A single (investigator) blind randomized controlled trial comparing McKenzie exercises and lumbar stabilization exercises in chronic low back pain

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ABSTRACT

Low back pain is a common problem, with a lifetime prevalence of 60-90% and an annual incidence of 5%. It becomes chronic in 40% cases. The present study was aimed to investigate the efficacy of McKenzie exercises and lumbar stabilization exercises in management of chronic low back pain. Material and Methods: The study is single (investigator) blind randomized controlled trial. A total of 30 subjects aged between 25 and 50 years were randomly assigned to two groups. One group received McKenzie exercises along with standard physical therapy and the other received lumbar stabilization exercises along with standard physical therapy. Subjects were evaluated before treatment and 4 weeks after treatment. Visual Analogue Scale and Oswestry Low Back Pain Questionnaires were used to measure pain and functional disability respectively. Analysis showed that there was significant improvement in visual analogue scale and Oswestry low back pain questionnaire score in both the groups after the treatment period (p<0.0001). On the other hand, the lumbar stabilization group also demonstrated significant improvement in both these outcomes (p<0.0001). The lumbar stabilization group demonstrated significantly more improvement in visual analogue scale score than McKenzie exercises group (p=0.040). However, no significant difference was found in Oswestry low back pain questionnaire score between both the groups. This study showed that both the exercise regimes are beneficial in patients with chronic low back pain.

Keywords: Chronic pain, low back pain, lumbar region, visual analogue scale

INTRODUCTION

Low back pain is a common problem, with a lifetime prevalence of 60-90% and an annual incidence of 5%. It becomes chronic in 40% cases [1]. In spite of the lack of specific diagnosis for low back pain, certain risk factors predisposing to low back pain have been identified. These include poor sitting posture, loss of extension and frequency of flexion [2]. The strength and endurance have been shown to be inferior in low back pain patients. It has been suggested that this weakness predisposes to low back pain [3].
The place of exercises in the treatment of patients suffering from low back pain has always excited controversy. There seems to be no agreement on the type of exercises that should be prescribed, the conditions in which they are of value, and the phase in which they should be instituted. “Back extension exercises” have been well described by Kraus and strongly advocated by Anderson and Hambly [3].

A systematic review of efficacy of McKenzie therapy in management of back pain was conducted by Clare et al [4]. This review showed that McKenzie therapy results in a greater decrease in pain and disability than other standard therapies like strength training, spinal mobilization, massage and back care.

A randomized controlled trial was performed to support the effectiveness of McKenzie method for patients with chronic low back pain [5]. However, it was found that McKenzie exercises and lumbar strengthening exercises appeared to be equally effective in treatment of patients with chronic low back pain at 14 months of follow up. Meta-analysis of randomized controlled trials to evaluate the effectiveness of McKenzie exercises for low back pain was done by Machado LA et al. They concluded that there is limited evidence for the use of McKenzie method in chronic low back pain [6].

Another aspect in the management of chronic low back patients has been specific training of the deep abdominal and lumbar multifidus muscles [7]. The role of stabilization exercises for treatment of pain and dysfunction in patients with low back pain was reviewed in a systematic review conducted in 2008 [8]. The authors concluded that for patients with chronic low back pain, stabilization exercises were not likely to produce outcomes that differ much from those of other active exercises or manual therapy interventions.

To our knowledge, only one randomized controlled trial has compared the McKenzie approach to a stabilization exercise program for low back pain [9]. This study showed that both interventions improved pain and function in patients with chronic low back pain, although no difference was found between both the groups.

To the knowledge of authors, no study has been done to compare these exercise programs after 2005. This study will fill the gap in the literature.

The present study was undertaken to investigate the efficacy of McKenzie exercises and lumbar stabilization exercises alone and their comparison in management of chronic low back pain.

**MATERIALS AND METHODS**

Thirty patients (10 males, 20 females) with chronic low back pain participated in this study from September, 2011 to January, 2012. 59 subjects recruited from the outpatient service of the University College of Physiotherapy, Faridkot, were screened and 30 were selected according to inclusion criteria. The subjects were already diagnosed by an orthopaedician. Ethical approval was granted by the Research Ethics Committee of University College of Physiotherapy, Faridkot. All patients gave informed consent to participate. Patients were eligible for inclusion if the patient was 25-50 years of age (male and female), consented for a four week treatment protocol and presented with chronic low back pain (more than 3 months duration) with or without radiation without traumatic origin. Exclusion criteria for enrollment in the study were any patient with metastatic cancer; previous spinal fusion or placement of stabilization hardware, instrumentation or artificial discs; motor signs of nerve root compression; alcohol or drug abuse; osseous stenosis; unstable spine (spondylolisthesis of grade II or more); infection or inflammatory disease; pregnancy; any therapeutic or medical intervention within last 3 months; concomitant severe medical problem; long term oral steroid intake and history of major psychiatric illness.

