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Manual therapy with steroid injections in low-back pain

Improvement of quality of life in a controlled trial with four months' follow-up

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Objective **– To compare prospectively the effect of manual treatment such as manipulation, specific mobilization, muscle stretching, auto-traction, and cortisone injections with standardized conventional but optimized activating treatment by primary health care teams.**
Design **– Prospective controlled multicentre trial with four months' follow-up.**
Setting **– Kopparberg County, Sweden. Six primary health care or occupational health care centres, representing a catchment area of 56000 residents participated.**
Participants **– 101 outpatients with acute or subacute low-back pain were, during the period February 1988 to April 1989, randomly allocated to one of two treatment groups.**
Main outcome measure **– Quality of life was assessed at baseline and at four months by means of visual analogue scales (VAS). The occurrence of 27 different symptoms of a psychosomatic character was surveyed initially and at four months by questions answered by "yes" or "no" in a questionnaire.**
Results **– There were significant differences concerning quality of life and presence of general symptoms in favour of the group receiving manual treatment with steroid injections.**
Conclusion **– Manual treatment with steroid injections was superior to conventional treatment in minimizing mental and somatic symptoms and increasing quality of life, in parallel with other measures of improvement.**

Key words: low-back pain, manual therapy, controlled randomized trial, primary health care, quality of life, psychosomatic symptoms.

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Low-back pain is a major diagnostic and therapeutic problem, causing much suffering and large costs to the community (1). Followers of manual therapy argue that the discipline to some extent offers a solution to this problem, but this form of therapy is still controversial and its possible efficacy is not yet considered satisfactorily documented. In spite of this, manual therapy is growing in popularity among physicians, physiotherapists, and patients.

Short-term effects achieved by manual therapy have been demonstrated in some well-designed and well-performed trials (2–5) but possible long-term effects are yet to be demonstrated. A randomized clinical trial in patients with low-back pain in which the effect of manual therapy was compared with that of conventional treatment was therefore performed.

An eight months' follow-up was presented in a previous article (6), in which the first indications of long-term effects of manual therapy were found – a significant reduction of sick-leave was demonstrated.

In a second article (7), the treatment effect was evaluated in a single-blind manner by standardized telephone interviews at 3, 7, 14, 21, and 90 days. Significant differences in favour of manual therapy were shown for pain score, disability rating, rate of recovery, and drug consumption both in the early phase and at the 3 months' follow-up.

In a third paper (8), clear differences were presented concerning objective findings (for example mobility, movements causing pain, and straight leg raising test) in favour of the group receiving manual treatment.

Differences have been demonstrated concerning

15 different disability rating scores and some other complaints in everyday life due to low-back symptoms in favour of the group receiving manual treatment (9).

The hypothesis to be tested in this report was that manual therapy with steroid injections, in parallel with other measures of improvement, can reduce the presence of general symptoms of a psychosomatic character more effectively than conventional treatment in Swedish primary health care. Manual treatment may in a similar way improve quality of life.

Study population and methods

The study was performed as a multicentre trial in Kopparberg County, Sweden, during the period February 1988 to April 1989. Six primary health care or occupational health care centres, representing a catchment area of 56000 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 to participate, 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.
- Symptom duration of 3 months or less, preceded by at least 2 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 4 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. The 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 when he/she had answered the questionnaires and after the physical examination, the GP called a secretary who randomly, using random numbers, allocated the patient to one of two groups, an experimental group (n=48) or a conventional treatment group (n=53). One hundred and one patients, 48 women and 53 men, were recruited. The two groups were similar in most of the pretrial variables, including age, sex, previous low-back pain problems, sick-leave, previous treatment, findings at the physical examination, quality-of-life score, disability rating, and pain score (6). 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 (6).

Treatment

The experimental group was treated at the Skönvik Rehabilitation Clinic and the control patients received treatment at the primary health care centres where they were recruited. In the present paper, the treatment in the two groups is described only briefly. A more detailed description has been given earlier (6, 9).

