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Physical Therapy Intervention for Chronic Soft Tissue Injury in the Low Back: A Systematic Review

Intervensi Fizikal Terapi untuk Kecederaan Kronik Tisu Lembut di Bahagian Bawah Belakang Badan: Satu Ulasan Sistematik

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Abstract

The objective of this systematic review was to assess the effectiveness of physical therapy interventions for chronic soft tissue injury to the low back. Only randomized controlled trials identifying physical therapy interventions within the scope of practice for Canadian physiotherapists and athletic therapists, with a clinical diagnosis of chronic soft tissue injury to the low back with symptoms lasting a minimum of three months were included. Only three studies of the 87 articles reviewed were deemed eligible for review based on the relevancy criteria set forth by the reviewers. Percutaneous electrical nerve stimulation (PENS) and therapist supervised active exercise programs may be a promising treatment modality for chronic low back pain (CLBP) by reducing pain, improving self-reported disability, and improving physical performance. The consensus amongst reviewers' was that the quality of the three articles were deemed of weak methodological quality making author inferences to the success of the reported physical interventions towards the modulation of pain, improved range of motion or patient satisfaction inconclusive. At the most basic level, there is a lack of uniformity in defining low back pain based on time, with definitions ranging anywhere from one week to six months. This is a major limitation in existing scientific literature. The ability to compare studies and results is hampered by the disparities in CLBP definition. The scientific rigor applied to studies devoted to therapeutic interventions and rehabilitation is poor.

Keywords Physical therapy intervention, chronic soft tissue injury, low back

Abstrak

Objektif kajian semula sistematik ini adalah untuk menilai keberkesanan intervensi terapi fizikal untuk kecederaan kronik tisu lembut pada bahagian bawah belakang badan. Hanya 'randomized controlled trials' yang mengenalpasti intervensi terapi fizikal dalam skop amalan oleh ahli-ahli fisioterapi dan terapis atletik di Kanada, dengan diagnosa secara klinikal kecederaan tisu lembut kronik pada bahagian bawah belakang badan dengan simptom yang berlarutan sehingga minimum tiga bulan sahaja terpilih. Tiga sahaja penyelidikan daripada 87 artikel yang telah dikaji semula dianggap layak untuk dikaji semula berdasarkan kriteria-kriteria relevan yang telah ditentukan lebih awal oleh para penyelidik. 'Percutaneous electrical nerve stimulation' (PENS) dan program-program senaman aktif yang diselia oleh terapis mungkin adalah rawatan modaliti yang berkesan untuk CLBP (sakit kronik bahagian bawah belakang badan) bagi mengurangkan kesakitan, mempertingkatkan ketidakmampuan yang dilaporkan sendiri, serta mempertingkatkan prestasi fizikal. Persetujuan antara para penyelidik adalah kualiti ketiga-tiga artikel tersebut menjurus terhadap kualiti metadologi yang lemah, mengakibatkan inferens penyelidikan terhadap kejayaan intervensi-intervensi terapi bagi modulasi sakit, mempertingkatkan julat pergerakan atau kepuasan pesakit adalah kurang menyeluruh. Pada dasarnya, kekurangan kesetaraan dalam mendefinisikan kesakitan bahagian bawah belakang badan berdasarkan masa, dalam lingkungan dari seminggu hingga enam bulan. Terdapat limitasi utama dalam literatur sains yang wujud. Kemampuan membandingkan penyelidikan-penyelidikan dan hasil-hasil kajian terjejas akibat ketidaksempurnaan dalam definisi CLBP. Penekanan saintifik kepada penyelidikan-penyelidikan yang bertumpukan intervensi terapeutik dan rehabilitasi adalah lemah.

Kata kunci *Intervensi fizikal terapi, kecederaan kronik tisu lembut, bahagian bawah belakang badan*

INTRODUCTION

Low back pain is one of the most prevalent health conditions in developed countries and contributes to soaring health care costs, work-related absenteeism, symptoms of disablement, depression (Rittweger, Just, Kautzsch, Reeg & Felsenberg, 2002) and reduced quality of life (Weiner et al., 2003). A large variety of therapeutic interventions are available for the management of chronic low back pain, mostly due to a lack of clear understanding of its etiology (Taimela & Harkapaa, 1996). The effectiveness of most physical therapy interventions has little or conflicting evidence, and many of the studies attempting to investigate this efficacy are marred with questionable methodology.

