

A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment

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A survey of 86 UK Physiotherapy Departments (Anderson, 1978; Sweetman, 1985) indicated that the most commonly used forms of therapy for low back pain included exercises, short wave diathermy and traction. A prospective randomized single blind parallel group therapeutic trial was organized to include the three above treatment groups and a subthermal short wave diathermy control group. 579 patients referred from general practice to a Rheumatology Out Patient Department were screened until 400 patients had been entered into the trial. Treatments were given three times a week for 2 weeks and the patients were then seen in the follow up clinic for assessment. There were no significant differences between the four treatment groups in the subjective opinions of the patients on benefit ($0.3 < p < 0.4$). It was postulated that within this series of patients there might be cases with distinctive patterns of back pain which could be shown to respond differently to the forms of treatment under study. 301 of the patients from the therapeutic trial had data suitable for a classification analysis in which seven distinct patterns of low back pain were recognized. The hypothesis was confirmed when testing nine treatment outcome measures for interaction between the four treatment groups and the seven patterns of back pain when a multivariate significance level of $p = 0.02$ was obtained. This indicated that there was a treatment effect summarizing different responses, dependent on the 'diagnoses'. For example, traction seemed to be most appropriate for patients with the type 5 pattern in which patients described a paradox referred to as 'contralateral' in which their low back pain at rest is on one side and yet tests prove tender or induce pain on the opposite side.

Keywords: low back pain; randomized controlled trial; physiotherapy; exercises; short wave diathermy; traction.

Introduction

Despite the many forms of treatment available (Grieve, 1981) back pain continues to be one of the commonest symptomatic problems in the community and a plague on industry causing disruption through frequent spells of sickness absence and also results in a heavy toll of premature retirement. This is presumably because preventative measures and treatments have failed to stem the rising tide of back pain problems, with UK sickness absence due to back pain doubling in each of the last few decades (National Back Pain Association, 1991/2). However, there is probably an even more profound explanation for this failure to control the problem. The inability to identify distinct types of back problem within the more common forms of low back pain means that it is difficult to arrange specific treatment or preventative measure for specific types of low back pain. Though this inability to develop a generally acceptable diagnostic system for the commoner forms of low back pain has been recognized long term, it seems that few have come to terms with the effect it has on attempts to study the treatment of low back pain.

Although there have been studies of particular forms of back pain including ankylosing spondylitis and the prolapsed intervertebral disc, these conditions only represent a small proportion of back problems overall; and even with these conditions there have been problems with diagnostic selection criteria.

With respect to the common presentation of back pain Koes *et al.*, (1991a,b) reviewed prospective randomized controlled trials of exercise (23 trials) and manipulation and mobilization (35 trials) and showed that there is

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little or no evidence of response to treatment in most of the studies, which had in the majority of instances been performed on consecutive cases attending the clinic, the 'selection' of cases being made merely on the basis of 'exclusion criteria'. One of their conclusions was that future trials should be conducted on distinct 'well defined subgroups of back pain patients' if any progress is to be made (Koes *et al.*, 1992).

The present study was conducted before Koes *et al.* published their reviews and opinions. Even then it was expected that a controlled trial of physiotherapy would show no significant differences in this unselected group of back pain patients. However, it was believed that it would be possible to divide the patients into sub-group patterns which would show specific responses to particular forms of therapy, and it was upon this basis that it was felt that such a study could be justified.

Method

A postal survey was conducted of major physiotherapy departments likely to be treating low back pain. The addresses were obtained using a list of names of Superintendent Physiotherapists. They were asked to place the therapies listed on the card in the order most frequently used for low back pain. The results of the survey were used to select the treatments included in the trial.

Low back pain patients referred from general practice to the Out Patient Rheumatology Clinic in the teaching hospital were first seen by a clinic metrologist using a fixed protocol and were then seen by the attending physician. The physicians made their own clinical assessment of the patient and came to a decision as to the need for further investigation and therapy.

The inclusion criteria for entry into the trial were:

1. The presence at the time of interview of low back pain which had in part to be within an area bounded by the inferior costal margins above and the gluteal folds below, and mid axillary lines laterally.
2. Pain of sufficient severity to warrant physiotherapy.
3. A history of back pain of more than 1 week although the nature of the hospital clinic tended to select patients with long standing problems.
4. Adults and teenagers. Patients were not admitted from the Paediatric Rheumatology Clinic. The youngest admitted was aged 12 years.
5. The likelihood that the back pain was due to low back musculoskeletal problems including possible disc disease. Specific care was taken to exclude pain referred from abdominal viscera.
6. The agreement of the physician.
7. The agreement of the patient.

