Therapeutics

CLINICAL TRIAL OF INTENSIVE MUSCLE TRAINING FOR CHRONIC LOW BACK PAIN

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Summary 105 patients who had chronic low back pain without clinical signs of lumbar nerve root compression or radiological evidence of spondylolysis or osteomalacia were randomised to three treatments: 30 sessions of intensive dynamic back extensor exercises over three months; a similar programme at one-fifth the exercise intensity; or one month of thermotherapy, massage, and mild exercises. The results consistently favoured intensive exercise, which had no adverse effects. Since these exercises can be conducted in groups, the intensive programme is no more costly than conventional strategies that require individual attention.

G. DOMENIGHETTI AND OTHERS: REFERENCES—*continued*

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INTRODUCTION

THE cause of chronic low back pain in the individual patient is often elusive,[1] but epidemiological studies[2-4] have indicated an association with subnormal endurance of the back musculature. The combination of a weak back and a back-straining occupation greatly increases the risk of low back trouble,[5,6] whereas physical training[7] seems to reduce the risk. In the treatment of low back pain, intensive strengthening exercises for the back extensor muscles were introduced in Denmark by Sparup[8] in 1960. The principles had been stated ten years earlier by de Lorme.[9] More recent advocates included McKenzie,[10] who reported benefit from an extension exercise regimen, and Plum and Rehfeld,[11] who described promising results with dynamic hyperextension exercises to back and gluteal muscles. These reports appeared at a time when the usual method of back training was isometric flexion exercises.

We report here a trial of the intensive back extensor exercises recommended by Plum and Rehfeld. Controlled investigations of this sort present great methodological difficulties[12] and we followed the guidelines set out by Nachemson and Larocca.[13]

For assessing low back pain we were not content with the existing rating scales.[14-16] Waddell[17] states that chronic low back disorders consist of three separate dimensions—pain, disability, and physical impairment. We scored these on a new scale devised by C. M.

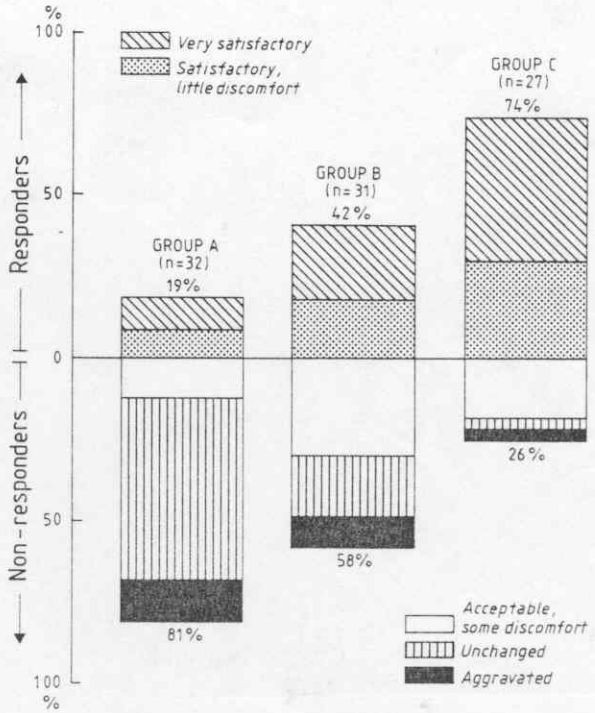
METHODS

All general practitioners in three Copenhagen municipalities were invited to refer patients with chronic low back pain to the host department. Enclosed with the invitation were the criteria for inclusion and exclusion.