CLBP has also come to mean a persistence of pain for at least three months such that there is an apparent discrepancy between the degree of identifiable impairment and the symptom severity (Carron, 1987 and Black, 1975). Though there are numerous systematic reviews published on the subject of chronic low back pain, many lack consistent injury definition and very few direct their reviews to clinical interventions that will help the therapist determine what physical therapy techniques will be most effective for their patient population.

The purpose of this study was to compile a systematic review of studies examining the treatment of chronic low back pain. The search criteria, as outlined in detail below, was restricted to randomized, controlled treatment studies, specific to the low back and within the scope of physical therapy and athletic therapy practice in Canada.

Methods and Results

The search strategies used in this systematic as review included an on-line computer search, hand searches of selected journals, as well a search of reference lists of selected papers for critical appraisal for this review. All randomized and quasi randomized controlled trials (RCT's) published in English meeting our criteria were identified through the Cochrane Controlled Trials Register, MEDLINE, EMBASE, CANCERLIT, CINAHL, HealthSTAR, PsycINFO, and ERIC. A hand search of key journals that publish a significant amount of research on chronic low back pain was conducted. Because RCTs are generally accepted as the bench mark or "gold standard" for intervention research due to their ability to ensure homogenous populations and scientific rigor, the reviewers only accepted RCT's for inclusion in this systematic review (Magee, 1998).

A minimum of two reviewers studied the article lists generated by the initial search and discarded articles with an initial study title indicating a report of interventions not within the scope of practice of Canadian physical therapists or athletic therapists. For an article to be discarded, a consensus between the two reviewers had to be achieved. If both reviewers were not in agreement, the article remained on the list for retrieval and further review.

The initial selection criteria to determine if a paper met the standards for inclusion in this systematic review were: 1) the study's focus included a physical therapy intervention or program; 2) the intervention was within the scope of practice in Canada for both a physical therapist and an athletic therapist; 3) the subjects were both male and female; 4) soft tissue injury to the low back; 4) low back pain was chronic in nature with chronicity defined as a presence of pain for a minimum of three months; 5) the selected study had to indicate that there was an absence of radicular symptoms, osseous disorders, systemic diseases, disc involvement and prior surgical intervention to the low back as these were considered as possible confounders that would influence intervention efficacy; 6) the study had to measure an appropriate outcome which is the case of this study was considered to be either range of motion (ROM), pain, and/or patient satisfaction; 7) and the study had to be prospective in nature with a true control group (RCT). The exclusion criteria were determined by listing the major potential confounders that hamper a researcher's ability to accurately measure an intervention's influence and outcome on a soft tissue injury.

An independent assessment of the studies was conducted by a minimum of two reviewers to avoid any reviewer bias. A tool was developed to ensure all relevancy criteria was addressed by the reviewers, and to assist in decreasing the likelihood of oversights. The tool was piloted prior to the independent assessment to ensure that the reviewers were familiar with the process and applied the same parameter definitions when judging inclusion and exclusion criteria.

The reviewers either accepted or rejected a study based on the inclusion and exclusion criteria reported in the study. A consensus between the two reviewers had to be made to continue with the critical appraisal of the study. If a consensus was not achieved, the reviewers returned to the published study and determined if there was a discrepancy in interpretation of criteria, a discrepancy in interpretation of the study, or a general oversight. If the consensus could still not be met, a third party was used to provide further direction and resolution.

Only three of the 87 articles reviewed met all criteria established in the relevancy tool. Once the relevancy criteria was applied to all identified articles retrieved through the initial search, a second hand search was conducted on the reference lists of the articles identified as being eligible for review. The selected studies were independently scrutinized by a minimum of two reviewers for their validity and methodological quality. A rating system was applied based on the studies reported information on the type of study, method of randomization, confounders controlled, subject agreement to participate, description of the intervention, data collection methods as well as information related to the number of subjects who discontinued their participation throughout the study and follow up period and reasons for discontinuing their involvement. Two tools were developed to track study information and related ratings. The tools were tested and are retested to assess validity (Magee, Oborn-Borrett, Turner & Ferning, 2000). Consensus from both reviewers was achieved on all validity ratings for all articles.

