Original articles

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A randomized study of manual therapy with steroid injections in low-back pain

Telephone interview follow-up of pain, disability, recovery and drug consumption

S. Blomberg, K. Svärdsudd, and G. Tibblin

Department of Family Medicine, Uppsala University, Uppsala, Sweden, and The Skönvik Rehabilitation Clinic, Säter, Sweden

Summary. A total of 101 outpatients with acute or subacute low-back pain was randomly allocated to one of two treatment groups. One group was given standardised conventional and optimised activating treatment by primary health care teams. The other group received, according to a pragmatic approach, another treatment programme including manipulation, specific mobilisation, muscle stretching, autotraction and cortisone injections. The treatment effect was evaluated by standardised telephone interviews 3, 7, 14, 21 and 90 days after the start of treatment. The two groups were similar in most of the pretrial variables, including age, sex, occupation, education, previous low-back pain problems, previous treatment, sick-leave, findings at the physical examination, quality-of-life score, presence of common symptoms, disability rating and pain score. In the early phase as well as at the 90 days' follow-up, the group receiving manual therapy had significantly less pain, less disability, faster rate of recovery and lower drug consumption, indicating that this type of treatment is superior to conventional treatment.

Key words: Low-back pain – Manual therapy – Pain score – Steroid injection

Low-back pain is a major diagnostic and therapeutic problem, causing much suffering and high costs to the community [1, 26–28]. Treatment has traditionally been conservative, consisting mainly of prolonged bed-rest or the use of spinal support. This regimen has been criticised during the last decade [28], and not surprisingly, there have been many attempts to improve the rate of recovery. Mechanical methods, for example manipulation, have been in use since antiquity in all kinds of cultures, and their continuing popularity suggests some benefit. However, this form of therapy is still controversial, and evaluation has, due to methodological problems, proved difficult.

Correspondence to: S. Blomberg, Department of Family Medicine, Academic Hospital, S-751 85 Uppsala, Sweden

Short-term effects of manual therapy have been demonstrated in some well-designed and well-performed trials [9, 14, 15, 18, 30, 31, 33], but possible long-term effects have yet to be demonstrated. For this reason, a randomised clinical trial in patients with low-back pain in which the effect of manual therapy was compared with that of conventional treatment in primary health care was performed.

In a thesis [2] based on five papers (including the present one), the results and various aspects of the present investigation are thoroughly discussed. The thesis also contains an extensive review of the literature on manual therapy including 47 controlled trials [manipulation/specific mobilisation (n = 32), autotraction (n = 3) and muscle stretching (n = 12)]. In addition, some uncontrolled studies and papers on morphological, biochemical and biomechanical adaptations to immobilisation have been reviewed. We will here only briefly refer to the main results from our four previous articles [3–6].

An 8 months' follow-up was presented in previous paper [3], in which the first indications of the long-term effects of manual therapy were noted – a significant reduction of sick-leave was demonstrated. After 1 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 questionnaire after 1, 2 and 4 months, in favour of the group receiving manual treatment were demonstrated as well, indicating a better long-term effect than with conventional treatment.

In a second paper [4], 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 [5].

Significant differences have also been reported concerning quality of life and presence of general symptoms in favour of the group receiving manual treatment with steroid injections [6].

In this article data on the treatment effect, obtained by frequent telephone interviews, during the first 3 months after the start of the study are presented. The hypothesis to be tested was that manual therapy with steroid injections, in the early phase as well as during the later follow-up, facilitates recovery and reduces pain, disability and drug consumption more effectively than conventional treatment in primary health care. Differences between the two treatment groups during the early phase are of special importance, since major effects from the steroid injections are not to be expected until the 3rd week, which argues against the belief that differences in treatment outcome between the two groups could be dependent on the steroid effect only.

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 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 participation, most frequently because of a long distance from home to the Skönvik Rehabilitation Clinic.

The criteria for inclusion were:

- Age 20–60 years.
- Acute or subacute low-back pain with or without pain radiating to one or both legs not necessitating surgical or rheumatological care. Patients with verified 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 jeopardise 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 cirteria 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 standardised 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 answered the questionnaires and undergone physical examination, the GP called the study coordinator, who randomly allocated the patient to one of two groups, an experimental group ($n = 48$) or a conventional treatment group ($n = 53$). Forty-eight women and 53 men were recruited. The two groups were similar in most of the pretrial variables, including age, sex, occupation, education, previous low-back pain problems, previous treatment, sick-leave, findings at the physical examination, quality-of-life score, presence of common symptoms, disability rating and pain score [2, 3]. 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 [2, 3].

