The Efficacy of Lumbar Stabilization Exercise Combined with Transforaminal Epidural Steroid Injection for Lumbar Radiating Pain

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Abstract

Objective: The purpose of this study was to evaluate the effects of exercises combined with transforaminal epidural steroid injection (TFESI) in patients with lumbar radiating pain.

Methods: Among 359 patients who were treated with TFESI for lumbar radiating pain, 118 subjects were eligible and analyzed. The injections were performed for all patients with 20 mg triamcinolone, 1 ml lidocaine (0.5%) and 0.5 ml normal saline. Exercise group (n=45) received TFESI as well as additional stabilization exercise for 30 minute sessions over 3 weeks (three times weekly), while control group (n=73) received TFESI and did not receive any additional stabilization exercise. The effects were evaluated using Numerical Rating Scale (NRS) at pre-injection, 4 weeks, 8 weeks, 12 weeks and 24 weeks after injection.

Results: Between Exercise and Control group, there were no significant differences in sex, age and baseline NRS score (P>0.05). Compared with that of the baseline, mean NRS scores decreased significantly in both groups after 4 weeks. The improvement sustained until 24 weeks in exercise group, while mean NRS scores slightly increased in control group. The proportion of treatment success at 24 weeks were 68.9% in exercise group and 41.1% in control group (p<0.05, odds ratio=3.17). The exercise group had moderate effect size (d=0.568) compared to the control group at 24 weeks.

Conclusion: Lumbar stabilization exercise combined with TFESI was more effective than TFESI alone for reducing lumbar radiating pain and reduced the rate of recurrence.

Keywords: Lumbar radiating pain; Stabilization exercise; Transforaminal epidural steroid injection; Recurrence

Introduction

Transforaminal epidural steroid injections (TFESI) are minimally invasive and safe for treating lumbar radiating pain, and its popularity is growing among physicians [1]. Many studies demonstrated effectiveness of the TFESIs in managing lumbar radiating pain [1,2]. It is reported that 50-75% of patients with lumbar radiating pain had temporary relief after TFESI. However, only 25-57% of patients showed long-term relief [3]. For this reason, additional treatments are required to maximize the effects of TFESIs and prevent symptoms from recurring.

Exercise therapy is utilized extensively as an intervention for patients with low back pain or lumbar radiating pain. According to systemic review, lumbar stabilization exercise is more effective in reducing recurrence for patients with low back pain than other conservative measures [4]. Many studies have demonstrated the effect of lumbar stabilization exercise on pain relief and normal performance [5-9], however, most of the studies were focused on patients with chronic non-specific low back pain, but not acute back pain caused by herniated lumbar disc. Acute radiating pain tend to be persistent and easily recurrent to usual nonoperative care including TFESI [10]. And previous study also showed that epidural injection of glucocorticoids plus lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine alone [11]. There is only one study that states stabilization exercises to be more effective on ADL performance in patients with herniated lumbar disc than no treatment during the short-term follow-up [12].

Theoretically, when the patients have an acute lumbosacral radiating pain due to disc herniation, TFESI should reduce the acute pain at short-term and then lumbar stabilization exercise may reduce the recurrence at long-term. We hypothesized that patients treated with stabilization exercise protocols after TFESI would achieve better outcomes for lumbar radiating pain due to synergistic effects, compared to TFESI applied alone. The aim of this study was to investigate the efficacy of stabilization exercise combined with TFESI for lumbar radiating pain.

Materials and Methods

Design

This was a single-center, quasi-experimental study of participants having received TFESIs for low back pain caused by HNP. We used...
customized data collection form for lumbar intervention registry and retrospective analysis was performed. Patients were divided into two groups to compare effects of additional lumbar stabilization exercise on mean changes in Numerical Rating Scale (NRS) scores during the 24 weeks follow-up period. Participants having received all of the required interventions and with available 24 week follow-up data were analyzed.

