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A controlled, multicentre trial of manual therapy with steroid injections in low-back pain: functional variables, side effects and complications during four months follow-up

S Blomberg and **G Tibblin** Department of Family Medicine, Uppsala University, Uppsala and The Skönvik Rehabilitation Clinic, Säter, Sweden

Outpatients with acute or subacute low-back pain were randomly allocated to one of two treatment groups. One group ($n = 53$) was given standardized but optimized conventional activating treatment by primary health care teams. The other group ($n = 48$) received specific manual treatment such as manipulation, specific mobilization, muscle stretching, autotraction and cortisone injections. There were significant differences on 15 disability rating scores and complaints in everyday life due to low-back problems in favour of the group receiving manual treatment, indicating that this treatment was superior to conventional treatment. The patients given manual treatment had a more positive view of treatment than those in the conventionally treated group. The experimental treatment was more painful than the conventional treatment, due to injections and muscle stretching. Only a few patients experienced manipulation and specific mobilization as painful. No persisting deterioration or complications were reported due to the experimental treatment.

Introduction

Low-back pain is a major diagnostic and therapeutic problem, as well as causing suffering and large costs to the community.[1–4] Manual therapy may offer a solution to this problem, but it is still controversial and its efficacy has not yet been considered satisfactorily documented.

We undertook a review of the literature, including 20 controlled trials on manipulation and/or specific mobilization in manual therapy. Six of them are well designed and well performed[5–10] and demonstrate short-term effects achieved by manual therapy. No follow-up longer than six weeks with an acceptable drop-out rate is available.[8] Two trials, as in the case of the present

Address for correspondence: Stefan Blomberg, Department of Family Medicine, Academic Hospital, S-751 85 Uppsala, Sweden.

study, used functional variables in their evaluations.[7,9] Rasmussen[9] reported similar results. However, there was no satisfactory presentation of baseline data and since the control treatment was short-wave, it might be questioned whether differences in expectation effect between the control treatment and the experimental treatment could influence the results. In our study, this problem was compensated for by using a more comprehensive and prolonged treatment in the control group than in the experimental group. The follow-up period was short, being only two weeks.

In Hadler's study,[7] the same therapist was used in both treatment groups, creating the possibility that results could have been influenced by the therapist transferring negative expectation effects to the patients in the control group. Highly significant differences between the groups were found only during short-term follow-up. After two weeks there were no significant differences. In spite of its shortcomings, Hadler's paper constitutes evidence for a short-term effect achieved by manual therapy.

The best previously published trial of manual treatment is, in our opinion, by Brodin on manual therapy for cervical pain with four weeks' follow-up and two control groups.[5] One of the control groups was given mock therapy, probably with an expectation effect corresponding to that in the experimental group. Highly significant differences in favour of manual treatment were achieved for objectively measured mobility and for self-assessed pain. There were no differences between this control group and the control group where drugs only (salicylates) were given. It could thus be claimed that the investigation supports the conclusions in other surveys with a lower expectation effect in the control group than in the experimental group.[9,11] Brodin's study is methodologically well performed with the exception that 11% of the patients were excluded after randomization. However, the differences in favour of manual therapy are convincing.

Some previous trials using objective efficacy measures have demonstrated a positive outcome using manual therapy.[5,6,8,9] Fisk[6] measured tension in the hamstring muscles – the tension was greater on the affected side in patients with unilateral low-back pain. Manipulation on the affected side normalized hamstring tension whereas manipulation on the contralateral side did not affect tension. Manipulation on healthy individuals without low-back pain produced increased tension instead. The trial is virtually free of shortcomings and is of great value, since it convincingly shows that manipulation has a physical effect which cannot be explained by an expectation effect. There is no reason to believe that the treatment used in the present investigation totally lacks such a 'true' effect.

Nwuga[8] used objective evaluations of mobility, straight leg raising and time taken for treatment. The subjects all had proven herniated discs, presumably with secondary dysfunctions treatable with manual therapy. Background variables in baseline data are poorly presented and the same therapist managed both groups. There is consequently a bias risk, but the clear differences concerning objective measures in favour of the manual treatment are not likely to be explained by this alone. The treatment time was less in the experimental group than in the control group, which implies faster recovery in the former group.

Drug consumption was used as an efficacy variable by Wreje.[10] She demonstrated decreased sick-leave in the group receiving manual treatment as well. Wreje tried to keep these efficacy measures patient-controlled. The disadvantage of having the same therapist in the experimental group and in the control group was compensated for by standardized communication with the patients. Pain score and an objective efficacy measure (a quantified Patrick's test) did not support the results for sick-leave and drug consumption in her study.

We performed a randomized clinical trial in patients with low-back pain in which the effect of manual therapy was compared with that of conventional treatment. We have previously presented an eight months' follow-up study[12] in which manual treatment was compared with conventional treatment. The first indications of long-term effects of manual therapy were found – a significantly larger reduction in sick-leave. After one month in the study, the proportion of patients on sick-leave was six times larger in the conventionally treated group than in the experimental group. Significant differences in pain score measured by postal questionnaires after one, two and four months in favour of the group receiving manual treatment were also demonstrated. The

treatment effect was also evaluated in a single-blind manner by standardized telephone interviews at three, seven, 14, 21 and 90 days.[13] The group receiving manual therapy had significantly less pain, less disability, a faster rate of recovery and less drug consumption. Clear differences concerning objective findings (mobility, movements causing pain and straight leg raising test, for example)[14] and in quality of life[15] in favour of the experimental group after four months were presented.

