Manipulation in the Treatment of Acute Low Back Pain

Janette E. Morton, *Dip Phty, M Hlth Sc (Ortho Manip T)*

Abstract: **Study Design.** This prospective research project statistically analyses the difference between two randomized groups of patients, one receiving manipulation plus exercises for acute low back pain of mechanical origin, the other receiving an exercise program alone. **Objectives.** To determine if orthopaedic manipulation is beneficial in treating acute low back pain of mechanical origin. **Summary of Background Data.** Orthopaedic manipulative physiotherapists have frequently observed dramatic results including elimination of pain and restoration of pain-free range of movement following manipulation of the acute locked back. Spinal manipulative therapy is a widely used method of treating lower back pain with millions of patient treatments performed each year, the majority in Western societies. Trials have emphasized the immediate and short-term symptomatic relief of low back pain following manipulation; however, the long-term difference in effects between manipulated and control groups has required further evaluation. **Methods.** A sample of convenience of acute low back pain participants were randomly assigned to two groups. A pre-test/post-test experimental design approach was used with 29 participants. This design included three dependent variables (pain, range of movement, and disability assessment) and one independent variable (15 participants in Group I received an exercise program with manipulation and 14 participants in Group II received an exercise program only). Participants were assessed for pain, range of movement, and disability before treatment. Participants were reassessed weekly for four weeks, then at two months and three months after initiation of treatment. **Results.** The findings of this study illustrate a statistically significant difference between the two treatments ($p = <0.0005$). Univariate post hoc tests concluded that the two treatment regimens had significantly different effects at three months on disability ($p = 0.001$), pain ($p = <0.0005$), and ROM ($p = <0.0005$). As well as being statistically significant, the magnitude of the relationships was strong, with 42.8% of the variability attributed to the disability measure, 64.3% of the variability attributed to the pain measure, and 65.9% of the variability attributed to the ROM measure. **Conclusion.** Patients who receive orthopaedic manipulation with an exercise program for acute low back pain of mechanical origin are likely to improve more than patients who receive an exercise program alone.

Key Words: Manipulation, Manual Therapy, Back Pain, Physical Therapy, Physiotherapy), ret

Manipulative physiotherapists have frequently observed dramatic results in eliminating pain and restoring pain-free range of movement following manipulation of the acute locked back[9,21,25,38,39,47,62,64].

Taylor and Twomey[60] proposed a biomechanical hypothesis for the dramatic results from a single manipulation as treatment for acute low back pain. They proposed that the acute locked back involved the zygoapophyseal joints, with articular cartilage caught between the articular surfaces blocking the movement. Because the articular cartilage is connected to a well-innervated capsule, considerable pain results. They further proposed that "gapping" or separating the joint surfaces through manipulation would allow the piece of firm articular cartilage to return to its normal position, thus taking the load off the capsule and resulting in restored movement and reduced pain. In a more recent study on the effects of mobilizations on the lumbar spine, Twomey and Taylor[64] suggest that the physiological effects of mobilization (a relatively gentle procedure) on the lumbar spine are similar to those of active exercise and passive joint movement. In addition, the value of passive joint movement in treating joint pain and dysfunction has been positively demonstrated[21].

Twomey and Taylor[64] postulated that the use of repetitive, low-stress, and small-amplitude movements of mobilization allows for efficient synovial fluid distribution over and through the articular cartilage and the disc as well as partial stretching of the ligamentous joint surfaces. These occurrences are needed on a regular basis for the efficient

Address all correspondence and request for reprints to:
Janette E. Morton
402 Oceanview Road
Ettalong NSW
Australia 2257
e-mail: jrmettalong@msn.com.au

The Journal of Manual & Manipulative Therapy
Vol. 7 No. 4 (1999), 182 - 189

functioning and repair of the structures involved. In the spine, the health of the joints depends largely on repeated small-amplitude movements. The intervertebral discs and articular cartilage of the facet joint are dependent on movement in order to maintain adequate fluid transfer and nutrition in the vascular cartilage[64].

