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# Manual Therapy With Steroid Injections—A New Approach to Treatment of Low Back Pain

## A Controlled Multicenter Trial With an Evaluation by Orthopedic Surgeons

Stefan Blomberg, MD, PhD,* G. Hallin, MD,† K. Grann, MD,† E. Berg, MD,† and U. Sennerby, MD†

Fifty-three acute or subacute patients with low back pain were given standardized but optimized activating conventional treatment by primary health care teams. Forty-eight patients received an experimental treatment that included specific manual treatment, such as manipulation and specific mobilization, muscle stretching, autotraction, and cortisone injections. After 4 months, the experimental group had a less restricted range of movement in extension, less restricted side-bending to the right and to the left, less local pain caused by extension and side-bending to the right, less pain radiating to the right leg caused by side-bending to the left, and a less positive straight leg raising test (both sides) than the conventionally treated group. Manual treatment was superior to the conventional activating treatment in normalizing pathologic findings on physical examination of the lower back. These results agree with the positive influence on pain, drug consumption, sick-leave, disability rating, and quality of life reported in other reports from the same study. [Key words: controlled randomized trial, low back pain, manual therapy, objective evaluation, orthopedic surgeons, primary health care]

Low back pain is a major diagnostic and therapeutic problem, causing much suffering and resulting in large financial costs to the community.[1,24–26] Followers of manual therapy argue that the discipline to some extent offers a solution to this problem. However, this mode of therapy is controversial and its possible efficacy is not yet considered satisfactorily documented.

Short-term effects achieved by manual therapy have been demonstrated in some trials,[8,13,15,28,29,31] but possible long-term effects have yet to be demonstrated. For this reason, a randomized clinical trial was performed in patients with low back pain that compared the effect of manual therapy with that of conventional treatment.

From the *Department of Family Medicine, Uppsala University, Uppsala, The Skönvik Rehabilitation Clinic, Säter, and †The Orthopedic Clinic, Falun Hospital, Falun, Sweden.
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In previous publications or in articles submitted for publication,[2–6] the first indications of a long-term effect of manual therapy were demonstrated. A significantly larger reduction of sick leave was demonstrated in the manual therapy group compared to the conventionally treated group. 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 and disability rating score—measured by mailed questionnaires after 1, 2, and 4 months—in favor of the group that received manual treatment were demonstrated as well. The treatment effect also was evaluated in a single-blind manner by standardized telephone interviews at 3, 7, 14, 21 and 90 days. The group that received manual therapy had significantly less pain, less disability, a faster rate of recovery, and less drug consumption. Improvement in the quality of life was significantly greater in the experimental group than in the conventionally treated group at 4 months' follow-up.

There has been no general agreement about whether manual therapy has short- or long-term effects on acute or subacute low back pain. The hypothesis tested in this report is that a pragmatic approach to low back pain, including the use of manipulation, specific mobilization, muscle stretching, specific home exercises, autotraction, and cortisone injections, can reduce patients' suffering from low back pain more effectively than the conventional treatment approach in primary health care. If there are no differences between the treatment groups, investigating the individual items is meaningless.

## Study Population and Methods

The study was performed as a multicenter trial in Kopparberg County, Sweden, February 1988 through April 1989. Six primary healthcare or occupational health care centers, representing a catchment area of 56,000 residents, and the Skönvik Rehabilitation Clinic participated. All patients attending the primary healthcare or occupational health care centers who fulfilled the inclusion criteria for the study were entered. Only

a few patients declined to participate, most frequently because of the long travel time between home and the Skönvik Rehabilitation Clinic.

The criteria for inclusion were the following.

Age 20–60 years.

Conditions with acute or subacute low back pain with or without pain radiating to one or both legs that does not require surgical or rheumatological treatment. Patients with proven or suspected herniated disk 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. Thus, patients with milder chronic symptoms were included, as long as they did not need 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 that might jeopardize completion of treatment and follow-up (e.g., alcoholism or severe psychiatric disorders).

