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The use of a back class teaching extension exercises in the treatment of acute low back pain in primary care

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Background. Back extension exercises are commonly recommended to treat acute low back pain. Evidence of their beneficial effect is, however, weak.

Objectives. We aimed to demonstrate a benefit of teaching back extension exercises in addition to usual GP care for acute low back pain.

Methods. Patients with acute simple low back pain of less than 28 days duration, presenting to a GP, were randomized either to attend a back class or to receive conventional management. Outcome was measured using changes in the Oswestry disability score and visual analogue pain scale (VAS) on six occasions during 1 year and also a VAS and patient assessment of degree of disability during the previous 6 months at 1 year.

Results. Seventy-five patients were recruited. The principal outcome measures showed no difference between the two groups. The treatment group reported less chronic disability at 1 year (50% versus 14%, $P < 0.007$).

Conclusions. A treatment effect has not been demonstrated, but some patients who would otherwise have reported mild pain were pain free after 1 year. This approach to treating back pain has not been shown to be effective. More much larger studies, with more intensive treatment, are required in order to decide whether physical therapy in primary care is beneficial as treatment for acute back pain.

Keywords. General practice, low back pain, McKenzie exercises.

Introduction

Low back pain is a common disorder with large and increasing social and economic costs. Both the Clinical Standards Advisory Group (CSAG)[1] and more recently the Royal College of General Practitioners[2] (RCGP) have recommended a 'revolution'[3] in the treatment of low back pain, with an emphasis on the treatment of acute low back pain in primary care, with physical therapy (osteopathy, chiropractic or physiotherapy), to prevent the development of chronic back pain. These recommendations are not well supported by research evidence.[4]

A popular physical therapy for low back pain is the McKenzie technique, which emphasizes passive extension exercises of the lumbar spine to reduce intradiscal pressure, causing the nucleus pulposus to migrate anteriorly and thus relieve pressure on pain sensitive structures such as the posterior longitudinal ligament and annulus fibrosus. A number of clinical trials have suggested that it may be of benefit compared with other physiotherapy treatments,[5–8] but the quality of their method, like that of most trials of physical treatment for low back pain, is poor.[9,10] Malmivaara *et al.*[11] have compared back extension exercises, bed rest and continuation of ordinary activity for acute back pain in an occupational setting. Those who continued normal activity had the best outcome.

We are not aware of any trials of the treatment of acute simple low back pain, based in primary care, which compare non-manipulative physical therapy with conventional treatment by a GP. Such studies are

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required to support the hypothesis that active treatment of acute low back pain will reduce the amount of chronic disability from low back pain.

A randomized controlled trial teaching extension exercises to patients with acute back pain in primary care is described.

Method

The trial was carried out over a 3-year period to the end of February 1995 in a single suburban general practice with 6600 patients and four doctors. Ethical approval was given by Trafford local research ethics committee. Doctors in the practice were asked to complete a short questionnaire on patients attending with back pain to identify those patients who might be eligible. Those patients who appeared to meet the entry criteria had a further examination by a single observer to confirm eligibility and, if appropriate, to perform an initial assessment.

Pre-randomization assessment

The entry criteria were:

(i) Pain for less than 28 days at the time that the first treatment would be given.
(ii) Symptom-free for at least 28 days before this episode of back pain.
(iii) Pain restricted subjectively within the following boundaries:
  (a) proximally, the 12th thoracic vertebra;
  (b) laterally, the lateral edges of the long back muscles and the lateral outlines of the buttocks;
  (c) distally, the buttock folds.
(iv) Patient aged between 16 and 70 and able to attend for treatment.
(v) Bilateral pain, but not necessarily uniform in nature.
(vi) Ten repeated extension exercises in the standing position did not peripheralize the pain; it might have been intensified, but the patient was still suitable if the pain was central.

The exclusion criteria were:

(i) Known inflammatory joint disease.
(ii) Known skeletal metastasis or infection.
(iii) Known spondylolisthesis.
(iv) A neurological deficit in structures innervated by lumbar or sacral roots that could not be ascribed to a previous episode or another pathology.
(v) Known osteomalacia or osteoporosis.
(vi) Visceral pathology that could refer pain to the lower back.
(vii) Pregnancy.
(viii) Those who had sought or intended to seek physical treatment elsewhere.
(ix) Transient patients.
(x) Lack of informed consent.
(xi) Previous trial entry.
(xii) Inability to read English.