One of the authors (SB), who treated all the experimental patients, mainly used techniques and home exercises (muscle stretching) according to Evjent/Hamberg (10, 11) and Mitchel (12). The therapy also had much in common with the techniques described by Lewit (13) and Stoddard (14). All patients were treated with thrust techniques or specific mobilization. A modified technique for treatment of dysfunctions of the sacroiliac joint (15) was essential. Fifteen per cent of the patients were treated with auto-traction (16). In order to reduce pain, 26 patients (54%) were given steroid injections, "needling" (13) and local anaesthetics. The injections were mostly given round the paracoccygeal structures and the insertion of the piriformis and the gluteus medius/minimus tendons on the greater trochanter.

Table I. *Quality-of-life measures. These variables were measured on a visual analogue scale, 100 millimetres long, where 0 mm represents the worst possible situation and 100 mm the best possible.*

	At baseline			At 4 months			Change over time
	Conv	Exp	p=	Conv	Exp	p=	p-values
Home and family situation	87	85	NS	86	89	NS	NS
Housing situation	88	84	NS	89	89	NS	NS
Work situation	66	68	NS	71	79	NS	NS
Leisure situation	76	77	NS	78	83	NS	NS
Economy	70	74	NS	72	76	NS	NS
Health	65	63	NS	70	84	0.0047	0.0019
Hearing	84	86	NS	82	92	0.0037	0.010
Eyesight	77	82	NS	81	88	NS	NS
Memory	73	75	NS	76	83	0.048	0.016
Fitness	53	53	NS	54	62	NS	NS
Appetite	87	83	NS	89	90	NS	NS
Mood	76	75	NS	78	84	NS	NS
Energy	71	73	NS	73	82	0.020	0.054
Patience	73	74	NS	75	81	NS	NS
Confidence	70	78	NS	78	82	NS	NS
Sleep	73	79	NS	77	87	0.031	NS
Concentration	75	76	NS	82	86	NS	NS
Sexual life	73	76	NS	78	84	NS	NS
Friends	80	79	NS	79	83	NS	NS
Fatigue without reason	67	71	NS	74	82	NS	NS
Morning fatigue	65	58	NS	68	69	NS	NS
Headache	73	76	NS	76	84	NS	0.052
Stomach problems	77	81	NS	84	88	NS	NS
Anxiety	77	79	NS	79	84	NS	NS

Conv = conventional
Exp = experimental

Treatment was also performed by seven physiotherapists, more or less specialized in manual therapy.

The control patients received active, optimized and standardized conventional treatment. All staff participating in the conventional treatment were co-trained. The therapeutic strategy was activation of the patients. In addition, they received drugs, ergonomic and other advice in writing and verbally, low-back pain school training, sick-leave, active back exercises, corsets, taping, short-wave, ultrasonic waves, TNS, TEMS, electric stimulation, heat (Steam-pac), cold (Cold-pac, ice), postural instructions and postural exercises, and in some cases plunge-bath training and massage.

Recurrences were treated in both groups, and the therapists could give as many treatments as they found indicated. The patients in the experimental group were seen by the doctor on average 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 on average 2.0 times. 19% of the patients also had 0.8 group treatments per patient (medical training therapy).

The patients in the control group were seen 3.8 times by a doctor and had physiotherapist treatment 8.6 times, 6.8 times individually and 1.8 times in groups. 89% received individual physiotherapy, compared to 56% in the experimental group.

The experimental patients were treated almost exclusively during the first 1–3 weeks, while the control patients received continuous treatment, to a larger extent.

