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ORIGINAL RESEARCH

Effectiveness of Physical Therapy Combined With Epidural Steroid Injection for Individuals With Lumbar Spinal Stenosis: A Randomized Parallel-Group Trial

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Abstract

Objective: To examine the effectiveness of epidural steroid injection (ESI) and back education with and without physical therapy (PT) in individuals with lumbar spinal stenosis (LSS).

Design: Randomized clinical trial.

Setting: Orthopedic spine clinics.

Participants: A total of 390 individuals were screened with 60 eligible and randomly selected to receive ESI and education with or without PT (N=54).

Interventions: A total of 54 individuals received 1-3 injections and education in a 10-week intervention period, with 31 receiving injections and education only (ESI) and 23 additionally receiving 8-10 sessions of multimodal PT (ESI+PT).

Main Outcome Measures: Disability, pain, quality of life, and global rating of change were collected at 10 weeks, 6 months, and 1 year and analyzed using linear mixed model analysis.

Results: No significant difference was found between ESI and ESI+PT in the Oswestry Disability Index at any time point, although the sample had significant improvements at 10 weeks ($P<.001$; 95% confidence interval [CI], −18.01 to −5.51) and 1 year ($P=.01$; 95% CI, −14.57 to −2.03) above minimal clinically important difference. Significant differences in the RAND 36-Item Short Form Health Survey 1.0 were found for ESI+PT at 10 weeks with higher emotional role function ($P=.03$; 95% CI, −49.05 to −8.01), emotional well-being ($P=.02$; 95% CI, −19.52 to -2.99), and general health perception ($P=.05$; 95% CI, −17.20 to −.78).

Conclusions: Epidural steroid injection plus PT was not superior to ESI alone for reducing disability in individuals with LSS. Significant benefit was found for the addition of PT related to quality of life factors of emotional function, emotional well-being, and perception of general health. Archives of Physical Medicine and Rehabilitation 2019;100:797-810

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Lumbar spinal stenosis (LSS) is a musculoskeletal condition recognized as a common cause of low back pain (LBP) and leg pain in elderly persons. An estimated 13%-14% who seek care from a specialty physician and 3%-4% who seek care from a

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general practitioner for LBP are diagnosed as having LSS.[1-4] Stenosis is the most common and fastest growing reason for spinal surgery in individuals older than 65 years,[5,6] with costs reaching $100,000 per procedure.[7] In studies comparing surgical and nonsurgical management,[8-12] at least half of individuals treated nonsurgically improved and did not experience a worsening in symptoms.[8,9,13]

One commonly used nonsurgical option is epidural steroid injection (ESI). Epidural steroid injection using corticosteroids may be helpful for short-term pain relief[8,14-17] as a nonsurgical alternative, especially in elderly individuals where surgery carries greater risk.[14,17,18] Evidence from 2 clinical trials suggest short- and long-term relief after ESI for individuals with LSS.[19,20] A recent systematic review and meta-analysis concluded there is no benefit from ESI for individuals with LSS but cited limited quality evidence.[21] Current practice patterns identify the frequent use of ESI specifically for LSS in 23% of all lumbosacral injections, 25% of ESI for Medicare patients, and 74% of ESI at Veterans Affairs medical centers.[22]

Physical therapy (PT) uses additional nonsurgical strategies for LSS but has mixed results depending on what interventions are actually delivered.[12,23,24] Evidence supports the use of manual therapy and exercise in the management of LSS.[25-29] Whitman et al[28] found individuals treated using a multimodal approach including manual therapy and exercise improved at a higher rate than those receiving a flexion-directed approach,[28] suggesting PT should include manual therapy and exercise prescribed specifically for individuals with LSS. Evidence-based PT is associated with a reduced likelihood of crossover to surgery and greater reductions on the RAND 36-Item Short Form Health Survey 1.0 (SF-36) physical functioning scale after 6 months[30] and 2 years.[31] Delitto et al[31] compared outcomes for individuals with LSS randomized to either decompression surgery or PT and found no significant difference in outcomes of physical function.