The hypothesis tested in this report was that a special manual therapy approach to low-back pain can improve the everyday function of patients suffering from low-back pain more effectively than the conventional treatment given by a Swedish primary health care team. The patients' view of treatment and the presence of side effects and complications were also evaluated.

Study population and methods

The study was performed as a multicentre trial in Kopparberg County, Sweden, between February 1988 and April 1989. Six primary health care or occupational health care centres, representing a catchment area of 56 000 residents, and the Skönvik Rehabilitation Clinic participated. All patients attending the primary health care or occupational health care centres who fulfilled the inclusion criteria for the study were entered. Only a few patients declined participation, most frequently because of a long distance from home to the Skönvik Rehabilitation Clinic.

The criteria for inclusion were:

- Age 20–60 years.
- Conditions with acute or subacute low-back pain with or without pain radiating to one or both legs not demanding surgical treatment or rheumatological treatment. Patients with proven or suspected herniated disc were included if surgery was not considered. Low-back pain was to dominate the clinical picture, but other musculoskeletal symptoms were allowed.
- Sympton duration of three months or less, preceded by at least two months' relative freedom from symptoms. Milder chronic cases were thus included, as long as they did not experience a need for treatment between the earlier acute periods.
- Consent to treatment and follow-up for four months.
- Agreement not to consult other therapists in addition to the treatment offered in the study.
- Absence of other conditions or circumstances which might jeopardize completion of treatment and follow-up (e.g. alcoholism or severe psychiatric disorders).

At the first contact with the patient, a preliminary assessment of the criteria for inclusion was made by the reception nurse. The final decision was made by the general practitioner (GP) at the first consultation, after which the patient received standardized information concerning the study. Patients were told that rapid treatment was guaranteed in both study groups – there were normally waiting-lists for physiotherapy at the centres. When the patient had accepted participation and had answered the questionnaires and had a physical examination, the GP called a secretary who randomly allocated the patient to one of two groups, an experimental group (n = 48) or a conventional treatment group (n = 53); 48 women and 53 men were recruited. The two groups were similar in most pretrial variables, including age, sex, previous low-back pain problems, sick-leave, previous treatment, findings at physical examination, quality-of-life score, disability rating and pain score.[12] The participants accepted the offered treatment in all cases except one in the experimental group. This patient was included in the analysis according to the intention-to-treat approach.[12]

Treatment

Patients in the experimental group were treated at the Skönvik Rehabilitation Clinic and those in the conventionally treated group were treated at the health care centre where they were recruited. Recurrences were treated in both groups and the therapists could give as many treatments as necessary.

Experimental treatment

The basis of Swedish manual therapy is the classical osteopathic techniques described by Stoddard[16] and the continental tradition as

represented by Lewit[17] and Janda.[18] These techniques for mobilization, manipulation and muscle stretching have been further developed by Kaltenborn, Evjent and Hamberg, as described in three therapeutic manuals,[19–21] and they form an important part of the experimental treatment. In Scandinavia, the use of specific 'locking techniques' has been developed.[20] Diagnostics according to 'Muscle energy technique' (MET)[22] were incorporated in the physical examination.

All patients were treated with thrust techniques or more gentle specific mobilization. Almost all patients were treated with muscle stretching and were taught muscle-stretching exercises according to Evjent and Hamberg.[23] According to the clinical experience of SB, an essential therapeutic manoeuvre was a mobilization for sacroiliac dysfunctions according to Kubis.[24] This was originally a thrust technique, but with the addition of an Evjent-Hamberg locking technique and a strictly applied MET procedure in the treatment situation, the manoeuvre has become very gentle. Seven of the patients (15%) were treated with autotraction[25,26] by SB, of whom six patients (13%) also received autotraction provided by physiotherapists.

Steroid injections (Lederspan®, triamcinolone), often in combination with 'needling'[17] and local anaesthetics (Citanest® 0.1%, prilocaine hydrochloride), were given according to manual diagnostic findings. Injection of the paracoccygeal structures is described by Cyriax.[27] These structures were also stretched per rectum in the manner described by Midttum and Bojsen-Möller.[28,29]

Two physicians were involved: SB treated all the patients and five therapy resistant patients were also seen by Franz Mildenberger (the head of Skönvik Rehabilitation Clinic). Treatment was also performed by seven physiotherapists who were specialists in manual therapy but who did not take part in the control treatment. They provided treatment individually or in groups. The latter consisted of Medical Training Therapy (MTT)[30] to improve strength, co-ordination and endurance. All patients in the experimental group received physiotherapy except those who recovered after the first treatment by SB. The physiotherapists finished their treatment when the patient had recovered or when no further improvement was expected.