In two of the three articles that met all criteria including a true control group, the primary outcome measurements were the effects of supervised physical exercises on patient reported pain as well as disability. The third study also measured pain and disability but percutaneous electrical nerve stimulation was the variable. Although all three studies attempted to determine values on the same primary outcome i.e. pain and disability, they all used varying tools to accomplish the same goal. The tools included the McGill Pain Questionnaire, the Roland Morris Back Pain Disability Pain Questionnaire, revised Oswestry low back pain questionnaire, pain diaries, pain locus questionnaire, pain self efficacy questionnaire, visual analogue scale, the pain disability index questionnaire, LE Mark 1 lumbar extension machine, shuttle walking test timed chair rise and functional reach.

Intervention descriptions such as dosage, time placement and well described active exercises were often either poorly reported or omitted from the publication. Researchers also failed to control for confounders such as medication and adjunct therapies during the study. The use of diaries to track compliance when home programs were an adjunct to the intervention and control protocol was overlooked. Though studies stated randomization and stratification, they often failed to mention the method of randomization. The research was also remiss in including instrument intra and inter-reliability. The majority of the studies did use therapist supervision when prescribing active exercise as an intervention.

Discussion

The reviewers were only able to define three articles that met all relevancy criteria, including the use of control groups, of the 87 articles retrieved for consideration for this systematic review. All three articles were considered weak due to the reviewers' assessment of the inability to produce science that met the rigors of reliability, validity and reproducibility. Basic study design that tracks essential confounders, appropriately describes the interventions along with thoroughly recorded dosage, time and placement during the study and prior to the follow up assessments are essential if therapists can use techniques and protocols that are not only statistically significant but clinically significant and relevant, and can positively influence the health and welfare of their

patients.

Weak Studies

Kankaanpaa et al. (1999) published the study "The efficacy of active rehabilitation in chronic low back pain: effect of pain intensity, self experienced disability, and lumbar fatigability" in *Spine.* There were 54 subjects (91%) completed the interventions and 49 individuals (83%) completed the study through the one year follow up. The reported subject baseline characteristics indicated that there were no significant differences ($P>0.05$) between groups in age, body mass index, and time since the first episode of low back pain. The authors reported there was a difference ($P<0.05$) in the weight category within males of active and passive groups, as well the men were both heavier and taller than females in both groups.

The active group received 24 sessions, supervised by a physiotherapist over a 12 week period. The sessions included physical exercises with specific equipment; together with stretching, relaxation exercises, and ergonomic advice. The authors cite four specially designed active training units focusing on lumbar flexion/extension, lateral flexion, and rotation designed by the David Back School (David Back Clinic, 1994). The authors briefly stated load objectives with subjectively strenuous loading applied throughout the study period. The control group received passive treatment that included thermal therapy and massage for the last four weeks of the 12 week study. The control group received one passive control session a week for four weeks. Kankaanpaa et al. (1999) provided minimal support in their literature review why massage and thermotherapy is considered ineffective leading to the assumption that it would be defined as a placebo effect. They used subjective patient reports to record low back pain. Measurements tools included the pain and disability index (PDI) (Pollard, 1984), and the visual analogue scale (VAS).

Outcome measures were performed before and after the interventions and at the six month and one year follow up visits. Those assessing the patients and the measurements were not blinded to the group at the follow up visits. At baseline, low back pain intensity and functional disability were similar between the active and control group. During the 12 week study, the authors reported a significant decrease in pain intensity and functional disability ($P<0.05$) with the active group and the increases were significantly larger ($P<0.05$) than the control group. They also stated that the between group difference in both pain intensity and functional disability became more significant at the six month and one year follow up assessments ($P< 0.01$). The authors concluded that active rehabilitation was effective in reducing back intensity and functional disability during a one year follow up as applied in this study.

In 1995, Frost et al. published a study in the *British Medical Journal* entitled "Randomized controlled trial for evaluation of fitness program for patients with chronic low back pain". The authors recruited 116 patients from the Nuffield Orthopaedic Centre to evaluate a progressive fitness program. There were 34 males and 37 females included in the final analysis. They were given a pain diary and four individual exercises, judged to be clinically appropriate for each patient. The subjects were requested to complete the pain diary before each session and continue at home with the exercises

twice daily until their follow up appointment, which was two to three days after the initial appointment. Subjects were then randomized using the minimization method to either a control group (back school) or to an active group (back school and fitness program). Minimization method is an assignment strategy, similar in intention to stratification that ensures balance between intervention groups for specified prognostic factors. After the first subject is randomly allocated to a group, the next participant is assigned to which ever group would minimize the imbalance between groups on specified prognostic factors (Treasure & MacRae, 1998; Altman, 1991).