Few studies have evaluated ESI with PT often seen in clinical practice. Koc et al[23] directly compared ESI to PT in a study where individuals with LSS (n=29) were treated with either ESI or inpatient PT that included ultrasound, hot pack, and transcutaneous electrical nerve stimulation 5 days a week for 2 weeks. They found both ESI and PT had significant improvements in pain and function over a 6-month period.[23] Hunter et al[32] (n=33) found preliminary evidence that combining ESI and PT may result in improved outcomes in LSS. Another study stated that 17% of the study population received both ESI and PT, although this subgroup was not analyzed.[33] A cohort study by Beyer et al[34] combined ESI and PT in the hospital for 1 week (n=38) and found significant improvements in Oswestry Disability Index (ODI), pain, and physical function in the short and long term.

List of abbreviations:

CI	**confidence interval**
ESI	**epidural steroid injection**
GRC	**global rating of change**
LBP	**low back pain**
LSS	**lumbar spinal stenosis**
MCID	**minimal clinically important difference**
MD	**mean difference**
NPRS	**numeric pain rating scale**
ODI	**Oswestry Disability Index**
PT	**physical therapy**
SF-36	**RAND 36-Item Short Form Health Survey 1.0**

Given the prevalence and cost associated with LSS, cost and complications associated with surgery, and the lack of evidence comparing nonsurgical options,[35] research evaluating optimal nonoperative management strategies is a high priority. The primary purpose of this study was to evaluate the clinical outcomes achieved by individuals receiving 2 conservative approaches (ESI and ESI+PT) in managing LSS.

Methods

Study design

This study was a patient level, multicenter, randomized clinical trial comparing 2 conservative approaches in the management of LSS: ESI vs ESI plus a multimodal evidenced based PT program (ESI+PT). Data recruitment and follow-up was standardized across 3 sites in the United States between 2009 and 2016. Outcomes were measured at 10 weeks, 6 months, and 1 year, with the primary outcome being improvement in disability on the modified ODI. Secondary outcomes were assessed by the numeric pain rating scale (NPRS), RAND 36-Item Health Survey 1.0 (SF-36), and global rating of change (GRC).

The current clinical trial was conducted following Consolidated Standards of Reporting Trials,[36] and informed consent was obtained for each subject with approval by the Institutional Review Board at each location. The trial was prospectively registered (ClinicalTrials.gov). It should be noted that small changes were made after registration, described in detail below.

Participants

Consecutive individuals with LBP who sought care in a primary or specialist practice in 3 locations were initially screened for eligibility and invited to participate. Participants had to meet the criteria outlined in box 1. Because imaging can be a barrier to care, either based on cost or standard practice in a clinic, a modification to the trial registration allowed the use of the self-administered, self-reported history questionnaire developed by Konno et al[37] as a validated method to diagnosis LSS.

Randomization

Participants were randomly assigned to receive ESI alone or in combination with PT. Concealed allocation using a computer-generated randomized table of numbers was created by a statistician who was not involved in the trial nor participated in analysis of results. Individual and sequentially numbered index cards with random assignment were concealed and prepared in sealed opaque envelopes. A researcher opened the envelope in consecutive enrollment and proceeded with intervention allocation at each site. Outcomes surveys were independently completed by participants and returned at each clinic (baseline, 10wk) or by mail delivery (10wk, 6mo, 1y). Outcomes were later assessed by researchers not involved in randomization, baseline assessment, or intervention delivery.