Conventional treatment

Patients received active, optimal (e.g. immediate and frequent consultations, minimal time on the physiotherapy waiting-list, early X-ray investigations, etc.), and standardized (e.g. the therapists were free to chose between different items in a defined therapeutic arsenal) conventional treatment. With the exception of a few patients who recovered within days after randomization, all patients received treatment provided by 17 physiotherapists (two to three per centre). Patients were assessed by the physiotherapists and treatment modalities were chosen according to need. All staff participating in the conventional treatment were trained in similar therapeutic techniques and diagnostic items. The therapeutic strategy to activate patients, an approach including informing the patients of the benign character of the condition, the adverse effects of inactivity and sick-leave, and encouraging them to take part in physical and other activities. This approach is consistent with official modern recommendations for low-back pain management in Sweden. With the exception of physical training, the experimental treatments are found neither in official recommendations for managing back pain nor in basic training for physicians and physiotherapists in Sweden.

Control patients received drugs, low-back pain school training, active back exercises, corsets, taping, short-wave ultrasonic waves, transcutaneous nerve stimulation (TNS), transcutaneous electric muscle stimulation (TEMS), heat, cold, postural exercises, and, in some cases, plunge-bath training and massage. Doctors were instructed to minimize sick-leave in various ways; for example, by ordering as short periods of sick-leave as possible at each consultation (some days up to a maximum of one week, at least during the first weeks of the follow-up).

Evaluations

Fifteen disability ratings (DRs) (physical exercise/sports, running, heavy physical work, carrying a bag, heavy lifting, leaning over a washstand, making a bed, moderate physical work, walks, lying still, walking up stairs, sitting still more than briefly, car-driving/car-riding, dressing/undressing, getting up from sitting) were recorded using visual analogue scales (VAS) at the baseline investigation. Follow-up

questionnaires were mailed to the patients after one, two and four months. The VAS scales were 100 mm long, the left end representing no disability (0 mm) and the right end maximum disability (100 mm). The distance in millimetres from the zero point to the patient's marking was used as the DR.

Questions concerning everyday life and drug consumption were also asked, answered by 'yes' or 'no' (difficulties in falling asleep due to back pain, waking up in back pain, morning stiffness, pain at rest, ability to take part in physical exercise, taking pain-killers or nonsteroidal anti-inflammatory drugs (NSAIDs), the drugs experienced as being effective. The daily number of hours spent resting during the daytime was determined.

Further questionnaires were administered at one, two and four months to detect side effects and complications due to the treatment in the two groups (the treatment hurts, items in treatment that hurt [muscle stretching, massage, injections, manipulation/mobilization, the exercises, short-wave, TNS, TEMS, ultrasonic waves], pain after treatment, duration of post-treatment pain, the treatment made the pain slightly worse). The questions were answered by 'yes, always', 'yes, sometimes' or 'no'. The frequencies at one, two and four months were summarized so that the figures represent percentages of the total number of times (three per patient × 101 = 303) that the participants had been questioned concerning painful treatment. Intensity of pain from treatment was measured using corresponding visual analogue scales, where 0 mm represents no pain and 100 mm represents unbearable pain.

Questions concerning the patients' view of the treatment were asked in a similar way after four months (comments on the explanations for the pain, the treatment made it easier to cope with the pain [at work, during leisure time, among friends], comments concerning the treatment [positive, negative]). Satisfactorily explained causes of the pain were rated on a visual analogue scale, where 0 mm represents 'very bad explanation' and 100 mm 'very good explanation'. Other questions were answered 'yes' or 'no'.

Drop-outs

Two patients (2%) did not fill in the one-month questionnaire and one patient (1%) was lost at the two months' follow-up. Three (3%) patients dropped out at four months. Two per cent of the questionnaires concerning side effects and complications were missing.

Statistical analysis

Possible differences were treated with Student's *t* test (Table 3) and Pitman's nonparametric permutation test (Tables 4 and 6).[31] The latter has the advantage that no assumptions have to be made about the distribution of the variables and the functional form of relationships. The results yielded are similar to those of Haenszel's Chi-square test.

Analyses of change over time, taking differences in initial values into account, were performed as multivariate analyses with Pitman's nonparametric permutation test in its multivariate form (Figures 1–3). In these analyses, the study population was subdivided into groups according to the initial value. Differences at four months between the groups were then tested in each of these groups. Subgroup p values were computed and then pooled to an overall p using the Mantel-Haenszel procedure. In this way, the confounding effect of differences in initial values was taken into account. Only two-tailed tests were used; p values less than 5% were regarded as indicating statistical significance.

Results

Treatment intensity

Patients in the experimental group were seen by SB an average of 3.5 times; 2.8 times for treatment and 0.7 times for short consultations (for those who showed complete recovery since the last visit). They were treated individually by a physiotherapist an average of 2.0 times and also received 0.8 group treatments (MTT) per patient. Two patients took part in the ordinary treatment programme of the Rehabilitation Clinic of Skönvik (e.g. daily training in group for three to four weeks).

