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# LUMBAR SPINAL MANIPULATION ON TRIAL PART I—CLINICAL ASSESSMENT

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## SUMMARY

Thirty-two patients with chronic low back pain were treated three times at weekly intervals with rotational manipulation. Patients with femoral or sciatic root pain were included provided they did not exhibit root compression signs. Background therapy of codeine phosphate was administered throughout.

There was a significant increase in spinal flexion measured clinically during the three-week period of manipulation followed by a significant decrease in the three-week period after manipulation. The first week of manipulative treatment was more painful than the corresponding week in the control group but in the second and third weeks there was less pain in the manipulated group. Pain scores were reduced to a significant degree within four weeks of starting treatment only in the group manipulated in the first treatment period. Patients benefitting subjectively from manipulation were more likely to be older and to have had symptoms for a shorter period than those not deriving benefit. The age of onset of symptoms was significantly later in the responders.

Reports of clinical trials on the effectiveness of lumbar spinal manipulation are limited and concern the use of a number of different techniques applied to patients with various pathological conditions in the lumbar spine. Coxhead (1974) compared nine different treatments including the manipulations advocated by Maitland (1973). Kane *et al.* (1974) reported a retrospective evaluation of chiropractic techniques and Riches (1930) that of manipulation under anaesthesia. Glover, Morris and Khosla (1974) described a controlled trial of rotational manipulation and Doran and Newell (1975) reported the results of a multicentre trial in which manipulation was compared with definitive physiotherapy, corsets and analgesics but the technique of manipulation was left to the discretion of the various manipulators involved. This trial was subject to considerable criticism (Barbor, 1975; Cyriax, 1975; Boag, 1975; Riches, 1975) due to the blanket acceptance of all patients complaining of low back pain and most of the critics advocated selection based on patients' histories rather than physical signs; but on the other hand their criteria for manipulation all differed. In the present trial one of the objects has been to try to define the type of backache syndrome, if any, that is likely to benefit from manipulation. A further criticism of Doran and Newell's trial is that widely differing manipulative techniques were used at the various centres and the results were all combined. Because of this difficulty inherent in multicentre trials, the present trial was undertaken to study a smaller number of patients in greater depth. The design was a simple cross-over of two three-week periods. In the first group, manipulation was given on days 0, 7 and 14 with 'rescue' analgesia allowed. The second three-week-phase treatment was with analgesics only. In the second group, the phases were reversed.

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## PATIENTS AND METHODS

Patients complaining of back pain, defined as pain arising from the inferior angles of the scapulae to the lower sacrum, and present for at least three weeks, were selected for the trial. Femoral or sciatic radiation of the pain was no bar to selection but those with femoral or sciatic root compression signs were excluded. Any previous treatment by traction or other forms of physiotherapy, surgical corsets, non-steroidal inflammatory drugs, etc., was abandoned at the screening examination (day −7) but the administration of various analgesics was allowed up until entry into the trial (day 0). Other exclusions included those patients who had received steroidal anti-inflammatory drugs during the previous two months, those with spondylitis, inflammatory polyarthritis and any overt chronic diseases or psychiatric conditions.

Patients selected on this basis were told the nature and objects of the trial and on consenting to participate they were accepted after screening by full clinical examination, routine haematological and biochemical profiles and radiographs to exclude any condition present other than degenerative changes in the lumbar spine.

Patients were then allocated according to a random list into two groups, A and B, and managed according to the timetable set out in Table I. Each was supplied with

TABLE I

TRIAL TIMETABLE

| Group | Trial Day | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | −7 | 0 | 7 | 14 | 21 | 28 | 35 | 42 |
| A | S<br>F<br>X | F<br>M | M | M | F<br>X<br>A | | | F<br>(X)<br>A |
| | codeine phosphate as necessary | | | | | | | |
| B | S<br>F<br>X | F | | | F<br>X<br>A<br>M | M | M | F<br>(X)<br>A |
| | codeine phosphate as necessary | | | | | | | |

S = Screening; F = Anterior spinal flexion measured; X = Radiograph of lumbar spine, ( ) only if over 45 years old; M = Lumbar spine manipulation; A = Assess.

codeine phosphate 16 mg capsules and instructed to take two capsules at intervals of not less than four hours when necessary to control pain. In addition diary cards were issued upon which patients were instructed to score the degree of pain experienced each day.

The following parameters were used to assess progress:

1. Lumbar spine anterior flexion measured by the method of Macrae and Wright (1969).

2. Daily pain score recorded by the patient using the scale: 0 = nil, 1 = mild, 2 = moderate, 3 = severe.

3. The number of codeine phosphate capsules consumed.

4. Patient's assessment of efficacy at the end of each three-week period using the scale: ineffective, equivocal, effective, highly effective.