Treatment

The patients in the experimental group were treated at the Skönvik Rehabilitation Clinic and those in the conventionally treated group 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. Detailed treatment descriptions are presented in earlier papers [2, 5].

Experimental treatment. The basis of Swedish manual therapy is the classical osteopathic techniques as described by Stoddard [32] and the continental tradition as represented by Lewit [22] and Janda [19]. These techniques for mobilisation, manipulation and muscle stretching have been further developed by Kaltenborn, Evjent and Hamberg, as described in three therapeutic manuals [11, 12, 20], and they form an important part of the experimental treatment. In Scandinavia, specific "locking techniques" have been developed [2, 12]. Diagnosis according to the "muscle energy technique" (MET) [25] was incorporated in the physical examination.

All patients were treated with high-velocity, short-lever, short-amplitude thrust techniques or corresponding more gentle specific mobilisation. Almost all patients were treated with muscle stretching, and they were taught muscle stretching exercises according to Evjent and Hamberg [13]. According to the clinical experience of S.B., an essential therapeutic manoeuvre was mobilisation for sacroiliac dysfunctions according to Kubis [21], which was originally a thrust technique, but with the addition of an Evjent and Hamberg locking technique and a strictly applied MET procedure in the treatment situation, the manoeuvre has become very gentle. Fifteen per cent (7 patients) was treated with autotraction [23, 29] by S.B., and six of them also received autotraction provided by physiotherapists (13%).

Patients not responding to manual therapy and who had painful parasacrococcygeal structures on rectal palpation and/or painful insertion on the greater trochanter of the piriformis muscle were given steroid injections (triamcinolone), often in combination with "needling" [22] and local anaesthetics (0.1% prilocaine hydrochloride). Injection of the parasacrococcygeal structures is described by Cyriax [10]. These structures were also stretched per rectum ad modum Midttun and Bojsen-Möller [16, 24]. Twenty-six patients (54% of the experimental group) received 1.7 injections per patient (range 1–4). The average for the whole group was 0.9 injections per patient. With the exception of physical training, the experimental treatments are found neither in official recommendations for managing back pain nor in basic training curricula for physicians and physiotherapists in Sweden [28].

Two physicians were involved. S.B. treated all the patients, and five refractory patients were also seen by Dr. Franz Mildenberger (the head of Skönvik Rehabilitation Clinic). Treatment was also performed by seven physiotherapists, specialised in manual therapy, who did not take part in the control treatment. They provided treatment individually or in groups. The latter consisted of medical training therapy, (MTT) [17], to improve strength, coordination and endurance. All patients in the experimental group received physiotherpy except those who recovered after the first treatment by S.B. The physiotherapists (in both groups) stopped their treatment when the patient had recovered or when no further improvement was to be expected.

Conventional treatment. The patients received active, optimal (e.g. immediate and frequent consultations, minimal time on the physiotherapy waiting-list, early X-ray investigations, etc.) and standardised (e.g. that the therapists were free to chose between different items in a defined therapeutic arsenal) conventional treatments. The therapeutic strategy was activation of the patients, an approach including informing the patients of the benign character of the condition and the adverse effects of inactivity and sick-leave and encouraging them to take part in physical and other activities. This approach, in which a behavioural therapeutic philosophy was included, is consistent with modern official recommendations for

low-back pain management in Sweden [28]. Thus, the main physiotherapeutic features in the conventionally treated group in the present study were low-back pain school training, ergonomic advice, active back exercises (with the aim of improving general mobility, strength, endurance and fitness), postural exercises and, in some cases, plunge-bath training. The doctors were instructed to minimise 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 1 week, at least during the first weeks of the follow-up). With the exception of a few patients who recovered within days after the randomisation, all patients received treatment provided by 17 physiotherapists (2 or 3 per centre).

In addition, the physicians and the therapists could provide drugs, corsets, taping, short-wave, ultrasonic waves, transcutaneous nerve stimulation (TNS), transcutaneous electric muscle stimulation (TEMS), heat, cold and, in some cases, massage. TNS and TEMS are well-documented pain-reducing treatments. The patients were assessed by the physiotherapists and the treatments were chosen according to need. All staff participating in the conventional treatment were trained in similar therapeutic techniques and diagnostic items.