Patients in the conventionally treated group were seen 3.8 times by a doctor and had physiotherapy 8.6 times (6.8 times individually and 1.8 times in groups); 89% received individual physiotherapy compared with 56% in the experimental group. Due to rapid recovery, 33% of

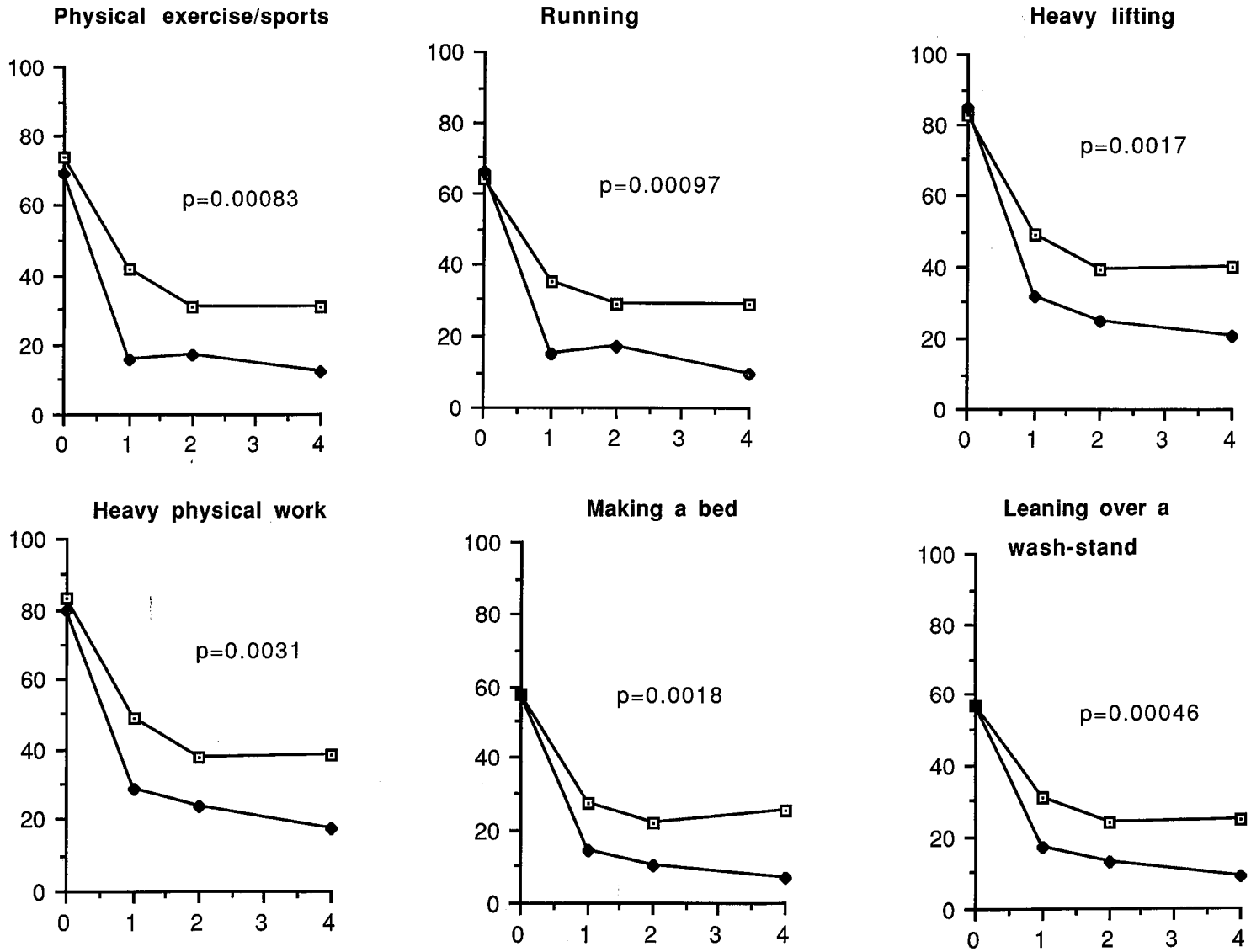

Figure 1 Means for six of the 15 disability rating scores. Unfilled squares represent the conventionally treated group and black squares represent the experimental group. 100 mm visual analogue scales were used; 0 = no disability, 100 mm = maximum disability. Vertical axis = visual analogue disability scale; horizontal axis = months of follow up.