The absolute exclusion criteria were:

1. Evidence of serious causes for the back pain including fracture, infection or malignancy.
2. Pregnancy.
3. Conditions where musculoskeletal integrity might be susceptible to disruption either by traction or exercise including inflammatory arthritis such as rheumatoid arthritis or bone disease such as osteoporosis or osteomalacia.
4. Where the physician suspected the treatments (trac-

tion and exercises in particular) might precipitate or exacerbate spinal cord or nerve root compromise.

5. Presence of metal in the region that might be subjected to short wave diathermy including IUD, shrapnel, and hip prosthesis.
6. When other therapy was thought to be specifically indicated.
7. Recent (within 6 weeks) steroid injections or oral steroid therapy.
8. Intercurrent treatment other than routine oral medication.

The relative exclusion criteria were:

1. Considerable recent improvement in the condition.
2. Too distressed or incapacitated to cope with the out patient regimen.
3. Other sites of rheumatic pain more severe than the low back pain.
4. Emotionally or intellectually unsuited to participate in the trial.
5. Frailty or impaired general health.
6. Regular attendance inconvenient for patient.
7. Previous exacerbation by any of the three treatments.

The following reasons did not necessarily exclude the patient (physician's discretion).

1. 'Sciaticiform' pain radiating down the legs or 'cruralgia' radiating into the groins.
2. Known causes for the back pain (i.e. spondylolysis, spondylolisthesis, osteoarthritis, pelvispondylitis).
3. Civil or industrial compensation claims.
4. Previous therapy.
5. Previous back operations.
6. Coincidental minor hip disease.

Suitable patients were then asked if they would be prepared to participate in the study of back pain treatments. Ethical committee approval (EC76/7/8) had been gained for both the prospective controlled trial as well as for the use of the metrologist to record the basic observations. The metrologist supplied those patients agreeing to participate in the study with a treatment folder which had been stored face down in a locked draw. Randomization had been organized by placing the sequentially numbered treatment folders in random order according to Documenta Geigy random number tables. The patient took the treatment folder to the Department of Physiotherapy to organize the treatment appointments. The treatment protocols as printed on the folders are shown in Figures 1-3.

Prone lying with pillow under abdomen and feet
six layers of towelling
pancake coil
Turn on and time in usual manner
Time 20 min
x 3 weekly
Return to doctor at end of second week

Figure 1. Short wave diathermy and control schemes. The control sub-thermal shortwave diathermy scheme was identical to the above save that after turning on and tuning to the point when the patient felt heat, the patient was then informed that the dose was sub-thermal and output turned down to minimum.

Patient in lying position with hips flexed to 90° over stool
 Traction given with constant pull (10 min)
 First week one third body weight
 Second week half body weight
 x 3 weekly
 Return to doctor at end of second week

Figure 2. Traction scheme.

| 1st Week | 2nd Week | | |
|----------|----------|-------------------------------|--|
| (1) | (2) | Prone kneeling | Hump and hollow |
| (1) | (2) | Prone kneeling | Alternate leg raise |
| (1) | (2) | Prone kneeling | Alternate arm raise |
| | (2) | Prone kneeling | Opposite leg and arm raise |
| (1) | (2) | Crouch lying | Bridging |
| (1) | (2) | Prone lying | Alternate leg raise |
| | (2) | Prone lying | Clasp hands behind back head and shoulder and both leg raise |
| | (2) | Forehead support Prone lying | Head and shoulder raise |
| | (2) | Prone lying over four pillows | Head and shoulder raise |

Figure 3. Extension exercises scheme.

Each treatment was supervised by an individual fully qualified and experienced physiotherapist, so that none of the patients were treated in groups or classes. For logistic reasons it could not be guaranteed that the same physiotherapist would attend all six sessions for each patient.

Patients could cease attendance for therapy both on account of exacerbation of their pain as well as for improvement. Those failing to attend for any treatment at all and/or failing to attend for follow up were included in the analysis and were not replaced.

At follow up the metrologist did not have the physiotherapy treatment results folder. The protocol for the follow up assessment was also such that the metrologist did not make any enquiry as to which type of treatment had been given. Sometimes the metrologist could not prevent the patient mentioning some detail that might go some way towards identifying the treatment given, though this would not have distinguished the control subthermal from the therapeutic thermal version of short wave diathermy. Furthermore the metrologist could not have been aware of which diagnostic pattern would be attributed to the patient by the subsequent computer classification analysis.