At the first meeting with the patient, a preliminary assessment of the criteria for inclusion was made by the nurse. The final decision was made by the general practitioner (GP) at the first consultation, after which the patient received standardized information regarding the study. The patients were told that rapid treatment was guaranteed in both study groups—there normally were waiting lists for physiotherapy at the centers. After the patient agreed to participate, answered the questionnaires, and underwent the 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). 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.[2,3] The participants accepted and fulfilled the offered treatment, except in one case 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. Those in the conventionally treated group were treated at the health care center where they were recruited. In the present report, the treatment in the two groups is described only briefly. A more detailed description was given previously.[2,3,5]

Two physicians were involved. SB treated all the patients, and three therapy-resistant patients were seen by Dr. Franz Mildenberger (the head of Skönvik Rehabilitation Clinic). SB mainly used techniques and home exercises (muscle stretching) according to Evjent/Hamberg,[10–12] Mitchel,[23] and Kaltenborn/Evjent.[17] The therapy also had much in common with the techniques described by Lewit,[19] Janda,[16] and Stoddard.[30] All patients were treated with thrust techniques or specific mobilization. A modified technique for treating dysfunctions of the sacroiliac joint according to Kubis[18] was essential. Fifteen percent of the patients were treated with autotraction.[20,27] Among the patients not responding to manual therapy during the first 1–2 weeks, 26 (54% of the experimental group) had painful paracoccygeal structures (possibly the sacrotuberous and sacrospinal ligaments) through per rectum palpation[9,22] or in the insertion on the greater trochanter of the piriformis muscle, where steroid injections, "needling,"[19] and local anesthetics were given. No injections were given during the first week. Treatment also was performed by seven physical therapists, more or less specialized in manual therapy. Except for 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.

The control 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. Except for a few patients who recovered within days after the randomization, all patients received treatment provided by 17 physical therapists (2–3 per center). The patients were assessed by the physical therapists and the modalities were chosen according to need. All staff that participated in the conventional treatment were trained in similar therapeutic techniques and diagnostic items. The therapeutic strategy was activation of the patients—an approach that included informing the patients of the benign character of the condition and the adverse effects of inactivity and sick-leave, and that encouraged them to participate in physical and other activities. This approach is consistent with modern official recommendations for low back pain management in Sweden. In addition, they received drugs, verbal and written ergonomic advice, 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, 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 were indicated. The patients in the experimental group were seen by the physician 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 previous visit). They were treated individually by a physical therapist an average of 2.0 times. Nineteen percent of the patients also had 0.8 group treatments per patient (Medical Training Therapy[14]).

The patients in the control group were seen 3.8 times by a doctor and had physical therapist treatment 8.6 times—6.8 times individually and 1.8 times in groups. Eighty-nine percent received individual physiotherapy compared to 56% in the experimental group. The estimated total duration of treatment in the experimental group for the physician was 90 minutes and for the physical therapists an average of 1 hour. The total duration of treatment in the control group for the physicians also was 90 minutes and for the physical therapists more than 3 hours.

Thirty-three percent of the experimental patients and 8% of the control patients did not see a physical therapist, mostly because of rapid recovery. The experimental patients were

**Table 1. The Evaluating Orthopedic Surgeons and Their Percentages of Examined Patients (n = 98)**

| | Conventionally Treated Group (%) | Experimental Group (%) | Total (%) |
|---|---|---|---|
| EB | 78 | 67 | 74 |
| KG | 8 | 20 | 13 |
| GH | 8 | 7 | 7 |
| US | 6 | 4 | 5 |
| BJ | 0 | 2 | 1 |

treated almost exclusively during the first 1–3 weeks; the control patients received continuous treatment to a larger extent.

**Measures of Efficacy.** A standardized physical examination was carried out at the beginning of the study by the GPs at their primary healthcare centers and after 4 months at the Rehabilitation Clinic of Skönvik by independent orthopedic surgeons, chosen by the head of the Falun Orthopedic Clinic (GH). Table 1 shows the percentages of patients whom the five evaluating orthopedic surgeons examined at four months' follow-up.