Treatment intensity during the first 4 months of follow-up. The patients in the experimental group were seen by S.B. on average 3.5 times, 2.8 times for treatment and 0.7 times for check-up consultations where no treatment was provided due to complete recovery since the last visit. They were treated individually by a physiotherapist on average 2.0 times, and they also received 0.8 group treatments (MTT) per patient.

The 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. In all, 89% received individual physiotherapy, compared with 56% in the experimental group. Due to rapid recovery, 33% of the experimental patients and 8% of the control patients were not seen by a physiotherapist.

The estimated total duration of treatment in the experimental group for the physician was 90 min and for the physiotherapists, on average 1 h. The total duration of treatment in the control group for the physicians was also 90 min and for the physiotherapists, more than 3 h. The corresponding figures for group treatment (physiotherapists) were 30 min in the experimental group and 1 h in the conventionally treated group. The difference in physiotherapy treatment volume between the two groups was partly due to the control patients' receiving more continuous treatment – the experimental patients were treated almost exclusively during the first 3 weeks. The numbers of visits to the doctors in the two treatment groups were comparable.

Measures of efficacy

Pain score and disability rating scores (DRS) at the start of the study were measured using visual analogue scales (100 mm VAS, 0 mm representing no pain or disability and 100 mm representing maximum pain or maximum disability) presented to the study population by the recruiting doctor before randomisation [2, 3].

The treatment effect was evaluated by standardised telephone interviews performed 3, 7, 14, 21 and 90 days after the start of the treatment. The interviewer did not know to which group the participants belonged. Four variables were used:

1. Pain score. The patients were asked to indicate their present pain level in 1 of 11 steps ranging from 0 (= no pain) to 10 (= unbearable pain).
2. Disability rating score, classified in 11 steps from 0 (= no disability) to 10 (= maximum disability). The patients were asked to give a global estimate of their functional status in the form of an average of the 15 different DRS they were familiar with, after having filled in the initial questionnaires (Table 1).
3. Rate of recovery, classified in 11 steps. The patients' reports concerning the degree of recovery were given numerical values: 10 = completely relieved, 9 = very much better, 8 = much better, 7 = distinctly better, 6 = slighlty better, 5 = unchanged, 4 = slightly deteriorated, 3–0 different grades of deterioration (0 representing the most pronounced deterioration). A "recovery score" was calculated as a total mean of the recorded values. The values 6–10 were called the 5-point "improvement scale".
4. Drug consumption (pain-killers and/or antiphlogistics).

Table 1. Mean disability rating scores (DRS) at baseline in the two groups (mm, means)

	Initial		*P*
	Conv	Exp	
Physical exercise/athletics	74	69	NS
Running	64	66	NS
Heavy physical work	83	80	NS
Carrying a bag	47	49	NS
Heavy lifting	83	85	NS
Leaning over a wash-stand	57	57	NS
Making a bed	58	58	NS
Moderate physical work	47	48	NS
Walks	38	44	NS
Lying still	33	34	NS
Walking up or down stairs	39	44	NS
Sitting still more than briefly	58	68	NS
Car riding	51	53	NS
Dressing/undressing	42	42	NS
Getting up from sitting	49	59	NS
Mean, all DRS variables	55	57	NS
Mean, 'heavy' DRS variables	76	74	NS
Mean, 'light' DRS variables	47	50	NS

Conv, Conventional group; Exp, experimental group

Drop-outs

A total of 505 telephone interviews was carried out at the planned point of time. There were no drop-outs. For one patients only (an Iranian immigrant), there were some uncertainties (registered as missing data) for some variables, due to language problems.

Statistical analysis

Summary statistics were computed using standard methods. Possible differences were tested with Student's *t*-test and Pitman's non-parametric permutation test [7]. 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 relationships. The results yielded are similar to those of Haenszel's chi-square test.

Only two-tailed tests were used. All significance tests were performed using variables before grouping (Fig. 2, 4, 6, 7; Table 2), and the full range of codes were used even when the variables were subgrouped. *P* values less than 5% were regarded as indicating statistical significance.

Results

Pain score

There were no significant differences in pain score between the two groups at the start of the study. Pain scores during follow-up in the two groups are presented in Fig. 1.

