Practice Research

Clinical trial of common treatments for low back pain in family practice

J R GILBERT, D W TAYLOR, A HILDEBRAND, C EVANS

Abstract

The results of a multicentred randomised clinical trial are reported of bed rest and of a physiotherapy and education programme for patients who presented in family practice with an acute episode of low back pain. No beneficial effect of either treatment was observed on several clinical outcome measures, including straight leg raising, lumbar flexion, activities of daily living, and pain. In fact the results favoured early mobilisation over bed rest and suggested that the physiotherapy and education programme was doing more harm than good. Moreover, additional analyses, which focused on clinically interesting patient subgroups, discovered no subset of patients who benefited from either of the treatments under study.

Having failed to identify any clinically important benefits, or other explanations for these negative results, we can only conclude that family doctors have little reason to prescribe either bed rest or isometric exercises to patients who suffer from low back pain.

Introduction

Many articles are published each year dealing with medical treatments for low back pain. Most are descriptive and uncontrolled, though five randomised clinical trials have been completed, primarily by British and Swedish investigators.[1-5]

Sims-Williams *et al* found that patients who received active physiotherapy showed significantly greater recovery at one month than those who received placebo physiotherapy.[1] This effect, however, disappeared after three months. The results of three other trials showed improvement with isometric exercises and patient education compared with mobilising or extensor exercises and standard physiotherapy treatment.[2-4] Bed rest, although commonly prescribed for low back pain in family practice, has only recently been tested in this setting. Wiesel reported that bed rest decreased the amount of time lost from work and the amount of discomfort experienced by patients by over 50%, compared with mobilisation.[5]

Although these trials have generated some positive results, interpreting them is hampered by the absence of valid and reliable measures of functional status, the failure to blind outcome assessments, small sample sizes, and subjective criteria for patient inclusion and exclusion.[6] Our study was designed both to overcome these shortcomings and to examine the two most promising treatments from previous trials: bed rest and physiotherapy combined with education.

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Methods

A randomised trial was performed to determine the effect of bed rest, a programme of physiotherapy and education, both of these treatments, or neither treatment on patients with acute low back pain.

INCLUSION OR EXCLUSION CRITERIA FOR PATIENTS

All patients who presented with low back pain to 22 participating family physicians over 10 months were considered for the trial. Physicians were drawn from both single handed and group practices, worked predominantly in urban areas, and cared for an average of 2000 patients. Patients were eligible if they were over 16 years of age, had pain in the lumbosacral region with or without radiation down the leg, and had been free of back pain for at least 30 days before the current episode. Patients were excluded if they had abnormal sensation, motor power, or reflexes or if their symptoms proved on preliminary investigation to be due to fracture, spondylolisthesis, spinal infection, disease of the hip or pelvis, gastrointestinal disease, primary or secondary tumours of the vertebral column, fractures of the vertebral column, Paget's disease, or rheumatoid disease. Pregnant women were also excluded.

BASELINE ASSESSMENT

Each physician used a standardised initial assessment form in which outlined the inclusion-exclusion criteria and included questions on the precipitating event, medications, previous back surgery, previous medical consultation, and results of laboratory tests performed. The physical examination was left to the discretion of the physician with the exception of two standardised objective measurements: straight leg raising and lumbar flexion. Straight leg raising, considered to be a valid test of nerve root irritation, was measured in both legs using a reliable gravity corrected OB goniometer. Lumbar flexion was measured using the method described by Moll and Wright.[7]

Patients were asked to complete a questionnaire that included personal information, history of back pain, the McGill Melzack pain questionnaire,[8] and the activities discomfort scale.[9] All patients were also given a diary in which to record daily estimates of the degree of pain, degree of restriction in usual daily activities, and degree of improvement, if any, since the previous day.

An important goal of treatment of low back pain is to return patients to normal physical functioning either at work or at home. This outcome was assessed by the activities discomfort scale in which patients rate the degree of discomfort associated with 18 specific activities of daily living.[9] This instrument has been found to predict pain intensity at follow up.[10] In our pilot study we found this scale to be very reliable (Cronbach's alpha = 0.95), and significantly related to the physician's judgment of pain.[11] The McGill-Melzack pain questionnaire has also been a sensitive, reliable, and valid tool for the measurement of clinical pain.[12]

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PRACTICE OBSERVED

Vocational Training

Is the distribution of training practices appropriate for the needs of general practice?

