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Manipulative Therapy Versus Education Programs in Chronic Low Back Pain

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Study Design. A randomized trial was conducted on a representative sample of patients with untreated low back pain lasting 7 weeks or longer, or having more than 6 episodes in 12 months.

Objectives. To contrast the effectiveness of manipulation, a manipulation mimic, and a back education program. Methodologic criticisms of earlier studies were addressed.

Summary of Background Data. Published meta-analyses suggest clinical benefit from manipulation for acute patients. Data are inconclusive for patients having symptoms for longer than 1 month.

Methods. A total of 1267 consecutive patients were screened. Block randomization was used to assign 209 qualifying patients to treatment groups. Self-reported pain and activity tolerance served as primary outcome measures. Patients were assessed at enrollment, after 2 weeks of treatment, and again after 2 weeks without treatment. Multiple teams conducted recruitment, randomization, assessment, treatment, and data analysis independently without sharing information. Treatments were carefully described, monitored, and balanced for physician attention and physical contact effects.

Results. A total of 81.3% of subjects completed the study. Confounding factors and missing data were identified in approximately 20% of those completing the final follow-up. Analysis of the remaining data was carried out. A strong time effect under treatment was observed. Greater improvement was noted in pain and activity tolerance in the manipulation group. Immediate benefit from pain relief continued to accrue after manipulation, even for the last encounter at the end of the 2-week treatment interval.

Conclusion. Time is a strong ally of the low back pain patient. In human terms, however, there appears to be clinical value to treatment according to a defined plan using manipulation even in low back pain exceeding 7 weeks' duration. [Key words: chronic low back pain, education programs, manipulation, randomized trial] **Spine 1995;20:948–955**

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The effectiveness of spinal manipulative therapy in the treatment of low back pain has been of increasing clinical interest during the past two decades. The analysis of recent research favorable to manipulation,[2,33] and the current emphasis on clinical outcomes from treatment of spinal pain patients, has resulted in a reconsideration of this mode of treatment. Evaluating the benefits from this type of treatment procedure has been difficult because of the diversity in research study methods and reporting. Specialized techniques for blending published research materials have been required[2,33] but are limited, for the most part, by the availability of research material to the topic of acute episodes of low back pain. Shekelle et al[33] reviewed 58 articles including 25 clinical trials, using techniques of meta-analysis. They concluded that manipulation resulted in a 34% improvement in recovery within 3 weeks of the start of therapy for acute low back pain when compared to various types of control groups.

Only five clinical trials have been located in the literature that have focused on the treatment of chronic low back pain patients.[3,17,24,32,39] All but one of these reports found significant favorable effects of treatment for at least one outcome parameter. It is more difficult to settle the question of benefits to the chronic low back pain population from using spinal manipulative therapy because of the methodologic diversity and limitations of such a small number of studies. The data on treatment for chronic low back pain are insufficient to support or refute its effectiveness.

Criticisms of past studies have included 1) relatively small sample sizes[2,9,16,25,28,29]; 2) uncertainty on responsiveness of outcome measures to expected clinical changes[14,25,38]; 3) generalizability of treatment procedures used[16,17,19,21,25,29]; 4) ambiguity in sample clinical characterizations[4,9,12,14,16,21,25]; 5) comparability of physician–patient contact time[1,14,26,36]; and 6) blinding of participants and investigators.[1,4,9,16,29] The current study was designed to evaluate the clinical effectiveness of spinal manipulative therapy alone for chronic low back pain patients when contrasted against two alternate treatment groups. Both were used as controls to account for the ambiguities of previous studies. The alternate treatment modes included a low-force manipulation mimic and a back education program.

Methods

A total of 1275 consecutive new patients with a presenting complaint of mechanical low back pain were screened for recruitment into this study. New patients were defined as those consulting the clinic for the first time or those who had abstained from treatment for the previous 6 months. Each of these patients was screened for eligibility. The inclusion criteria required a minimum age of 18, and pain anywhere from L1 to L5 and the sacroiliac joints, inclusively. Nonradicular extremity pain was permitted. Duration of symptoms longer than 50 days or a history of 6 or more episodes in the preceding 12 months was necessary to establish chronicity. On examination, each patient had to experience palpatory tenderness over one or more zygapophysial articulations. Patients were excluded from the study if they had evidence of neuropathy, systemic disease potentially affecting the musculoskeletal system, severe osteoporosis, fracture, or osseous pathology of the spine. Persons taking medication on an irregular schedule, receiving other treatment intended to relieve symptoms associated with their low back pain, and those involved in worker's compensation or pending litigation claims were similarly excused.