5. Patient's preference at the end of the trial as to the best three-week period.

6. Patient's global assessment at the end of the trial comparing their condition at that time with that at the beginning using the scale: deteriorated, no change, slight improvement, marked improvement.

Manipulations were all given by an experienced medically qualified manipulator (MSB) using a rotational thrust with distraction both to the right and to the left. Spinal anterior flexion was measured throughout by the same examiner (DPE) who was unaware of the nature of the previous treatment. Non-parametric statistical tests as described by Siegel (1965) were used for assessing the results.

Thirty-six patients entered the trial but four were lost to follow-up for various reasons leaving 32 of whom three defaulted in the final week but their results up to that time have been included. Seventeen were female and 15 male. Group A contained 15 patients and Group B 17 patients, their ages ranging from 25–63 years (median 44.5 years). Five patients had been taking anti-inflammatory drugs at the start of the screening week and four had been wearing surgical corsets but these treatments were stopped. Back pain was relieved by rest in 21 patients and it radiated to the buttock(s) or lower limb(s) in 23. The duration of back pain ranged from 0.2 to 31 years (median 4 years) and the current attack had been present for 6–676 weeks (median 39 weeks). In addition to these variables the patients' weights, heights, sites of pain, character of pain and the effects of movement, coughing and sneezing on the pain were recorded. The distributions of all of these parameters were similar in the two treatment groups and in no instance did the groups differ from each other significantly.

## RESULTS

From the Anterior Spinal Flexion measurements recorded on days −7 and 0 a pre-treatment mean was calculated to form a baseline for each patient. Medians of baseline and subsequent measurements are shown in Table II. Because of the magnitude of

TABLE II

ANTERIOR SPINAL FLEXION MEASUREMENTS (USING METHOD OF MACRAE AND WRIGHT, 1969)

| Group | Median (range) anterior spinal flexion (cm) | | |
|---|---|---|---|
| | Baseline | Day 21 | Day 42 |
| A | 5.2 (2.6–7.1) | 5.4 (3.5–8.9) | 5.2 (3.8–6.6) |
| B | 6.1 (3.0–9.1) | 5.8 (2.0–9.0) | 6.3 (2.6–9.8) |

the difference between baseline medians, the two groups could not be compared validly at day 21. The anterior spinal flexion medians of patients in both groups increased during their respective manipulative treatment periods and decreased during the corresponding control periods. If the results from both groups are combined, the spinal flexions during the manipulative treatment period of three weeks increase to a statistically significant degree ($P = 0.017$, Wilcoxon Test for Pair Differences). The spinal flexions recorded in

Group A decreased significantly ($P<0.05$) in the period from one week post-manipulation to four weeks post-manipulation and in Group B the spinal flexions also decreased during the control period although only at the 10% significance level (Wilcoxon Tests for Pair Differences).

The daily pain scores and codeine phosphate capsule consumption were extracted from the patients' diary cards. The combined pain scores of all patients in the group divided by the number of patients in the group are shown week by week in Table III

TABLE III

TOTAL PAIN SCORES OF EACH GROUP DIVIDED BY THE NUMBER OF PATIENTS IN THE GROUP

| Group | Total pain scores in | | | | | |
|---|---|---|---|---|---|---|
| | week 1 | week 2 | week 3 | week 4 | week 5 | week 6 |
| A | Manipulation | | | Control | | |
| | 12.20 | 10.87 | 10.47 | 10.00 | 10.93 | 10.40 |
| B | Control | | | Manipulation | | |
| | 9.59 | 8.88 | 9.53 | 9.35 | 8.53 | 8.71 |

for Groups A and B. The pain scores correlated with the number of codeine capsules consumed each week to a very highly significant degree ($r = 0.92$, d.f. $= 10$, $P<0.001$) and because of this positive correlation only pain scores were analysed further. In Group A, the weekly pain scores had significantly decreased by week 4 ($P<0.05$, Wilcoxon Test for Pair Differences) but this was compared to week 1, which was itself a week preceded by manipulation. The weekly pain scores in Group B did not differ significantly from one week to any other but they suggest, like those in Group A, that any benefit from pain relief associated with manipulation occurs in the second and third weeks rather than in the first week.

Fig. 1 shows the daily cumulative pain score of all 35 patients in their control period subtracted from the cumulative pain score of all patients in their manipulative treatment period. The data confirm that the first week of manipulative treatment was more painful than the corresponding week in the control group but in the second and third weeks there was less pain in the manipulated group.