T S MURRAY

Abstract

The distribution of practices that train general practitioners in the west of Scotland was examined. The concentration of training practices is lowest in conurbations that are grossly deprived. Several topics require debate: should trainees be given experience in such areas as an elective? Should the criteria for selecting training practices be similar in all areas? Should practices in deprived areas be encouraged to apply to become training practices?

Introduction

The criteria for appointing general practice trainers have been evolved over several years, and any doctor who wants to become a trainer must show a willingness to teach. This is only one of the many necessary criteria, and the full criteria are published in *Training for General Practice*.[1] These criteria are an adequate model for a region to build on. There has been some concern that trainees get experience of a certain type of general practice that they may not experience in their long term careers. Hasler showed that trainees may see a different pattern of clinical problems from trainers.[2] The overall aim of the training year in practice is to ensure that the trainee acquires basic competence in general practice and to help lay a sound foundation for further professional development. This further development might be worrying if it is an environment that is totally different from the one that they have been trained in.

The Joint Committee on Postgraduate Training for General Practice believes that the aims of training may be achieved in a practice that provides the trainee with sheltered working conditions in which there is the time and opportunity to explore the range of general practice. The trainee should be challenged so as to be sufficiently stretched and intellectually stimulated. Unfortunately, the training year gives little experience of the high demand, socially deprived areas where many of the trainees will work as principals. It is important that young principals maintain their standards in their new environment.

I carried out a survey in the west of Scotland to determine whether the distribution of training practices was appropriate to the needs of the region. The distribution of principals in general practice in each health board area was obtained from the primary care administrator from health boards in the west of Scotland. This distribution was then compared with the current list of trainers in the west of Scotland.

Findings

Table I gives the distribution of training practices throughout the west of Scotland according to their health board areas. In Argyll and Clyde there is considerable variation within the districts, and almost 15% of principals in the Dumbarton district are trainers but only half of this number in the other three districts—Argyll and Bute, Paisley, and Inverclyde. In Ayrshire almost 9% of the principals in north Ayrshire are trainers but only 7% in south Ayrshire, and in Forth Valley there is a slightly higher number in the Stirling area than in the Falkirk area.

TABLE I—*Distribution of trainers in Health Board areas*

Health board	No of general practitioner principals	No of trainers	Percentage of general practitioner principals who are trainers
Argyll and Clyde	[illegible]	[illegible]	[illegible]
Ayrshire	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
Lanarkshire	[illegible]	[illegible]	[illegible]
Forth Valley	[illegible]	[illegible]	[illegible]
Greater Glasgow	[illegible]	[illegible]	[illegible]
Total in region	[illegible]	[illegible]	[illegible]

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TABLE II—*Distribution of trainers in Lanarkshire*

Area	No of general practitioner principals	No of trainers	Percentage of general practitioner principals
Hamilton/East Kilbride	[illegible]	9	[illegible]
Motherwell/Clydesdale	98	[illegible]	[illegible]
Monklands/Cumbernauld	[illegible]	4	[illegible]
Total in Lanarkshire	[illegible]	16	[illegible]

Table II gives the distribution in the Lanarkshire Health Board area. In the East Kilbride/Hamilton area the percentage of training practices in East Kilbride town is relatively high compared with the Hamilton area, with the town of Hamilton providing a third of the practitioners but only a ninth of the trainers. In the Monklands/Cumbernauld area Airdrie and Coatbridge, an area of gross deprivation, only one (2·3%) doctor out of 43 is a trainer.

Table III gives the distribution of the five Glasgow districts, highlighting two areas with a higher than average number of trainers: the Northern District and the South West District. In Glasgow Northern District is the town of Kirkintilloch, where a third of the 21 principals are trainers. In the remainder of the Northern District, with gross areas of inner city decay, less than 4% of the principals are trainers.