**Research Design**

The research design was an investigator-blinded randomized controlled trial. Two physiotherapists who were unaware of outcome evaluation results were given the responsibility for the initial screening of the incoming referrals, onward referral of patients to the research therapist and treatment of patients entered into the trial. The research therapist (who was blind to group allocation), performed the baseline and outcome measures. Randomization was achieved by an independent researcher not otherwise involved in the trial by assigning patients...
according to group designation indicated on a folded piece of paper taped, closed and drawn from a jar set up before the beginning of subject enrollment. Patients and therapists were instructed not to reveal to the research therapist the treatment group to which they had been allocated and it was ensured that the research therapist had no exposure to treatment given to participants. (Figure 1)

Intervention
Data about demographic characteristics were obtained. Each patient completed a self administered Oswestry Low Back Pain Disability Questionnaire (OLBPQ) [10] to assess subjective disability as well as a 10 cm visual analogue scale (VAS) for evaluation of pain. Two interventions were compared. The patients in the group 1 (ME) were given standard physical therapy with McKenzie exercises and the group 2 (LS) was given standard physical therapy with lumbar stabilization exercises. The standard physical therapy program included hot packs and Russian current. All treatments were applied on the same day with a few minutes resting time between the therapies. Hot pack was given for ten minutes to the low back for local superficial heat. Analgesic pulsar (model AP439) was used (10/50/10 treatment regimen was followed) for Russian current. The exercise program was performed in 3 sets with 5 repetitions and repetitions were gradually increased until they reached 20. The treatment was given 6 days a week. All patients tolerated and completed the treatment protocol. The treatment period was four weeks. All patients were given instructions on correct posture and ergonomic principles in activities of daily living. Pain medications were not allowed during the treatment period. Patients were not permitted to receive any other types of manual therapy, electrotherapy or any other additional interventions (acupuncture, taping, corset etc.) during the intervention period of the trial.

Technique

The following exercises were used:
1. Prone Lying: The patient adopts the prone lying position with the arms alongside the trunk and the head turned to one side. This position is maintained for 5 minutes.

2. Prone Lying on Elbows: The patient, already lying prone, places the elbows under the shoulders and raises the top half of his body so that he comes to lean on elbows and forearms while pelvis and thighs remain on the couch.

3. Prone Press Ups/Extension in Lying: The patient, already lying prone, places the hands (palms down) near the shoulders as for the traditional press up exercise. He now presses the top half of his body up by straightening the arms, while the bottom half from the pelvis down is allowed to sag with gravity. The top half of the body is then lowered and the exercise is repeated.

4. Sustained Extension: The patient lies prone with a pillow placed under the chest. After several minutes, add a second pillow. If it doesn’t hurt, add a third pillow after a few more minutes. Remove pillows one at a time over several minutes.

5. Standing Extension: The patient stand with the feet well apart and places the hands (fingers pointing backwards) in small of the back across the belt line. He leans backwards as far as possible using the hands as a fulcrum, and then returns to neutral standing.

Lumbar Stabilization exercises [12] The following exercises were used:
1. The patient is in supine lying. He is then instructed to practice antero-posterior pelvic tilts – repeatedly 10 times in each direction.
2. The patient is then asked to pull his navel into his spine and for exhaling thoroughly while maintaining the neutral spine position.
3. The patient is in supine lying with one knee bent. The patient is then asked to tighten his abdominals and buttocks & raise the other leg at about 12 inches while keeping the knee straight.

4. With one leg raised the patient is asked to make circles and squares with that leg.
5. The patient is in kneeling position. He is asked to tighten abdominals and buttocks keeping back in neutral position. While keeping his hands on his hips, patient places his one foot on the floor in front, kneeling on the other knee. He then lunges forwards, moving at hips. Holds this position for 3 counts. Return back to kneeling & then repeat. Repeat this exercise with the opposite leg.