Strong evidence exists that exercise and movement play an important role in controlling acute and chronic low back pain[56]. Much reported research has demonstrated that the cartilaginous structures of the body respond adversely to disuse and conditions of sustained loading, and positively to movement and exercises[30,44,61,63,64].

Several neurophysiological theories have been postulated to explain the decrease in pain perception following mobilization and manipulation. Paris[47] and Zusman[66] independently hypothesized that a decrease in pain perception may follow an inhibition of reflex muscle contraction mediated maximally by the afferent nerve supply to the joints with end range of passive movement (i.e., joint mobilization/manipulation). More recently, Butler[6] has linked the neurophysiological concepts related to a mechanical compromise of neural tissue and axoplasmic flow. These are interesting concepts as they may clarify the importance of manipulative techniques before commencing localized stabilization exercise regimens in the early stages of rehabilitating patients with acute pain of the lumbar spine.

Spinal manipulative therapy has become a widely used method for treating vertebral column pain. Millions of patient treatments are performed each year, the majority in Western societies. In the literature, many researchers have demonstrated the benefits of joint mobilization and manipulation to relieve pain and to increase range of movement in the lumbar spine[9,21,25,38,39,47,62].

DiFabio[9] reviewed the literature and identified 11 well-designed, randomized, controlled clinical trials that demonstrated the efficiency of manipulation in treating low back pain. These studies were important as they used randomized clinical trials and reported significant improvements in pain, flexibility, and disability status. Of particular interest were the trials that emphasized the immediate and short-term symptomatic relief of low back pain for the manipulated group. However, any long-term difference in effects between the manipulated and control groups was not significant either statistically or clinically.

Hadler et al,[25] Mathews, Morkel and Matthews,[38] Meade et al,[39] Kettle[34] and Shekelle[57] also conducted structured controlled studies that were able to demonstrate rapid pain reduction and increased mobility in those patients receiving manipulation. Once more it is interesting to note that the difference in the short-term results (< 4 weeks) were significant statistically and clinically compared with other conservative treatments. However, whilst mobilization and manipulation hastened improvements, these studies failed to show any effect on long-term status (> 3 months), disability, and/or recurrence.

Further review of the literature reveals that many researchers have demonstrated the benefits of joint manipulation to relieve pain and to increase range of movement in the lumbar spine. However, what is lacking is the presence of control groups, random assignment to control and treatment groups, and blind assessments of the outcome of intervention on the effectiveness of manipulative therapy. These are critical factors for a valid clinical trial[8,17,34,45].

Review of the literature also indicates that the interpretive efficiency of lumbar manual therapy often hinges on the experimental design and the protocol of the research project[8]. It has been found that few of the controlled studies that produced positive effects for joint manipulation can be replicated with ease[63]. The immediate advantage of manipulation has been reported by Glover, Morris, and Khosla[23] who found manipulation to be more effective than placebo. Haldeman[26] evaluated the scientific basis for manipulative therapy and proposed that such therapy must be demonstrated to have consistent results under controlled conditions and to have a specific effect on the musculoskeletal system and neuromuscular system before it can be designated as the most effective conservative treatment for low back pain.

McKenzie[40] has long advocated an extension exercise program that relieves acute mechanical low back pain, one which is widely recognized as a conservative treatment for acute low back pain. Its effectiveness for reducing pain and increasing range of movement in subacute low back pain is well documented[10-16,20,42,54,58]. Basically, the McKenzie program involves therapeutic regimens emphasizing assessment and patient self-treatment for the current acute episode as well as continuing exercises to prevent recurrences[2,40-43].

Thus, it has been shown that exercise and movement have a central role in managing acute and chronic low back pain. However, the current exercise programs for rehabilitation of the lumbar spine following acute exacerbations emphasize enhancing and maintaining active trunk muscle stabilization before the universally-accepted larger range of movement, aerobic, and muscle-strengthening programs can be implemented so as to improve overall muscle strength, endurance, and hypertrophy and thereby acting as a protection against severe dysfunction from low back pain, both acute and chronic[32].