Interventions

All clinicians were trained in the study procedures. Every participant received identical educational support and ESI

Box 1 Inclusion and exclusion criteria

Inclusion Criteria

1. Age greater than or equal to 50 years.
2. Magnetic resonance imaging findings consistent with lateral foraminal and/or central lumbar spinal stenosis (evidence of compression of lumbar spinal nerve root(s) by degenerative lesions of the facet joint, disc, and/or ligamentum flavum) and/or additional criteria including diagnosis of LSS using self-administered, self-reported history questionnaire (SSHQ).
3. Chief complaint of pain in the low back, buttock and/or lower extremities.
4. Presence of symptoms consistent with neurogenic claudication (numbness, tingling, cramping, and downward radiating pain that is not exacerbated with biking, uphill ambulation, and lumbar flexion but is not alleviated with standing; or does not include signs of pulselessness, paralysis, or pallor).
5. Rates sitting as a better position with respect to symptom severity than standing or walking.
6. Lives within 1 hour of a research site.
7. Can attend 10 regular physical therapy appointments spread over 10 weeks and 4 examination appointments (baseline, end of treatment, 6 months, and 1 year).
8. Sufficient English reading and language skills and mental capability to complete self-report assessment questionnaires.
9. No contraindications to magnetic resonance imaging.

Exclusion Criteria

1. Severe vascular, pulmonary, or coronary artery disease that limits ambulation (as determined by the referring physician or the therapist).
2. Other orthopedic conditions or physical impairments of unrelated nature that would limit ambulation or prevent the subject from fully participating in any other aspect of the rehabilitation exercises (as determined by the referring physician or the therapist).
3. Previous spinal surgery that included fusion of 2 or more vertebrae.
4. History of spinal tumors, spinal infection, or lumbar vertebral fractures other than spondylolysis or spondylolisthesis.
5. Signs/symptoms suggestive of potential nonbenign or pathologic condition as the origin of symptoms.
6. Presence of any absolute contraindications to submaximal treadmill testing per the American College of Sports Medicine (ACSM) standards.
7. Epidural steroid injection within the last 365 days.

technique by the treating physician. Standardized technique described by Botwin et al[38] was used for ESI. Prior to the injection, the physician confirmed the patient did not have allergies and was not taking blood thinners. Plain radiographs in the anteroposterior and lateral views were taken after injections to document both the contrast pattern and needle placement. All participants were monitored by pulse oximetry, blood pressure, and electrocardiogram before, during, and after procedures. One to 3 ESIs were performed during the 10-week intervention period following a standardized algorithm for ESI (appendix 1). Additionally, all participants were educated using *The Back Book*.[39] Evidence has shown *The Back Book* is a simple educational tool providing advice to remain active that can be used in primary care with a positive effect on patients' beliefs and self-reported disability in activities of daily living. Participants randomized to the ESI+PT group received all of the above plus an evidence-based multimodal PT program.[28] The ESI+PT included 8-10 sessions of manual physical therapy, mobility, aerobic exercise, and muscle endurance and stabilization exercises during the 10-week period using the algorithm for PT (appendix 2).[26-28,40]

Outcome measures

The primary outcome of interest was the change of disability measured by the modified ODI. The ODI is a 10-item region-specific physical disability scale for individuals with LBP. The ODI exhibits excellent test-retest reliability in a patient population with LSS (intraclass correlation coefficient, 0.84).[41] The MCID in a population receiving nonsurgical management for LSS is 5% points.[41]

Secondary outcomes included the NPRS. The NPRS is a measure of rating pain on an 11-point scale (0=no pain to 10=highest pain). The MCID for NPRS in LSS has been shown to be between 1.25 and 1.5.[41] Additionally, the SF-36 is a 36-item, generic self-report measure of health status covering 8 domains: physical functioning, role limitation as a result of physical health problems, role limitations as a result of emotional health problems, energy/fatigue, emotional well-being, social functioning, bodily pain, and general health perceptions.[42,43] The SF-36 is widely used in studies of individuals with LBP and has well-established psychometric properties.[42-45] Finally, the global rating of change (GRC) asks individuals to rate change in their physical status since the initiation of intervention on a 15-point scale ranging from −7 (a very great deal worse) to +7 (a very great deal better).[46] Previous literature has shown individuals with a score of +3 (somewhat better) or higher exhibit a favorable response to intervention.[28,47]