Participants

Changes in the overall pain intensity have been assessed retrospectively in 118 patients who received TFESI for acute or subacute lumbar radiating pain caused by lumbosacral herniated nucleus pulposus (HNP) at the rehabilitation department of the CHA Medical Center from January 2010 to December 2011. The inclusion criteria were as follows: presence of lower extremity radiating pain, onset of less than 3 months, lumbosacral herniated nucleus pulposus (HNP) confirmed by MRI, those who received treatment with TFESI and had outpatient follow-up at the 24 week period. Patients with a history of vertebral compression fracture, metabolic disease, rheumatoid arthritis, and spinal surgery were excluded.

The types of HNP were categorized as bulging, protrusion, extrusion and sequestration [13]. For the grading system of lumbar foraminal stenosis, we selected the Wildermuth’s MRI grading system to classify the severity of lumbar foraminal stenosis as previous literature described [14,15]. Foraminal stenosis was defined as the grade of 2 or 3.

The subjects were divided into two groups. First is the exercise group where patients agreed for physical therapy prescription in addition to TFESIs. The participants prescribed with physical therapy received our gradable stabilization exercise protocol. The other is the control group where patients refused the exercise prescription and received TFESIs only. Of the 118 patients, 45 were allocated to the exercise group while the remaining 73 patients were allocated to the control group (Figure 1).

Transformalinal epidural steroid injection

For both exercise and control groups, MRI was available for evaluating the cause of radiating pain and the level of TFESI was determined accordingly at unilateral, single level. Additional TFESI was permitted only one time for patients showing NRS more than 40 at the next visit (two week later). The procedure was performed with strict aseptic technique, in prone position, under fluoroscopic guidance, using a dorsal oblique approach. A 23-gauge 5 inch spinal needle; Spinal needle SpinoCan (BRAUN, Melsungen, Germany) was used for the injection. Contrast dye; Opaque was used to examine the spreading pattern. The injection material consisted of 20 mg of triamcinolone (0.5 cc), 1 cc of 1% lidocaine and 0.5 cc of normal saline. Therefore, a totally of 2 cc was injected.

Exercise protocol

The exercise group received the gradable stabilization exercise protocol. The gradable stabilization exercise protocol was practiced by one physical therapist. The exercise protocol was based on previous studies [16-18]. The exercise protocol consisted of two parts: the stretching exercises and stabilization exercises. All patients had a warm-up period with the stretching exercises for 5 minutes before beginning the stabilization exercises. Stretching exercises included a pelvic tilting exercise, a knee to chest exercise, and stretching exercises for the hamstrings, quadratus lumborum, iliopsoas, and pyriformis muscles. After the stretching exercises, patients were instructed to complete the stabilization exercises for 25 minutes. This program was based on patients’ condition, and ranged from easy to difficult. We gradually increased the degree of instability until the most unstable posture was achieved (five steps, Figure 2, Appendix 1). Each step had five basic positions: supine position, dead bug position, side lying position, prone position, and bird dog position. At the beginning, patients were placed into the adequate exercise level to have the posture be somewhat difficult. In order to challenge the stabilization of all trunk muscles (anterior, lateral and posterior), including the transverse abdominis, rectus abdominis, erector spinae and multifidus, internal oblique abdominals, and quadrates lumborum, subjects were instructed to complete all five exercise positions in each section. Patients repeated each posture 5 times for about 30 seconds, to the best of their ability, with total participation in 5 postures, requiring 25 minutes.

Subjects

All patients were given informed consent for the use of their clinical details and the study protocol was approved by the Institutional Review Board of the CHA Bundang Medical Center.

Figure 1: Subjects Flow Chart.

Figure 2: Gradable Stabilization Exercises protocol.