While the patient is in supine lying, the pressure pad on the Blood pressure apparatus (Aneroid sphygmomanometer mechanical- Novaphon made), inflated to 20 mm of Hg is positioned into the space between lumbar curve and exercise surface. The dial is positioned in such a way to give the patient visual feedback of pressure variation. The patient watches the pressure dial and draws in the abdominal wall. The pressure will increase (10-15 mm Hg). The patient is instructed to keep the pressure level steady throughout the task he is performing.

Outcome measures
The first outcome used was change in pain measured on a visual analogue scale (VAS) in the form of a ten score ruler from 0 (no pain) to 10 (unbearable pain). Disability was measured by Oswestry low back pain questionnaire (OLBPQ). The original English version was used. This questionnaire is a brief measure of the effect of LBP on daily function by explaining ten domains with ten questions (pain, self care, lifting, walking, sitting, standing, sleep, sexual life, social life and travelling) scored on an ordinal scale. Outcome measures were recorded at baseline and at the end of 4 weeks.

Statistical analysis
All data were scored and entered into the Statistical Package for the Social Sciences (version11.5) for analysis. Intention to treat analysis was performed. Paired sample t-test was used to assess the changes within each group after the intervention period. Unpaired t-test was used to assess the changes in scores between the groups for each measure after the intervention period. The level of statistical significance was set at p < 0.05.

RESULTS

Compliance with treatment & follow up
A total of 59 patients were screened and 30 patients entered the trial (Figure 2)

All patients received the treatment to which they were allocated and all patients completed the treatment. Subjects in each group received a similar number of treatments, time at each session & ensuring equal contact time for each group. We had no complications associated with either of the techniques during our study with no subjects showing worsening of pain or preintervention Oswestry Disability Index score.

Patient demographics
The mean age of subjects in McKenzie Exercises (ME) group (n=15) and Lumbar stabilization (LS) group (n=15) were 38.2±8.5 (range 26-50) years and 38.4±8.4 (range 26-50) years respectively and the difference was not statistically significant (p=0.966). The ME group had 6 (40%) males and 9 (60%) females, whereas LS group had 4 (26.7%) males and 11 (73.3%) females.

Results of intervention
Comparison between the values of VAS and ODI is presented in Table 1 and 2. At baseline, there was no significant difference in VAS and OLBPQ score between the two groups. In ME group, there the other hand, the LS group also demonstrated significant improvement in both these outcomes (p<0.0001).

The next line of analysis involved between group comparisons after the completion of treatment i.e. after 4 weeks. The results showed that LS group demonstrated significantly more improvement in VAS score than ME group (p=0.040). However, no significant difference was found in OLBPQ score between both the groups.
Figure 1 - Clinical trial procedure

Patient referred to UCOP OPD by orthopaedician

Referrals screened by two physiotherapists, potential trial patients identified and passed to principle researcher

Inclusion criteria confirmed by principle researcher, written consent obtained, outcome measures completed. Randomization (concealed) and begin treatment on the same day.

Patients not fulfilling the criteria or who did not want to participate were be returned to routine care.

Group ME (n=15)
- Hot pack
- Russian currents
- McKenzie exercises

Group LS (n=15)
- Hot pack
- Russian currents
- Lumbar stabilization exercises

Outcome measures
- VAS at baseline and 4 week
- OLBPO at baseline and 4 week
Figure 2. Consort flow diagram

Assessed for eligibility (n=59)
- Excluded (n=29)
  * Not meeting inclusion criteria (n=27)
  * Other reasons (n=2)

Randomized (n=30)

Allocated to ME group intervention (n=15)
  * Received allocated intervention treatment (n=15)
  * Did not received allocated treatment (n=0)

Lost to follow up (n=0)
  Discontinued treatment (n=0)

Analyzed (n=15)
  * Excluded from analysis (n=0)

Allocated to LS group intervention (n=15)
  * Received allocated intervention treatment (n=15)
  * Did not received allocated treatment (n=0)

Lost to follow up (n=0)
  Discontinued treatment (n=0)

Analyzed (n=15)
  * Excluded from analysis (n=0)
DISCUSSION

Among the different approaches for the treatment of low back pain, exercise therapy is the most important aspect of treatment. McKenzie exercises are a very popular means of treatment for low back pain among the physical therapists [13, 14]. A recent focus in physiotherapy management of the patients with chronic low back pain has been the specific training of muscles around the lumbar spine, whose primary role is considered to be the provision of dynamic stability and segmental control to the spine [15]. The purpose of the study conducted was to compare the effectiveness of McKenzie exercises and lumbar stabilization exercises in chronic low back pain patients. The result showed that both the exercise regimes are beneficial in reducing pain and functional disability in patients after four weeks of treatment. But lumbar stabilization exercises prove to be slightly more beneficial.