Every effort was made to ensure that investigators were masked, by establishing separate evaluation and treatment teams that were rigorously segregated in terms of duties and familiarity with patient information. Patient screening for candidacy was carried out by team 1. Recruitment, primary outcome measures, and administration of the randomized treatment assignment tables were the responsibility of team 2. Secondary outcome measures were obtained by team 3. Treatment was administered by team 4 according to random assignment. Finally, data analysis was carried out at the end of the study by team 5, which consisted of the principal investigator and project methodologist. No information crossed team boundaries with the exception of the methodologist who participated on teams 2 and 5.

From a total of 366 (366 of 1275; 28.7%) patients who qualified, 209 patients agreed to participate. The patients were assigned for treatment using a block randomization scheme constructed before the study was begun, and retained by an administrator independent of the study teams who relayed the next assignment in sequence on confirmation of informed consent for each subject. Treatment allocation resulted in patient placement into one of three groups: 1) high velocity, low amplitude spinal manipulation (HVLA); 2) high velocity, low force (HVLF) mimic; and 3) a back education program (BEP). High velocity, low amplitude spinal manipulation, and HVLF procedures were applied to the lumbar and pelvic site or sites that, in the opinion of the treating physician, defined the area of lesion. HVLF procedures were intended to balance the study design to account for physician contact and the physical handling of the patient, a potential source of bias for previous studies. The HVLF mimic was limited to use at one site to avoid potential accumulation effects. The BEP training was expressly conducted with no physical contact or administration of individualized exercises, and with organization of physician–patient interaction time to be comparable to that of the HVLA and HVLF treatment procedures.

Manual manipulation of the spine can be characterized by four primary elements: patient positioning, location of applied load, peak velocity of loading that is achieved, and peak load developed. The total displacement of body segments (*i.e.*, pelvic girdle or torso) is believed to be a property controlled by a combination of patient positioning and peak load. The HVLA method was chosen from approximately 45 types of diversified lumbar procedures available for treatment of low back pain.[5] Its selection was guided by its common usage among chiropractic health care providers. For the HVLA, the patient was placed in a lateral decubitus posture close to the leading edge of the treatment table. The free leg, not resting on the table, is flexed at the knee and the pelvis to cause a relative flexion of the lumbar spine.[10] As this leg is unsupported by the table, it causes a relative moment to develop around the long axis of the spine (manuscript in preparation). Loading of the spine can be achieved through several contacts. We opted for common contact sites, dependent on spinal level, several centimeters lateral to the spinal axis. Loads applied through such locations have the potential to induce further axial moments. The amplitude of the loading impulse is controlled by the intent of the treating physician.