The classification study used 301 of the 400 patients entering the therapeutic trial. These 301 cases had all

been seen by the same metrologist and physician in order to reduce inter-observer error and that physician had made an extra set of observations which helped in the classification study. Thus the 99 patients not entered into the classification study were excluded either because they had failed to attend for treatment and/or follow up assessment or had been seen by one of the other physicians and would thus not have had the extra classification data. The classification study identified seven patterns of low back pain (Heinrich *et al.*, 1985, 1986; Sweetman, 1985; Sweetman *et al.*, 1992, 1993). Details of the selection of outcome measures are also given in the above references.

The response to treatment was then assessed using multivariate analysis of variance (MANOVA) to investigate whether the nine main outcome measures could distinguish distinct treatment response amongst the seven different patterns of back pain. Multivariate tests were performed to safeguard against spurious significance levels likely to be obtained in repeated testing on several correlated outcome measures (Bock, 1975).

Results

Of the 86 Physiotherapy Departments contacted in the postal survey 68 replied (79%) although five of those that did reply failed to state rank orders. The results from the 63 departments (73%) that supplied useful information showed that exercises, short wave diathermy and traction were the most popular treatments and were thus adopted as the treatment regimens for the therapeutic trial.

The extension exercises were selected to represent the exercise treatment group despite the departmental preference for lumbar isometric flexion exercises (LIFE) as it was felt that those patients who had a 'flat' lordosis could not sensibly be expected to perform the lordosis flattening part of the LIFE regimen.

Figure 4 shows how the therapeutic and classification study populations were derived.

579 patients were screened until 400 had been entered into the therapeutic trial with 100 in each treatment group and with each group containing equal numbers of men and women. Age and back pain severity details

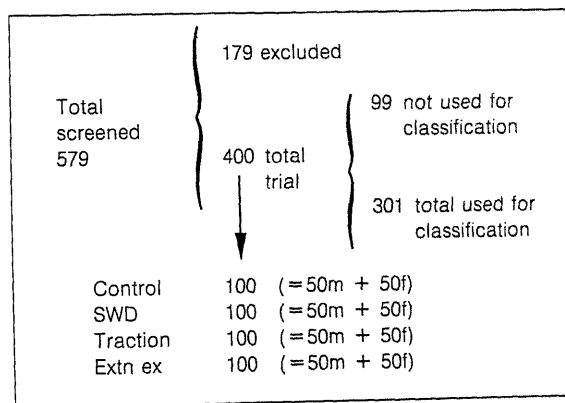


Figure 4. Diagram of patient groupings.

Table 1. Age and back pain severity gradings

| | Total screen | Excl | Total trial | Treatment groups | | | | Classification | | |
|-----------|-----------------|------|----------------|------------------|------|----------|---------|----------------|----------------|--------------|
| | | | | Control | SWD | Traction | Extn Ex | No fu | Total clsfn | Not clsfn |
| <i>n</i> | 579 | 179 | 400 | 100 | 100 | 100 | 100 | 51 | 301 | 99 |
| Ages | | | | | | | | | | |
| Mean | 41.3 | 42.2 | 41.0 | 41.2 | 40.4 | 40.4 | 42.0 | 39.9 | 41.1 | 40.4 |
| SD | 14.6 | 15.0 | 14.4 | 14.9 | 14.2 | 14.0 | 14.7 | 15.1 | 14.3 | 14.8 |
| Minimum | 12 | 14 | 12 | 14 | 13 | 18 | 12 | 14 | 12 | 13 |
| Maximum | 79 | 79 | 78 | 78 | 76 | 78 | 77 | 77 | 78 | 77 |
| Severity | | | | | | | | | | |
| Mildest 1 | 51 | 19 | 32 | 5 | 8 | 11 | 8 | 6 | 21 | 11 |
| 2 | 148 | 44 | 104 | 28 | 25 | 25 | 26 | 12 | 85 | 19 |
| 3 | 141 | 38 | 103 | 25 | 28 | 27 | 23 | 12 | 79 | 24 |
| Worst 4 | 239 | 78 | 161 | 42 | 39 | 37 | 43 | 21 | 116 | 45 |

The various patient groups include: all those screened (Total screen), those excluded (Excl), those entering the trial (Total trial), the control and treatment groups, those with no follow up (No fu), and those whose data were used for the classification analysis (Total Clsfn), and those from the trial not included in the classification analysis (Not clsfn). The low back pain severity peak gradings by impairment of activity for present episode were: 1. pain made it difficult to dress (esp. putting on footwear); 2. pain can make it difficult to get about (i.e., walking); 3. back pain and/or sciatica exacerbated by cough, sneeze or strain; 4. bedridden. SWD, short wave diathermy; Extn Ex, extension exercises.