The involved GPs were cotrained under the direction of SB; the physical examination was virtually a traditional orthopedic examination. The orthopedic surgeons were informed by KG and SB. Radiating or local pain provoked by movement and pseudoradicular or radicular pain were stated by the participants. The other findings were observed by the physicians without the use of instruments such as a kyphometer or a goniometer. The straight leg raising test (SLR) was considered positive if raising the leg provoked pain in the lifted leg or in the contralateral leg or in the lower back. If the patient merely experienced tightness in the hamstrings without pain, the test was considered negative.

An intragroup comparison over time was performed. The initial value for each variable was compared to the four months' value, and the change is presented as improvement over time.

A low back examination score and a corresponding score regarding neurologic findings were calculated for each patient. The findings were differently weighted to constitute appropriate scores. Each finding noted in Table 2 was counted as one point. The remaining findings were counted as one, two, three, four, or five points each, according to Table 3. The points were summarized for each patient into a score (range 0–36). The score regarding neurologic findings ranged from 0 to 10. Patellar or Achilles reflex weaker on one side than the other, weak big toe extensor, decreased leg strength, inability to walk on toes or heels, and disturbed sensibility were counted as one point. If present on both sides, the finding was counted as two points. The presence of true radicular pain was counted as three points (six points if bilateral).

After completing the examination, the orthopedic surgeon marked in a questionnaire which of the two treatment groups he thought the patient belonged to. If he had no opinion, he was asked to guess. He finished by asking the patient if he or she had attended therapy during the follow-up other than that intended in the respective treatment groups.

**Table 2. Findings Upon Physical Examination—Restricted or Painful Lumbar Mobility**

| | Initial (%) | | | At Four Months (%) | | | Change Over Time (%) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Conv | Exp | *P* | Conv | Exp | *P* | Conv | Exp | *P* |
| Restricted | | | | | | | | | |
| Flexion | 60 | 77 | NS | 17 | 24 | NS | 72 | 69 | NS |
| Extension | 34 | 44 | NS | 29 | 11 | 0.048 | 15 | 75 | 0.035 |
| Side-bending | | | | | | | | | |
| To the right | 45 | 44 | NS | 29 | 7 | 0.008 | 36 | 86 | 0.006 |
| To the left | 43 | 46 | NS | 33 | 9 | 0.007 | 23 | 84 | 0.003 |
| Local pain caused by | | | | | | | | | |
| Flexion | 64 | 85 | 0.025 | 27 | 17 | NS | 58 | 80 | NS |
| Extension | 45 | 60 | NS | 33 | 13 | 0.038 | 27 | 78 | 0.032 |
| Side-bending | | | | | | | | | |
| To the right | 49 | 44 | NS | 33 | 9 | 0.007 | 33 | 80 | 0.009 |
| To the left | 38 | 50 | NS | 27 | 13 | NS | 29 | 74 | NS |
| Pain radiating to the right leg caused by | | | | | | | | | |
| Flexion | 19 | 25 | NS | 10 | 4 | NS | 47 | 84 | NS |
| Extension | 15 | 6 | NS | 4 | 2 | NS | 73 | 67 | NS |
| Side-bending | | | | | | | | | |
| To the right | 15 | 10 | NS | 2 | 0 | 0.044 | 87 | 100 | NS |
| To the left | 13 | 15 | NS | 2 | 0 | 0.044 | 85 | 100 | 0.045 |
| Pain radiating to the left leg caused by | | | | | | | | | |
| Flexion | 19 | 19 | NS | 2 | 4 | NS | 89 | 79 | NS |
| Extension | 11 | 4 | NS | 4 | 2 | NS | 64 | 50 | NS |
| Side-bending | | | | | | | | | |
| To the right | 8 | 8 | NS | 4 | 0 | NS | 50 | 100 | NS |
| To the left | 8 | 10 | NS | 2 | 2 | NS | 75 | 80 | NS |