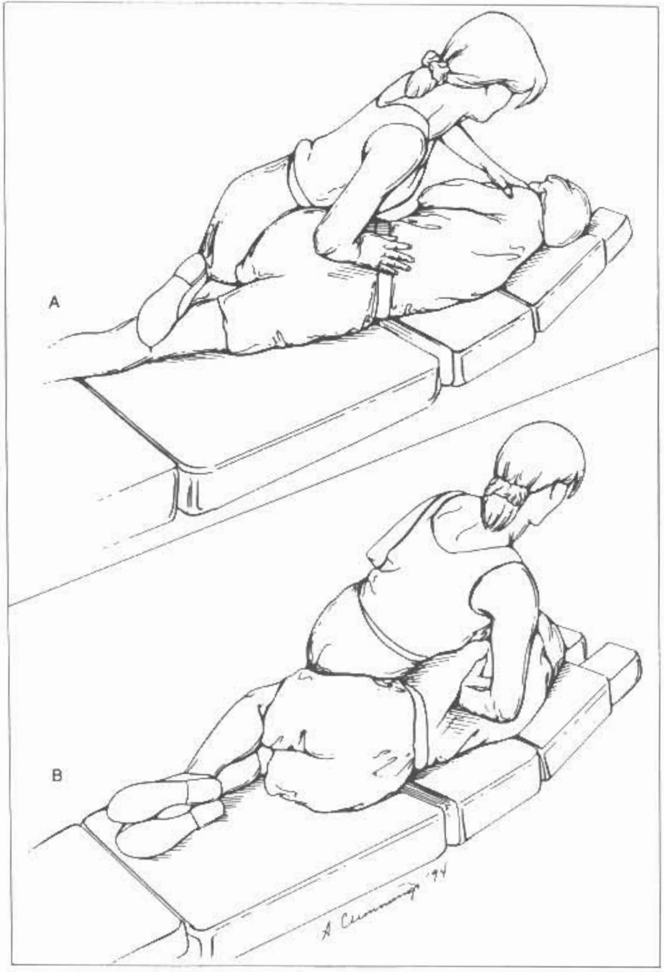

Figure 1. The high velocity, low amplitude spinal manipulation procedure (**A**) patient positioning with paraspinal load to enhance axial spine torsion. The high velocity, low force spinal manipulation procedure (**B**) moves the patient away from the provider, bends both knees and applies load in the mid-sagittal plane.

Figure 1 shows the elements of the procedure that were varied to permit development of the HVLF mimic as a control for physician–patient contact effects. Specific modifications were made in terms of patient positioning, location of the applied load, and peak load developed. The HVLF mimic was designed to minimize both the magnitude of applied load and the potential for moment development around the longitudinal axis of the spine. The patient was positioned toward the center of the table with legs bent bilaterally. The biomechanical effect of this adaptation was twofold. First, it reduced the mechanical advantage that could be exerted by the treating physician by requiring a greater reach distance and minimizing the ability to use his/her body weight when administering the treatment. Second, the modified position gave support to both lower extremities so that no additional relative moment could develop from the action of the body segment masses. Similarly, the site of loading application was moved from its usual paraspinal location to one coincident with the long axis of the spine.

Earlier work[7,8] with manipulation showed the difference in peak amplitude of force between HVLA and HVLF procedures was accompanied by a distinction in responsiveness of polymorphonuclear neutrophils to a particulate challenge lasting for 15–45 minutes. Based on this previous experience, the peak amplitude of force was used to determine a biomechanical cutoff operationally defining HVLA and HVLF procedures. Participating chiropractic physicians were trained to deliver loads that developed forces either above (HVLA) or below (HVLF) 400 N at will. Using a specially developed load sensing table, each provider rehearsed treatment techniques to be able to reliably deliver the requisite procedure as needed. Throughout the duration of the study, each physician was tested on an aperiodic schedule for adequate performance and skill in delivery of the requisite forces. During the initial phase of the study, blood samples were collected on a random schedule by members of team 3 from every patient assigned to the HVLA and HVLF groups 15 minutes before and 15 minutes after treatment. The treating physician was unaware of the day the blood sample was to be collected. Samples were transported to the laboratory where the respiratory burst was determined using the chemiluminescent response to a particulate challenge as previously described.[7,8] This quality control showed the modifications of the HVLF to be highly successful and further biologic testing was discontinued after 8 months.

The BEP treatment group was intended as a contrast for the physical contact between provider and patient that is offered by both the HVLA and HVLF mimic procedures, while maintaining physician attention. The elements of the BEP included attractive, color graphics coupled with common anatomic and biomechanical information on spinal function and hygiene. Each treatment session consisted of a didactic presentation conducted with physical separation between patient and provider. Salient features of the lesson were contained on information sheets that were given to the patient. Exercise was described in general terms, but none were specifically recommended.

Treatment sessions[11] were scheduled at the onset of subject participation during a 2-week interval. Sessions were held daily, on the basis of a 6-day/week clinic schedule. A requirement for subject data inclusion for the analysis was an adherence to the scheduled interval within a 72-hour window. A predetermined criterion of patient compliance was set at attendance to seven or more sessions. This definition was based on observance of common practice patterns, and ensured that

Table 1. Characteristics of Eligible Members of the Sample Population According to Agreement to Participate in the Study

Characteristic		Participants			Nonparticipants		
		Number	Mean	SD	Number	Mean	SD
Gender	Male	113			83		
	Female	96			74		
Age		209	41.6	14.7	157	43.1	15.3
Height		208	67.5	4.3	139	67.1	3.9
Weight		209	179.7	38.5	141	173.1	40.8
Oswestry		202	17.6	14.2	141	20.2	16.2
VAS		206	38.9	24.1	154	41.8	24.3
Zung		194	15.6	7.3	140	14.9	8.5

No statistically significant differences were found between participants and nonparticipants.
SD = standard deviation, VAS = visual analog scale.

the treatment protocol would provide a minimum of comparable case management. Outcome measures quantifying patient status were obtained before initiation of treatment, at the time of the last treatment 2 weeks later and, after an additional 2-week follow-up interval during which the patient received no treatment for the low back region.