for all groupings including the 400 patients entered into the therapeutic trial are shown in Table 1. There were thus 179 patients who were screened and not entered for reasons covered by the exclusion criteria. For some patients there were multiple reasons for exclusion but in this analysis the most important reason was selected so that only one reason for exclusion is given per patient. For 39 their back pain was already improving or better. In 15 the back pain was too bad to participate or other treatment was indicated. In 28 other sites of pain such as cervical, dorsal or coccygeal spinal pain or hip, knee or ankle pain predominated. Four patients were thought to be too anxious to participate or did not appear able to understand some of the questions. It was too far to travel for treatment or patients were unable to take time off work in 19 cases. Eighteen had already had one or more of the treatments with exacerbation or no improvement or were fearful of one of the three options. For 11 the evidence for neurological deficit prompted the physician to exclude the patient from the trial. Twenty-four were excluded on account of serious or potentially serious pathology with cases of carcinoma of the breast with metastases; a suspected pancreatic tumour; osteoporosis with vertebral collapse; an L2/3 vertebral anomaly on X-ray; four requiring investigation on account of findings such as elevated ESR or enlarged liver; three with polyarthropathy; eight with potential abdominal pathology including two men with haematuria and three women with intermenstrual or postmenopausal haematuria, pyelonephritis, another renal problem, and tenderness in the left iliac fossa; and some miscellaneous conditions such as malaria, and Behçet's and Reiter's disease. This list of pathology presenting to a back pain clinic perhaps represents a cautionary note suggesting that an orthodox medical assessment is appropriate prior to undertaking therapy for back problems. For 21 cases the reasons were not recorded and in

these subjects it was noted that the patients had often failed to have initial tests and had failed to reattend.

Table 2 shows some baseline characteristics for the patients in each of the treatment groups, and as each treatment group had 100 patients, the figures can be read as percentages. The tabulations are by and large self-explanatory and indicate that the randomization procedures had resulted in a similar constitution of the four groups with no significant differences.

The therapeutic trial was analysed by intention to treat and the 400 patients included 51 (12.8%) who failed to attend for follow up. From amongst these 51 patients there were 29 who attended for some treatment but failed to attend for follow up assessment and 22 who failed to attend for both the treatment and the follow up assessment.

The results of the therapeutic trial are shown in Table 3 judged in terms of the patients' opinion as to the effect of the treatment (worse, same, better) which was described as the subjective opinion of efficacy (EFFS). There was an overall trend to improvement (sig $p < 0.0001$): 43% said they were better, 29% said there had been no change in their condition, and 15% said they were worse. For 13% there was no follow up. There was no significant difference in response between the four treatment groups. The items that show interesting deviations from the expected but which do not reach significance at the 0.05 level are the 49 made better by traction (6.5 patients more than expected) and related to this observation there were fewer made worse by traction. There were 21 made worse by exercises (5.5 patients more than expected) and yet fewer than expected failed to attend for treatment and follow-up in the exercise group.

There were several other indicators that were also used as measures of outcome in response to treatment. The patients were asked how their back pain felt at the follow up visit compared with the initial visit. This is

Table 2. Comparability of some of the baseline characteristics for the patients in the four treatment groups. There were 100 patients in each group and so the figures can also be read as percentages

| Variable or characteristic | Control | SWD | Traction | Extn Ex |
|---|---------|-----|----------|---------|
| Duration of present episode | | | | |
| Weeks (less than 5 weeks) | 31 | 33 | 28 | 26 |
| Months (5 weeks +) | 52 | 50 | 50 | 64 |
| Years (10 months +) | 17 | 17 | 22 | 10 |
| Progression of back pain in last month: | | | | |
| Getting worse | 44 | 35 | 31 | 26 |
| Staying much the same | 30 | 35 | 36 | 35 |
| Some improvement | 26 | 30 | 33 | 39 |
| Weather can affect back pain | 30 | 40 | 34 | 39 |
| Pain causes difficulty getting off to sleep | 51 | 45 | 49 | 41 |
| Job heaviness | | | | |
| No heaviness | 6 | 4 | 5 | 6 |
| Minimum | 25 | 26 | 27 | 23 |
| Light occasionally | 32 | 39 | 35 | 44 |
| Light sustained | 4 | 4 | 3 | 1 |
| Heavy occasionally | 25 | 15 | 18 | 19 |
| Heavy sustained | 8 | 12 | 12 | 7 |
| Work status | | | | |
| Working | 42 | 45 | 48 | 46 |
| Light work | 31 | 29 | 18 | 26 |
| Off work | 27 | 26 | 34 | 28 |
| Extent of sciatica (pain down leg) | | | | |
| Iliac crest | 19 | 23 | 14 | 27 |
| Buttock | 4 | 6 | 7 | 5 |
| Gluteal fold | 3 | 2 | 4 | 6 |
| Mid thigh | 17 | 18 | 13 | 17 |
| Knee | 10 | 8 | 8 | 4 |
| Mid calf | 3 | 7 | 12 | 8 |
| Ankle/heel | 23 | 19 | 23 | 16 |
| Mid tarsal | 0 | 2 | 2 | 3 |
| Big toe | 12 | 7 | 7 | 3 |
| Little toe | 9 | 8 | 10 | 11 |
| Absent knee or ankle reflexes | 8 | 14 | 7 | 9 |