Evaluations

Information on quality of life and the presence of 27 symptoms at the beginning of the study and at the four months' follow-up was obtained by questionnaires. Quality of life was measured in a modified way according to Tibblin (17, 18) using visual analogue scales (VAS). Eight variables, concentration, sexual life, friends, fatigue without reason, morning

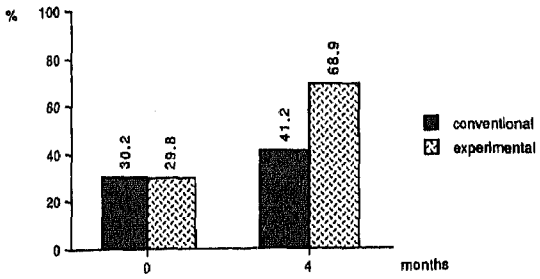

Fig. 1. Percentage (%) of patients with high scores (80–100 mm VAS) concerning "health" at baseline and at the 4 month follow-up.

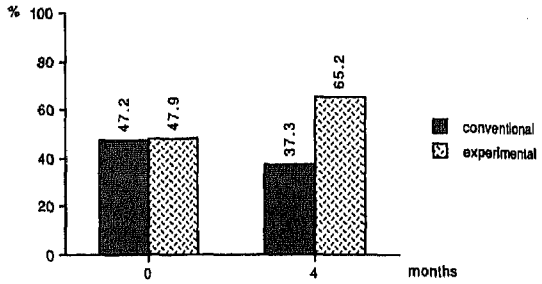

Fig. 2. Percentage (%) of patients with high scores (80–100 mm VAS) concerning "energy" at baseline and at the 4 month follow-up.

fatigue, headache, stomach problems, and anxiety, were added to the original 16 variables of Tibblin. The scale was 100 millimetres (mm) long, the left end representing "very bad" (0 mm) and the right end representing "excellent, could not be better" (100 mm). The distance in mm from the zero point to the patient's marking was used as the score for the quality-of-life variable in question.

The 27 symptoms were surveyed in the same questionnaire by questions to be answered by "yes" or "no" concerning the presence of symptoms during the preceding three months. This instrument of quality-of-life "complaint score" has been thoroughly evaluated (17, 18). Thirty symptoms are usually included. In the present trial three of the symptoms concerning the locomotor system have been left out so as not to disturb the frequent other corresponding measures of efficacy.

Drop-outs

Three patients (one control patient and two in the experimental group) did not return their questionnaires.

Parallel therapy

Four patients in the control group and no patient in the experimental group received parallel treatment, mainly by chiropractors or doctors of naprapathy.

Statistical analysis

Summary statistics were computed using standard methods. Possible relationships were tested with Student's t-test and Pitman's non-parametric permutation test (19). 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 non-parametric permutation test in its multivariate form. 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 generally regarded as indicating statistical significance.

Results

Quality of life

Quality-of-life data measured at baseline and at the four months' follow-up are shown in Table I. There were only minor differences between the two treatment groups at baseline and none of these were statistically significant. At the four months' follow-up there were significant differences for five variables (health, hearing, memory, energy, and sleep).

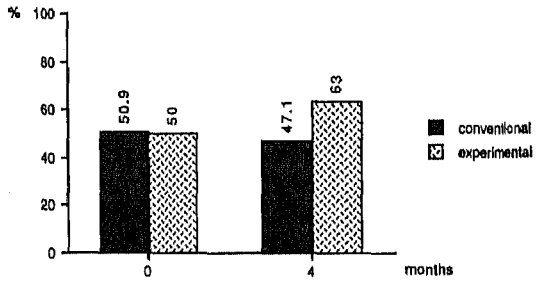

Fig. 3. Percentage (%) of patients with high scores (80–100 mm VAS) concerning "memory" at baseline and at the 4 month follow-up.

Table II. *The prevalence (%) of the three variables with significant outcome difference between the two groups at the four month follow-up and change over time (negative values indicating deterioration).*

%	Initial			4 months			Change over time (%)		
	Conv	Exp	p=	Conv	Exp	p=	Conv	Exp	p=
Depression	40	31	NS	44	20	0.016	10	35	0.016
Abdominal pain	19	19	NS	29	7	0.0078	−53	63	0.0078
Sweating	19	10	NS	21	4	0.027	−11	60	0.027

Conv = conventional
Exp = experimental

As illustrated in Figures 1–3, the differences between the treatment groups concerning health, energy, and memory depend on a larger proportion of the patients in the experimental group scoring highly (80–100 mm VAS). The proportion of patients with high scores for energy decreased in the conventionally treated group during the follow-up. At the four months' follow-up higher scores were found for the experimental group than for the conventionally treated group concerning 23 of the 24 variables, compared with 16 variables at baseline.

