women. However, there is no consensus among health authorities in Britain as to whether biochemical screening for Down's syndrome should be offered and if so to which groups of pregnant women.[3] The main issues that have been the topics of professional and public debate are the ethics of prenatal screening; the performance of biochemical screening tests; the choice of test; the relative costs, both personal and monetary; whether centres which introduced biochemical screening early have done the right thing; and the importance of counselling.[4-7]

The consequences of screening for Down's syndrome are various. They may include changes in the number of Down's syndrome babies detected, the number of Down's syndrome babies born, the number of unaffected babies born, the number of pregnancies lost by miscarriage, the amount of anxiety generated, and the direct and indirect financial costs of the programme to the NHS, other agencies, and pregnant women and their families. Most published contributions to the debate have provided information about only one or two measures of outcome such as detection rate[1] or psychological costs.[5 8] Others have used summary measures such as overall cost or saving per Down's syndrome case detected.[9] However, a decision to implement a particular screening programme should be based on as full an assessment of as many as possible of the relevant outcomes of a screening programme. In 1993, in the absence of clear regional or national guidance, Oxfordshire health authority had not decided whether to purchase a serum screening programme. In that same year about a third of pregnant women over 35 years in Oxfordshire chose to pay around £50 each to have biochemical tests for Down's syndrome performed privately; this choice was available only to those who could afford to pay. This was widely regarded as unsatisfactory. A decision was required about the NHS provision of serum screening for Down's syndrome for the women of Oxfordshire. The district health authority sought a screening option that was as effective or better at detecting Down's syndrome than current practice; addressed the controversy surrounding stress and the screening of younger women; and was cost neutral or cheaper in direct NHS costs than current practice.

We wanted to use the large amount of national and local data that is available about biochemical screening for Down's syndrome to quantify as many as possible of the likely consequences of different screening options for the population of Oxfordshire. We used the technique of decision analysis, which is a well