SWD, short wave diathermy; Extn Ex, extension exercises.

Table 3. Patients' opinion of EFFect (subjective) of treatment (EFFS)

| | Better | Same | Worse | No follow up | Total |
|-----------|--------|------|-------|--------------|-------|
| Control | 37 | 32 | 15 | 16 | 100 |
| SWD | 39 | 34 | 15 | 12 | 100 |
| Traction | 49 | 25 | 11 | 15 | 100 |
| Exercises | 45 | 26 | 21 | 8 | 100 |
| Total | 170 | 117 | 62 | 51 | 400 |

$\chi^2 = 10.5$; 9 df; $0.3 < p < 0.4$; not significant.

not necessarily the same as the effect of treatment. Intervening mishaps could have made them worse by the time they were seen at follow up even if treatment had helped. Some found the treatment painful but despite this eventually seemed to gain benefit. Again, no significant difference was shown by this measure or when outcome was measured comparing initial versus follow up data for such variables as pain on the subjective 0-10 pain scale, lumbar sagittal mobility, touch toes gap or reduced straight leg raise. The comments made by the physiotherapists at each of the patients' attendances have been documented elsewhere (Sweetman, 1985).

It is intended to publish further details of the outcome criteria and severity measures. The majority of the

outcome measures were calculated as the difference between observations made at the initial and follow up visit, and were thus called 'change' variables. The short list of nine most useful outcome measures include the subjective effectiveness; change in difficulty in getting off to sleep; change in area of lumbago; change in extent of sciatica; change in count of number of directions of back movement that caused pain; change in count of leg tests that caused pain; change in the ipsilateral and contralateral indices which measure whether tests were painful or tender on the same or opposite side to the side of pain at rest, and change in straight leg raise.

The patterns identified in the classification analysis are in some cases believed to represent conditions as distinct as pelvispondylitis (pattern 2), facet joint osteoarthrosis (pattern 4), lower lumbar instability (pattern 5), and nerve root irritation or nerve root compression (patterns 1 and 7) respectively.

Multivariate analysis of variance (MANOVA) was employed to study the respective effects of the different treatments on those 301 patients in whom there were sufficient data to formulate a 'pattern diagnosis'.

For this smaller size population of 301 patients in the classification study there was only one case given traction with the pattern 7 syndrome and so this cell was excluded in the MANOVA analysis. This imbalance occurred in the process of reducing the numbers from 400 in the trial to the 301 classifiable patients. For all intents and purposes an absent reflex is synonymous with pattern 7, and there were 38 such patients in the 400 patients entering the trial. The last row in Table 2 shows a sufficiently well balanced allocation of such cases to each of the treatment groups and suggests that there was no bias against entering such patients to the traction regimen. One would have expected about nine or 10 patients ($38 \div 4 = 9.5$) per treatment group, and in practice there were seven in the traction group, eight in the control group, nine in the exercise group, and 14 in the short wave diathermy group.

Furthermore sciatica radiating to the toes (69 such cases) is another feature which might have suggested nerve root compression due to disc prolapse, and again there is no evidence of avoidance of allocation of such cases to traction, with 17 expected in each cell ($69 \div 4 = 17.25$). In practice 14 were allocated to the exercise regimen, 15 to short wave diathermy, 19 to traction, and 21 to control.