Inclusion criteria were: chronic low back pain at rest, or associated with back strain, for at least one year; acute low back pain for the third time or more in the past six months, with or without sciatica (extension into lower limbs); age between 20 and 70 years, inclusive; radiological examination of lumbar spine in past two years. They also had to be able to get themselves to hospital. Exclusion criteria were: evidence of recent root pressure (suggestive history, positive Lasègue's sign (radiation of pain on straight leg raising),[18] and sensory loss/motor paralysis in lower limb; spondylolysis; painful hip arthrosis; osteomalacia of the spine; malignant disease in the musculoskeletal system or in other organ systems with poor prognosis; inflammatory disease of the joints; present or previous somatic disease that might interfere with training; mental illness; and inability to cooperate. The patients with radiological abnormalities and those with signs of root pressure were excluded for fear that the exercises might cause fractures or worsen symptoms.[19]

TABLE I—CHARACTERISTICS OF INITIAL 105 PATIENTS

—	No	Median	10/90 centile
Personal data			
Age (yr)		45	32–57
Height (cm)		170	160–182
Weight (kg)		67	55–88
Low back pain duration (yr)		15	5–34
Sciatica duration (yr)	65	9	2–23
Full-time employed	58		
Part-time employed	20		
Back straining work	44		
X-ray findings			
Lumbar disc degeneration	22		
Lumbar spondylosis	15		
Lumbar disc degen + spondylosis	15		
Scheuermann's disease	17		
Other abnormal findings	9		
Nothing abnormal	27		



Patient's evaluation after treatment.

Of a total of 140 patients referred, 105 were entered consecutively after interview and examination. The patients were told that they would be entered into one of three groups at random (by drawing of lots), each group having a varied programme of back exercises. Their data were then encoded according to C. M.'s rating scale.

Pain experience was registered on the eleven-point box scale, which has proved useful in the past.[20] The patients were asked about their low back pain at the moment (0–10 points), the worst low back pain within the past two weeks, (0–10), and the average level of low back pain within the past two weeks (0–10). Disability was registered by questioning about 15 everyday activities—eg, "Does low back pain interfere with sleep at night?" or "Can you put on shoes and stockings yourself?" (0–30 points). Use of the same observer in all examinations ensures that the questions are understood and interpreted uniformly. To register physical impairment, four measurements were employed. Back endurance was assessed by placing the patient prone, with legs strapped to a couch and trunk unsupported from the iliac crest, and recording the time for which the patient could remain horizontal, clear of the floor (0–10 points).[21-23] Back mobility was assessed by Schober's modified test (0–10 points).[24] From lying supine on a flat couch 80 cm above the floor, the patient stepped onto the floor next to the couch, went to the foot of the bed, performed a deep knee-bending movement, and returned to the starting position (0–10) points). Drug consumption was also scored 0–10 points, the maximum being given for centrally acting analgesics used five times a week or more.* Data encoding was repeated at the conclusion of treatment (about three months later) and again after six months.

All data were collected by a single observer who did not know the group to which the patient was assigned. After data encoding, the patients were allocated by a block randomisation procedure to one of the three treatment groups as follows:

Group A (Alternative)

Applications of hot compresses and massage of back and gluteal muscles in combination with mainly isometric exercises for the lumbar spine:[25] 1, (prone)

*A full version of the low back pain rating scale is available from C. M. on request.

isometric back extension; 2, (supine) crooklying (knees flexed, feet flat on couch) and isometric abdominal contraction; 3, (supine) crooklying and sit-up exercise; 4, (supine) maximal curl-up exercise, knees to shoulders.

The exercises were repeated ten times each within the limits of pain. Treatment time about 1 h. A total of eight sessions were distributed over 1 month. Thereafter no treatment for 2 months.

Group C (Intensive Back Strengthening)

1, *trunk lifting*.—Prone on a couch, hips at the edge, upper part of the body free, but supported by the hands against the floor. Strap fixation over the calves. With hands on forehead, trunk is lifted to the greatest possible extension in hips and spine, if necessary starting with support from physiotherapist.

2, *leg lifting*.—Standing by the end of the couch, leaning over to a prone position, with the hips against the edge in 90° flexion, knees 45°, and feet on the floor. Strap fixation over the chest. Knee straightening and leg lifting bilaterally to greatest possible extension of hips and spine, again with support from physiotherapist if necessary.