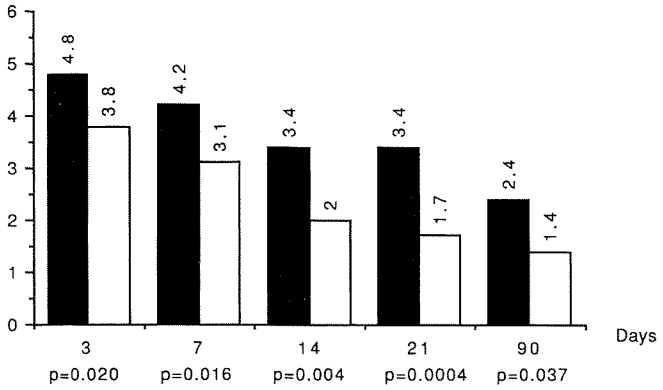

Fig. 1. Mean pain score at 3, 7, 14, 21 and 90 days of the study in the two groups. ■ Conventional; □ experimental

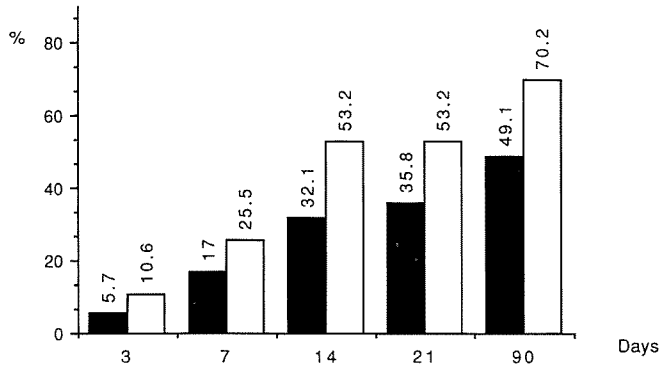

Fig. 2. Proportion of patients (%) who were free or almost free from pain at 3, 7, 14, 21 and 90 days in the two groups. ■ Conventional; □ experimental

Pain decreased with time in both groups, but there was significantly less pain reported in the experimental group than in the conventionally treated group. The largest difference was found after 21 days, when the mean pain score was twice as high in the conventionally treated group as in the experimental group.

The proportion of patient who were free or almost free from pain (patient's rating 0–1) is shown in Fig. 2. At 14 days of follow-up, 53% of the experimental group was pain-free, which is more than the proportion of pain-free patients at 90 days in the conventionally treated group (49%).

Disability rating score

There were no significant differences in DRS at the start of the study. The DRS during follow-up for each group is shown in Fig. 3. It was significantly lower in the experimental group. At 21 days it was twice as high in the conventionally treated group as in the experimental group. The percentages of patients with restored or almost restored function (scoring 9–10) are shown in Fig. 4. The percentage of patients with restored function in the experimental group after 14 days (62%) exceeded the percentage of patients with restored function at 90 days in the conventionally treated group (55%).

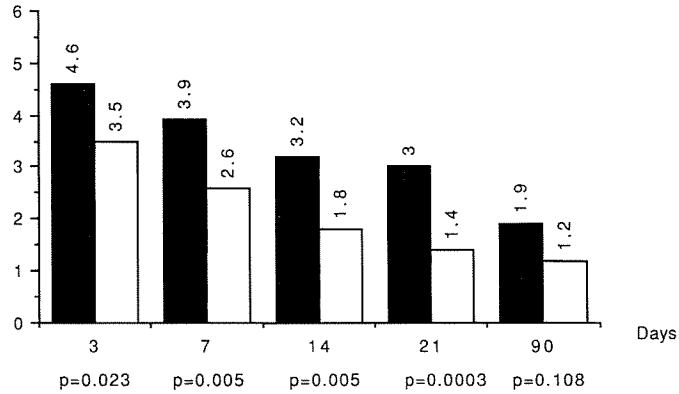

Fig. 3. Mean disability rating score at 3, 7, 14, 21 and 90 days in the two groups. ■ Conventional; □ experimental

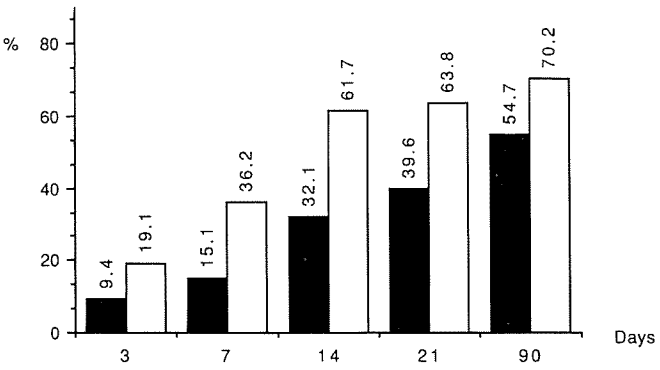

Fig. 4. Proportion of patients (%) who had a restored or almost restored function (DRS) at 3, 7, 14, 21 and 90 days in the groups. ■ Conventional; □ experimental