Statistical analyses

To evaluate the primary study purpose ESI vs ESI+PT across time, the study used intention-to-treat principles with all participants analyzed in the group to which they were randomized. Initial analyses included frequency counts of participant characteristics and descriptive statistics (mean ± SE) for all outcome variables. All analyses were performed using SPSS version 24.0.[a]

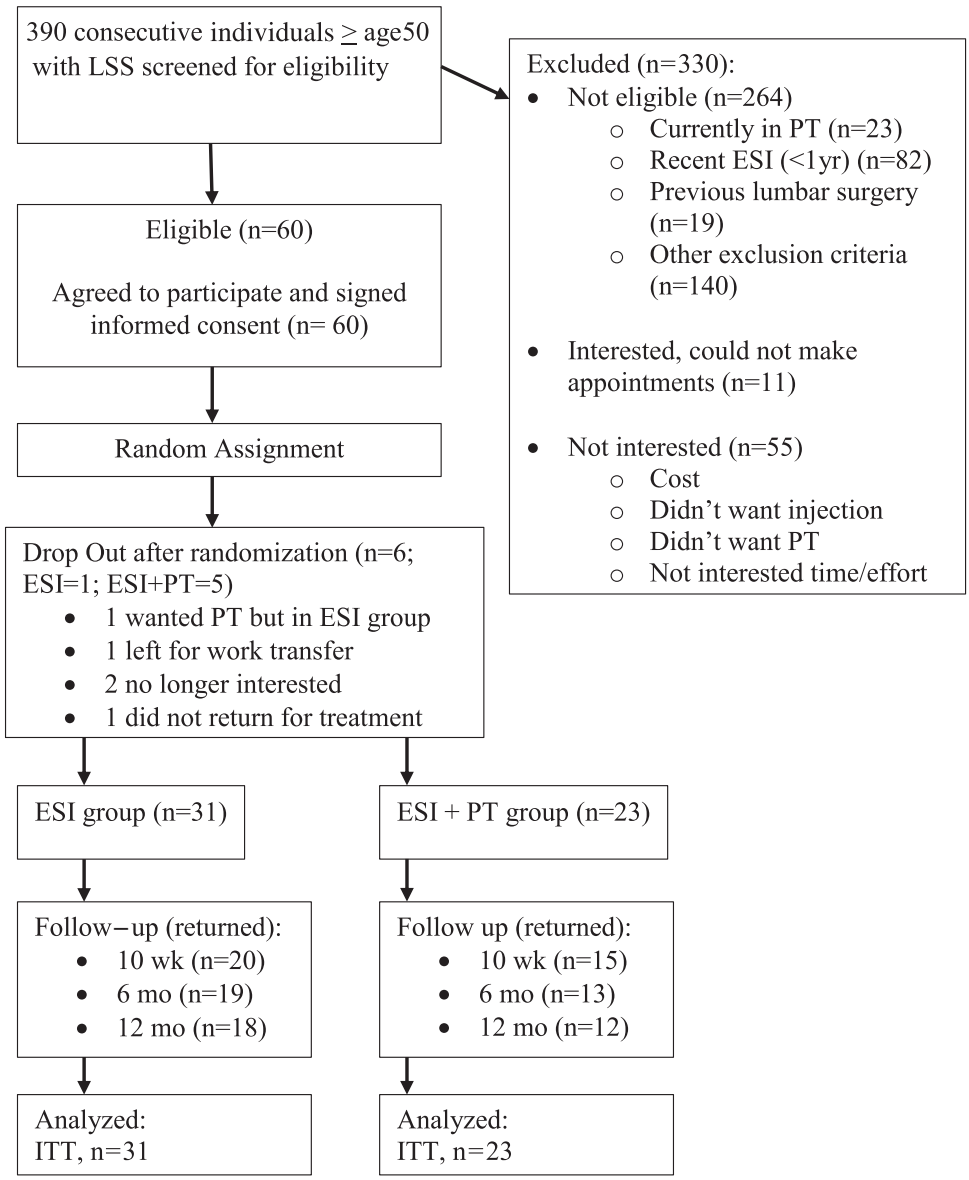

Fig 1 Randomization and retention. Missing data represent individuals who did not return survey packets for that follow-up period but returned data other periods. Abbreviation: ITT, intention to treat.