The nine best outcome response criteria (change measures) were used to test for interaction between the seven diagnoses (patterns) and the four treatment groups. A multivariate significance level (Bock, 1975) of 0.02 was obtained (Table 4). This indicates that there was a treatment effect due to differing responses dependent upon the specific diagnoses. Details of this are shown in Table 5. For instance, traction seemed to be most appropriate for patients suffering from pattern 5 (the 'contralateral' syndrome) in whom there was pain at rest on one side of the back and yet tender signs or pain induced on the opposite side with tests. It is thought that some of these patients may have an element of instability in the lower back. Short wave diathermy seemed better for patients with pattern 2 (the 'switching' syndrome) in whom the side of pain could switch between episodes. This phenomenon can be seen in patients with pelvispondylitis.

Table 4. Multivariate analysis of variance (MANOVA) on the nine treatment response variables for the seven diagnoses and the four treatments

| Two way MANOVA for classification sample (n = 301) | | | | |
|--|----|-------|--------|-------------------|
| Source | df | Wilks | Lambda | p |
| Diagnoses ^b | 5 | 0.522 | | 0.00 ^a |
| Treatments | 3 | 0.846 | | 0.04 |
| Diagnoses × treatments | 15 | 0.503 | | 0.02 |

^aSignificance level <0.01.

^bThe pattern 7 group was excluded from the analysis since only one patient received traction.

Although the treatment groups in this trial were probably the largest of any comparable study, the analysis using the single subjective outcome criteria without attempts to distinguish patterns of back pain failed to show significant differences between the treatment groups. Once the patients were subdivided amongst the seven patterns/diagnoses, the treatment groups became much smaller. There is now a need to conduct further controlled trials of these and other types of treatment in larger numbers of patients with each of the different patterns/diagnoses to see if the indications of diagnosis specific response to treatment shown in this study can be confirmed.

Discussion

The main objective of the study was to see if distinct patterns of low back pain could be identified amongst patients presenting with common forms of low back pain. Only a small proportion of low back pain patients can be given a generally accepted diagnosis (Dillane *et al.*, 1966) and the majority of patients are only given non-specific descriptive labels.

At the time of planning this research it was recognized that previous therapeutic trials had tended to indicate little evidence of benefit comparing active treatments with control regimens in studies which were conducted on series of patients with little or no attempt to distinguish distinct types of back pain. Factors affecting selection of patients and different sets of exclusion criteria also meant that the previous studies proved difficult to compare.

It seemed reasonable to assume that if there were distinct patterns of symptoms and signs within the spectrum of back pain commonly presenting, it might then be expected that different treatments would have different effects on the different patterns of back pain.

In view of the existing confusion over diagnostic methods and the lack of a generally acceptable classification it was understandable that research into classification tended to be given less priority than therapeutic trials, presumably because it was thought that immediate benefits would accrue if a particular treatment was found to work. In order to take the matter further it was apparent that a therapeutic trial would have to be organized in order that a classification study could be incorporated at the same time.

Table 5. Specification of the diagnoses against treatments interaction. The one way MANOVA of treatment effects for each of the seven patterns/diagnostic groups are given separately

| Pattern No. Name and (? implication) | Sample size | | | | | Multivariate significance levels Pairwise treatment group contrasts | | | | | | |
|--|-------------|-----|----------|------------|-------|--|-------------------|-------------------|-------------------|-------------------|-------------|-------------|
| | Control | SWD | Traction | Extn Ex | Total | Overall | Tra/ SWD | Tra/ Ext | Tra/ Con | SWD/ Ext | SWD/ Con | Ext/ Con |
| 1 Sciatica | 15 | 14 | 15 | 15 | 29 | 0.04 | 0.00 ^a | 0.35 | 0.03 | 0.35 | 0.31 | 0.22 |
| 7 Sciatica and Lost reflex ^b | 8 | 12 | (1) | 8 | 29 | 0.03 | - | - | - | 0.34 | 0.06 | 0.01 |
| 2 Switching (? spondylitis) | 8 | 11 | 11 | 12 | 42 | 0.06 | 0.01 | 0.87 | 0.81 | 0.00 ^a | 0.12 | 0.62 |
| 3 Symmetrical (? symmetric OA) | 10 | 4 | 13 | 9 | 36 | 0.04 | 0.10 | 0.02 | 0.19 | 0.15 | 0.32 | 0.31 |
| 4 Contraband (? facet OA) | 9 | 8 | 7 | 6 | 30 | 0.01 | 0.01 | 0.01 | 0.01 | 0.56 | 0.14 | 0.31 |
| 5 Contralateral (? instability) | 5 | 3 | 5 | 9 | 22 | 0.00 ^a | 0.00 ^a | 0.00 ^a | 0.00 ^a | 0.40 | 0.33 | 0.22 |
| 6 Few signs (? dorsolumbar) | 21 | 20 | 20 | 22 | 83 | 0.05 | 0.05 | 0.16 | 0.02 | 0.09 | 0.63 | 0.35 |

^aSignificance level <0.01.