Jull and Richardson[32,53] have developed a "rehabilitation of active stabilization of the lumbar spine" exercise protocol that emphasizes facilitating active trunk muscle stabilization as a vital tool in enabling the eventual resumption of pain-free activities of daily living following an episode of acute low back pain.

Researchers have found that the oblique and transverse abdominal muscles have roles in spinal support and control[28,52,59]. Their anatomical design and location provide a dynamic corset-like structure for fixation and support. The transversus abdominis and, to a lesser extent, the internal obliques further contribute to lumbar non-contractive supportive mechanisms through their attachments to the thoracolumbar fascia[36].

The rationale for using the stabilization program in this pilot research study is enhanced by the findings of previous research, illustrating the local stabilizing effects of the multifidus muscle on the lumbar motion segment. Any injury to a lumbar segment leads to long-term inhibition of the multifidus muscle involved in that segment with direct effects on lumbar segmental stability from eventual disuse atrophy or "deconditioning"[27,51]. Biomechanical studies have shown the lumbar multifidus to be an important muscle in lumbar segmental stability, as it is capable of rendering segmental tautness and of controlling motion in the neutral zone[46].

The stabilization exercise regimen involves clinically assessing the specific supporting muscle dysfunction (initially postural analysis and assessment and correction of muscle lengths) progressing to the subsequent training or retraining of the transversus abdominis musculature (independent of the rectus abdominis) usually with co-contraction of the multifidus musculature, and progressing eventually to co-contraction of the gluteus maximus and medius. The multifidus has been shown to be inhibited and eventually atrophied at the dysfunctional segmental level following acute lumbar injury[27].

This program is facilitated by a simple pressure sensor used as a biofeedback for the patient and therapist, to ensure that the specific musculature is used (e.g., transversus abdominis)[31]. This lumbar stabilization program is designed to reactivate the stabilizing musculature so as to retrain its endurance as well as its ability to contract appropriately with other synergists in supporting and protecting the spine under various functional loads. Once this stabilization and exercise regimen has been accomplished and automatic protective muscle stabilization is occurring during slow movement, a greater range of active/aerobic exercise regimen can be implemented into this routine, for example, some extension and flexion in lying exercises, a tailored gym program, and an active free swimming regimen[32].

Pope et al[50] found problems with previous research on manipulation efficacy, including the following limitations:

1. Outcome measures gave poor or unmeasured reliability and/or validity.
2. Many trials had poor design and potential type-2 errors in both data acquisition and analysis.
3. Randomization procedure was poor or inadequate.
4. Non-blind assessment was used.

Others have found further limitations:

5. The majority of the clinical trials that have been concluded have been criticized because descriptions of the technique do not allow the study to be replicated[64].
6. Interpretations of the efficiency of spinal mobilization and manipulation are limited when the effects of manual therapy are confounded by other elements of physical therapy treatment, including electrical stimulation, ultrasound, massage, and corsets[8].