As the previous study has found that the use of a booklet or back school had no significant effect on post-treatment pain [8], we used a
hospital-based supervised exercise program that lasted 3 weeks with 6-8 visitations (two or three visits per week). Participants practiced the gradable exercise protocols and were encouraged to continue the exercise at home to strengthen their lumbar muscles. At the following visit, patients moved on to a more advanced step with a more difficult protocol. After completing the program, individualized gradable exercise programs (posture, duration, frequency) were formed, depending on each patient's physical state. Usually, the final protocols were decided with the most difficult and applicable posture in five basic positions and were designed not to last more than 30 minutes. Regardless of group assignment, all patients continued their previous treatment, such as physical therapy (hot pack, ultrasound, TENS and ICT) or medication.

Measurement

The effects of the interventions were evaluated by measuring the Numerical Rating Scale (NRS, 0–10) before the procedures and 4 weeks (3 to 5 weeks), 8 weeks (7 to 9 weeks), 12 weeks (10 to 14 weeks) and 24 weeks (20 to 28 weeks) after the procedure. The primary outcome was determined at the 24 week follow-up: pain resolution below 50% of baseline NRS without additional treatment was considered as treatment success while pain persistence or recurrence over 50% of baseline NRS was determined to be treatment failure.

Statistical analysis

For comparison of differences between Exercise and Control groups, independent t-tests and Chi-square tests were used. To analyze the changes of NRS after interventions in both groups, paired t-tests was used. The results are presented as means ± standard deviation or %. P-values of <0.05 were considered statistically significant. The effect size was calculated by Cohen's d. Statistical analysis was performed using SPSS version 21.0 (SPSS Inc., Chicago, IL, USA).

Results

Demographic information and clinical findings of subjects are described in Table 1. There were no significant differences in age, gender ratio, duration of symptoms, MRI findings between two groups (Table 1). The mean durations from pain onset to TFESI were 52.1 ± 27.0 days in the exercise group, 53.7 ± 32.1 days in the control group.

| MRI Findings                  | Exercise Group (n=45) | Control Group (n=73) | P-value |
|------------------------------|-----------------------|----------------------|---------|
| Sex                          | 17/28                 | 22/51                | 0.39    |
| Mean age (year)              | 54.3 ± 9.5            | 52.8 ± 12.2          | 0.71    |
| Duration of pain (day)       | 52.1 ± 27.0           | 53.7 ± 32.1          | 0.92    |

Table 1: Demographic Information and Clinical Findings of Participants. Values are presented as mean ± standard deviation. HNP, herniated nucleus pulposus; N.A, not applicable. a duration from pain onset to TFESI.

At the initial evaluation, mean NRS scores were not significantly different between exercise and control groups (8.1 ± 1.8, 8.4 ± 1.8 respectively in each group). Compared with that of the baseline, mean NRS scores decreased significantly in both groups after 4 weeks. The improvement was sustained during the follow-up period in the exercise group while mean NRS scores gradually increased after 12 weeks in the control group (Table 2 and Figure 3).

| Week | Exercise Group | Control Group | P-value |
|------|----------------|---------------|---------|
| 4    | 8.0 ± 1.7      | 8.4 ± 1.8     | 0.37    |
| 8    | 4.1 ± 2.7      | 4.0 ± 2.8     | 0.006***|
| 12   | 4.5 ± 3.0      | 5.2 ± 2.9     | <0.001***|

Table 2: Comparison of mean Visual Analogue Scale. Values are presented as mean ± standard deviation. * P<0.05, ** P<0.01, *** P<0.001.

Figure 3: This graph shows the change from initial NRS during 24 weeks in both exercise group and the control group. In Exercise Group, the NRS scores reduced at 4 weeks from 8.1 to 3.1, and low NRS score sustained until 24 weeks. However, in the control group, decreased NRS score at 4 weeks slightly increased to 24 weeks from 6.8 to 5.2.