The patients' assessments of treatment are shown in Table IV. If 'ineffective' assessments are combined with 'equivocal' assessments and 'effective' are combined with 'highly effective', the assessments for the first treatment are significantly better in Group A than in Group B ($P<0.05$, $\chi^2 = 4.43$ with Yates' correction). If the assessments relating to the second treatment are combined in the same way, the two groups do not differ significantly from each other. Thus the manipulative treatments were associated with better assessments than control in the first treatment period but not in the second period. The two manipulative treatment periods (first in Group A versus second in Group B) were associated with similar ratings but the two control treatment periods were associated with ratings which were not only dissimilar but different by a highly significant degree ($P<0.01$, $\chi^2 = 7.32$ with Yates' correction). This paradox could be explained by a carry-over effect in Group A from the manipulative treatment period of the first three weeks to the control period.

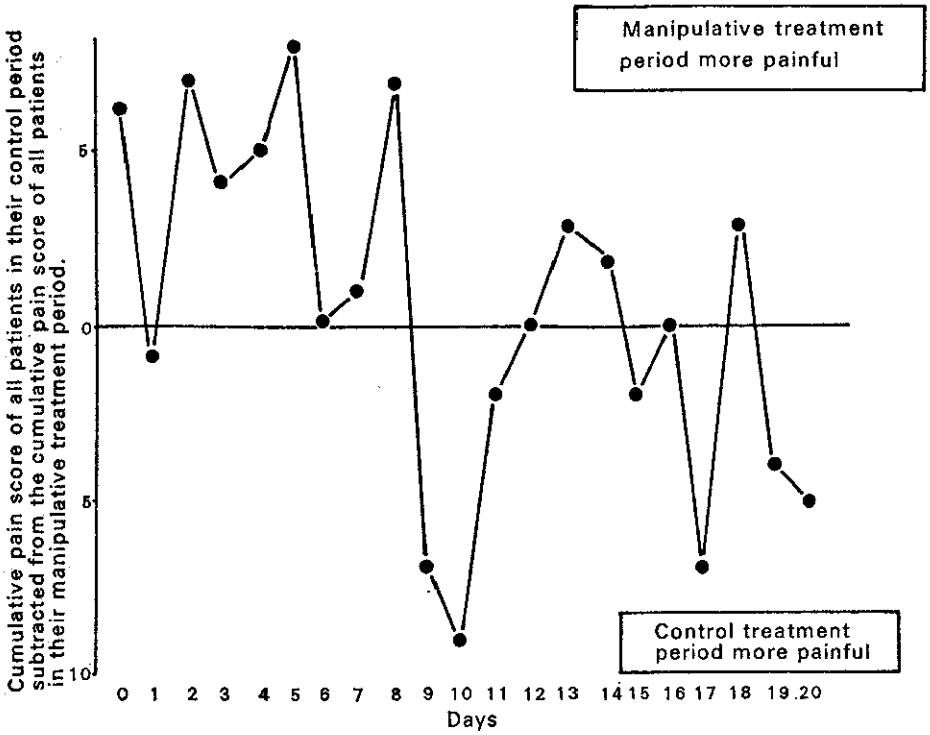


FIG. 1.—Pain scores summated of all patients: manipulative treatment period minus control treatment period.

TABLE IV

PATIENTS' ASSESSMENTS

| Group | For trial period finishing at | Number of patients assessing treatment period as | | Defaulters |
|---|---|---|---|---|
| | | Ineffective/ Equivocal | Effective/ Highly effective | |
| A | Mid-point | 6 | 9 | 0 |
| | End | 3 | 9 | 3 |
| B | Mid-point | 14 | 3 | 0 |
| | End | 5 | 12 | 0 |

In regard to the patients' preferences at the end of the trial, of those in Group At one felt equally well in both treatment periods, six preferred the manipulative treatment period and five preferred the control period. This was different, but not to a significan, degree, from Group B in which four patients felt equally well in both treatment periods. three preferred the control period and 10 preferred the manipulative treatment period, These preferences also suggest a beneficial carry-over effect from manipulative treatment in the first three weeks to the control period in the second three weeks.

The patients' global assessments comparing their condition at the end of the trial to the beginning were graded as follows: two deteriorated, six remained the same, seven slightly improved and 14 markedly improved. These scores were used to correlate reported improvement or otherwise with various clinical features which are set out in Table V. The eight patients who deteriorated or remained unchanged (non-responders) were compared to the 14 who markedly improved (responders).