Subjects were stratified, based on the minimization method, according to duration of symptoms, previous episodes of low back pain, age, and sex. The control group participated in a back school intervention program that included a discussion of the patient's problem, functional anatomy, applied body mechanics, relaxation techniques, ergonomic advice, practical workshops and a prevention video. They were also instructed to maintain their home exercise protocol prescribed in the original assessment as well as their pain dairy. The active group participated in a protocol consisting of eight sessions over a four week period. Each session was supervised by a therapist and included warm up and stretching, followed by a circuit of 15 progressive exercises. The sessions finished with stretching and light aerobic exercise. Frost et al. (1995) reported the use of psychological principles and encouragement of participants to "think for themselves as sports people trying to improve fitness". The subjects also participated in the same back school as the control group. They were also instructed to maintain a pain diary. The ability to reproduce this study is grossly limited by the lack of information and protocol clarity on the intervention as well as lack of control of potential confounders such as medication type and the ability to track compliance with the home program for the control group.

Multiple outcome measures were recorded before and after the treatment and at a six month follow up via questionnaire. The assessor was blinded to the subject's treatment allocation. *The revised Oswestry low back disability index* (Baker et al. 1989) was used as the main subjective measure of functional disability and the only tool used to assess at the six month follow up. *Pain diaries* (Jensen & Macfarland, 1993) were used to record the affective and sensory components of pain using a 100 point numerical scale four times daily for one week before and after treatment for each component. *The pain locus of control questionnaire* (Main & Waddell, 1991) was used to investigate the patients' control over their pain. *The pain self efficacy 10 part questionnaire* (Nicholas, Wilson & Goyen, 1992) was used to record the patient's control over pain. *The general health questionnaire* (Singh et al. 1992) was used to evaluate a subject's psychological state. The authors cited literature on the validity and reliability for all tools used in outcome measures.

After the subjects completed the treatment, Frost et al. (1995) reported that on a scale of 0-100, both the active and the control group subjectively reported benefits. Though the active group scored significantly higher than the control group in their reported subjective appraisal of treatment benefits, the control group showed increased scores in comparison to their before treatment evaluation. The active group mean (SD) was calculated as 65.6 (25.8) *versus* the control group's 45.0 (25.0). The active group median was calculated as 67.5 (0-100) *versus* the control's 50.0 (0-90) ($P<0.001$). The

authors also reported that significant differences between the groups were shown on all outcome measures with the exception of *the general health and pain locus of control questionnaire*. There was a 42% reduction in reported sensory pain ($P<0.005$) and a 42% reduction in affective pain ($P<0.05$) in the active group versus a 21% sensory reduction and 0.02% affective reduction in the control group. The authors did highlight that they were surprised by the large differences; and hypothesized that these differences might be due to increased production of opioid peptides, and an improvement in self efficacy due to their participation in activities they might have once not thought possible.

The six month follow up was assessed using the Oswestry low back pain disability index questionnaire. The authors received 86% response rate with a significant difference in the change of scores. The active group reduced their scores by approximately six percentage points in comparison to the control group ($P<0.005$). Frost et al. do question the validity of the long term follow up due to the cross over of 12 subjects from the control group to the active group. The authors concluded that patients with chronic low back pain who attended a back school and participated in supervised fitness programs, with additional home exercises, were more likely to reduce pain and increase their functional abilities; thereby influencing their activities of daily living more so than those who exercised independently and attended a school for low back injury education.

In 2003, Weiner, et al. published the study "Efficacy of percutaneous electrical nerve stimulation (PENS) for the treatment of chronic low back pain in older adults" in the *Journal of American Geriatrics Society*. Subjects were selected based on a screened telephone interview using a structured questionnaire. Of the initial 105 individuals who volunteered for the study, only 54 (51.4%) were deemed eligible to continue. The researchers continued the selection process with a secondary history and physical evaluation to screen for further no degenerative conditions. The authors stated that forty-six of the fifty individuals (92%) met the inclusion/exclusion criteria from the secondary assessment. Twelve of the forty-six subjects declined to further participate. The remaining thirty-four subjects, aged 65 years of age or older, were randomized into a) PENS and physical therapy (PT), or b)Sham PENS and physical therapy group. A computer generated randomization scheme was used to assign patients to either the sham or active PENS group. Age and sex as potential confounders were controlled through inclusion criteria and gender was grouped separately in the results tables.