3, *pull to neck*.—Sitting on a stool with the arms straight and abducted over the head and hands grasping a weight lever (pulley device). Against submaximal resistance the lever is pulled down behind neck and shoulders. Before starting the three exercises the patient is offered a hot pack for 15 min. Each exercise is done in series of ten attempts, with 1 min rests in between. Exercise 1 is done fifty times, followed by exercise 2 fifty times, and so on. The training cycle is performed twice, interrupted by rest with a hot pack for 15 min. Treatment time totals 1½ h. A total of thirty sessions was given over 3 months (three training episodes a week for the first month and two a week for the next 2 months).

Group B (Placebo)

Modified back strengthening programme.—The exercises are done in exactly the same way as in group C except that each exercise is repeated only twenty times. The dosage is thus one-fifth that in group C. Treatment time 45 min, thirty training episodes over three months.

Treatment was begun soon after randomisation and, throughout the entire sequence, the same four therapists were in charge; they sought to maintain a neutral attitude to the treatment. Patients were to be excluded after randomisation if they showed clinical signs of root pressure, if they became mentally or physically ill, or if they missed more than 30% of treatment sessions.

Statistics

We used nonparametric methods in the program Medstat.[26] Statistical significance was registered at the 5% level.

RESULTS

Table I summarises the characteristics of the 105 patients (64 women) entered into the study.

Qualitative Indices

The figure indicates patients' answers to five questions at conclusion of treatment. Only "very satisfactory" and "satisfactory, little discomfort" were regarded as an acceptable outcome after protracted and intensive treatment. Regimen C was superior to both A ($p < 0.00005$, Fisher's exact test) and B ($p < 0.05$). The difference between A and B was not significant.

Quantitative Indices

Table II shows medians and 10–90 centiles for data in the three groups, and table III gives the corresponding statistical calculations. Treatment C was superior to the other regimens both at conclusion of treatment and at 3 months' follow-up. Point scores improved significantly in groups B and C but not in A (table IV). Scores on the rating scale ($total_1$) were strongly related to patients' qualitative evaluation of treatment outcome ($r = 0.75$).

20 consecutive patients were asked to complete the rating scale (pain + disability) a second time at home on the evening of the same day so as to measure short-term

TABLE II—LOW BACK PAIN RATING SCALE, QUANTITATIVE INDICES

Scores	Median (10/90 centile) A	B	C
Before treatment			
Pain	11·7 (7·3/19·4)	14·0 (5·2/20·9)	13·3 (7·6/19·6)
Disability	10·2 (5·2/20·7)	11·4 (5·1/19·8)	10·3 (5·4/17·2)
Physical impairment	12·2 (5·3/22·7)	13·3 (8·1/18·8)	10·4 (5·8/22·4)
Total	34·0 (22·9/57·1)	39·0 (21·6/53·0)	35·6 (23·1/54·2)
After treatment			
Pain	9·2 (2·3/29·1)	10·3 (0·4/22·6)	5·7 (0·0/17·6)
Disability	8·5 (4·3/23·1)	8·8 (1·8/19·9)	9·0 (1·8/14·6)
Physical impairment	11·0 (5·9/18·7)	10·8 (4·8/15·9)	4·4 (0·4/12·6)
Total	29·0 (18·1/65·7)	29·0 (8·2/53·0)	21·3 (6·8/37·8)
At follow-up			
Pain	11·5 (1·9/22·9)	11·1 (0·6/24·8)	5·0 (0·0/18·6)
Disability	7·8 (3·9/19·4)	8·3 (2·0/19·6)	5·9 (1·8/18·2)
*Physical impairment	11·0 (6·2/18·0)	10·3 (5·9/18·0)	4·7 (0·4/16·2)
*Total	33·0 (15·5/66·5)	30·0 (11·0/57·0)	17·0 (7·3/47·2)
Before treatment minus after treatment			
$\Delta Total_1$	2·0 (−11·7/19·5)	5·7 (−4·4/23·7)	14·7 (−3·2/29·4)
Before treatment minus follow-up			
$\Delta Total_2$	5·5 (−12·8/19·5)	7·0 (−11·0/21·5)	15·0 (−8·4/31·4)

*10 patients did not present for follow-up clinical examination.