**Table 3. Findings on Physical Examination—Observed Signs, Palpation, and Straight Leg Raising Test (SLR)**

| | Initial | | | At Four Months | | | Change Over Time | | |
|---|---|---|---|---|---|---|---|---|---|
| | Conv | Exp | *P* | Conv | Exp | *P* | Conv | Exp | *P* |
| Lameness due to low-back pain (%), 3 | 31 | 33 | NS | 8 | 2 | NS | 74 | 94 | NS |
| Severe pain scoliosis (%), 3 | 8 | 13 | NS | 0 | 0 | NS | 100 | 100 | NS |
| Severe observed pain influence (%), 3 | 4 | 13 | NS | 0 | 0 | NS | 100 | 100 | NS |
| Observed stiff mobility pattern (%), 2 | 2 | 13 | NS | 2 | 2 | NS | 0 | 85 | NS |
| Observed difficulties in walking (%), 2 | 15 | 31 | 0.016 | 2 | 2 | NS | 87 | 94 | NS |
| Pronounced lumbar lordosis (%) | 2 | 6 | NS | 0 | 4 | NS | 100 | 33 | NS |
| Lumbar spine flattened (%), 2 | 38 | 44 | NS | 2 | 7 | NS | 95 | 84 | NS |
| Lumbar scoliosis (%) | 21 | 27 | NS | 12 | 22 | NS | 43 | 19 | NS |
| Lumbar spine tenderness (%) | | | | | | | | | |
| Interspinal, 1 | 36 | 42 | NS | 14 | 11 | NS | 61 | 74 | NS |
| Paravertebral | | | | | | | | | |
| Right, 1 | 40 | 35 | NS | 23 | 11 | NS | 43 | 69 | NS |
| Left, 1 | 45 | 38 | NS | 17 | 15 | NS | 62 | 61 | NS |
| Tender sacroiliac joint (%) | | | | | | | | | |
| Right, 1 | 34 | 35 | NS | 27 | 17 | NS | 21 | 51 | NS |
| Left, 1 | 21 | 23 | NS | 15 | 11 | NS | 29 | 52 | NS |
| Positive SLR (%) | | | | | | | | | |
| Right, 4 | 19 | 40 | 0.037 | 17 | 9 | NS | 11 | 78 | NS |
| Left, 4 | 15 | 25 | NS | 15 | 7 | NS | 0 | 72 | 0.029 |
| SLR (degrees), mean* | | | | | | | | | |
| Right leg | 84 | 76 | 0.025 | 84 | 88 | NS | 0 | 16 | 0.009 |
| Left leg | 84 | 81 | NS | 86 | 88 | NS | 2 | 9 | NS |
| Pseudoradicular pain (%) | | | | | | | | | |
| Right leg, 4 | 9 | 21 | NS | 4 | 2 | NS | 56 | 90 | NS |
| Left leg, 4 | 8 | 8 | NS | 6 | 2 | NS | 25 | 75 | NS |
| True radicular pain (%) | | | | | | | | | |
| Right leg, 5 | 8 | 13 | NS | 4 | 2 | NS | 50 | 85 | NS |
| Left leg, 5 | 4 | 13 | NS | 2 | 2 | NS | 50 | 85 | NS |
| Trendelenburg (%), 3 | 6 | 6 | NS | 4 | 2 | NS | 33 | 67 | NS |

1, 2, 3, 4, and 5 = 1, 2, 3, 4, and 5 points in low-back examination score, respectively. * Increased value over time means improvement.

**Drop-Outs.** Three patients (one control patient and two patients in the experimental group) did not attend the final examination despite being reminded by mail and phone.

**Parallel Therapy.** Eight percent of the patients in the control group had received parallel treatment other than that provided by the GPs and the physical therapists, mainly by chiropractors or doctors of naprapathy. In all cases, this was known by the GPs or the physical therapists and had been reported to SB earlier. No experimental patient received parallel therapy.

**Statistical Analysis.** Summary statistics were computed using standard methods. Possible differences were tested with Student's *t* test and Pitman's nonparametric permutation test.[7] The latter has the advantage in that no assumptions need 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-squared test.

Analyses of change over time that take differences in initial values into account were performed as multivariate analyses with Pitman's nonparametric permutation test in its multivariate form. In these analyses, the study population was subdivided into groups according to the initial value. Differences at 4 months between the groups then were tested in each of these groups. Subgroup *P* values were computed and then pooled to an overall *P* using the Mantel-Haenszel procedure. This allowed the confounding effect of differences in initial values to be taken into account.