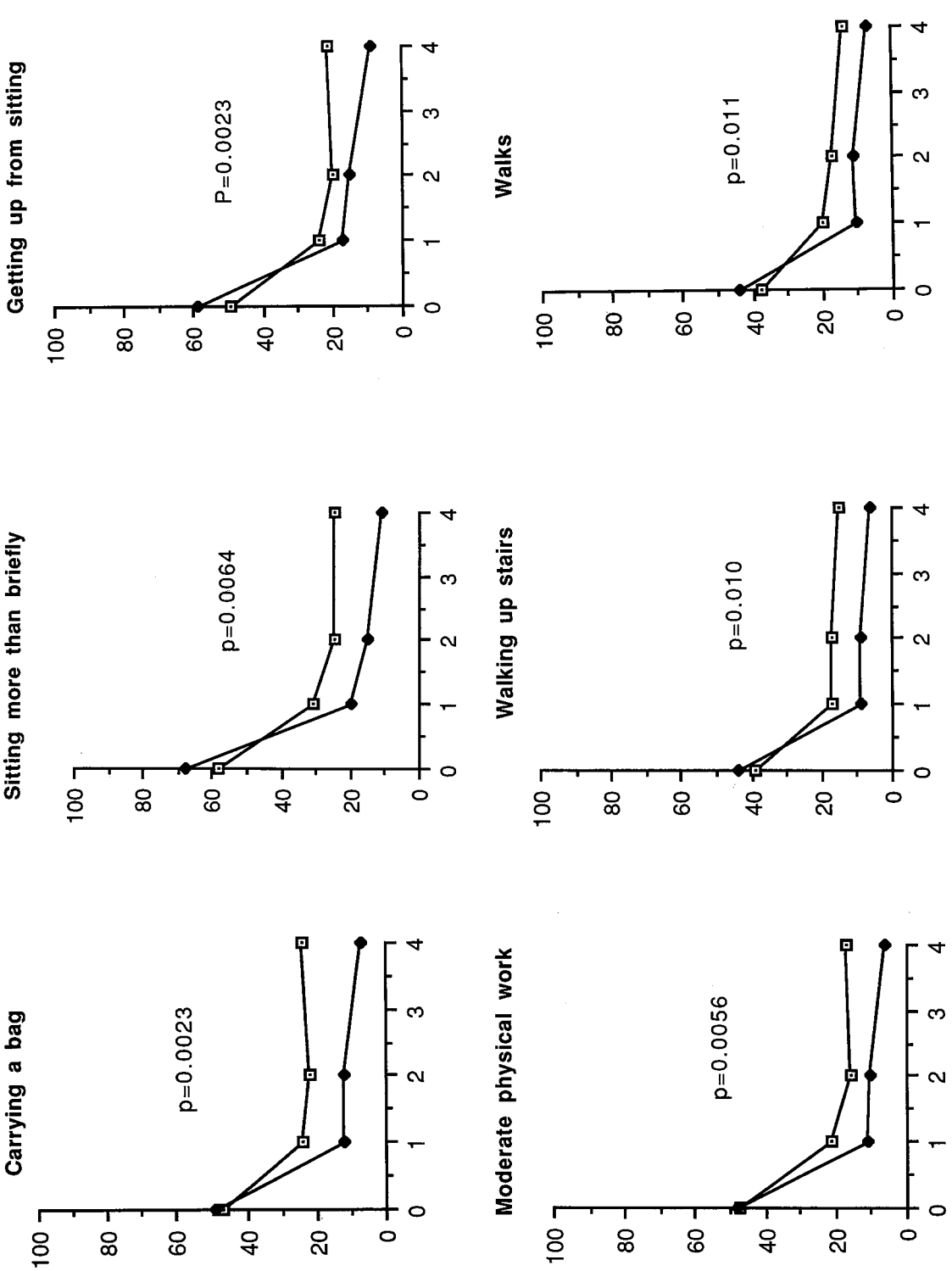

Figure 2 Means for six of the 15 disability rating scores. Unfilled squares represent the conventionally treated group and black squares represent the experimental group. 100 mm visual analogue scales were used; 0 = no disability, 100 mm = maximum disability. Vertical axis = visual analogue disability scale; horizontal axis = months of follow up.