Table 2: Comparison of mean Visual Analogue Scale. Values are presented as mean ± standard deviation. * P<0.05, ** P<0.01, *** P<0.001.
When we compared the mean NRS between the two groups, those of the control group were significantly higher at 4 weeks, 8 weeks, 12 weeks and 24 weeks than those of exercise group (Table 2). In addition, we compared the extent of pain improvement compared to the initial baseline between the groups for each follow-up period. At 4 weeks, no significant difference in extent of pain improvement was found between the groups. However, at 8 weeks, 12 weeks and 24 weeks, pain improvement of the exercise group was significantly better than that of the control group (Table 3). The effect size of exercise group against a control group on the degree of NRS decrease at 24 weeks were moderate (d=0.568). The rate of treatment success was 68.9% among patients assigned to exercise group, as compared with 41.1% among those assigned to control group (unadjusted odds ratio for successful outcome with exercise, 3.17; 95% CI, 1.45 to 6.96) (Figure 4).

**Table 3**: Extent of pain improvement compared to baseline in mean Visual Analogue Scale. Values are presented as mean ± standard deviation. *P<0.05, **P<0.01, ***P<0.001.

|          | Exercise Group (n=45) | Control Group (n=73) | P-value |
|----------|-----------------------|----------------------|---------|
| After 4 weeks (n=45,73) | 4.7 ± 2.4             | 4.2 ± 2.9            | 0.38    |
| After 8 weeks (n=45,55) | 5.3 ± 2.5             | 4.2 ± 2.9            | 0.04*   |
| After 12 weeks (n=45,53) | 5.0 ± 3.1             | 3.7 ± 3.1            | 0.04*   |
| After 24 weeks (n=45,71) | 4.9 ± 3.0             | 3.1 ± 3.1            | 0.004** |

Figure 4: This graph shows the comparison of the success rate after 6 months.

The rate of treatment success was 68.9% in patients of exercise group, as compared with 41.1% in those of control group (unadjusted odds ratio for successful outcome with exercise, 3.1; 95% CI, 1.45 to 6.96).

**Discussion**

The aim of this study was to compare the effect of adjuvant lumbar stabilization exercise on conventional TFESI for treatment outcome in patients with lumbar radiating pain. We found that the combination therapy was significantly more effective at 8 weeks, 12 weeks and 24 weeks compared to conventional TFESI alone. The extent of pain reduction, as well as the rate of treatment success at 6 months was better for the exercise group.

Panjabi MM provided the theoretic basis in understanding spinal stability and injury, asserting that stability of the vertebral column is required for its normal function [19]. It has also been proposed that the effective muscle activity surrounding the vertebrae may help increase vertebral column stability by controlling movement of the adjacent vertebrae [20]. Among various muscles, the transverse abdominal, multifidus, and internal oblique muscles are believed to be the key muscles that contribute to the spinal and pelvic stability [21-23]. After the initial episode of acute low back pain, localized segmental dysfunction of the multifidus and transverses abdominis muscles can occur [24,25]. Specific exercises targeting the multifidus and transverses abdominis muscles have been shown to decrease pain and disability in patients with low back pain [26,27]. Many studies demonstrated that segmental stabilization exercises have good effects for pain reduction and functional capacity in patients with acute and chronic low back pain [26-29]. A randomized controlled trial by Hides et al., compared patients with low back pain treated by specific exercise programs for rehabilitating the multifidus and transverse abdominis muscles in addition to medical management against patients treated solely with medications [28]. The exercise group showed better outcomes than the non-exercise group after 1 year and 3 years in NRS. These results are consistent with our results. In our study, we used TFESI in place of medical management for additional intervention combined to the stabilization exercise.