Only two-tailed tests were used. *P* values less than .05 were generally regarded as indicating statistical significance.

## ■ Results

### *Physical Examination*

Findings upon physical examination at baseline and after 4 months' follow-up are shown in Tables 2 and 3. Data on descriptive measures, such as findings in parts of the locomotor system other than the lower back and neurologic findings, are available from the authors upon request.

Statistically significant differences regarding initial data were found for four variables: 1) local pain provoked by lumbar flexion (Table 2); 2) observed difficulties concerning certain everyday situations (sitting, walking, standing, lying down, standing up from sitting position, and turning around in the lying position); 3) positive SLR test right leg (Table 3); and 4) average angle SLR right leg (Table 3). The experimental group was more affected than the group that received conventional treatment. These significant differences disappeared during the follow-up.

At the study start, all patients had restricted movement in one or more directions. The figures for decreased mobility generally were slightly lower than the frequency of mobility that caused pain, which means

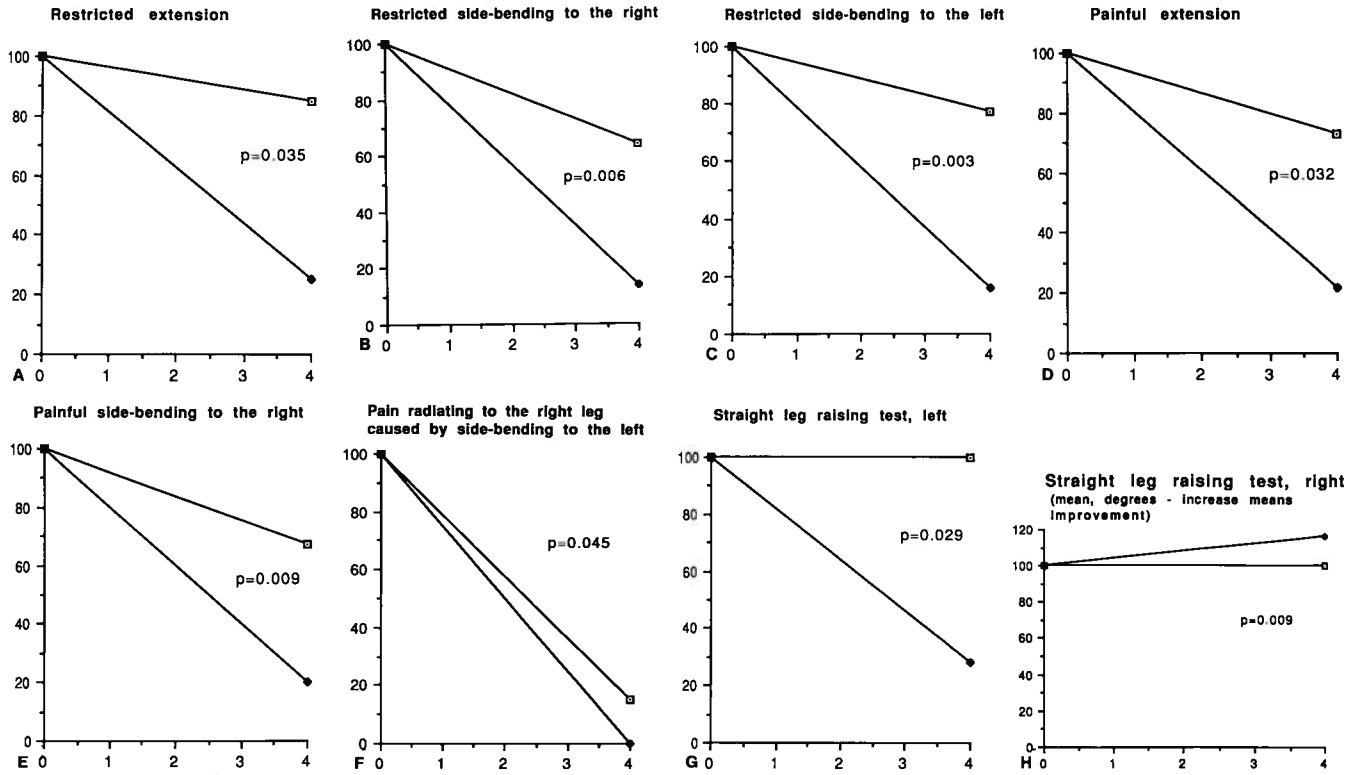


Figure 1. Percent change over time, with eight physical examination items on the vertical axis and months of follow up on the horizontal axis. Unfilled squares represent the conventionally treated group, and the black squares represent the experimental group.