Three primary outcome measures designed to evaluate perceived pain, functional activity, and limited emotional status were selected on the basis of a feasibility study,[38] which confirmed the findings of Deyo[15] regarding their reliability and validity within our patient population. Patient self-report instruments were considered for primary outcomes because physical measures, *e.g.*, muscle strength and range of motion, are only weakly correlated with actual patient behavior or symptoms.[15] Behavior or symptoms, as perceived by the patient, need to be measured as directly as possible. The patient's perception of pain intensity was determined using a standard 100 mm visual analog scale (VAS).[27] Perceived limitations in activities of daily living as a result of pain were measured using the Oswestry Low Back Pain Disability Questionnaire.[18] Pain and activity scores for each sampling were screened for initial values less than 5%, which were excluded from analysis for the related sample time. The cutoff value was chosen on the basis of smallest discernible responsiveness of these outcome instruments from the feasibility study.[38] The relative level of psychologic depression was similarly estimated using the Modified Zung Depression Index.[20] Secondary outcome measures, including physical performance assessments and biologic parameters, were also obtained but are not a subject of this report. Analysis of the primary outcomes reported here was completed by using repeated measures analysis of variance (ANOVA) and ANOVA techniques.

Reliability of all three primary outcome measures was confirmed by intraclass correlation coefficient for results acquired before and after the initial patient assessment. The time separation between administration of the questionnaires for reliability was approximately 2 hours. During the interim, the patient was evaluated and recruited for the study without receiving treatment. Finally, short-term beneficial effects that might develop from individual treatment interventions were tested. For this purpose, primary outcome measures were obtained before and after the final treatment encounter. These were compared for changes associated with the treatment itself.

Table 2. Characteristics of Patients Completing the Study Versus Those Not Completing the Test Protocol

		Completing study			Dropping out		
Characteristic		Number	Mean	SD	Number	Mean	SD
Gender	Male	94			19		
	Female	76			20		
Age		170	42.0	14.4	39	39.7	15.7
Height		170	67.7	4.3	38	66.7	4.3
Weight		170	180.0	37.3	39	178.3	44.0
Oswestry		163	17.0	14.2	39	20.4	14.6
VAS		167	37.8	24.4	39	43.7	22.6
Zung		156	15.5	7.5	38	16.0	6.4

No statistically significant differences were found between participants completing the follow-up and those who did not.
SD = standard deviation, VAS = visual analog scale.

Results

A total of 366 patients met the criteria for inclusion in the study and 209 agreed to participate. From all three treatment groups, only 18.7% (7 HVLA; 14 HVLF; 18 BEP) elected to drop out of the study before completion. All 170 remaining subjects completed seven or more of the prescheduled treatment sessions with a mean of 10.5 (SD = 0.91). During the debriefing interview on completion of the study protocol for each participant, 25 patients were identified who had serious confounding factors. Types of confounding factors included unblinding of the participant, new trauma occurring during the intervening time between accepting the patient into the study and protocol completion, and cointerventions capable of altering results on study outcome measures. Examples include leg fracture and use of analgesics. Data from these subjects were eliminated from analysis, leaving a total sample population of 145 (62 women and 83 men). No statistically significant differences were found in those eligible to participate between those who agreed to be subjects in the study and those who did not (Table 1). Of those who agreed to participate, there were no statistically significant differences between those who eventually dropped out of the study and those who completed the final follow-up (Table 2). Profiles of the patients on whom complete data were available resembled the typical low back pain cases reported in the literature. The mean age of the total sample of 42.3 years (SD = 14.3). Mean height and weight were 67.7 inches (SD = 4.4) and 180.6 lb (SD = 37.4), respectively. No statistically significant differences were observed in patient height/weight ratios between treatment groups.