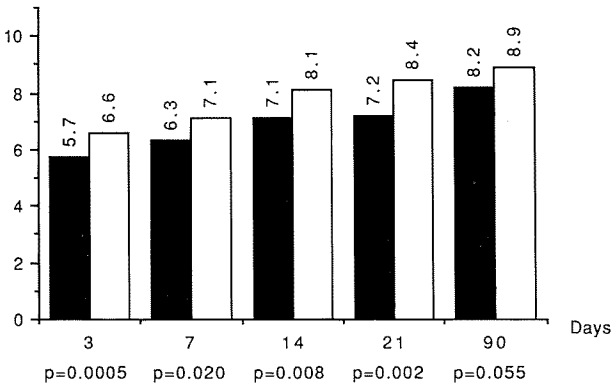

Fig. 5. Mean level of recovery at 3, 7, 14, 21 and 90 days in the two groups. ■ Conventional; □ experimental

Recovery

In Fig. 5 the recovery rate is presented as means for the two groups. A significant difference was already seen after 3 days.

The proportion of patients completely or almost completely cured (rating 9–10) is shown in Fig. 6. Half of the patients in the experimental group considered themselves cured after 2 weeks and 72%, after 3 months. In the con-

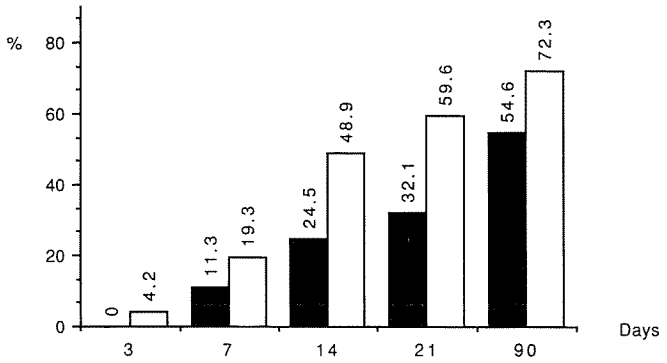

Fig. 6. Proportion of patients (%) who were completely or almost completely recovered at 3, 7, 14, 21 and 90 days in the two groups. ■ Conventional; □ experimental

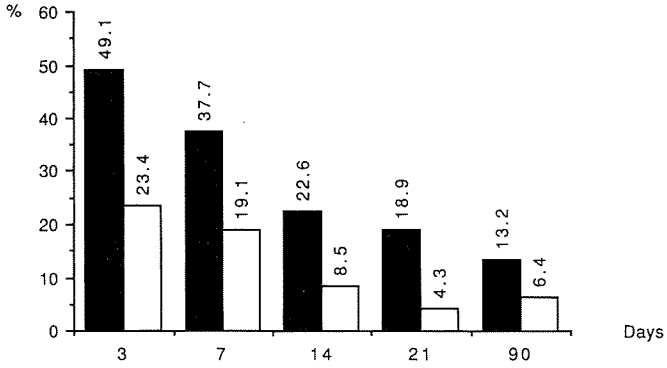

Fig. 7. Proportion of patients (%) whose condition was unchanged or deteriorated at 3, 7, 14, 21 and 90 days in the two groups. ■ Conventional; □ experimental

Table 2. Recovery rates scores subgrouped in four intervals: deteriorated (0–4), unchanged (5), improved (6–8), recovered (9–10). Proportion (%) in the two treatment groups at 3, 7, 14, 21 and 90 days

	3 days	7 days	14 days	21 days	90 days
Recovered					
Conv	0	11	25	32	55
Exp	4	19	49	60	72
Improved					
Conv	51	51	52	49	32
Exp	73	62	43	36	22
Unchanged					
Conv	43	32	17	9	9
Exp	19	17	4	4	6
Deteriorated					
Conv	6	6	6	10	4
Exp	4	2	4	0	0

Conv, Conventional group; Exp, experimental group

ventionally treated group, consistently fewer participants were cured than in the experimental group.