that some patients had normal but painful mobility. This applies to all registered movement directions (flexion, extension, side-bending to the right and to the left).

There were large differences in favor of the experimental group at 4 months' follow-up, and significant differences were found for five out of eight variables for mobility and painful mobility (restricted range of movement in extension, side-bending to the right and to the left, local pain caused by extension and side-bending to the right; Table 2). If we consider the significant initial difference for painful flexion as well, there were significant differences for six out of eight variables regarding mobility and painful motion.

Radiating pain provoked by motion was rather infrequent in both treatment groups (the highest scores on forward flexion; Table 2). Significant differences after 4 months were found only for pain radiating to the right leg caused by side-bending to the left and to the right. However, when the initial differences between the groups were taken into account, only the difference for pain radiating to the right leg caused by side-bending to the left was significant (Table 2, right column). Few neurologic signs and few findings in the lower extremities and other parts of the vertebral column were found. Differences concerning change over time in favor of the experimental group were found for almost all variables (Tables 2 and 3). Six of the eight significant differences already had been found before the differences in initial data were taken into account. The two additional significant changes concerned the proportion of patients with positive SLR left side and SLR right side. The eight variables with significant changes over time are presented in Figure 1 as well; the baseline values are put at 100%, and at 4 months the numeric values are similarly transferred into percentages.

In Table 4, the low back examination score and

**Table 4. Low-Back Examination Scores and Neurologic Examination Scores Presented As Means in the Two Groups**

| | Initial | | | At Four Months | | | Change Over Time | | |
|---|---|---|---|---|---|---|---|---|---|
| Points | Conv | Exp | *P* | Conv | Exp | *P* | Conv | Exp | *P* |
| Low-back examination score | 11.6 | 15.7 | 0.023 | 5.8 | 3.1 | NS | 50 | 80 | 0.026 |
| Neurologic examination score | 0.9 | 1.5 | NS | 0.8 | 0.3 | NS | 11 | 80 | NS |

**Table 5. Evaluation of the Blinding Procedure**

| | Correct Group Indicated | | |
|---|---|---|---|
| | Convinced (%) | Guessed (%) | Total, CI (%) |
| Conventional | 33 | 29 | 62 (49–75) |
| Experimental | 20 | 28 | 48 (34–62) |
| Total | 26 | 29 | 55 (45–65) |

CI = confidence interval.

neurologic examination score are presented as means for the two groups at baseline and at 4 months with analysis of change over time. The low back examination score was significantly higher in the experimental group than in the conventionally treated group at baseline. There was no significant difference between the treatment groups after four months. The considerably larger decrease over time (80%) in the experimental group than in the conventionally treated group (50%) was significant. For the neurologic examination score, there was a similar but nonsignificant trend ($P = 0.078$).

The separate effect of manual therapy and steroid injections were evaluated. There were highly significant differences between the two treatment groups in favor of manual treatment after 3, 5, 7, and 14 days.[2,4] Major effects of the steroid injections were not expected until the third week. No injections were given during the first week, and maximum clinical effects were expected after 2–3 weeks.

### *Evaluation of the Blinding Procedure*

The results from this procedure are shown in Table 5. After completing the examination, the orthopedic surgeon marked in a questionnaire which of the two treatment groups he thought the patient belonged to. This allowed him to associate 26% of the total population with the right group. If the evaluating doctor had no opinion at all, he was asked to guess, allowing him allocate a further 29% of the total population to the right group. Thus, 55% of the total population was correctly allocated.