Data obtained within a 2-hour interval on the first visit without intervening treatment yielded high reliability by intraclass correlation coefficient. The values for the intraclass correlation coefficient for the VAS, Oswestry, and Modified Zung scores were 0.88, 0.95, and 0.86, respectively.

Measures of peak forces during aperiodic assessments of physician ability to provide HVLA and HVLF procedures on demand were collected throughout the conduct of the study. Mean magnitudes for the HVLA were 1008.0 (501.0) N whereas HVLF mimic procedures were found to be 212.0 (109.0) N. Using an unpaired Student t test, differences between them were statistically significant ($P = 0.000$). The mean after treatment *vs.* before treatment difference and associated standard error in the chemiluminescent response from the randomly sampled HVLA treatment group was 3.164 ± 0.682 peak counts/second/cell. For the random sampling of the HVLF treatment group, the mean difference and associated standard error was −0.435 ± 0.350 peak counts/second/cell. High velocity, low amplitude spinal manipulation versus HVLF treatment responses were found to be statistically significantly different from one another (Student unpaired $t = 4.593$; $P = 0.000$). These quality control data (Figures 2A, B) confirm that intended differences in HVLA and HVLF procedures were achieved.

Primary data analysis consisted of repeated measures ANOVA for the three equidistant sample times including the initial scores obtained before patient assessment, intermediate score at the end of the 2-week treatment intervention, and final score obtained at completion of the 2-week follow-up when no treatment was administered. Repeated measures ANOVA was undertaken for all three outcome scores; the Oswestry, VAS, and Modified Zung. Each completed questionnaire was examined for adherence to the instructions by the patient. If incorrectly filled out, the data were discarded from analysis. For the Oswestry, VAS, and Modified Zung, the

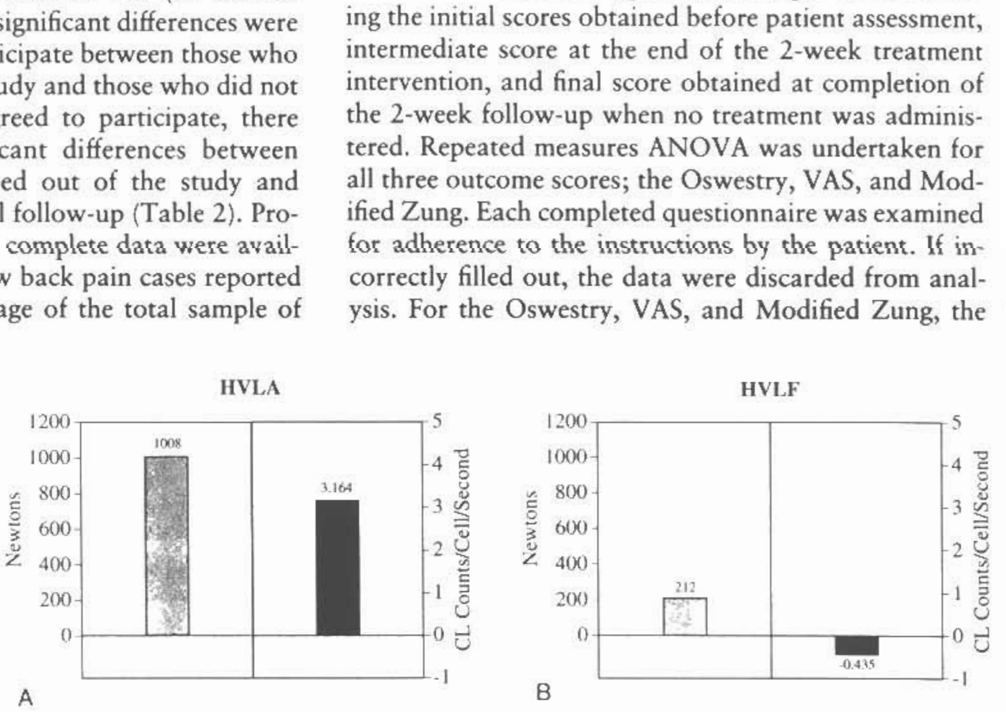

Figure 2. Mean peak amplitude of forces and change in polymorphonuclear neutrophil/chemiluminescent responses for high velocity, low amplitude spinal manipulation (**A**) and high velocity, low force spinal manipulation (**B**) procedures as determined from separate aperiodic samplings.