TABLE III—*Distribution of trainers in Glasgow*

Area	No of doctors	No (%) of trainers
Western	146	11 (7·5)
Northern	120	11 (9·2)
Eastern	124	8 (6·5)
South east	137	9 (6·6)
South west	94	10 (10·7)
Total in Glasgow	621	49 (7·9)

Discussion

Though the results are from the west of Scotland, this experience would probably be repeated in the other major conurbations in the United Kingdom. It is important to have high standards in training practices and to instil the trainee with appropriate standards. If, however, trainees become principals in grossly deprived areas with little hope of putting their standards into practice this might lead to disillusionment followed by the adoption of the standards of those who practise around them.

Thus a month's elective might provide the trainee with some experience of working in a deprived area. It would also be invaluable experience for the practice that he or she is attached to. If, within any district, several trainees are doing electives it might provide good experience for the other trainees in the district. Such an elective seems to be particularly relevant now as the choice of practice vacancies for the trainee becomes more restricted. Undoubtedly, areas with a high concentration of training practices provide a high quality of care, which is desirable for the trainee to see. But is the doctor who has trained in this environment prepared for the hurly burly of a grossly deprived area?

The trainee's main aim at the end of vocational training is to obtain a practice, and many now obtain this in the area they work in without the post being advertised. One advantage of working in an area that is sparsely supplied by trainees is that chances for employment are decidedly improved. Despite the arguments for and against the present policy, each region tends to provide its own principals in general practice. Should the criteria for training practices be similar throughout the region? Should the regional committee be more flexible to its own needs and make allowances for practices in deprived areas with high workloads?

Practices tend not to put themselves forward from deprived areas. Is this because they are unaware of training standards, having few local peers to compare themselves with? Are they afraid of rejection? Do they think that trainees will know more than they do and are therefore afraid to apply? Does the high workload prevent them from becoming trainers? Many other reasons may be postulated for this discrepancy, but an educative programme is required in the deprived areas to identify practices of potential and advise them how to reach the necessary standards, which must be decided by each regional committee, taking into account the needs of their own area. Collaboration with the local medical committees would be of great help in this task. Freeman *et al* showed that modelling is a powerful means of learning in vocational training.[3] It is important that the trainee who is appointed as a principal can cope with a new role.

References

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2 Hasler JC. *Clinical experience of trainees in general practice.* London: University of London, 1982. (MD thesis.)

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Multicultural medicine

Mongolian spots and culture—This is an ethnic characteristic. These congenital, macular, and non-inflammatory patches are common in ethnic Asian infants—Indian, Pakistani, Bangladeshi, and Sri Lankan. These are not uncommon in Afro-Caribbeans, especially West Indians (in the West Indies there is "an African as well as an Asian" population). Occasionally these are noted in Eskimos and Europeans of Celtic origin, especially those with dark hair. They are collections of spindle shaped melanocytes located deep in the dermis. These are blue, slate grey, or black, commonly occurring in the sacral region but may occur anywhere on the skin, including the face. These spots vary in shape and size. Some can resemble finger marks and mimic a bruise. The colour usually fades during the first year and they disappear by the end of the first decade. No treatment is required. The cause is unknown, thus more research is needed. It is important not to confuse them with bruises as the condition is often mistaken for a bruise if it has not been seen before. Many British general practitioners, health visitors, and consultant paediatricians in the National Health Service, especially those from South Africa, may never have examined an Asian or Afro-Caribbean infant.

In Asian culture to secure the extended family system, marriages are arranged—the less you see of the others, the more you stick to one—and the husband is often more loyal to his mother than to his wife. A woman is expected to give birth to a spotless baby, especially if it is a male. It is not surprising, therefore, that the mother may feel guilty and believe that this Mongolian spot is her genetic failure. The mother in law, who believed when she was young that her own mother in law was awful and now thinks that her daughter in law is horrible, might think of it as a curse and be ready to blame the mother. A general practitioner should not only reassure the mother, but also explain this to the family.

Fuel can be added to the fire when an English health visitor sees such an infant on her first visit and suspects child abuse. The mother in law may collude with her and, despite the mother's denials and tears, she calls a "case conference" to be chaired by a consultant paediatrician. The general practitioner, unlike the consultant, is not salaried and is paid on a "service per item" basis, knowing that there is no fee for such an attendance, carries on looking after his sick patients, and declines the invitation to attend, and no wonder. A lot of time and money is wasted.

If every medical student, general practitioner trainee, and health visitor could be shown such cases, much expense, stress, and tears could be avoided.