The pre-randomization assessment included: body mass index, fitness for work, occupation, straight leg raising, modified Schober's distance as described by Macrae and Wright,[12] the distance the patient's fingertips could be moved down the thigh on lateral flexion without anterior spinal flexion, subjective assessment of thoraco-lumbar extension and a simple neurological examination.

Patients unable to stand for measurements of spinal mobility had these measurements omitted and recorded as zero for the analysis. A *post hoc* classification of occupations into light and heavy was made by a doctor who was unaware of the randomization.

Randomization

Randomization was in the manner described by Zelen,[13] that in which only those individuals in the intervention group are aware that that they are involved in a trial of treatment. During the examination the patients received an explanation of the study as one of the natural history of acute low back pain. Verbal agreement was obtained for participation in such a study, to complete a questionnaire whilst in the consulting room and six further questionnaires over a 1-year period. While the patient was completing the first assessment questionnaire the sealed opaque randomization envelope was opened.

Treatment

All patients received general advice about treating their back pain which included avoidance of prolonged rest, gradually increasing exercise, use of regular analgesics and the return to normal activity as soon as possible. Those patients randomized to treatment were told that the study was not only one of the natural history of the condition but also one of treatment for back pain and they were given an appointment to see a physiotherapist (JM) usually within a week of the assessment but always within 28 days of the onset of their back pain. No restrictions were placed on other therapeutic interventions. This pragmatic approach to co-interventions meant that although patients may have received some contradictory advice and variable drug or other treatments, it matched closely the usual situation in primary care and the intervention being tested, if shown to be successful, could be translated directly into routine use.

A group teaching session of between one and five acute back pain sufferers, which included some patients referred by other local practices, was conducted by JM,

weekly. She had been trained in the McKenzie technique to level C and had 13 years' postgraduate experience. Each session lasted for up to 1 hour, depending upon the number of patients attending. Patients were offered the opportunity to return for a further session if their pain recurred. The teaching was as described by McKenzie[14] and reinforced by an educational leaflet. Copies of the detailed treatment protocol and educational leaflet are available on request. At the time of the initial consultation the patients were provided with dated follow-up questionnaires to be completed after 1 and 2 weeks and returned by post after completion. Subsequent assessment questionnaires were posted, with up to two reminders, 4, 8, 12 and 52 weeks after entry to the trial.

Outcome measures

The principal outcome measures were the Oswestry Low Back Disability Questionnaire (Oswestry disability score),[15] which is one of the leading specific measures of functional outcome in low back pain,[16] and a visual analogue scale (VAS) to measure pain. The VAS consisted of a 10 cm linear scale with the words 'Slight', 'Moderate', 'Severe' spread out evenly along the bottom and 'No pain' or 'Pain as bad as it could be' as the two end points;[17] the distance from the 'No Pain' end was measured in mm. For both measures a score of less than 20, which the authors of the Oswestry disability score considered minimal disability, was used to define a good outcome. The change of both scores from the pre-randomization values were used, in the manner of Meade *et al.*,[18] to compare overall improvement in both groups. The patients were also asked how many pain killers they had taken in the previous 24 hours, if they were fit for work and if they had seen another physical therapist since the previous assessment.

In the final questionnaire the patients were asked additionally to assess how many days they had had back pain over the previous 6 months, to grade how much of a problem their back had been to them during this time and to complete a VAS asking how much pain they had had in their back during this time.

At the end of the study a practice receptionist, unaware of the randomization, transcribed the consultation records for the 1-year period after randomization. A doctor, unaware of the randomization, then calculated the consultation rate. For the patients who were unable to work at randomization, a return to work date was obtained, defined as the first recorded return to work date in either the medical record or a returned questionnaire.

Statistical considerations

No previous studies have studied a similar group of patients with the same outcome measures which would have allowed accurate estimates of sample size. A sample size of 50 in each group was chosen because Koes *et al.*[8,9] in their criteria for assessing the quality of studies of physical treatment for low back pain used a sample size of 50 in each group as the lower cut off point for giving weight according to sample size. Published figures[19] suggested that to recruit 100 patients with acute back pain over a 2-year period was a reasonable proposition. All the analyses were made using two-tailed tests of significance. Categorical variables were analysed using a chi-square test with Yates' continuity correction or Fisher's exact test as appropriate. CIs for difference in proportion were calculated in the manner described by Fleiss.[20] For continuous variables, means and CIs were compared using a *t*-test or a Mann–Whitney U test as appropriate.