Table 3. Oswestry Disability Scores Obtained at Each Sample Time for Each Treatment Group

	Number*	IS	IMS	FS
HVLA	39	17.5 (12.8)	9.5 (6.3)	10.6 (11.7)
HVLF	40	21.7 (15.0)	15.5 (10.8)	14.0 (11.7)
BEP	38	20.2 (13.6)	12.3 (8.4)	11.4 (10.3)

* Number sizes vary according to the number of confounding cases eliminated. Mean and standard deviation (in parentheses).
IS = initial sample; IMS = intermediate sample after 2 weeks of treatment; FS = final sample after 2 weeks of treatment withdrawal; HVLA = high velocity, low amplitude manipulation, HVLF = high velocity, low force; BEP = back education program.
Differences between the groups at IMS are significant at $P = 0.012$.

Table 4. Visual Analog Pain Scores Obtained at Each Sample Time for Each Treatment Group

	Number*	IS	IMS	FS
HVLA	47	38.4 (23.4)	13.9 (15.3)	13.3 (15.9)
HVLF	39	37.4 (23.7)	19.8 (18.3)	21.7 (24.4)
BEP	43	35.6 (23.0)	19.6 (17.6)	15.1 (19.4)

* Number sizes vary according to the number of confounding cases eliminated. Mean and standard deviation (in parentheses).
IS = initial sample; IMS = intermediate sample after 2 weeks of treatment; FS = final sample after 2 weeks of treatment withdrawal; HVLA = high velocity, low amplitude manipulation; HVLF = high velocity, low force; BEP = back education program.

total number of cases eliminated on this basis was 3, 5, and 14, respectively. Using the criteria developed in the earlier feasibility study[38] for sufficient severity of complaint, an additional 25 Oswestry and 12 VAS scores were eliminated from their separate analyses. As described in Methods, a minimum initial value of 5% self-reported severity of complaint was required in each questionnaire as necessary to detect discernible change in clinical status.

For all three outcome parameters, the repeated measures ANOVA indicated a strong effect for change over time (Oswestry: F = 20.553, $P = 0.000$; VAS: F = 51.886, $P = 0.000$; Zung: F = 23.198, $P = 0.000$).

Oswestry scores remaining for analysis totaled 117 subjects and were distributed with 39 in HVLA, 40 in HVLF mimic, and 38 in BEP groups. Table 3 lists means and standard deviations for each group at the three sample times. No time by group interaction was observed (F = 0.758, $P = 0.554$), however, ANOVA of the differences among groups for the intermediate score sample was statistically significant (F = 4.61, $P = 0.012$). The HVLA group had the lowest score. Although the initial Oswestry score appeared lower for the manipulation group, this was not confirmed statistically (F = 0.89, $P = 0.413$) and no overall differences between groups could be observed (F = 2.31, $P = 0.104$). That is, no pretreatment differences in the Oswestry scores were observed.

Complete sets of VAS scores were available for 129 subjects. The resulting distribution was 47 HVLA, 39 HVLF mimic, and 43 BEP. Table 4 depicts the means and standard deviations for each group by sample time. Visual analog score measures demonstrated the largest clinically relevant improvement for the HVLA group with a decline in mean score of 24.6% during the course of the initial 2 weeks of treatment. During the follow-up interval when all treatment was withdrawn, the pain scores remained stable. The HVLF mimic group showed an initial mean decline of 17.6% that increased 1.94% during the therapeutic withdrawal period. Behavior of the VAS scores for the BEP group paralleled the response of the mimic group initially with a 16% reduction in the mean. During the withdrawal of treatment, this group continued to recover by an additional 4.5%. Repeated measures ANOVA indicated a time by group interaction reflecting these changes that was nearly statistically significant (F = 2.145, $P = 0.076$). When all five test samples were included, (before and after initial score, before and after intermediate score, and final score points per subject) in the analysis, a strong time by group interaction was found (F = 3.165, $P = 0.002$).

Table 5 gives the means and standard deviations of the Modified Zung scores. No clinical or statistical significance was found for changes between treatment groups. The only observation was one of improvement with time that was comparable among the groups.