In the conceptual review of the literature identifying similar research, a comparable research project was not found. The nearest comparable research project identified was that of Erhard, Delitto, and Cibulka[17] on the effectiveness of an extension exercise program and a combined program of manipulation and flexion and extension exercises in patients with acute low back pain syndrome. In this study, 24 patients with a brief history of acute low back pain (3 months or less) were randomly assigned into two groups. A clinical trial comparing the regimens was conducted for one week Outcome was assessed using an Oswestry low back pain questionnaire before treatment and at 3 and 5 days post-treatment, with data analysis using 2 x 3 (group x time) analysis of variance. A significant interaction between the group and time variables was demonstrated, indicating that the rate of positive response was greater in the manipulation with flexion and extension exercise group than in the extension exercise alone group. The authors concluded that in patients with acute low back pain (less than 3 months), the use of manipulation as an adjunct to an ongoing exercise program appears warranted. This study was well designed (although the fact that the groups used different exercises posed a confounding variable that may have confused the results) and appears to support the use of manipulation for acute low back pain patients. However, this research would have greater credibility if the authors had further assessed the participants for other dependent variables including range of movement and pain together with covariants age, sex, and body mass index (BMI). My research project differed in that a completely different stabilization exercise variable was implemented. This stabilization exercise regimen has been well recognized in treatment of acute low back pain[32,33]. However, Hides, Richardson and Jull[27] found no significant difference in results when they compared a stabilization exercise program with a control group over 4 weeks (41 patients) for pain, range of movement, and disability; their findings support the conclusion that time was the determinant for both groups. The present study assumed that both groups would improve with the exercise regimen over time, and was initiated to determine whether manipulation would provide further benefits for this patient population. The present study illustrates only that manipulation plus stabilization exercises are of benefit, compared with stabilization exercises alone, which according to Hides, et al is of no benefit over time and therefore may be arguably regarded as a control (placebo) group. Whether the addition of stabilization exercises is necessary for the effect of manipulation on treatment outcome is yet to be established.

The purpose of the present study is to evaluate the effectiveness of manipulation in addition to a stabilization exercise program on acute mechanical low back pain compared with a stabilization exercise program alone over 3 months.

The working definition of a manipulation for the lumbosacral spine in this study is "a high velocity thrust to a joint so that the joint is briefly forced beyond its restricted range of movement"[9] or "a sudden high-velocity short-amplitude motion delivered at the pathological limit of an accessory range of motion in order to gap the joint"[47].

Also for the purpose of this study the characteristics of the exercise program for the lumbo-sacral spine involves therapeutic exercises designed to re-educate the multifidus musculature in its stabilizing role, e.g., facilitating an active, isometric multifidus contraction in co-contraction with the tranversus abdominis musculature. Patients commenced training in a hands-knees position, then progressed to a standing position with lumbar spine in neutral enhanced by use of the pelvic stabilizer i.e., the pressure sensor biofeedback unit[29,32].

Methods

Participants were referred to my physiotherapy practice by local doctors in the area; they were entered into the research project following written informed consent and meeting the pre-determined criteria. The inclusion and exclusion criteria have face validity, being the criteria used in numerous research studies that include manipulative procedures[1,17,19,25,39,50]. This convenience sampling (i.e., quota sampling) resulted in 29 patients who participated in the study. The patients were male and female between the ages of 18 and 70 years old with acute mechanical low back pain of approximately four weeks or less. Their pain had to be located between T12 and the gluteal fold (it might radiate to one lower limb) as used in previous research[19,27]. Exclusion criteria were contra-indications for manipulations[7,24] including neoplastic disease; bone disease e.g., osteomyelitis, tuberculosis, Paget's disease, and osteoporosis; inflammatory arthritis e.g., gout, rheumatoid arthritis, ankylosing spondylitis, and septic arthritis; advanced diabetes mellitus; vascular abnormalities +/- visceral arterial disease; congenital generalized hypermobility; severe nerve root pain; undiagnosed pain; taking anticoagulant medication; taking any significant amount of medications (analgesics and NSAIDs were allowed); a positive Waddell's test;[65] previous lumbar spine surgery; gross or significant spinal abnormalities indicated on history, examination, or x-ray; abnormalities detected on neurological examination, including cord pressure signs in limbs, cauda equina lesions, and neurological diseases, such as transverse myelitis; pregnancy; and third-party, public liability or workers' compensation claimants. This study was approved by the School of Health and Human Services Ethics Committee at Charles Sturt University, Australia.

Randomization (by flip of a coin) resulted in the assignment of 15 participants to Group I (manipulation with an exercise program) and 14 participants to Group II (exercise program alone). There were 4 males and 11 females in Group I, and 6 males and 8 females in Group II. The mean age of participants in Group I was 42.9 years ±9.1 (range, 18-70), in Group II 46.4 years ±9.0 (range, 25-70). Group I had an average Body Mass Index (BMI) of 25.26 ±5.17 (range, 19.07-34.63); Group II had an average BMI of 26.47 ±4.98 (range, 20.52-37.11).