Symptom profile

Out of the 27 symptoms, the patients in the conventionally treated group initially had 5.5 symptoms on average, compared with 4.8 symptoms per patient in the experimental group. This difference was not significant. After four months, the corresponding rates were 5.0 and 2.8, respectively (p = 0.007). There were thus almost twice as many symptoms in the conventionally treated group after four months as in the experimental group. The symptom frequency in the experimental group decreased by 42% during the follow-up, compared with a 9% decrease in the conventionally treated group. There were no initial significant differences between the two groups for any of the 27 variables, while there were significant differences for three variables (depression, abdominal pain, and sweating) after four months (Table II). 40% in the conventionally treated group had experienced depression during the three months preceding the study start, increasing to 44% at four months. The corresponding figures for the experimental group were 31% and 20%, respectively. There was a considerable increase (53%) of abdominal pain during the follow-up in the conventionally treated group, compared with a decrease (63%) in the experimental group.

In Figure 4, the initial profile of the 27 symptoms is shown graphically for the two groups. Figure 5

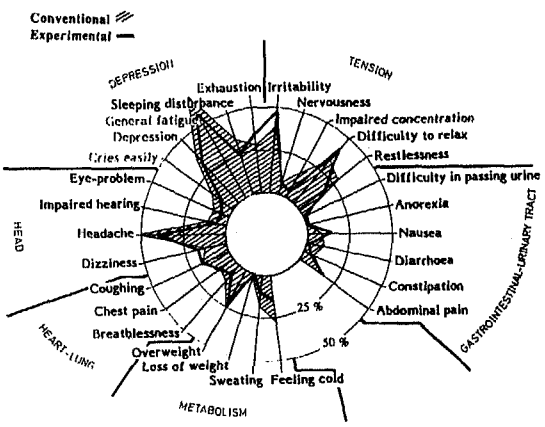

Fig. 4. Prevalence (%) of the 27 symptoms in the two groups during the three months before the start of the study. The inner, middle, and outer circles represent 0%, 25%, and 50%, respectively. The symptoms are grouped into categories.

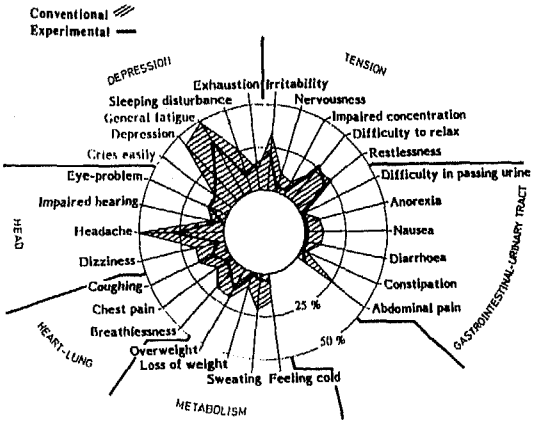

Fig. 5. Prevalence (%) of the 27 symptoms in the two groups during the three months preceding the four month follow-up. The inner, middle, and outer circles represent 0%, 25%, and 50%, respectively. The symptoms are grouped into categories.

illustrates the differences between the two groups at four months. There were generally more symptoms in the conventionally treated group than in the experimental group.

Abdominal pain, chest pain, headache, and dizziness, which are frequently closely connected to dysfunctions in the vertebral column, were analysed separately. Initially, the mean number of these four symptoms was 0.89 in the conventionally treated group and 0.88 in the experimental group. After four months, the corresponding figures were 1.04 and 0.46, respectively. There is a strong significance concerning the 48% decrease of frequency in the experimental group compared with the 17% increase in the conventionally treated group ($p = 0.0011$).