Primary analyses of outcomes were assessed using linear mixed modeling with repeated measures using restricted maximum likelihood estimation. Linear mixed modeling procedures included fixed and random effects, whereby fixed effects were modeled by group, time, and group by time effects and random effects modeled by subject effect. Group allocation was separated by intervention: ESI and ESI+PT. Time was categorized by outcome scores measured at 4 assessment points; baseline, 10 weeks, 6 months, and 1 year. For all linear mixed models, an α level equal to .05 was determined to represent statistical significance.

Using the GRC, secondary analyses included Fisher exact test to compare the proportions of successful outcomes in each intervention group. Those scoring below a +3 were classified as worsening or stable; ratings of +3 to +7 were classified as improved.[47]

Multiple imputation was used to account for data determined to be missing completely at random. Missing data were found at a rate of <40% for baseline, 10 weeks, and 6 months for most variables but exceeded 40% at 6 months and 1 year because of a reduced return rate and/or incomplete survey packets. Multiple imputation was used to account for the severity of such missingness and thereby reduce bias of parameter estimates.[48-50] Five datasets were derived using all available scores for primary outcome variables and used to estimate parameters of interest.

Sample size determination

A priori power analysis was performed based on a comparison of means between the baseline and the 6-month follow-up examination detecting a 5% point difference between groups in ODI at 6 months, assuming a standard deviation of 7% points, a 2-tailed test, α level equal to 0.05, and a desired power of 80%. The estimated desired sample was calculated to be 33 participants per group. A dropout percentage of 20% was expected, so a goal of 40 participants per group was planned.

Table 1 Participant characteristics

Variable	All Subjects (N=54)	ESI (n=31)	ESI+PT (n=23)
Age (y), mean ± SE	67.2±9.7	67.8±1.8	66.3±1.9
Sex, n (%)			
Male	27 (50)	15 (50)	11 (47.8)
Female	27 (50)	15 (50)	12 (52.2)
Race, n (%)			
Asian	2 (3.9)	0	2 (9.1)
Pacific Islander	2 (3.9)	1 (3.4)	1 (4.5)
Black	7 (13.7)	4 (13.8)	3 (13.6)
White	39 (76.5)	24 (82.8)	15 (68.2)
Hispanic	1 (2.0)	0	1 (4.5)
Symptom duration (mo), mean ± SE	13.8±16.9	13.0±2.3	14.7±5.5
Marital status, n (%)			
Single	5 (9.6)	4 (13.8)	1 (4.3)
Married	32 (61.5)	17 (58.6)	15 (65.2)
Divorced	5 (9.6)	1 (3.4)	4 (17.4)
Widowed	10 (19.2)	7 (24.1)	3 (13)
Education level, n (%)			
Less than high school	1 (1.9)	1 (3.4)	0
High school	15 (28.8)	7 (24.1)	8 (34.8)
Some college	15 (28.8)	9 (31.0)	6 (26.1)
Graduated college	7 (13.5)	6 (20.7)	1 (4.3)
Some post grad	4 (7.7)	2 (6.9)	2 (8.7)
Completed post grad	10 (19.2)	4 (13.8)	6 (26.1)
Current smoker, n (%)			
No	28 (84.8)	16 (84.2)	12 (85.7)
Yes	5 (15.2)	3 (15.8)	2 (14.3)
Employment, n (%)			
Full-time	9 (17.6)	3 (10.7)	6 (26.1)
Mod part-time	3 (5.9)	2 (7.1)	1 (4.3)
Permanently unable	7 (13.7)	5 (17.9)	2 (8.7)
Retired	26 (51)	13 (46.4)	13 (56.5)
Homemaker	6 (11.8)	5 (17.9)	1 (4.3)
Medication use, n (%)			
Not at all	9 (18)	5 (17.9)	4 (18.2)
Once/wk	2 (4)	1 (3.6)	1 (4.5)
Every 2 d	9 (18)	4 (14.3)	5 (22.7)
Once or twice/d	14 (28)	5 (17.9)	9 (40.9)
3 or more/d	16 (32)	13 (46.4)	3 (13.6)
Physical activity, n (%)			
<3 d	27 (54)	15 (53.6)	12 (54.5)
3-4 d	8 (16)	5 (17.9)	3 (13.6)
5 d	9 (18)	6 (21.4)	3 (13.6)
>5 d	6 (12)	2 (7.1)	4 (18.2)
Bothersome Index (0-5), mean ± SE, (n=51)*			
Low back/buttock	3.69±0.18		
Lower extremity	3.55±0.21		
Numbness	2.65±0.23		
Weakness	2.71±0.27		
Outcome variables, mean ± SD			
ODI total (0-100)*	41.43±1.79	41.14±2.28	41.82±2.91
NPRS (0-10)*	5.63±0.37	6.37±0.48	4.64±0.51
SF-36 (0-100)			
SF36-Physical Functioning	40.59±2.76	40.53±3.79	40.68±4.07
SF36-Physical Role Functioning	13.04±3.83	9.81±3.95	17.39±7.28
SF36-Emotional Role Functioning	38.49±6.13	41.25±7.99	34.78±9.71
SF36-Energy/Fatigue	43.95±2.95	46.44±3.94	40.60±4.46