In Table 2 the recovery rate scores are presented as four intervals: deteriorated (0–4), unchanged (5), improved (6–8) and recovered (9–10). There were large differences in favour of manual therapy concerning the proportion of patients who had no positive response to the treatment at all. The proportion of patients whose condition was unchanged or deteriorated was more than 4 times larger in the conventionally treated group than in the experimental group at 21 days (Fig. 7; Table 2). After 2 weeks there were no patients in the experimental group whose condition had deteriorated at all, while in the conventionally treated group five patients at 3 weeks and two patients at the 3 months' follow-up considered themselves worse off (Table 2).

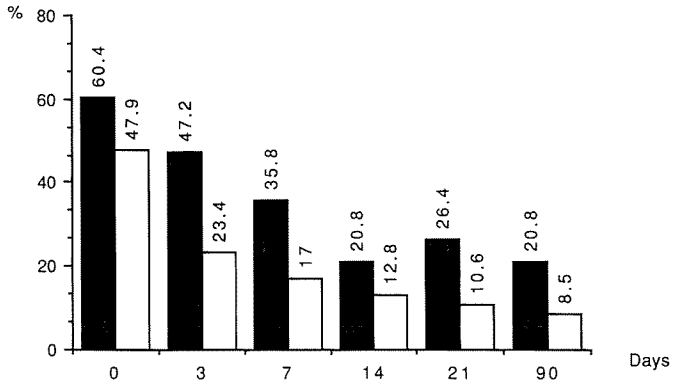

Fig. 8. Proportion of patients (%) using pain-killing drugs or antiphlogistics in the two groups at 3, 7, 14, 21 and 90 days. ■ Conventional; □ experimental

Drug consumption

The percentages of patients taking drugs are presented in Fig. 8. The drug consumption decreased over time in both groups and was over the trial period significantly lower in the experimental group ($P = 0.02$). When the initial insignificant differences was taken into account, the difference between the two groups was still significant ($P = 0.05$).

Discussion

Controlled trials of manual therapy can be divided into two main types, "pragmatic" and "fastidious". In a pragmatic trial, one tests what happens in everyday practice, where the type, frequency and duration of the treatment are at the discretion of the therapist, whereas in a "fastidious" trial, a single standardised therapeutic manoeuvre is compared with a placebo manoeuvre which is not distinguishable from the experimental treatment by the patient.

The advantage of a fastidious trial is that it is more likely to identify specific components of treatments that are effective. The drawback of this type of trial is that there may not be a single-tool therapy available giving a demonstrable long-term effect with a manageable sample size. There may not be an accurate way to identify patients who will respond to a single-tool technique in advance. Single-tool treatments may be of minor immediate interest to the patient, creating a great risk of drop-out problems, especially in long-term follow-ups. In addition,

the results of single-tool therapies might have only limited clinical applicability.

A pragmatic treatment approach is of the most immediate interest to the patients, but this type of trial has the disadvantage that, if one treatment is more successful than the other, it might not be possible to identify the item(s) in the therapeutic arsenal responsible for the positive effects.

This is a pragmatic study in which two different approaches, with defined and complete therapeutic arsenals, were compared. Thus, we have compared "care according to the principles of Swedish manual medicine" with "low-back management in Swedish primary health care", rather than "manual therapy" with a "control treatment". The therapists in both treatment groups were, depending on diagnostic findings, free to choose between different items of two different defined therapeutic arsenals.

In this study, strenuous efforts were made to keep a potential bias under control. According to a frequently used rule-of-thumb, a study population of more than 300 patients is needed to achieve a similarity of baseline characteristics in most respects when patients are randomly allocated to two treatment groups. In this study, the patient group was smaller, and some differences in baseline characteristics might therefore be expected. Overall, these differences favoured the conventional treatment group, indicating that had the two groups been more alike at baseline, the differences in treatment effect might have been larger. A more pronounced pretrial tendency towards spontaneous recovery in the conventionally treated group than in the experimental group was found, presumably again favouring the conventional treatment group [2, 3].

All measurements were made in a standardised way. In some studies in which different aspects of manual therapy have been evaluated, sham treatment was provided in the control group by the same therapist as in the experimental group [18, 33]. In the present study, according to a pragmatic approach, the aim was to see whether it was of value to add manual therapy with steroid injections to the established treatment of low-back pain in primary care in the long run. In order to achieve the same level of enthusiasm among the physicians, they were allowed to continue with the treatment they were used to. Sham techniques are not applicable in a study covering 2 years. The problem of alternative or parallel treatment given by independent therapists was closely supervised. 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 3 months of the follow-up period. This again probably favoured the conventionally treated group to some extent but had no crucial influence on the results. During the analyses, the intention-to-treat approach was used, which means that no patients were excluded after randomisation even if they did not receive the intended treatment or if they, after the start of the study, turned out not to fulfil the criteria for inclusion.