A secondary analysis was completed on the Oswestry scores with respect to potential age effects. Patient scores were partitioned into two categories: 50 years of age and older, or younger than 50 years. This cutoff point was selected based on post hoc inspection of apparent data clustering. Again, repeated measures ANOVA was used to test the effects. An overall statistically significant difference between treatment groups was observed in the 50 years and older sample (ANOVA F = 3.95, $P = 0.029$) with groups discernible at both the intermediate score (F = 5.50, $P = 0.009$) and final score data points (F = 5.27, $P = 0.011$). A 10.2% benefit for older patients enrolled in the BEP program was observed at the completion of the 2-week treatment intervention period. This trend continued to an additional 2% improvement in clinical status after 2 weeks of therapeutic withdrawal. For the final score sample time,

Table 5. Zung Scores Obtained at Each Sample Time for Each Treatment Group

	Number*	IS	IMS	FS
HVLA	48	14.4 (7.4)	11.1 (7.2)	10.9 (6.9)
HVLF	42	14.1 (6.2)	12.1 (6.6)	11.7 (6.6)
BEP	41	16.5 (7.5)	13.9 (7.2)	12.3 (8.0)

* Number sizes vary according to the number of confounding cases eliminated. Mean and standard deviation (in parentheses).
IS = initial sample; IMS = intermediate sample after 2 weeks of treatment; FS = final sample after 2 weeks of treatment withdrawal; HVLA = high velocity, low amplitude manipulation; HVLF = high velocity, low force; BEP = back education program.

older patients in the BEP and HVLA groups fared better than older patients in the HVLF mimic group.

Short-term pain relief was obtained with treatment at the final intervention at the end of 2 weeks. Differences for the VAS and Oswestry, evaluated by ANOVA for the immediate effect of the final treatment at the end of 2 weeks, were significant for the VAS scores only. Oswestry results were $F = 1.181$ having a probability of 0.311. VAS results were statistically different among the three treatment groups with $F = 3.919$ and $P = 0.022$. Contrast of means between treatments showed that the treatment effect responsible was the 3.8% decrease in pain scores for the HVLA *vs.* the BEP groups ($F = 7.794$, $P = 0.006$). The HVLF pain scores were virtually unchanged.

Discussion

This study examined the potential benefit of manipulation of the spine for chronic low back pain in a setting where the patient sample was likely to represent the cases seen in general practice. Patient demographics and clinical presentations were tested in a feasibility study[11] completed before initiation of data collection for the trial reported here. Both types of characteristics were found similar to that reported in the literature on private practice experience. Methodologically, a number of the criticisms aimed at previous studies have been addressed. Systematic limiting of knowledge about patient treatment, stronger homogeneity of the sample, physical contact, patient attention, and clear treatment descriptions have been considered.

Some ambiguity exists about the definitions that are used to classify patients according to duration of their symptoms and whether such distinctions are clinically meaningful. The content of this study focused on patients having pain in the low back, that could include sclerotomal radiating pain, that coincide with classifications 1–4 of the Quebec Task Force[35] and duration longer than 7 weeks.[23] This is a population of patients for which there is little information on the response to spinal manipulative therapy. Alternative definitions have been proposed[34] that would reclassify the sample used in this study to a subacute category. Classified in this manner, only the report of Berquist-Ullman et al (1977)[6] includes patients using a criterion that their pain had to be less than 90 days in duration. However, 87.6% of their subjects had pain for less than 5 weeks and only 1% had symptoms 8 weeks or longer. The criteria for patient inclusion used in this study did not record the recalled duration of symptoms for all patients other than to ensure that it was longer than 7 weeks. Regardless of classification scheme adopted, this is a critical time during which many patients begin to evince signs of inappropriate illness behavior, and other signs of chronicity and pending chronicity.[31]

All group means demonstrated improvement with time, however, a clinically strong but statistically insignificant pain modulating effect of HVLA at 2 weeks after the onset of daily treatment in a chronic low back pain population was observed. A series of treatment sessions over 2 weeks resulted in a higher return of function for the HVLA and a trend for significantly reduced pain in the same group. The higher return to function by the HVLA group was observed only in the cross-sectional rather than the overall repeated measures analysis. Because the clinical differences observed in the study were consistent with expectations about treatment, a power analysis was completed to assess for problems with the sample size. The power was calculated at 55% with a sample size of 67 patients per group required for 80% power at the observed level of clinical change. In fact, a total of 201 cases without confounding factors would be required. Dropouts and uncontrollable factors reduced our sample size from the enrolled 209.