(*continued on next page*)

Table 1 (*continued*)

Variable	All Subjects (N=54)	ESI (n=31)	ESI+PT (n=23)
SF36-Emotional Well-Being	72.36±2.63	74.29±2.81	69.75±4.90
SF36-Social Functioning	59.92±3.46	60.01±4.94	59.78±4.78
SF36-Bodily Pain	41.81±2.46	41.54±3.52	42.17±3.40
SF36-General Health Perceptions	64.41±2.48	65.92±2.95	62.39±4.31

* Lower score is better. In all other scales, higher score is better.

Results

A total of 390 consecutive older adults with LBP were screened for eligibility. Sixty (15%) satisfied all criteria, agreed to participate and were randomly allocated into groups with 6 dropping out after inclusion, leaving 31 in the ESI group and 23 in the ESI+PT group (fig 1). The sample size was smaller than planned based on original power calculations because the trial was stopped before recruitment was complete due to time and funding constraints with no interim analysis performed before stopping. The average age was 67 years and included an equal proportion of men (n=27) to women (n=27) per group (ESI, 15:16; ESI+PT, 11:12). Duration of symptoms persisted an average of 13-14 months. Baseline demographics and outcome variables can be seen in table 1.

For the entire sample, ODI scores decreased from baseline to 6 months, indicating reduced disability, and rose slightly at 1 year, although was still below baseline and 10-week levels (table 2). Pain scores decreased from baseline to 1 year. During the 10-week intervention period, adverse events were seen in 3 (5.6%) participants in ESI; 2 reported mild allergic reaction and 1 reported increased pain symptoms. No other adverse reactions were reported.