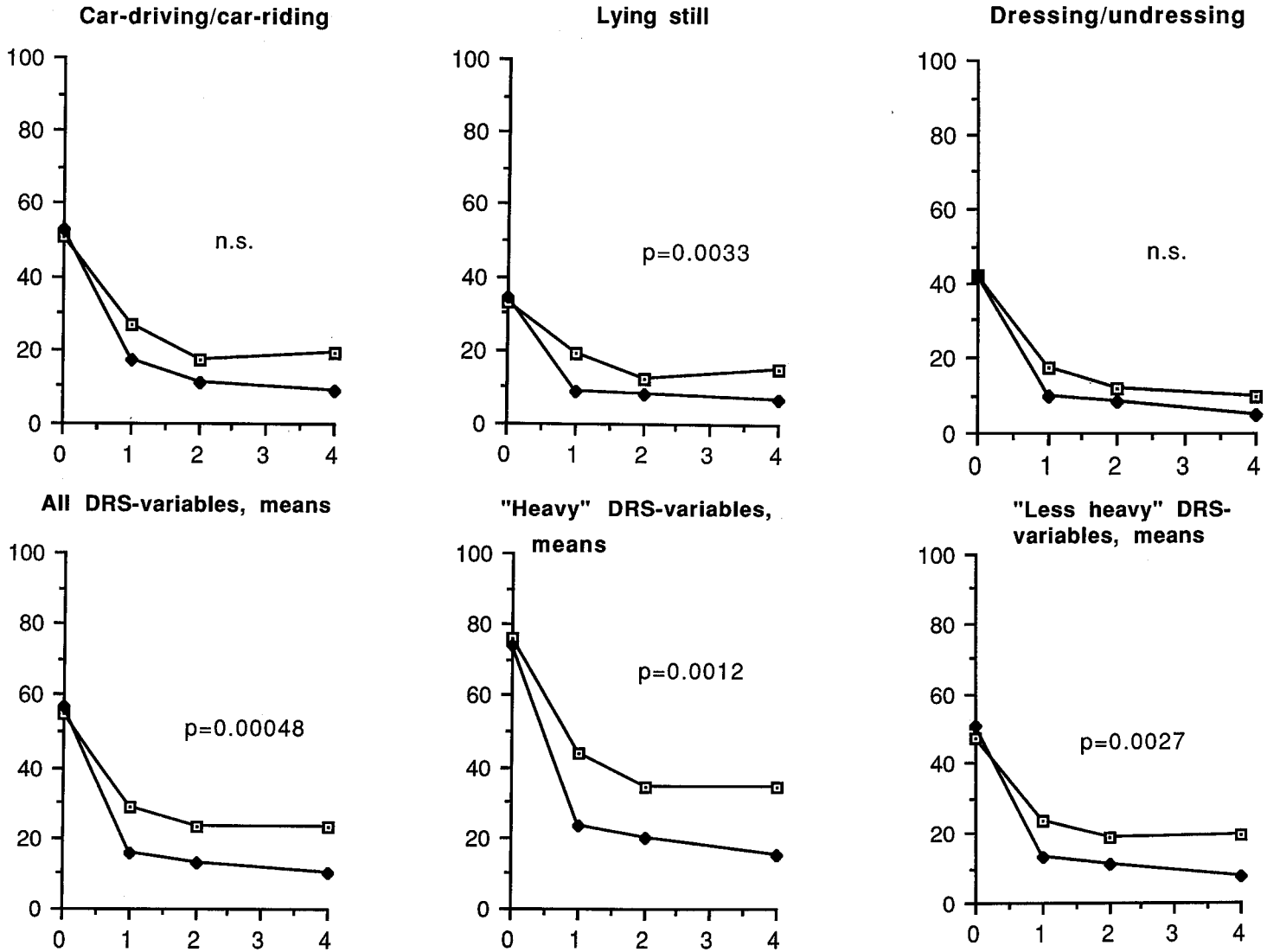

Figure 3 Means for three of the 15 disability rating scores (DRS). The three last graphs illustrate means for the 15 variables in total, the four 'heavy' and the 11 'less heavy' DRS variables respectively. Unfilled squares represent the conventionally treated group and black squares represent the experimental group. 100 mm visual analogue scales were used; 0 = no disability, 100 mm = maximum disability. Vertical axis = visual analogue disability scale; horizontal axis = months of follow up.

Table 1 Treatment content and X-ray investigations in the experimental group

(%)	Physician	Physiotherapist
Sacro-iliac mobilization	81	17
Lumbar mobilization	77	31
Lumbar manipulation (thrust techniques)	40	4
Muscle stretching	83	31
Massage	15	4
Deep frictions	10	2
Paracoccygeal structures		
Stretching	67	0
Steroid injections	42	–
Piriformis/gl med/min steroid injections	29	–
Other steroid injections	17	–
Pelvic corset (CAMP®)	13	2
Corset	2	4
Cork-wedge (due to anatomical short leg)	15	0
Autotraction	15	13
Cervical mobilization/manipulation	4	0
Computerized tomography	11	–
Home exercises for muscle stretching	21	40
Home exercises for specific mobilization	4	38
Medical training therapy	0	19
Other back exercises	6	10
Thoracic mobilization/manipulation	25	2
X-ray	19	–

the experimental patients and 8% of the control patients were not seen by a physiotherapist. The experimental patients were treated almost exclusively during the first three weeks, while the control patients received more continuous treatment. The detailed treatment content in the experimental group and in the conventionally treated group is shown in Tables 1 and 2.

Table 2 Treatment content in the conventionally treated group

	%
Low-back pain school training	21
Ergonomic advice etc.	76
Active back exercises	70
Postural exercises	38
Ultrasonic waves	25
TNS, TEMS	34
Heat (steam-pack)	57
Cold (cold-pack)	2
Short-wave	0
Electric stimulation	21
Taping	0
Corset	17
Massage	13
Plunge-bath training	15
Unspecific traction	4
Other treatment	8

Steroid injections

Among the patients not responding to manual therapy during the first one to two weeks, 26 (54% of the experimental group) had painful paracoccygeal structures by per rectum palpation (possibly the sacrotuberous and sacrospinal ligaments) and/or in the insertion on the greater trochanter of the piriformis muscle, where steroid injections, 'needling' and local anaesthetics were given (1.7 injections per patient, range 1–4). The average for the whole group was 0.9 injections per patient.

Disability rating

The 15 DR variables at baseline and after one, two and four months are shown in Figures 1–3. There were no significant differences between the two treatment groups at baseline, but there were significant changes over time in favour of manual therapy for 13 of the 15 variables. The difference for car-driving was significant only at the four months' follow-up.

The average of the 15 variables at baseline and during follow-up is shown in Figure 3. They were also grouped into 'heavy' and 'less heavy' DR variables respectively, demonstrating the larger

difference for 'heavy' DR variables.

The results concerning other complaints due to low-back pain (difficulties in falling asleep, waking up in pain, morning stiffness, pain at rest, not being able to take part in physical exercise, proportion of time at rest during the day-time and need for pain-killers or NSAIDs), are shown in Table 3. There were no significant initial differences between the groups. At follow-up examinations there were significant differences in most of the variables in favour of the experimental treatment.

Side effects and complications

Side effects and complications are presented in Table 4. Due to painful muscle stretching and injections, the manual treatment was significantly more painful than the conventional treatment. No other significant differences were found.