Assessment Procedures

Assessments were performed by independent examiners who were blinded to group allocation. The following outcome measures (3 dependent variables) were recorded.

1. Active physiological range of movement (ROM) was measured in degrees, specifically by the forward flexion test using the Plurimeter, an international standard neutral zero measuring goniometer[22].
2. Disability was assessed with the Roland Morris Disability Index[3-5,35,55].
3. Pain was measured by the absolute visual analogue scale (AVAS), a method of assessing the intensity of pain and recording it as a numerical value (ratio variable)[67].

All measurements were taken on the initial assessment and following treatment at the end of each week at approximately the same time (e.g., between 2pm and 4pm) to maintain reliability. The participants were assessed (for pain, disability, and range of movement) prior to treatment. They were then treated twice weekly for a total of 8 treatments. Post-treatment assessment was performed weekly for 4 weeks, then again (without further manipulation but continuing with the stabilizatgion exercise programe at home) at 2 months and 3 months post-initiation of treatment.

Intervention and Patient Treatment

Exercise therapy: Patients commenced training in the hands-knee position, gradually progressing to a standing position with lumbar spine in neutral and enhanced by use of the pelvic stabilizer i.e., the pressure sensor biofeedback unit. The therapeutic exercises were designed to re-educate the multifidus musculature in its stabilizing role, i.e., facilitating an active, isometric multifidus contraction in co-contraction with tranversus abdominus musculature[32].

The manipulation performed was either L1-L5 or L5-S1 traction gap manipulation[18].

Statistical Analysis

As the research goal was to evaluate the effect of manipulation on participants with acute low back pain, a one-way MANOVA was used, with further analysis using MANCOVA to eliminate discrepancies due to age, sex, and body mass index was utilized. The MANOVA and MANCOVA statistical analysis obtained the most meaningful results from the raw data of a pre- and post-test design comparing a nominal dichotomous independent variable (two different treatment regimen groups of patients) with the three dependent variables: pain (ratio variable), range of movement (ratio variable), and functional disability index (interval variable) before and after treatment49. Functional disability index (interval variable) before treatment (0 weeks), pain (ratio variable) before treatment (0 weeks), range of movement (ratio variable) before treatment (0 weeks), sex (independent dichotomous variable), age (independent ratio variable), and BMI (independent ratio variable) were the six covariants considered. Uneven distribution of these covariants may obscure the effect of manipulation on the dependent variables; therefore, MANCOVA was performed to redress their effect.

Results

Baseline Characteristics Group Comparability:

The results of the MANCOVA and MANOVA statistical analysis revealed no significant difference (Wilks' Lambda = 0.796 with $F_{3,22}$ = 1.88, p = 0.163) between the two treatment groups before commencement of treatment (0 weeks). Box's M test was performed on the dependent variables of pain, disability and range of movement at zero weeks (before commencement of treatment). The Box's M tested the null hypothesis that the observed covariance matrices (age, BMI, and sex) of the dependent variables (pain, disability and range of movement at zero weeks) were equal across the 2 groups. Rejection of the null hypothesis was not allowed, and as $F_{6,5205}$ = 0.979, p = 0.438 allowed confident acceptance of homogeneity between the 2 groups at zero weeks (before treatment). Univariate post hoc tests included cross-tabulation of sex with group analyzed to give a Chi-square value 0.84 consistent with no association between sex and allocated group p = 0.36; an independent t-test failing to show a significant difference between the age of those in Group I compared with Group II, with t27 = -0.494, p = 0.625, and another independent t-test failing to show a significant difference between BMI of those in Group I compared with Group II, with t27 = -0.641, p = 0.527. There was no significant difference between the mean duration of symptoms prior to treatment for participants in Group I and Group II, being 10.00 days and 14.64 days respectively ($F_{1,27}$ = 2.350, p = 0.137).