Discussion

Baseline data (6) indicate that we have recruited a patient group with advanced low-back suffering. In spite of the active, conventional treatment in the control group, 19% of the patients were still on sick-leave after 8 months, compared with 8% in the experimental group (6). Thus, on the whole, rather severe cases were frequent in the studied population. However, nothing speaks against the population being representative for the low-back pain population consulting the primary health care with a need for sick-leave.

The present study shows that manual therapy increased quality of life and reduced general symptoms in a low-back pain population more effectively than does conventional treatment supplied by Swedish primary health care teams. This change over time occurred in parallel with other measures of improvement (6–9). The rationale for this might be that extended low-back suffering secondarily jeopardizes psychological well-being and that psychological factors may be secondarily and positively influenced by treatment based on the consideration of somatic factors in the suffering of the low-back patients.

The results of this study support the conclusions in our earlier reports concerning the favourable effect of manual therapy on sick-leave. It has been possible to reduce sick-leave without secondary adverse effects on quality of life and general symptoms, which might have been the case if sick-leave figures were reduced merely by the doctor taking an authoritative attitude to the patient.

It is of interest that both groups in the study population initially had considerably more tension and depression symptoms than in most other investigations (17, 18). From a psychological point of view, the patients in the experimental group improved considerably during the follow-up, suggesting that their psychological status at the start of the study was not their habitual status but secondarily influenced by their low-back suffering.

Short-term effects of manual therapy are demonstrated in some trials (2–5) that are commented upon in our previous papers. However, there are no previous trials in which psychological measures such as the prevalence of psychosomatic and other general symptoms or quality-of-life scores have been applied as efficacy measures.

Four symptoms (abdominal pain, chest pain, headache, and dizziness), of special interest and importance in low-back pain patients according to the theoretical model in the manual treatment applied in this trial, were analysed separately, and a particularly strong significance for the considerable difference in favour of the group receiving manual therapy was found. These symptoms are frequently interpreted as being of prime psychological origin. The results of the present study constitute indirect evidence that such symptoms can be dependent on reversible and treatable somatic dysfunctions as well.

The considerable difference in favour of the manual therapy group concerning "health" is of special interest. In a study by Eklund et al. (20), a similar measure was shown to be the most reliable predictor for good prognosis in occupational rehabilitation of low-back patients on extended sick-leave. In other words, a patient at great risk for early retirement due to low-back pain, but still experiencing good health, is able to rehabilitate back to the labour market. The very same variable is the one of the 24 variables most positively influenced by the manual therapy, which might be of crucial importance for the prognosis in this patient population.

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 fully explained by a "charisma factor" in the experimental treatment. It is difficult to falsify such a hypothesis in the present study, but the striking differences in sick-leave, pain, disability, quality of life and in evaluation by blinded and independent orthopaedic surgeons (6–9) speak against the view that the positive results depend on "charisma-effect"

only. 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 "succeeded cases" in the latter group were treated during the first 1–3 weeks of the study. Placebo effects are usually considered as being transient and can hardly explain major differences in measures 3–4 months after treatment (8 months when it comes to sick-leave figures). The differences between the two groups for the majority of the efficacy measures also increased after two months of follow-up, in spite of the experimental group getting no further treatment contrary to the conventionally treated group (6, 9). A reproducibility study is going on at the moment, in which the GPs were educated in manual therapy by SB (21).

Conclusions

The results of this study show that manual therapy with steroid injections is better than conventional optimized activating treatment in Swedish primary health care, when it comes to reducing the presence of general symptoms in parallel with reduction of pain and restoration of everyday function in patients suffering from low-back pain. Manual treatment improves quality of life more effectively as well.

The patients received no psychotherapy. The experimental treatment approach mainly considered the somatic part of their psychosomatic suffering. In spite of this, the patients' psychological status improved in parallel with the disappearance of somatic symptoms and findings. Since there is a possibility that there is some "charisma-effect" in the experimental treatment, our results should be reproduced in future studies before definite conclusions are drawn.

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