The efficacy of McKenzie exercises is well determined by Stankovic [6] and Tom Peterson [17]. Stankovic compared the effect of McKenzie method of treatment with patient education in ‘mini back school’ in patients with acute low back pain and found that McKenzie method was superior. They further concluded that recurrence of pain episodes is also less during 5 year follow up. Tom Peterson found that McKenzie therapy is a useful aid in treatment of patients with subacute or chronic low back pain.

The result of the study is in consistence with Richardson and Jull [6] who purposed that specific training of these muscles is beneficial for patients with low back pain.

According to McKenzie [2], low back pain occurs when certain soft tissues structures are overstretched or because of adaptive shortening of soft tissues structures. McKenzie exercises basically relieve stress on the offended normal tissues and cause stretching of the shortened tissues. It usually takes 4-6 weeks to gain sufficient remodeling of the short structures to bring about full range of motion [18]. The presenting pain typically fades away as full range of motion is restored.

In regards to spinal instability, Panjabi described a neutral zone in which the interplay between the spine’s passive, active, and neutral elements function in concert to control motion between intervertebral segments. If one of the elements is compromised through disc degeneration, spinal injury, or muscular dysfunction, a resultant lack of control occurs within the neutral zone and instability results [19]. Panjabi hypothesized that it is through regaining neutral control of the muscles that provide segmental stabilization to the spine that instability can be managed.
## TABLE 2 Between Group Comparison of VAS and ODI score

<table>
<thead>
<tr>
<th>COMPARISON OF SCORES</th>
<th>GROUP ME</th>
<th>GROUP LS</th>
<th>p-value (0 wk between gp)</th>
<th>p-value (4 wk between)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>5.6±1.2</td>
<td>5.8±1.4</td>
<td>0.582</td>
<td>0.040*</td>
</tr>
<tr>
<td>ODIPO</td>
<td>36.5±7.1</td>
<td>37.03±6.8</td>
<td>0.861</td>
<td>0.065</td>
</tr>
</tbody>
</table>

Data are presented as mean ± Standard deviation

* p < 0.05 (within group comparison, dependent t-test)
Whereas the stabilization exercises act as a protective mechanism by providing a “corset action” around the spine. The muscles which are reflexly inhibited (shutdown) in low back pain patients (mainly lumbar multifidus and transverses abdominis), do not spontaneously recover even if the patients are pain free with a return to normal activity level [20]. This leads to recurring episodes of pain. Despite the stability provided by osseous-ligamentous structures, the spinal column devoid of musculature is incapable of carrying normal physiological loads [19]. The large movement of the spine, especially when under load requires stabilization and protection of many individual joints. This relies on the coordinated contraction of many muscles (muscles of abdominal wall and paravertebral muscles) working in fine balance to provide the background stabilization while at the same time allows smooth coordinated functional movement.

Our study has a few limitations. The main limitation of this study is the application of hot pack and Russian stimulation on top of the two forms of exercise. So it is difficult to isolate the effect of exercises alone. But keeping in view the fact that the patients coming to the OPD were more satisfied psychologically with the application of electrotherapy rather than exercises alone. So for the better compliance of patients, we used hot pack and Russian current in conjunction with exercises. Another limitation is that the current study was comprised of subjects who were referred to an outpatient physical therapy clinic. Thus, the sample may not be representative of all individuals with CLBP, thereby limiting generalizability of the results. The results are further limited by a small sample size. Furthermore, the trial had no true control (nonintervention). A randomized controlled trial with a larger sample size is required to further investigate the effects of these exercises in patients with back pain.

CONCLUSION

Both the exercise regimes have proved to be effective for treatment of patients with chronic low back pain patients. However, lumbar stabilization exercises induced more reduction in pain.

As both the exercises are effective, their selection can be based on patient’s need and compliance. Further investigation of the treatment approaches studied with comparison to a control group and a longer intervention period may provide more guidance to physical therapists working with this patient population. Studies investigating the application of these interventions to other population such as those individuals with low back pain that are post surgery, post partum, or experiencing CLBP with a more specific diagnosis of disc degeneration, disc prolapse or spinal stenosis are recommended for future research.

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REFERENCES