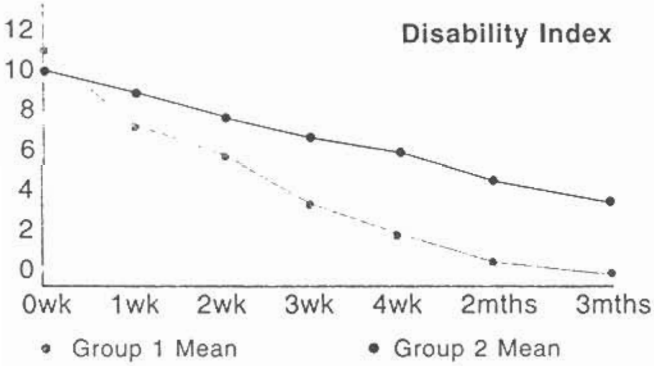

Fig. 1: Line graph comparing disability (Roland Morris Disability Index) between the 2 treatment groups from 0 weeks to 3 months using the mean values for the respective groups as tabled below (Table 1).

Table 1.

		Dis 0wk	Dis 1wks	Dis 2wks	Dis 3wks	Dis 4wks	Dis 2mths	Dis 3mths
Group 1	Mean	10.60	6.93	5.97	3.67	1.93	0.87	0.33
	SD	5.23	4.13	2.30	3.70	2.52	1.81	0.82
Group 1	Mean	10.07	9.07	7.93	7.00	6.00	4.50	3.64
	SD	6.40	5.90	6.34	6.08	5.22	3.44	2.80

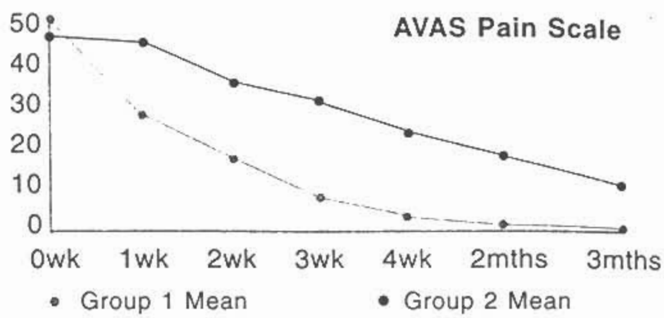

Fig. 2: Line graph comparing mean pain at different times [absolute visual analogue scale (AVAS) of pain intensity] between the 2 treatment groups from 0 weeks to 3 months, as tabled below (Table 2).

Table 2.

		Pain 0wk	Pain 1wks	Pain 2wks	Pain 3wks	Pain 4wks	Pain 2mths	Pain 3mths
Group 1	Mean	49.73	27.60	17.40	7.53	2.40	0.80	0.00
	SD	23.62	15.15	13.91	6.40	3.00	1.70	0.00
Group 1	Mean	46.57	46.36	36.64	34.50	25.43	17.50	13.57
	SD	25.10	23.27	24.58	23.00	17.34	11.23	9.40

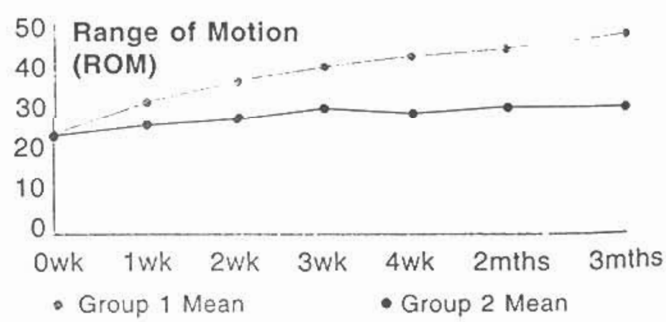

Fig. 3 Line graph comparing mean range of movement (ROM) in degrees of flexion at different times between the 2 treatment groups from 0 weeks to 3 months, as tabled below (Table 3).