The results were analysed principally using SPSS for Windows v 6.01. Some chi-square and Fisher's exact test analyses were made using Epi info v 6.

Results

The planned sample size was not obtained both because potentially eligible patients were not always referred for assessment and because later in the recruitment period some patients who would otherwise have been eligible had been included previously. Seventy-eight patients were referred for assessment. Two were excluded during the examination, one with unilateral pain and one who was illiterate. One further patient was excluded, after randomization, because lumbar extension caused lateralization of the pain when attending for treatment. Baseline information is summarized in Table 1. Of the 35 patients randomized for treatment, 32 (91%) attended and no patients attended with a recurrence. The mean duration of symptoms on starting treatment was 11 days (range 1–24). Control (201/240) and treatment (176/210) groups both returned 84% of possible follow-up questionnaires. The follow-up results for the principal outcome measures are summarized in Tables 2 and 3. Twenty-five patients were unable to work at randomization, 14 were controls and 11 were treated. They were able to return to work after a mean of 18 and 21 days, respectively ($P < 0.55$). There were no differences in the proportions reporting that they were unable to work at each assessment. During the 1-year study period, three control and four treated patients reported seeing another physical therapist.

The results of the additional assessments at one year are summarized in Table 4 and show that significantly more of the treated patients recorded that their back had been no problem to them in the preceding 6 months ($P < 0.007$).

Consultation data were obtained for 61 patients (81%), 29 treated and 33 controls. These show no difference between the two groups for the number of back pain consultations ($P < 0.18$, Mann–Whitney U Test);

TABLE 1 *Characteristics of control and treatment group*

	Treated (n = 35)	Control (n = 40)
Mean age	40	41
Sex: number of males	23 (66%)	22 (55%)
Mean duration of pain at initial assessment	7.9 days	6.7 days
Mean body mass index	25.6	25.2
Not fit to work because of back pain	15 (48%)	18 (50%)
	n = 31	n = 36
Number performing 'heavy' work	6 (18%)	11 (28%)
	n = 34	n =39
Patients with mean of right and left straight leg raising <90°	13 (37%)	20 (50%)
Mean Schober's measurement	5.2 cm	4.6 cm
Mean of average lateral spinal flexion	16.8 cm	14.7 cm
Lumbar extension subjectively normal	20 (61%)	15 (42%)
	n = 33	n = 36
Had taken pain killers in the previous 24 hours	15 (43%)[a]	27 (69%)
Mean Oswestry score	26.2	35.6
Mean visual analogue scale	44.4	50.4

Analysis was using the t-test, chi-square test or Mann–Whitney U test as appropriate.
[a] $P < 0.03$.

the control group had significantly more consultations for conditions other than back pain. ($P < 0.01$, Mann–Whitney U Test).

Discussion

The initial hypothesis, that early intervention with a small class teaching McKenzie back extension exercises for patients with acute simple low back pain in primary care will reduce long-term disability, has not been proven. The principal outcome measures, to which the greatest weight should be given, show no significant difference between the two groups. There is a suggestion that more of the treatment group were free of back problems at 1 year.

In spite of randomization, the two groups were not exactly matched at study entry—the control group had higher scores for disability, pain and analgesic intake, although only the latter was statistically significant. As the differences were all in the same direction it is possible that those in the control group either had more severe disease or perceived themselves as having more severe disease. It is not biologically plausible that the significant difference in the consultation rate for other conditions during the follow-up period was due to intervention specifically for back pain. It may be that the control group were different psychologically, leading to higher initial perception of pain and disability, resulting in higher analgesic intake and subsequent consultations for other causes. This possible mismatch between the two groups and the large number of comparisons made mean that any apparent improvement in outcome for the treated group must be interpreted with caution. There were no differences in the proportions with moderate or severe disability. This would

TABLE 2 *Number of patients with an Oswestry disability score or VAS score of <20*