—BASHIR QURESHI, general practitioner, Hounslow, Middlesex

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INCLUSION AND EXCLUSION CRITERIA FOR PATIENTS

All patients who presented with low back pain to 22 participating family physicians over 10 months were considered for the trial. Physicians were drawn from both singlehanded and group practices, worked predominantly in urban areas, and cared for an average of 2000 patients. Patients were eligible if they were over 16 years of age, had pain in the lumbosacral region with or without radiation down the leg, and had been free of back pain for at least 30 days before the current episode. Patients were excluded if they had abnormal sensation, motor power, or reflexes or if their symptoms proved on preliminary investigation to be due to fracture, spondylolisthesis, spinal infection, disease of the hip or pelvis, gastrointestinal disease, primary or secondary tumours of the vertebral column, fractures of the vertebral column, Paget's disease, or rheumatoid disease. Pregnant women were also excluded.

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An important goal of treatment of low back pain is to return patients to normal physical functioning either at work or at home. This outcome was assessed by the activities discomfort scale in which patients rate the degree of discomfort associated with 18 specific activities of daily living. This instrument has been found to predict pain intensity at follow up. In our pilot study we found this scale to be very reliable (Cronbach's alpha = 0·95) and significantly related to the physician's judgment of pain. The McGill-Melzack pain questionnaire has also been a sensitive, reliable, and valid tool for the measurement of clinical pain.

ALLOCATION TO TREATMENT

After obtaining informed consent from patients, physicians telephoned a centralised patient registry and randomisation service in the department of clinical epidemiology and biostatistics, McMaster University. Patients were stratified within each practice by whether their physicians intended to place them on major or minor medications. Minor medications were defined as regular analgesics (taking muscle relaxants or any analgesic containing fewer than eight aspirins per day, or both). Major medications were defined as anti-inflammatory agents (taking any non-steroidal anti-inflammatory drug or any analgesic containing eight or more aspirins per day). Within each of these strata patients were randomly assigned to one of four treatment groups comprising a 2 × 2 factorial design: (i) physiotherapy and education plus bed rest, (ii) physiotherapy and education only, (iii) bed rest only, and (iv) control (none of the above).

REGIMENS

Patients who were randomised to physiotherapy and education (groups i and ii) saw a 20 minute slide tape presentation about the back and its care and were given a two page summary of the presentation for future reference. They were also seen by the study physiotherapist shortly after randomisation at which time the isometric flexion exercises were taught and supervised. Each patient was given a form with both written and pictorial directions for each exercise and was instructed to repeat the exercises at home three times a day. Repeat visits were scheduled by the physiotherapist as necessary to insure that all patients had mastered the exercise programme.

Patients who were randomised to bed rest (groups i and iii) were instructed to stay in bed for at least four days and given written instructions depicting appropriate positions for bed rest.

Patients who were randomised to the control group (iv) were given the same analgesic prescription as other groups and received no other instructions or treatments.

PATIENT FOLLOW UP

Patient progress was determined by follow up visits by the physician, daily patient diaries, self administered questionnaires, telephone interviews, and a medical record audit. All follow up assessments were performed by a physician or research assistant who was blind to the patient's assigned treatment.

All patients were re-evaluated in their physician's practice at roughly 10 day intervals for one month or until they were free of pain. At each follow up visit patients returned their latest diary, completed the patient questionnaire, and were examined by a physician who was blind to their assigned treatment.

Telephone follow up was performed six and 12 weeks after randomisation by a research assistant who was blind to the patient's assigned treatment. Using a standard questionnaire, all patients were asked to report the degree of their pain, restrictions in activities of daily living, and what, if anything, they were taking or doing for back pain.

A final long term follow up was conducted one year after entry to the study. A questionnaire was mailed to each patient which inquired about the present state of their back, the frequency and severity of any episodes of low back pain, their current activity level, and whether they had seen a professional for back pain (and, if so, the type and duration of treatment that they had received). Information regarding preventive measures being used by the patient to prevent further episodes of back pain was also obtained. To validate the accuracy of these patient reports reviews of medical records were conducted for all patients.