Table 3.

	ROM 0wk	ROM 1wks	ROM 2wks	ROM 3wks	ROM 4wks	ROM 2mths	ROM 3mths
Group 1 Mean	23.93	33.27	36.87	40.20	41.87	43.93	45.60
SD	9.60	8.58	7.58	7.98	7.81	6.78	6.95
Group 1 Mean	23.50	26.79	28.00	28.71	28.43	31.14	31.14
SD	11.24	11.17	8.88	8.95	8.78	7.43	7.48

Progress Outcomes

As treatment time progressed, the results in the 2 groups diverged with respect to all 3 measured outcome variables (Figures and Tables 1, 2, and 3).

Statistical difference between the two groups appears at the first post treatment measurements (at one week) for the composite effect on the 3 dependent variable outcome measurements with Wilks' Lambda = 0.36 with $F_{3,19}$ = 11.22, p = <0.0005.

For univariate post hoc test measurements, statistical difference (at $\alpha = 0.05$) between the two groups appears at 1 week for pain ($F_{1,21} = 7.80$, p = 0.011), 1 week for ROM ($F_{1,21} = 30.18$, p = <0.0005), and at 4 weeks for disability ($F_{1,21} = 9.05$, p = 0.007); all further increase with time.

Final Outcomes

Comparison of the 2 treatment groups [Group I (manipulation with stabilization exercises) and Group II (stabilization exercises alone)], with MANOVA (comparing the treatment outcome differences) and further analysis with MANCOVA (removing variability attributed to covariates disability 0 weeks, pain 0 weeks, ROM 0 weeks, age, BMI, and sex) was performed on the outcome measurements at 3 months with the following results:

A Box's M test result of 14.33 meant inability to reject the null hypothesis that the observed covariance matrices (disability 0 weeks, pain 0 weeks, ROM 0 weeks, age, BMI, and sex) of the dependent variables (difference of pain, disability and range of movement between 3 months and 0 weeks) were equal across the 2 groups ($F_{6,5205}$ = 2.097, p = 0.05). Therefore the ability exists to accept homogeneity between the 2 groups at 3 months of treatment (completion of study treatment program) at α = 0.001 as recommended by Tabachnick and Fidell[59].

The multivariate tests of significance revealed the combined effect [composite (of the differences between measurements at 3 months and 0 weeks) dependent variable] of the covariates (disability 0 weeks, pain 0 weeks, ROM 0 weeks, age, BMI, and sex) and independent variable (group). Four MANOVA statistics (Pillai's trace criterion, Hotelling's trace criterion, Wilks' lambda, Roy's greatest characteristic root criterion) indicated that, overall the covariants (disability 0 weeks, pain 0 weeks, ROM 0 weeks, age, BMI and sex) and group explained a significant proportion of the variance of the composite dependent variable. All these MANOVA statistics gave a significance level of < 0.000549. Wilks' lambda statistic was 0.00118 with obtained R-squared = 0.9988, explaining about 99.9% of the variance, making a significant hidden covariant highly unlikely.

The univariate tests of significance (post hoc tests) shows that all 3 dependent variables (differences between measurements at 3 months and 0 weeks) were significant beyond the 0.0005 level, indicating that they are significantly affected by the covariants and group and, therefore, one of them alone is not producing the multivariate result. The p < 0.0005 level obtained for each of the univariate post hoc tests (individual ANCOVAs on each of the dependent variables) on the differences between the outcome values was substantially more significant than the significant results with the raw scores.

Univariate regression analyses indicated that overall the measured outcomes (disability, pain and ROM at 3 months) were little affected by the multiple measured covariants except for initial measurements at commencement of the study.

The MANCOVA results illustrated a statistically significant difference between the two treatment effects (Wilks' Lambda statistic = 0.13412 with $F_{3,19}$ = 40.89, p = <0.0005), demonstrating that patients who receive manipulation with an exercise program for acute low back pain of mechanical origin improve to a greater extent than patients who receive an exercise program alone. As well as being statistically significant the magnitude of the relationship is powerful with 86.6% of the variability in outcome measures attributable to the effect of group ($eta^2 = 0.866$)[49].