	Oswestry					VAS				
	Treatment (n = 35)		Control (n = 40)			Treatment (n = 35)		Control (n = 40)		
	n	score <20 (%)	n	score <20 (%)	P	n	score <20 (%)	n	score <20 (%)	P
Before randomization	35	16 (46)	39	13 (33)	0.28	35	4 (11)	39	7 (18)	0.40
Week 1	32	23 (71)	36	17 (47)	0.07	31	11 (35)	36	10 (28)	0.68
Week 2	29	25 (88)	33	23 (70)	0.21	26	13 (50)	33	10 (30)	0.20
Week 4	32	27 (84)	37	29 (78)	0.74	31	20 (65)	33	16 (48)	0.30
Week 8	29	27 (93)	32	30 (93)	>0.99	29	22 (76)	28	18 (64)	0.51
Week 12	29	26 (89)	33	30 (91)	>0.99	28	19 (68)	28	22 (79)	0.55
Week 52	23	22 (96)	28	24 (86)	0.36	21	16 (76)	26	18 (69)	0.84

Analysis was using chi-square test or Fisher's exact test as appropriate.

TABLE 3 Comparison of the improvement in Oswestry disability scores and VAS scores from baseline

	Oswestry					VAS				
	Treated (T)		Control (C)		Difference T–C (95% CI)	Treated (T)		Control (C)		Difference T–C (95% CI)
Mean baseline score at randomization	26.2		35.6			44.4		50.4		
	n	mean decrease	*n*	mean decrease		*n*	mean decrease	*n*	mean decrease	
Reduction at week 1	32	8.4	35	9.9	−1.5 (− 9.9, 6.8)	31	15.1	36	12.6	2.5 (− 8.3, 13.2)
Reduction at week 2	29	14.1	32	18.2	−4.1 (−14.3, 6.0)	26	24.3	36	19.8	4.4 (−10.5, 19.3)
Reduction at week 4	32	18.6	36	24.1	−5.5 (−15.4, 4.2)	31	26.4	33	27.0	−0.6 (−14.8, 13.6)
Reduction at week 8	29	20.4	31	26.7	−6.2 (−16.5, 4.0)	29	29.6	28	37.4	−7.8 (−21.9, 6.27)
Reduction at week 12	29	21.5	32	28.6	−7.1 (−17.5, 3.4)	28	33.3	28	38.4	−5.1 (−19.9, 9.6)
Reduction at week 52	23	21.5	27	27.6	−6.1 (−18.0, 5.8)	21	35.8	25	36.7	−0.9 (−19.7, 17.9)

TABLE 4 *Additional outcome measures after 1 year*

	Treatment		Control		
	n	result	*n*	result	*P*
VAS for pain in previous 6 months	21	Median = 4 IQ range 0–45	25	Median = 26 IQ range 8–40	0.17[a]
VAS score for previous 6 months <20	21	12 (57%)	25	11 (44%)	0.55[b]
Back pain no problem in previous 6 months	24	12 (50%)	29	4 (14%)	0.007[c]
No days with back pain in the previous 6 months	24	10 (42%)	30	6 (20%)	0.15[b]

[a]Mann–Whitney U test.
[b]chi-square test.
[c]Fisher's exact test.

suggest that any possible treatment benefit is no more than improving some patients who would otherwise report only a minor problem to report no problem. This may be useful to individual patients but is unlikely to reduce the health and social impact of low back pain in the community since this will principally be in the more severely affected individuals.

It is possible that a single session of education was insufficient to affect the outcome and that a more prolonged course of education and supervised exercises would be effective. A single therapist was used; it is possible that other therapists could be either more or less effective in treating back pain. This restricts the generalizations that can be made from these results.

The small sample size, although comparable in size to some other studies of physical treatment for low back pain[9,10] means there is a risk of making a type II error and erroneously concluding that this treatment approach has, at the most, only a minor benefit. Overall, 10% of these patients had Oswestry disability scores of 20 or more after 12 weeks and could be considered to have continuing moderate or severe disability. In order to test the hypothesis that early intervention with physical therapy in these patients would reduce this to 5%, with an α of 0.05 and a β of 0.2, 948 patients would have been required, which is larger then any published study and far in excess of the pre-trial sample size assumptions.

The type of therapeutic approach that we have tested has been recommended by the CSAG and RCGP, and of an intensity that it could be made generally available within primary care. Although the approach to treatment was acceptable to the patients, the failure to show a convincing difference between the two groups does not support the widespread introduction of such additional services into primary care. This agrees with the findings of Malmivaara *et al.*[11] There is a clear need for further studies to try to confirm the validity of the CSAG and RCGP recommendations. These should be based within primary care and should be designed with sufficient statistical power that purchasers can use the results to inform future rational planning of services for back pain.

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