^bThe pattern 7 group was excluded from this analysis as only one patient received traction.

Information concerning response to therapy was not used in the classification study and only data available from the initial assessment were used. We had wondered whether response to treatment might be useful for diagnostic purposes and this was inspected and although an effect was evident, the symptoms and signs at presentation proved far more useful in constructing the diagnostic classification.

It can be seen that attempts were made to include several aspects of research design to answer a number of questions. Research design can have far reaching consequences and Fletcher and Fletcher (1979) observed, on reviewing articles in the *New England Journal of Medicine*, *Journal of the American Medical Association* and the *Lancet*, that research design was weak and getting worse. Furthermore, the extent to which analysis can be carried out may also have a bearing on useful findings. Anderson and Phillips (1981) analysed the results of the multi-centre trial of back pain treatment of Doran and Newell (1975) and were able to obtain further useful information concerning prognostic factors.

Within this context the results of this study are thought to be of help in four particular ways. Firstly, it did seem from most of the previous studies that there was little prospect of showing any objective evidence to justify the continued use of the more commonly used forms of physiotherapy. That we have been able to show some diagnostic specific responses to treatment gives new hope that we can improve our ability to prescribe specific treatment for specific conditions in this area of rheumatic morbidity. Secondly, and perhaps equally as important, the results seem to afford an element of validation for the classification system, in that the seven patterns identified seem to have some bearing on the response to treatment. It is believed that a classification system that proves useful in this manner, and which has also been subjected to reproducibility studies may help to elucidate some of the mysteries and

uncertainties that have for a very long time surrounded the management of common low back pain problems. Thirdly it is also felt that this study showed how a therapeutic trial can serve purposes other than solely comparing efficacy of selected treatments. The numerical analyses (CLUSTAN cluster analysis and MANOVA) employed in this study are in essence standard techniques but promise further insight than that provided by standard contingency table analyses alone. Finally now that a fully worked example has been provided it should be much easier to design studies so that as much attention can be expended on selecting variables that give indications of diagnosis, severity, prognosis, and outcome as is spent on specifying components of treatment and the control regimens.

It is hoped that the suggestions implicit in the pairwise treatment comparisons (Table 5) might provide the basis for selecting treatments for further study. There were also a good number of contrasts that showed little evidence of distinctive response to treatment in given patterns, and this information might help researchers avoid such studies in order to tackle more promising comparisons.

Examples that seem worthy of further study are where short wave diathermy seemed to help more patients, but where exercises made more patients worse in the pattern 2 group, which is thought to represent pelvispondylitis. Furthermore in pattern 1 with patients showing unilateral persistent sciatica without loss of lower limb reflex, more patients improved with traction and fewer with short wave diathermy, and this particular contrast appeared to be significant. The response to traction in the group thought to have lumbar instability (pattern 5) was of particular interest.

It is important to stress that larger groups of patients with the different patterns of low back need to be enrolled in further such trials of different forms of treatment before definitive statements can be made as to the

respective merits and risks of the different sorts of treatment.

Conclusion

As expected, a randomized trial of different forms of physiotherapy showed no obvious differences between the treatment and control groups. A reproducible classification system which was developed distinguished seven patterns of low back pain and using nine outcome criteria it was shown that there was a statistically significant response to the various forms of treatment dependent upon diagnosis which had in effect been hidden in the original 'simple' analysis. It is hoped that this result will encourage further examination of the various forms of therapy which showed significant benefit in the defined patterns of commonly presenting forms of low back pain.