## ■ Discussion

In the present study, strenuous efforts were made to keep potential bias under control, and no obvious bias affected the conclusions. This is discussed in detail in other reports.[2–4] Some differences in baseline characteristics were found, as expected. Overall, these differences favored the conventionally treated group, as shown in the present report and in previous reports.

The drop-out rate (3%) in this investigation is negligible. Eight percent of the control patients and none in the experimental group received parallel therapy by chiropractors or doctors of naprapathy during the first 4 months of the follow-up period. This had no crucial influence on the results.

The study shows that manual therapy reduced the presence of clinical findings in a low back pain population more effectively than did conventional treatment supplied by primary health care teams. This is especially true for mobility and local pain provoked by low back movements; there were significant differences for five out of eight variables regarding mobility/painful motion. There was a significant difference for pain radiating to the right leg caused by side-bending to the left. Furthermore, the four significant differences in baseline data, indicating slightly more severe cases in the experimental group than in the conventionally treated group, disappeared during the follow-up. Because there were some differences between the groups in baseline data, it is important to ensure that the significant differences between the study groups at four months' follow-up were not just an effect of a slight difference between the groups at baseline becoming a little more pronounced during the follow-up. Consequently, an analysis of improvement over time was performed, in which two further significant differences between the two groups were found (positive SLR test left side and mean angle SLR test right side; Table 3) and four of the other six significant differences were enhanced in favor of the experimental treatment (Table 2). The significant difference after 4 months for pain radiating to the right leg caused by side-bending to the right depended on a difference in initial values between the groups. It is apparent from Figure 1 that the eight significant differences for change over time are considerable. The differences between the two groups at baseline and over time are clearly reflected by the low back examination score (Table 4).

Thus, we have used (in addition to subjective efficacy measures assessed by the patient) objective variables assessed by independent and unbiased observers. Objective variables, compared to subjective variables, drug consumption, sick-leave statistics, etc., have the advantage of being less likely to be influenced by factors such as the therapist's attitude and level of enthusiasm in patient contact or expectations of the patient. Some of the measures might have poor repeatability. However, because such a factor influences the two groups similarly, it has no influence on the results. The same is true for the uncertain relationship of these measures to pathology.

The mean SLR values are rather close to 90°, the reason being that the value for patients with negative SLR was set to 90°, which is according to common practice in Scandinavia. More values for SLR right side below 45° in the experimental group (strongly indicating suspected disk hernia) are responsible for the relatively slight (but significant) difference between the values presented in Table 3.

It is not self-evident that it is possible to perform a single-blind evaluation when the investigator is in close

contact with the patient during the long time required for a complete physical examination of the back and lower extremities. Also, because of necessary verbal instructions to the patient, it is not possible to avoid verbal communication between the patient and the evaluating physician completely. This has not been considered in previous investigations. The evaluating physicians were able to associate the patients with the right group in 55% of the total population (confidence interval 45%–65%; Table 5), implying that the orthopedic surgeons' guesses were random. In other words, the blinding procedure in this investigation was proven to be successful.

A problem with the design of our study is that the two groups were treated at different centers. In a multicenter study that involved six centers and 53 patients treated during 15 months, it was the only possible solution. However, we believe this had no major influence on the results. For technical reasons, it was not possible to have the same evaluating physicians at the start of the study and at the follow-up. There may be systematic differences regarding the diagnostic criteria of the GPs compared to the orthopedic surgeons. If one of the two categories of doctors underdiagnoses or overdiagnoses, it will influence the slope of recovery over time graphs. However, it will not affect our results because the possible effect will be the same in both treatment groups. Furthermore, the GPs were thoroughly cotrained after discussions with and instructions from one of the orthopedic surgeons (KG) on this aspect. This produced a homogeneous group of recruiting doctors who should not have diagnosed very differently from the evaluating physicians.

The principle of allowing a complete manual therapeutic arsenal in the experimental group, emulating clinical reality, was essential to the positive outcome of manual therapy in this trial. We do not believe that any of the single items in this therapeutic arsenal have the corresponding positive effects on low back pain, especially regarding long-term effect. The different items might even have a "synergistic" effect, not merely an additive effect. This approach might be the only available treatment that has a long-term effect on low back pain. Because doubt surrounds whether there is any effective medical treatment for low back pain at all, aside from surgery on the herniated disk,[26] it is necessary to evaluate a complete therapeutic arsenal first.