The patients received twice-weekly interventions for six weeks, and were measured at baseline, post intervention at six weeks, and three months following the conclusion of the interventions. The PENS treatment involved the anatomically oriented placement of acupuncture needles with a delivery of electrical stimulation at various frequencies and durations. The Sham PENS (control group) received identical acupuncture needle application as the active group. The same acupuncturist remained standard between both groups. The physical therapy treatment sessions were monitored by physical therapists that were blinded to the patients' group allocation.

The primary outcome measures of this study included pain intensity, quantified using the McGill Pain Questionnaire (MPQ) short form (Melzack, 1987) and the Pain Severity Scale of the Multidimensional Pain Inventory (MPI) (Kerns, Turk & Rudy, 1985). The other primary outcome measure was pain-related disability, measured using the Roland Morris Pain Disability Questionnaire (Roland & Morris, 1983)

and the Pain Interference Scale of the MPI (Kerns, Turk & Rudy, 1985). Secondary outcome measures included physical performance (timed chair rise, functional reach, gait speed, static and isoinertial lifting). Psychosocial factors were also measured in the subcategories of mood (Geriatric Depression Scale) (Yesavage et al. 1983), sleep (Pittsburgh Sleep Quality Index) (Buysse et al. 1989) and life control (Life Control scale of the MPI) (Kerns, Turk & Rudy, 1985). Cognitive function was the third and last secondary outcome measure and addressed measures of attention and concentration (Trail Making Test Part B) (Reitan & Wolfson, 1993), and mental flexibility (Hopkins Verbal Learning Test). All outcome measures were measured against a baseline pre-intervention assessment that used the same tools.

Results in the PENS plus PT group showed significant ($P<0.001$) reductions in pain intensity measures between the pre-test and post-test measures. The reductions were maintained at three-month follow-up. The sham PENS plus PT group did not show significant reductions in the same category ($P=0.94$). The PENS plus PT group also displayed significant reductions in pain-related disability from pre-test to post-test ($P=0.002$), also maintained at three-month follow-up. Again Weiner et al. (2005) reported the sham group did not show reductions in pain-related disability ($P=0.81$). For the secondary outcomes, the PENS group again showed significant improvements in psychosocial function, timed chair rise and isoinertial lifting endurance, while the sham group did not show improvements among those same measures.

Many outcome measures were used, mostly scales/questionnaires such as the McGill pain questionnaire, MPI pain interference scale, MPI pain severity scale and the Roland disability scale. To Weiner's credit, it was recorded that no medication changes were made by any of the subjects during the six weeks of the study. The follow up period had no information recorded for this potential confounder. The authors made no attempt to track record or control any adjunct therapies such as chiropractic care, massage therapy, alternative naturopathic remedies or psychological counselling received during the study.

Weiner et al. (2003) provided a healthy discussion related to the difficulty in obtaining a true control or sham group when acupuncture needles are used as well as when exploring alternate control group scenarios for this type of study and intervention. The study refers to research that has shown that random needle placement can lead to pain reduction and the release of endorphins (LeBars et al. 1972)**,** which in this case could cloud the final results reported for the sham and comparison group regardless of the applied electrical stimulation to the needles in a PENS study and the relationship with a therapeutic effect.

Conclusion

The use of therapist supervised active exercise programs, along with percutaneous electrical nerve stimulation may have a positive influence on the modulation of pain and subject reported disability management in CLBP patients. Although the evidence presented in this review showed statistical significance, the ability of the authors to establish strong evidence inferring that the reported physical therapy interventions positively influence patient pain and disability and should be part of a rehabilitation

protocol for chronic low back pain is extremely difficult. There is an urgent need for more physical therapy trials that follow sound RCT protocol as well as a unified definition of chronic low back pain, especially if time lines are used as a parameter definition for study protocol. The reviewers concluded that the selected physical therapy interventions effect on pain and disability were inconclusive. The reviewed studies did not report any adverse or negative effects.

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