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References

- Anderson JA and Phillips PR (1981) Regression, discrimination and measurement models for ordered variables. *Appl Stat* 30, 22-31.
- Anderson JAD (1978) Submission to working group on back pain. Faculty of Community Medicine of Royal College of Physicians. Newsletter (Precursor of *J Pub Health Med*) 5, 72-79.
- Bock RD (1975) *Multivariate Statistical Methods in Behavioural Research*. New York: McGraw-Hill.
- Dillane JB, Fry J and Kalton G (1966) Acute back syndrome - a study from general practice. *Br Med J* 2, 82-84.
- Doran DML and Newell DJ (1975) Manipulation in treatment for low back pain: a multicentre study. *Br Med J* 2, 161-164.
- Fletcher RH and Fletcher SW (1979) Weak research design; *N Engl J Med* 301, 180.
- Grieve GP (1981) *Common Vertebral Joint Problems*. Edinburgh: Churchill Livingstone; p. 377.
- Heinrich I, O'Hare H, Sweetman BJ and Anderson JAD (1985) Validation aspects of an empirically derived classification for 'non-specific' low back pain. *Statisticalian* 34, 215-230.
- Heinrich I, Sweetman BJ and Anderson JAD (1986) Application of an empirically derived classification of 'non-specific low back pain'. *J Appl Stat* 13, 89-96.
- Koes BW, Assendelft WJJ, van Der Heijden GJMG, Bouter LM and Knipschild PG (1991) Spinal manipulation and mobilisation for back and neck pain: a blinded review. *Br Med J* 303, 1298-1303.
- Koes BW, Bouter LM, Beckerman H, van der Heijden GJMG and Knipschild PG (1991b) Physiotherapy exercises and back pain: a blinded review *Br Med J* 302, 1572-1576.
- Koes B, van der Heijden G, Assenfeldt P, Bouter L and Knipschild P (1992) Spinal manipulation and mobilisation for back and neck pain; reply to correspondence. *Br Med J* 304, 185.
- National Back Pain Association (1991/2) *Annual General Report*; p. 3.
- Sweetman BJ (1985) Numerical classification of common low back pain. MD Thesis, University of London.
- Sweetman BJ, Heinrich I and Anderson JAD (1992) Clinical tests and patterns of low back pain. *J Orthop Rheumatol* 5, 209-222.
- Sweetman BJ, Heinrich I and Anderson JAD (1993) Review of selected tests that help distinguish common patterns of low back pain and some possible implications. *J Orthop Rheumatol* 6, 3-9.

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A randomized controlled trial of exercises, short wave diathermy, and traction for low back pain, with evidence of diagnosis-related response to treatment

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A survey of 86 UK Physiotherapy Departments (Anderson, 1978; Sweetman, 1985) indicated that the most commonly used forms of therapy for low back pain included exercises, short wave diathermy and traction. A prospective randomized single blind parallel group therapeutic trial was organized to include the three above treatment groups and a subthermal short wave diathermy control group. 579 patients referred from general practice to a Rheumatology Out Patient Department were screened until 400 patients had been entered into the trial. Treatments were given three times a week for 2 weeks and the patients were then seen in the follow up clinic for assessment. There were no significant differences between the four treatment groups in the subjective opinions of the patients on benefit ($0.3 < p < 0.4$). It was postulated that within this series of patients there might be cases with distinctive patterns of back pain which could be shown to respond differently to the forms of treatment under study. 301 of the patients from the therapeutic trial had data suitable for a classification analysis in which seven distinct patterns of low back pain were recognized. The hypothesis was confirmed when testing nine treatment outcome measures for interaction between the four treatment groups and the seven patterns of back pain when a multivariate significance level of $p = 0.02$ was obtained. This indicated that there was a treatment effect summarizing different responses, dependent on the 'diagnoses'. For example, traction seemed to be most appropriate for patients with the type 5 pattern in which patients described a paradox referred to as 'contralateral' in which their low back pain at rest is on one side and yet tests prove tender or induce pain on the opposite side.

Keywords: low back pain; randomized controlled trial; physiotherapy; exercises; short wave diathermy; traction.

Introduction

Despite the many forms of treatment available (Grieve, 1981) back pain continues to be one of the commonest symptomatic problems in the community and a plague on industry causing disruption through frequent spells of sickness absence and also results in a heavy toll of premature retirement. This is presumably because preventative measures and treatments have failed to stem the rising tide of back pain problems, with UK sickness absence due to back pain doubling in each of the last few decades (National Back Pain Association, 1991/2). However, there is probably an even more profound explanation for this failure to control the problem. The inability to identify distinct types of back problem within the more common forms of low back pain means that it is difficult to arrange specific treatment or preventative measure for specific types of low back pain. Though this inability to develop a generally acceptable diagnostic system for the commoner forms of low back pain has been recognized long term, it seems that few have come to terms with the effect it has on attempts to study the treatment of low back pain.

Although there have been studies of particular forms of back pain including ankylosing spondylitis and the prolapsed intervertebral disc, these conditions only represent a small proportion of back problems overall; and even with these conditions there have been problems with diagnostic selection criteria.

With respect to the common presentation of back pain Koes *et al.*, (1991a,b) reviewed prospective randomized controlled trials of exercise (23 trials) and manipulation and mobilization (35 trials) and showed that there is

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