COMPLIANCE AND CONTAMINATION

Patients were asked at each follow up whether they had seen anyone else for their back pain, including physiotherapists, chiropractors, acupuncturists, or specialists, or all of those. Compliance with drug treatment and bed rest was measured by self report. Patients in all four treatment groups were provided with a diary which they completed each night before retiring until they were discharged from the study. Patients were asked to record: (*a*) the level of pain that they had experienced that day, (*b*) the extent to which the pain interfered with their usual daily activities, (*c*) the level of improvement since the previous day, (*d*) the name, strength, and number of both prescription and non-prescription medications taken that day, (*e*) the time spent resting and exercising, and (*f*) any other measures that they used to alleviate pain.

In addition to the patient diary compliance with bed rest was assessed using a recently developed large scale integrated motor activity monitor. This device, which is slightly larger than a wristwatch, records body movement and was used to monitor physical activity unobtrusively but objectively.

Compliance with physiotherapy was determined in part by patients returning for their physiotherapy education. Patients who received physiotherapy were also asked at the end of their six and 12 week follow up interviews whether they had used the exercises and, if so, how long they had continued to do so.

STATISTICAL METHODS

In designing the trial the activity discomfort scale was identified as the main outcome measure. A treatment effect equal to one standard deviation on the activity discomfort scale was considered clinically important, whether it occurred as a main effect or as interaction between bed rest and the physiotherapy and education programme. This, and the choice of alpha = 0·05 (2 tailed) and power = 80%, lead to a target sample size of 65 patients/cell (total = 260).

Physicians were asked to follow patients up every 10 days until recovery or for a maximum of 30 days. At each assessment five major outcomes were assessed: straight leg raising, lumbar flexion, restriction in activities of daily living, and pain assessed by the McGill/Melzack total and word count scales. Ten day follow up was a guideline and was not mandatory. Recognising that each patient would be followed up in family practice only until the patient and physician were satisfied with the degree of recovery, that clinically acceptable recovery would occur at different times for different patients, and that all patients could not be seen for outcome assessment on a rigid time schedule, we proposed the following strategy for analysis. To control for varying durations of follow up by physicians outcomes were expressed as the amount of change from the baseline assessment to the final assessment divided by the number of days between randomisation and the final follow up by the physician. In effect, we examined the rate of change in each outcome measure during physician management of the episode of low back pain.

Since most patients completed at least one 10 day diary, 10 day total scores were constructed for each of the three scales assessed daily. These included "any improvement," "activity level," and "pain" and provided short term outcome measures. For each scale a lower total score corresponds to a better clinical result. A 2 × 2 factorial analysis of variance, controlling for baseline measures, was used to compare the four treatment groups on the above physician and patient diary outcomes.

In addition, survival analysis using the Cox proportional hazards model was used to compare treatment groups on the time to clinically interesting events. The diary data were used to identify the date on which the patient first reported "feeling a lot better," "normal level of activities," "no pain," and "stopped taking drugs." In addition, "recovery" was defined as the first follow up by the physician on which the doctor and patient agreed that pain had disappeared or declined to a mild level or, failing this, the first telephone follow up on which the patient alone reported this result. Again, the 13 baseline variables described in table I, were included as covariates in these analyses.

Results

ADHERENCE TO PROTOCOL

A total of 270 patients was entered into the trial. Of these, eight were exluded on review of their baseline data for failure to meet the trial's predefined criteria for inclusion and exclusion. A further 10 patients refused to accept the treatment that was randomly assigned to them (one control, six bed rest, and three bed rest plus education). Thus 252 eligible patients began treatment. Follow up data were obtained for all but one patient, with 219 (87%) returning to their physician for follow up evaluation, 224 (89%) completing at least one 10 day patient diary, 242 (96%) completing the six and 12 week telephone follow ups, and 227 (90%) completing the long term one year follow up. The duration of patient follow up by physicians ranged from three to 44 days, median 12 days.

The diaries showed that patients who were randomised to bed rest spent an average of three days longer in bed than non-bed rest patients ($p = 0\cdot0007$). Unfortunately, the large scale integrated motor activity monitor proved unreliable and thus no objective measure of compliance with bed rest could be obtained.

All but two of the patients who were randomised to physiotherapy and education saw the physiotherapist at least once, and none of the patients in the non-physiotherapy groups received the physiotherapy and education programme.