In the case of positive results for the experimental treatment, as in our study, future studies could look more closely at the different items. The importance of steroid injections is investigated in another trial that began in February 1992.[21] In some other trials,[8,13,15,28,31] placebo treatment (which was not likely to be distinguished by the patient from the real therapy) was used in the control group, or thoroughly evaluated objective measuring methods were applied. Thus, documentation of a real therapeutic effect somewhat related to double-blinding was achieved. These studies make it unnecessary to perform further studies that try to separate the placebo effect from the true effect by double-blinding with sham therapy as control treatment. There is no reason to believe that the specific techniques used in the present trial lack such a true therapeutic effect.

Using mock therapy as control treatment leads to methodological difficulties and conditions too far from the clinical reality, which largely eliminates the possibility of demonstrating the effect of manual treatment, especially when it comes to evaluating the long-term effect. Furthermore, treatment volume is very important and in the present study was considerably larger in the conventionally treated group than in the experimental group.

An essential component of this arsenal might be the steroid injections, which have not been used with manual treatment in previous investigations. According to the theoretical model of the manual treatment applied in this trial, there are common pain focuses secondary to the primary pelvic or lumbar spine dysfunctions, not the least of which are paracoccygeal structures and the insertion on the greater trochanter of the piriformis muscle. In many cases, the only causal therapy with a rapid effect on noziception from these foci appears to be steroid injections or needling.[20] Correction of pelvic dysfunctions by manual therapy seems to aggravate existing irritation, especially in the paracoccygeal structures. This mechanism is believed to be responsible in most cases where the normalization of pelvic/lumbar dysfunction does not lead to rapid subjective improvement or where it even aggravates the patient's symptoms for weeks and sometimes longer.

One could argue that the positive results of the experimental treatment in the present study depended on the steroid injections only and that the manual therapy was ineffective. That there were highly significant differences between the two treatment groups after 3, 5, 7, and 14 days[2,4] speaks against this belief, because major effects of the steroid injections are not expected until the third week. No injections were given during the first week, and maximum clinical effects were expected after 2–3 weeks because of the slow release of the steroid used (Lederspan, triamcinolone).

On the assumption that the doctor performing the manual therapy (SB) was enthusiastic and believed strongly in his treatment, whereas the GPs representing the conventional treatment might have been less involved, it could be argued that our findings can 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,[2–6] and in evaluation by blinded and independent orthopedic surgeons quells speculations that the positive treatment effect in this trial could be fully explained by a charisma factor in the experimental treatment.[2,3] Furthermore, it should be

noted that almost all "succeeded cases" in the latter group were treated during the first 1–3 weeks of the study. The differences between the two groups for the majority of the efficacy measures also increased after 2 months of follow-up, despite that the experimental group got no further treatment, in contrast to the conventionally treated group.[2–6] A reproducibility study now is being conducted in which the GPs were educated in manual therapy by SB.[21]

## ■ Conclusions

The results of this study show that manual therapy with cortisone injections is superior to conventional activating treatment in primary healthcare in terms of reducing objective findings low back pain upon physical examination of patients. These results agree with the positive influence on pain, drug consumption, sick-leave, disability rating, and quality of life reported in other studies of the same population.[2–6] The manual treatment appeared to be less costly despite the better treatment results, because the treatment volume was considerably less in the experimental group than in the conventionally treated group.

The difference in objective measures between the two groups after relatively long follow-up, (as assessed by unbiased and independent orthopedic surgeons), despite that the conventionally treated group received continuous treatment during the follow-up more so than the manual group, implies a lasting treatment effect that cannot be explained solely as an expectation or charisma effect. The same is indicated by persistent long-term differences concerning sick-leave frequency, even after 8 months' follow-up.

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*Address reprint requests to*

Dr. Stefan Blomberg
*Department of Family Medicine*
*Academic Hospital*
*S-751 85 Uppsala, Sweden*