In an ideal situation, when treatment is evaluated, the patients are blinded, not knowing whether they are receiving experimental or control treatment. One possible confounding factor in the present study is that the control patients knew that they were treated, albeit in an optimal way, using the resources of the health care centre, while the experimental group was treated by a specialist in manual therapy at a centre nearby. This factor alone could hardly explain the positive results of the experimental treatment, however.

The present work, being entirely without drop-outs, is the longest follow-up in the literature up to now. Six weeks is the longest follow-up we have found with an acceptable drop-out rate and an acceptable rate of contaminating therapy [30]. Drop-out problems are rarely discussed in many previous papers with high drop-out rates.

The study shows that manual therapy reduced pain, decreased disability, gave a faster recovery rate and minimised the need for pain-killers and antiphlogistics.

The pain scores, rated on VAS in questionnaires mailed to the participants, were significantly lower in the manual treatment group after 1, 2 and 4 months [2, 3]. This difference was unexpectedly found to increase over time, and the pain score was 2.5 times higher in the conventionally treated group than in the experimental group at 4 months of follow-up. The pain score results according to the telephone interviews in the present paper were similar to these results both in the early phase and at 90 days' follow-up.

An influence on pain score of manual therapy had previously been demonstrated by Rasmussen [31] and Brodin [8, 9]. In Rasmussen's investigation, the follow-up period was short, 2 weeks. The trial was also burdened with some further short-comings: 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 and the experimental treatment could have influenced the results. In our study, this problem was compensated for by using a complete therapeutic strategy in the control group and by allowing a considerably larger treatment volume in the control group than in the experimental group. The control patients in Brodin's trial on low-back pain [8] were put on a waiting-list, and the trial thus had the same shortcoming. The best previously published trial on manual treatment is another paper by Brodin on cervical pain and manual therapy with 4 weeks' follow-up and two control groups [9]. One of the control groups was given sham 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. It is of special interest that there were no differences between this control group and the other 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 than in the experimental group [8, 31]. Brodin's study is methodologically well performed with the exception that 11% of the patients was excluded after randomisation. However, the differences in favour of manual therapy are convincing.

In the present study differences in favour of manual therapy for disability rating were found. Similar results were reported by Rasmussen [31] and Hadler et al. [18]. However, in the latter study the same therapist was used in both treatment groups. Highly significant differences

between the groups were found only during short-term follow-up. After 2 weeks there were no significant differences. Due to the study design, the possibilities of demonstrating significant differences favouring manual therapy were small. In spite of its shortcomings, Hadler's paper constitutes convincing evidence for a short-term effect achieved by manual therapy.

Data concerning recovery in the present study suggest a more rapid recovery achieved by manual therapy. The differences between the two groups might not at first sight seem very impressive, but at every follow-up all patients in the experimental group in fact were about one step higher than the conventionally treated group on the 5-step "improvement scale", which is a considerable difference. No similar rating of recovery has been used in previous well-designed and well-performed trials.

Since the prescription of drugs was a more primary treatment feature in the conventionally treated group than in the experimental group, the recruiting physician prescribed drugs to the control patients to a greater extent than to the experimental patients, who, for ethical reasons, received drugs only if they were in severe pain, to be taken during the time they were waiting for treatment by S.B. (0–3 days). Some patients received drugs before filling in their baseline questionnaires and thus had the prescription from the recruiting GP in mind when filling in the questionnaire. This explains the non-significant difference between the two groups initially. About twice as many patients or more in the conventionally treated group were taking drugs on all five follow-up occasions. More than half of the experimental patients stopped taking drugs during the first 3 days, compared with 22% in the conventionally treated group. Drug consumption in a study like this could be influenced by the physicians. Drug consumption as the sole efficacy variable is thus insufficient. The same is true for sick-leave statistics [2, 3]. Drug consumption and sick-leave statistics may be considered efficacy measures as long as other variables, which cannot be correspondingly controlled by the therapist, show, as in the present study, similar differences between the groups. Drug consumption was used as an efficacy variable with a positive outcome in favour of manual treatment by Wreje [33]. She could demonstrate 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 standardised communication with the patients. Pain scores and an objective efficacy measure (a quantified Patrick's test) did not support the results for sick-leave and drug consumption in her study.