TABLE III—ANALYSIS OF QUANTITATIVE INDICES (TABLE II)

	Test	AB	AC	BC
$\Delta Total_1$	Mann-Whitney	$p < 0.05$	$p < 0.0001$	$p < 0.01$
	Kruskal-Wallis / Jonckheere-Terpstra		ABC $p < 0.0002$ $p < 0.00001$	
$\Delta Total_2$	Mann-Whitney	NS	$p < 0.002$	$p < 0.01$
	Kruskal-Wallis / Jonckheere-Terpstra		ABC $p < 0.005$ $p < 0.0005$	

TABLE IV—DIFFERENCES IN RATINGS BEFORE AND AFTER TREATMENT (WILCOXON'S TEST)

—	A	B	C
Pain	NS	NS	$p < 0.001$
Disability	NS	$p < 0.001$	$p < 0.01$
Endurance	NS	$p < 0.02$	$p < 0.001$
Schober's test	NS	$p < 0.02$	$p < 0.001$
Physical impairment	NS	$p < 0.001$	$p < 0.001$
$\Delta Total_1$	NS	$p < 0.01$	$p < 0.001$

TABLE V—DROP-OUTS

—	A	B	C
Side-effects			
Aggravation of back pain	1	1	1
+ aggravation of sciatica		2	1
Other reasons			
Colon cancer diagnosed			1
Not compatible with work	1	1	1
Absence from treatment without reason	1		1
Prolonged travel to home country	1		
Personal		1	1

repeatability. The Spearman correlation coefficientbetween the two sets of scores was 0·99.

Drop-outs

15 of the 105 randomised patients dropped out before conclusion of treatment, usually soon after the beginning of treatment. In 6 instances the patients believed that treatment had aggravated their back pains or sciatica but these cases were not concentrated in any particular group (table V). 3 of the 6 were excluded by the examining physician because of newly developed radiating pains; in no instance was there additional evidence of root compression. 2 cases of subacromial and one case of trochanteric bursitis were observed, but in none of these cases was exclusion necessary. 1 patient experienced acutely developed sciatic pain during the follow-up period and was later operated on for a lumbar disc protrusion. No other side-effects, somatic or psychological, were observed in connection with the trial treatment.

The patients who dropped out are not included in the statistical tests. If we assign the poorest possible qualitative outcome to the 6 who dropped out because of side-effects, on the intention-to-treat principle, the statistical results are unaltered.

DISCUSSION

In view of the marginal results of previous back training studies we were surprised to find such a pronounced difference between the groups. Part of the explanation, we think, lies in the duration of exercise treatment. In previous studies of this kind the treatment period was only one month,[27-31] and in the first month of treatment many of our patients had increased discomfort from muscles (fatigue, tenderness) and continued back trouble; not until the second and third months did a gradual improvement become apparent.

In this study the form of treatment has been tested as a whole. Thus, we are not able to say whether the benefit is attributable to the intensive back muscle training or to the hyperextension back exercises. In future studies, we will attempt to identify more clearly the effective mechanisms; and further, in accordance with theoretical considerations,[33,34] we propose to include an abdominal muscle exercise as well as general physical training.[35] The intensive exercise regimen was safe, with a low frequency of side-effects requiring withdrawal. In no instance were symptoms provoked that indicated existence of a lumbar disc protrusion or spondylolysis.

Since this intensive treatment can advantageously be conducted in groups, it consumes no more resources than alternatives that require individual attention.

For the time being we believe that such training should be preceded by radiological examination of the spine and by clinical examination. Patients with signs of acute lumbar root pressure, spondylolysis, or osteomalacia should be excluded. At the beginning of treatment—the phase in which basic instruction and rehabilitation takes place—there should be one physiotherapist to every 2 or 3 patients. Side-effects can be noted and guidance given when needed. After a couple of months, the training can be undertaken with less supervision in larger groups (8–10 patients); some patients will be able to train at home. On theoretical grounds, the treatment should probably be lifelong.[33]

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