Transient worsening of the pain caused by treatment was reported by two patients in the experimental group after one month. No persisting deterioration and no complications were reported in the experimental group. Three

Table 3 The presence of certain complaints due to low-back pain and drug consumption at 0, 1, 2 and 4 months

	Initial			1 month			2 months			4 months		
	Conv.	Exp.	*p*	Conv.	Exp.	*p*	Conv.	Exp.	*p*	Conv.	Exp.	*p*
Difficulties in falling asleep due to back pain (%)	68	73	NS	37	11	0.002	28	15	NS	31	11	0.01
Waking up in back pain (%)	72	63	NS	34	15	0.03	34	13	0.01	33	7	0.001
Morning stiffness (%)	64	67	NS	48	45	NS	51	44	NS	55	26	0.004
Pain at rest (%)	57	50	NS	28	11	0.02	23	10	NS	28	11	0.04
Inability to take part in physical exercise (%)	85	80	NS	54	10	0.001	37	14	0.01	40	14	0.005
Taking pain-killers or NSAID (%)	60	48	NS	36	13	0.006	25	15	NS	24	13	NS
The drugs experienced as being effective (%)	80	77	NS	84	83	NS	77	100	NS	92	100	NS
Resting during daytime (hours/day)	1.8	2.5	NS	0.8	0.3	0.005	0.06	0.2	NS	0.4	0.3	NS

NS = not significant ($p \geq 0.05$)

Table 4 Reported side effects and complications at 1, 2 and 4 months, percentages of all 303 responses

	Conv.	Exp.	*p*
The treatment hurts (%)	27	50	0.029
always	1	9	NS
sometimes	26	41	NS
VAS concerning painful treatment (mm, mean)	10	17	0.048
Item in treatment that hurts (%)			
experimental group			
muscle stretching	–	38	
injections	–	14	
manipulation/mobilization	–	9	
massage	–	1	
do not know which item	–	2	
conventional group			
the exercises	18	–	
massage	9	–	
short-wave, ultrasonic waves, TNS, etc.	9	–	
do not know which item	3	–	
Pain after treatment (%)	37	29	NS
always	3	7	NS
sometimes	34	22	NS
VAS concerning pain after treatment (mm, mean)	10	12	NS
Duration of post-treatment pain (hours)	7	13	NS
The treatment made the pain slightly worse (%)	4	1	NS

NS = not significant ($p \geq 0.05$)

Table 5 Patients' views of the treatment after four months

	Conv.	Exp.	*p*
Explanation given by the doctor for the pain (mm, mean)	67	93	0.001
Comments on the explanations for the pain (%)			
positive	8	11	
negative	23	2	0.001*
no comment	69	87	
The treatment made it easier to cope with the pain (%)			
during work	61	92	0.013
during leisure time	66	90	0.047
among friends	68	89	NS
Comments concerning the treatment (%)			
positive	4	13	NS
negative	19	7	NS*
none	77	80	NS

NS = not significant ($p \geq 0.05$)
*Calculated on the distribution of positive and negative comments

patients in the conventionally treated group reported persisting deterioration caused by the treatment at the four-month follow-up.

Patients' views of the treatment

The results from the patients' subjective view of the treatment are shown in Table 5. The experimental patients had a significantly more positive view of their treatment than the patients in the conventionally treated group, measured as positive and negative comments on the information concerning the causes of the back pain. Significantly more patients in the experimental group than in the conventionally treated group also stated that the treatment made it easier to cope with their pain at work, during leisure time and among friends. There was a significant difference in favour of the experimental group for the ratings of the explanation given for the pain by the doctor.

Discussion

In this study, strenuous efforts were made to keep potential bias under control. This is discussed in detail in other publications.[12–14] Some differences in baseline characteristics were found. Overall, these differences favoured the conventionally treated group, as shown in the present paper and in previous reports. Consequently, if the two groups had been more alike at baseline, differences in treatment effect could have been larger.

The drop-out rate in this investigation is negligible. Eight per cent of the control patients and none in the experimental group received parallel therapy by chiropractors or doctors of naprapathy during the first four months of the follow-up period. This probably favoured the conventionally treated group but had no crucial influence on the results.

This study shows that the experimental manual therapy improved everyday function in a low-back pain population more effectively than conventional treatment provided by Swedish primary health care teams. The results of this paper and three other reports[13–15] support the conclusions in our first article concerning the favourable effect of manual therapy.[12] All our measures up to four months indicate the same thing: manual therapy is superior to conventional management of low-back pain. Sick-leave statistics as the sole efficacy variable are insufficient,[12] but in the case of our trial there is no reason to believe that the sick-leave results would suddenly cease fluctuating together with the other variables after four months. Thus, sick-leave statistics as a single efficacy measure after four months are sufficient and we claim that our trial, as one of the first studies in the literature, provides convincing evidence of the long-term efficacy of manual therapy.

A two-year follow-up with a drop-out rate of 2% has been carried out, but the results are yet to be reported.

It is of special interest that the curves representing the two treatment groups diverge from

each other after two months in 15 of the 18 graphs in Figures 1–3, whereas in previous published studies on manual treatment the differences in favour of the experimental treatment have decreased over time. This happened in spite of the conventionally treated group receiving continuous treatment during the follow-up whereas the experimental group was treated almost exclusively during the first three weeks.