TABLE V

NON-RESPONDERS TO SPINAL MANIPULATION COMPARED TO RESPONDERS

| | Treatment group | Age (years) | Sex | Root pain | Duration of pain (years) | Duration of present attack (weeks) | Age of onset (years) | Change in spinal flexion (cm) (end of trial minus beginning) |
|---|---|---|---|---|---|---|---|---|
| Non-responders | A | 36 | M | yes | 9 | 104 | 27 | −0.7 |
| | A | 25 | F | yes | 11 | 14 | 14 | −0.9 |
| | A | 26 | M | yes | 2.5 | 6 | 23.5 | 0.3 |
| | A | 52 | F | no | 12 | 6 | 40 | −0.2 |
| | B | 46 | M | yes | 12 | 104 | 34 | 0.5 |
| | B | 56 | F | yes | 31 | 676 | 25 | −0.4 |
| | B | 37 | M | no | 6 | 39 | 31 | −0.4 |
| | B | 32 | F | yes | 6 | 30 | 26 | −0.3 |
| median | | 36.5 | | | 10.0 | 71 | 26.5 | −0.35 |
| Responders | A | 46 | F | yes | 1.5 | 10 | 44.5 | 0.5 |
| | A | 33 | M | yes | 4 | 13 | 29 | 0.6 |
| | A | 41 | F | no | 14 | 520 | 27 | −0.5 |
| | A | 63 | M | yes | 20 | 104 | 43 | 1.4 |
| | A | 46 | M | yes | 5 | 260 | 41 | 0.3 |
| | B | 57 | F | yes | 4 | 39 | 53 | 0.5 |
| | B | 62 | M | no | 0.5 | 26 | 61.5 | −0.8 |
| | B | 36 | F | no | 2 | 104 | 34 | −1.0 |
| | B | 43 | F | yes | 15 | 260 | 28 | 2.1 |
| | B | 55 | F | no | 0.5 | 26 | 54.5 | 0.5 |
| | B | 58 | M | yes | 0.5 | 26 | 57.5 | 0.2 |
| | B | 44 | F | yes | 0.8 | 30 | 43.2 | 0.7 |
| | B | 59 | F | yes | 0.2 | 8 | 58.8 | −0.2 |
| | B | 54 | F | yes | 15 | 312 | 39 | 0 |
| median | | 50.0 | | | 3.0 | 34 | 43.1 | +0.40 |

The non-responders are significantly younger than the responders ($P<0.05$, Wilcoxon Test for Two Samples). There was no significant difference between the groups with regard to sex, the ratio of weight to average weight of adults of same sex and height, the presence or absence of sciatic-distribution pain or location of back pain assessed clinically (upper, mid or lower lumbar). The duration of back pain was longer in the non-responders though different only at the 10% significance level (Wilcoxon Test for Two Samples) in spite of the younger ages of the patients in that group. The 'age of onset' of back pain was calculated from the patients' ages and durations of symptoms. This age of onset was highly significantly earlier in non-responders (median 26.5 years) compared to responders (median 43.1 years) ($P<0.01$, Wilcoxon Test for Two Samples). The

difference in the durations of the present attack was not significant in spite of the magnitude of the difference between the medians. The character of the pain and the effect of movement upon the pain did not differ significantly between the two groups. The change in anterior spinal flexion from baseline to day 42 differed between the two groups, though only at the 10% significance level (Wilcoxon Test for Two Samples).

Results of radiological investigations are reported in Part II.

There were no side-effects in the control or manipulative treatment periods except one patient who complained of constipation having consumed 24 codeine phosphate capsules in the first four days. One patient reported relief of symptoms after the first manipulative treatment but return of symptoms after the second and two patients reported relief of symptoms after the second manipulative treatment with return of symptoms after the third treatment.

## DISCUSSION

If an untested treatment is compared with 'no treatment', any response obtained cannot be differentiated from a 'placebo response'. Thus the treatment is often compared to placebo to see if it has an effect different from placebo. A 'placebo manipulation' is impracticable (Ebbetts, 1975) so the value of a placebo control is lessened in trials of spinal manipulation and the technique most commonly used to reduce bias, the double-blind trial, cannot be employed. We have tried to reduce bias by blinding the observer—keeping him unaware of the treatment previously given—and by measuring anterior spinal flexion by a method which has been found to correlate very closely with anterior flexion measured radiologically (Macrae and Wright, 1969). In addition we have compared manipulation plus an alternative treatment (analgesics) with the alternative treatment alone. The inclusion of the background treatment, whether it produces a placebo or an active response, reduces the possibility of attributing a difference where none exists (error of the first kind) to treatment with manipulation.

Glover, Morris and Khosla (1974) stratified their group of patients by number and duration of attacks. Their stratum most resembling the patients in this trial—those in their second or subsequent attack with pain lasting for seven days or more—behaved similarly in that during the first week after manipulation the manipulated group suffered more pain than the control group.

Doran and Newell (1975) used a similar short-term time-scale to that used in the present trial. Their results hinted that manipulative treatment might give quicker relief than the other treatments used, but by three weeks there were no marked differences. The present trial confirmed that pain relief is obtained more quickly with manipulation than without it (Table III). By equating subjective assessments in both these trials very similar results are evident at three weeks in the two groups receiving manipulative treatment but Doran and Newell's analgesic group ratings are the better. They excluded patients with root pain and so it is probable that they were dealing with less severe disease. This could explain the better effect of analgesics in their trial and might indicate a relatively better response to manipulation in the present trial.

### Acknowledgment

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