Consequently, persisting differences after 8 months for sick-leave and the fact that the differences between the two groups for many major outcome measures increased, for example concerning the 15 different DRS [2, 3, 5] after 2 months of follow-up despite, contrary to the conventionally treated group, the experimental group receiving no further treatment, seem to constitute the first evidence of long-term efficacy of manual therapy in the literature. A 2-year follow-up with a drop-out rate of 2% has been carried out, but the results have yet to be reported.

Some patients entered the present study with a short history of back pain. The natural course of these patients' conditions might have culminated after the start of the study. Consequently, some patients deteriorated in both groups during the first 2 weeks, but afterwards deterioration occurred only in the conventionally treated group, which is contrary to the common belief that manual therapy, even though it might offer temporary pain relief occasionally, may worsen the patients' condition and should therefore not be recommended. No complications were seen after manual therapy in the present investigation.

The principle of allowing a complete manual therapeutic arsenal in the experimental group, emulating clinical reality, was vital for the positive outcome in this trial. An essential component of this arsenal might be steroid injections, which have not been used in combination with manual treatment in any previous investigation. For empirical reasons, we do not think that any of the single items in this therapeutic arsenal has a corresponding positive effect on low-back pain, especially as far as long-term effects are concerned. The different items might even have a "synergistic" effect, not merely an additive effect. This approach could represent 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, besides surgery on the herniated disc [28], 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 of positive effects of steroid injections in managing low-back pain. A hypothesis for the mechanism in the management of low-back pain with a treatment approach in which manual therapy is combined with steroid injections has been discussed in detail previously [2–5].

The results from our investigation concerning the early phase of the follow-up presented herein, are of especial importance since they argue against the belief that the positive of the experimental treatment in this study might be dependent on the steroid injections only and that the manual therapy was ineffective. There were already highly significant differences between the two treatment groups after 3, 5, 7 and 14 days – major effects of steroid injections are not to be expected until the 3rd week, since no injections were given during the first week and since the maximum clinical effects are usually expected after 2 or 3 weeks due to the slow release of the steroid used (triamcinolone).

Assuming that the doctor performing the manual therapy (S.B.) was enthusiastic and believed strongly in his treatment, while the GPs representing the conventional treatment might have been less enthusiastic, 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 a study design like this, but the striking differences in sick-leave, pain, disability, qualitiy-of-life, presence of common somatic and mental symptoms and evaluation by blinded and independent orthopaedic surgeons make speculations that the pos-

itive treatment effect in this trial could be fully explained by a charisma factor very far-fetched. 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 3 weeks of the study. Placebo effects are usually considered to be 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 many major outcome measures also, as discussed above, increased after 2 months of follow-up. Two reproducibility studies, in which the GPs and physiotherapists were educated in manual therapy be S.B., are going on at the moment.

Fewer patients in the experimental group were seen by a physiotherapist. The reason is that many experimental patients experienced complete recovery after the first treatment by S.B. The difference is not explained by different treatment compliance (due, for example, to difficulties in travelling to Skönvik) in the two groups. The delay from randomisation to the start of the physiotherapy was short in both groups and comparable. The outcome difference between the two groups thus cannot be explained by a difference in waiting time for physiotherapy.

Conclusions

The results of this study indicate that a pragmatic approach to low-back pain including manual therapy, muscle stretching autotraction and steroid injections is superior to the predominant conventional, activating treatment in Swedish primary health care as far as reducing pain, disability and drug consumption, and facilitating recovery is concerned. These results support the conclusions in a previous report where an effect on sick-leave statistics was shown. Manual treatment appears to be less costly, since the treatment volume was considerably less in the experimental group than in the conventionally treated group. Drug costs and sick-leave costs in the experimental group were lower as well. The differences between the two groups decreased during the follow-up, but in spite of the fact the conventionally treated group received continuous treatment during follow-up to a greater extent than the manually treated group, there were convincing and persisting differences even after 3 months. Persisting differences after 8 months for sick-leave imply a persisting treatment effect which could hardly be explained as an expectation effect or charisma effect only. Differences during the early phase argue against the belief that the difference in treatment outcome between the two groups could be dependent on steroid effects only.

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