Surgical treatment and interventions like TFESI are good options for patients with lumbosacral radiating pain due to herniated disc. However, they have limitations when used alone. A randomized study reported that only 54% of patients with lumbar HNP responded to TFESI [30]. Another study reported that 43-75% of patients did not have long-term effects after TFESI for acute low back pain [3]. Previous study also showed that epidural steroid injection did not presented long term benefit in patients with spinal stenosis [11]. After lumbar disc surgery, it has been reported that 22-45% of patients still report sciatica and 30-70% of patients complain of low back pain [31,32]. Overall recurrence rates in patients with acute low back pain range from 60% to 86%, particularly in the first year after the acute episode [33,34]. Our study showed that 57.8% of patients who did not receive stabilization exercise experienced the recurrence of symptoms, while 31.1% of patients who received TFESI and stabilization exercise did not. Without stabilization exercise, reduced protection of the spinal segments may increase the likelihood of symptoms recurrence [28]. Our study proves the evidence that stabilization exercises is a good option for combination with TFESI to prevent recurrence. Optimal lumbar segmental muscle function is very important for protection of the spinal segments following injury.

The present study has limitations. Because this study was not a randomized controlled trial, the results may be prone to selection bias. But as the major factors in the baseline characteristics were not significantly different, the results are reliable. Next, data of the actual changes in lumbar stabilizing ability regarding the patient’s fitness are not available. The actual effect of exercise on the lumbar motor control and power were not accessed. Furthermore, measuring of cross-sectional area in multifidus using MRI or extension strength using the MedX lumbar extension machine, would have given us more information on the actual significance of the result of exercise. Future
studies should contain information regarding the effects of stabilization exercise on the actual musculature of patients with low back pain with strict RCT design.

Conclusion

In patients with lumbosacral radiating pain, both lumbar TFESI alone and combination therapy of TFESI with lumbar stabilization exercises reduced the pain severity after 4, 8, 12, and 24 weeks. However, compared to that of TFESI alone, combination therapy of TFESI and stabilization exercise was more effective for relieving pain and preventing recurrence.

Acknowledgment

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References

1. Roberts ST, Willick SE, Rho ME, Rittenberg JD (2009) Efficacy of lumbosacral transforaminal epidural steroid injections: a systematic review. PM R 1: 657-668.
2. Boswell MV, Hansen HC, Trescot AM, Hirsch JA (2003) Epidural steroids in the management of chronic spinal pain and radiculopathy. Pain Physician 6: 319-334.
3. McLain RF, Kapural L, Mekhail NA (2005) Epidural steroid therapy for lumbosacral radiculopathy. In patients with lumbosacral radiating pain, both lumbar TFESI and stabilization exercise was more effective for relieving pain and preventing recurrence.
4. Lewis JS, Hewitt JS, Billington L, Cole S, Byng J, et al. (2005) A randomized clinical trial comparing two physiotherapy interventions for chronic low back pain. Spine (Philadelphia, Pa:1976) 30: 711-721.
5. Mannon AF, Helbling D, Pulkovski N, Sprott H (2009) Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. Eur Spine J 18: 1881-1891.
6. van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, et al. (2011) A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. Eur Spine J 20: 19-39.
7. van Tulder M, Malmivaara A, Esmail R, Koes B (2000) Exercise therapy for low back pain: a systematic review within the framework of the cochrane collaboration back review group. Spine (Philadelphia, Pa:1976) 25: 2784-2796.
8. Suri P, Pearson AM, Scherer EA, Zhao W, Leine JS, et al. (2016) Recurrence of Pain After Usual Nonoperative Care for Symptomatic Lumbar Disk Herniation: Analysis of Data From the Spine Patient Outcomes Research Trial. PM R 8: 405-414.
9. Friedly JL, Comstock BA, Turner JA, Heagerty PJ, Deyo RA, et al. (2014) A randomized trial of epidural glucocorticoid injections for spinal stenosis. The New England journal of medicine 371: 11-21.
10. Bakhtiar AH, Safavi-Farokhi Z, Rezasoltani A (2005) Lumbar stabilizing exercises improve activities of daily living in patients with lumbar disc herniation. Journal of back and musculoskeletal rehabilitation 18: 55-60.
11. Fardon DF (2001) Nomenclature and classification of lumbar disc pathology. Spine (Philadelphia, Pa:1976) 26: 461-462.