Following the significant overall MANCOVA, post hoc tests were performed to identify which dependent variables were contributing to the result. Univariate ANCOVAs were performed for the 3 dependent variables (disability, pain, and ROM at 3 months) with variability attributed to the covariates (disability 0 weeks, pain 0 weeks, ROM 0 weeks, age, BMI, and sex) removed. The univariate ANCOVAs indicated that group had a significant effect on all 3 dependent variables when considered separately. It should be noted that for a significance criterion of α = 0.05, the p value for individual ANOVA F tests would have to be < 0.017 with 3 dependent variables. Despite the higher level of significance (< 0.017) required, our univariate post hoc test (individual ANCOVAs) determined that all 3 individual treatment outcomes (dependent variables) easily met the $\alpha < 0.017$ requirement, being highly significant with disability at 3 months $F_{1,21} = 15.732$, $p = 0.001$; pain at 3 months $F_{1,21} = 37.83$, p = <0.0005; and ROM $F_{1,21} = 40.57$, p = <0.0005. Thus, we can conclude that after controlling for initial levels of disability, pain, and ROM together with removal of variability attributed to covariates (age, BMI, and sex), the two treatment regimens had significantly different effects on disability, pain, and ROM at 3 months. Again, as well as being statistically significant, the magnitude of the relationships were strong, with 42.8% of the variability in disability measure, 64.3% of the variability in pain measure, and 65.9% of the variability in ROM measure attributable to the effect of group[49].

Three months following commencement of treatment, Group I (manipulation with stabilization exercises) had a mean disability score (Roland Morris Disability Index[55]) 90.93% less than Group II (stabilization exercises alone). Eleven of the 15 patients of Group I had no disability at the end of 3 months treatment compared with Group II where only 1 of the 14 patients had no disability at that time.

Three months following commencement of treatment, Group I (manipulation with stabilization exercises) had a mean pain measurement [absolute visual analogue scale (AVAS) of pain intensity[67]] 100% less than Group II (stabilization exercises alone). None of the 15 patients of Group I had pain at the end of 3 months treatment compared with 13 of the 14 patients in Group II who still had pain.

Three months following commencement of treatment, Group I (manipulation with stabilization exercises) had a mean range of movement (ROM) (measured as degrees of lumbar flexion) 46.44% more than Group II (stabilization exercises alone).

Discussion

The outcome findings appear similar to those found for the comparable research project of Erhard, Delitto, and Cibulka[17] on the relative effectiveness of an extension program and a combined program of manipulation and flexion and extension exercises in patients with acute low back syndrome. Erhard et al, concluded that the use of manipulation as an adjunct to an ongoing exercise program appears warranted.

The clinical significance of this research project is the definite inference that patients who receive manipulation with exercises for acute low back pain of mechanical origin will improve more and faster than patients who receive an exercise program alone. The magnitude of the relationships are strong, the magnitude of the effects are large, the difference between the two groups appears early, and statistical significance ($p < 0.0005$) is established with a small sample population ($n = 29$).

Manipulation appears cost-effective as exercises were the greatest component of treatment time, being approximately 30 minutes to 1 hour per patient irrespective of group. No extra equipment was required for the participants in the manipulation with exercise group compared with the exercise alone group. However, in any debate regarding cost-effectiveness of manipulation with exercise vs exercise alone, it should be acknowledged that orthopaedic manipulative physiotherapy training is a prerequisite to administering treatment to Group I.

No adverse side effects were documented for either group. The "placebo effect" must be considered as a potential threat to the internal validity due to its potential influence on the outcome measures. This is difficult to control in this type of experimental research as "double blind" studies cannot be performed in this particular research situation[48]. Further research including replication of this research study, is recommended to enhance the external validity of the research findings. ■

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