The significance of Oswestry score differences between treatment groups disappears by the final scores. However, the potential impact on lost productivity time and costs associated with an earlier improved function attended by our observed results at intermediate score theoretically can be quite large. This observation is supported by the workers' compensation claims experience reported by Jarvis et al in 1991.[28] Benefits in function were retained for the HVLA and BEP groups, but HVLF group during the follow-up interval for patients older than 50 years. This observation of age effect in response to BEP is based on a post hoc assessment and, while novel, needs to be independently confirmed. If true, the apparent benefits may accrue during the full 4 weeks as a consequence of reducing the biomechanical stress on the spine using newly acquired information. Overall, the mean BEP gains nearly matched the HVLA at the end of the study interval.

Benefit in activities of daily living was the most significant effect over time, favoring the HVLA treatment. Insufficient information is available to evaluate whether the deterioration in functional scores after withdrawal of the treatment is clinically meaningful. Future work may be fruitful in this area.

The clinical applications of the information in this study may be considered by examining the potential interplay of manipulation with other forms of therapy for chronic back pain patients. Leading alternative approaches to treatment of chronic low back pain include functional restoration,[31] behavioral modification methods,[22] and chronic pain programs.[13] All of these methods, while beneficial in their own right, are high-cost approaches that focus on late-stage cases where nearly heroic effort is required. Functional restoration generally focuses on physical exercise and functional simulation of critical activities of the patient's preinjury activities of daily living or work. In a randomized trial, Mitchell and Carmen[30] concluded that the principal benefit to be achieved was a reduction in total disability award to those undergoing functional restoration treatment than to the control group. Its use is commonly reserved for patients who remain intolerant of activity for 3 months or more, and usually are no longer attempting to work. Fordyce[22] demonstrated the value of behavioral methods in treating disproportionate disability which has generally been noted as a major component in the minority of back pain cases who become chronic. Cutler et al,[13] in a meta-analysis of chronic pain programs, concluded that the multidisciplinary team approach has a 50% greater return to work rate than control groups. Pain program management is considered appropriate for patients who have lost 3 months of work time in 1 year after a first work absence.[13]

Aggressive treatment of acute injury at an early stage leads to satisfactory results in 80% of cases.[30] A similar treatment strategy is advocated for use of spinal manipulative therapy[37] for enhanced symptom control. The experience of persistent pain and the perception of disability can lead to fear of motion and enhanced risk of chronicity.[13,22,30,31] Risk of potentiating chronicity and fostering physician dependence is believed to result from overutilization of passive means of treatment. Future work may be helpful in examining ensembles of treatment that vary the sequence and interaction of spinal manipulative therapy with patient activation and exercise.

The data reported here confirm a strong time-based recovery effect, for all forms of treatment studied, similar to that observed by Mitchell and Carmen.[31] The enhanced rate of recovery noted for the HVLA group, however, may prove useful in restoring patient willingness and confidence in becoming active. For those patients whose pain has not completely resolved with early treatment or who have delayed treatment into the later stages past 50 days, HVLA may be combined with a graded shifting of emphasis toward active care. Better clinical results might be obtained. This speculation seems feasible in light of the cost benefits and reduced work time lost observed by Jarvis et al.[28] Their study showed earlier return to work and reduced costs for comparable nonsurgical worker's compensation cases including payment for all reasonable and necessary medical expenses by ICD-9 code.

■ Conclusion

Analysis of results from treatment of 145 chronic low back pain patients, as defined by the Quebec Task Force,[35] demonstrated clinical utility for use of spinal manipulative therapy. Persistent benefit, in the form of immediate reduction of reported pain after individual treatment encounters, was observed at the end of 2 weeks of treatment. Self-reported functional levels were similarly enhanced in the HVLA group *vs.* HVLF and BEP. This randomized trial successfully accounted for a number of the more serious criticisms of earlier studies on spinal manipulative therapy using a methodologically more rigorous protocol. The project was conducted in a clinical setting where earlier feasibility study demonstrated a practice profile closely representing common practice experience.[11] Time remains, perhaps, the strongest ally of patients with back pain complaints. In human terms, however, there appears to be treatment available to benefit patients with low back pain that lasts longer than 50 days.

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