The graphs in Figures 1–3 are arranged in order of the magnitude of the difference between the two treatment groups. The differences in favour of the experimental treatment concerning activities which make great demands upon the lower back are larger than the differences concerning everyday activities which make moderate demands upon the lower back function. The order of the variables in Figures 1–3 is about the same as if the activities were listed according to the degree of demand they make upon the lower back function.

There were differences in favour of the experimental treatment concerning other complaints due to low-back pain. Morning stiffness was frequent in both treatment groups during the earlier follow-ups, however, and a significant difference was not found until the four-month follow-up. There were only borderline differences concerning drug consumption, but significant differences concerning drug consumption according to the telephone interviews are presented in an earlier paper.[13] It is noteworthy that the vast majority of patients in both groups considered the drugs effective.

The manual treatment was considerably more painful than the conventional treatment. Muscle stretching and injections were the dominating causes of pain during treatment. During stretching of shortened iliocrural muscles (hamstrings, m. rectus femoris, m. iliopsoas, m. tensor fasciae latae, etc.) Evjent and Hamberg suggest that pain in the muscle is allowed provided the patient can stand the pain and is able to relax the muscle during the stretching phase.[19]

No persisting deterioration or complications were reported in the experimental group. The possibility of side effects and/or complications has not been taken into consideration in previous studies.

The patients in the experimental group had a more positive view of the treatment than the patients in the conventionally treated group. The patients in the experimental group were generally content with the treatment. This may have contributed to the positive results in favour of the manual therapy in this trial.

The principle of allowing a complete manual therapeutic arsenal in the experimental group, emulating clinical reality, was vital for the positive outcome of manual therapy in this trial. An essential component of this arsenal might be the steroid injections, which have not been used in combination with manual treatment in any previous investigation. We do not think that any of the single items in this therapeutic arsenal have the corresponding positive effects on low-back pain, especially as far as long-term effect is concerned. The different items might even have a 'synergistic' effect, not merely an additive effect. This approach might even be the only available treatment with a long-term effect on low-back pain. Since it is doubted whether there is any effective medical treatment for low-back pain apart from surgery on the herniated disc,[4] it is necessary to evaluate a complete therapeutic arsenal first. If there is no difference in outcome between the groups in such a study, it is meaningless to investigate the single items. In the case of positive results for the experimental treatment as in our study, it is a task for future studies to evaluate the different items. Our results might constitute the first indications on positive effects of steroid injections in managing low-back pain. A hypothesis for the mechanism in managing low-back pain with a treatment approach where manual therapy is combined with steroid injections has been discussed in detail previously.[12–14]

One could also argue that the positive results of the experimental treatment in this study could be dependent on the steroid injections only and that the manual therapy was ineffective. This is unlikely as there were highly significant differences between the two treatment groups after three, five, seven and 14 days, whereas major effects of the steroid injections would not be expected until the third week. No injections were given during the first week and maximum clinical effects are to be expected after two to three weeks due to the slow release of the used steroid.

On the assumption that the doctor performing

the manual therapy (SB) was enthusiastic and believed strongly in his treatment, while the GPs representing the conventional treatment might have been less involved, it could be argued that our findings could be explained by a 'charisma factor'. This is possible, but the striking difference in sick-leave, pain, objective findings evaluated by blinded and independent orthopaedic surgeons, quality of life, drug consumption[12–15] and in disability make this unlikely. Furthermore, it should be pointed out that the treatment volume was considerably larger in the conventionally treated group than in the experimental group and that almost all 'successful' cases in the latter group were treated during the first three weeks of the study. Placebo effects are usually considered as transient and can hardly explain major differences in measures three to four months after treatment. The differences between the two groups for the majority of the efficacy measures also increased with time, in spite of the fact that the experimental group received no further treatment, unlike the conventionally treated group.

Fewer patients in the experimental group were seen by a physiotherapist. This difference is explained by the fact that many experimental patients experienced complete recovery after the first treatment by SB. The difference is not explained by different treatment compliance (due to, for example, difficulties in travelling to Skönvik) in the two groups either. The duration from randomization to the start of the physiotherapy was short and comparable in both groups. The outcome difference between the two groups can thus not be explained by a difference in waiting-time for physiotherapy.

Conclusions

The results of this study show that the present manual therapy concept, in conjunction with steroid injections, is superior to conventional activating treatment in Swedish primary health care in improving the everyday function of patients with low-back pain.

Many of the differences in favour of manual treatment increased during the follow-up period, implying a persisting long-term treatment effect. This supports long-term differences in sick-leave frequency after eight months' follow-up.

Specific manual therapy seems to be particularly important in the long term for activities which make great demands upon the lower back function such as sports, running, heavy lifting, heavy physical work, making a bed, leaning over a washstand, carrying a bag, sitting more than briefly and getting up from sitting.

The experimental patients had a more positive view of the treatment than the patients in the conventionally treated group.

As expected, the experimental treatment was, due to injections and muscle stretching, more painful than the conventional treatment. No persisting deterioration or complications due to the experimental treatment were reported.

It seems reasonable to conclude that it would be possible to achieve large public cost savings by supplying manual therapy to patients with acute or subacute low-back pain, if these results can be replicated in future studies.

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