Table 2 Outcome scores over time for all participants

Outcome Variable (N=54)	Baseline	10 wk	6 mo	1 y
ODI total (0-100)*	41.43±1.79	37.17±1.83	29.05±1.49	31.57±1.95
ESI	41.14±2.28	34.88±2.53	28.30±1.91	30.12±2.58
ESI+PT	41.82±2.91	40.25±2.53	30.06±2.41	33.52±3.00
NPRS (0-10)*	5.63±0.37	3.249±0.31	2.95±0.32	2.50±0.28
ESI	6.37±0.48	4.77±0.42	4.14±0.41	3.27±0.46
ESI+PT	4.64±0.51	4.73±0.54	4.40±0.54	3.97±0.49
SF-36 (0-100)				
SF-36 Physical Functioning	40.59±2.76	42.62±2.48	54.43±2.34	52.08±2.49
ESI	40.53±3.79	41.69±3.55	56.88±3.21	51.79±3.10
ESI+PT	40.68±4.07	43.87±3.41	51.12±3.34	52.45±4.14
SF-36 Physical Role Functioning	13.04±3.83	13.83±3.34	18.17±3.32	13.63±2.87
ESI	9.81±3.95	13.34±4.45	17.36±4.51	15.42±4.37
ESI+PT	17.39±7.28	14.49±5.20	19.27±4.98	11.21±3.25
SF-36 Emotional Role Functioning	38.49±6.13	46.76±5.20	46.61±4.53	49.51±4.84
ESI	41.25±7.99	44.72±6.87	37.21±6.24	47.72±6.80
ESI+PT	34.78±9.71	49.50±8.13	59.27±5.58	51.92±6.82
SF-36 Energy/Fatigue	43.95±2.95	49.11±2.25	58.25±2.23	53.47±2.55
ESI	46.44±3.94	51.14±2.96	56.61±3.16	54.09±3.13
ESI+PT	40.60±4.46	46.37±3.46	60.44±2.97	52.62±4.33
SF-36 Emotional Well-Being	72.36±2.63	75.23±2.19	79.87±1.52	75.57±1.92
ESI	74.29±2.81	78.31±2.33	77.01±2.18	75.05±2.56
ESI+PT	69.75±4.90	71.08±3.97	83.72±1.73	76.27±2.93
SF-36 Social Functioning	59.92±3.46	63.96±3.36	78.83±2.66	54.96±2.55
ESI	60.01±4.94	66.01±4.43	76.38±3.94	54.68±3.36
ESI+PT	59.78±4.78	61.20±5.21	82.12±3.23	55.33±3.96
SF-36 Bodily Pain	41.81±2.46	52.24±1.98	59.89±2.40	58.86±2.42
ESI	41.54±3.52	51.99±2.88	57.94±3.70	58.98±3.45
ESI+PT	42.17±3.40	52.58±2.64	62.50±2.66	58.70±3.35
SF-36 General Health Perceptions	64.41±2.48	54.90±2.04	67.53±1.72	64.47±1.95
ESI	65.92±2.95	54.03±2.72	65.20±2.43	63.80±2.55
ESI+PT	62.39±4.31	56.06±3.16	70.66±2.28	65.37±3.08

NOTE. Values are mean ± SE.
* Lower score is better. In all other scales, higher score is better.

Table 3 Adjusted estimated change in outcome scores by treatment group

Variable	ESI	ESI+PT*	Mean Difference† (95% CI)	*P* Value
ODI (0-100)				
10 wk	−12.84	−11.76	−1.08 (−8.10 to 5.94)	.80
6 mo	−6.27	−1.57	−4.70 (−11.72 to 2.32)	.27
12 mo	−11.02	−8.30	−2.72 (−9.74 to 4.30)	.52
NPRS Current (0-10)‡				
10 wk	−1.59	0.08	−1.68 (−3.08 to −0.29)	.07
6 mo	−2.23	−0.24	−1.99 (−3.38 to −0.60)	.04§
12 mo	−3.11	−0.67	−2.44 (−3.80 to −1.08)	.004‖
SF-36 Emotional Role (0-100)¶				
10 wk	−4.03	24.50	−28.53 (−49.05 to −8.01)	.03§
6 mo	3.47	14.72	−11.25 (−31.77 to 9.27)	.39
12 mo	6.47	17.14	−10.67 (−31.19 to 9.85)	.41
SF-36 Emotional Well-Being (0-100)¶				
10 wk	2.72	13.98	−11.26 (−19.52 to −2.99)	.02§
6 mo	4.02	1.33	2.69 (−5.57 to 10.95)	.59
12 mo	0.76	6.52	−5.76 (−14.02 to 2.50)	.24
SF-36 General Health Perception (0-100)‖				
10 wk	−0.72	8.27	−8.99 (−17.20 to −0.78)	.05§
6 mo	−11.88	−6.33	−5.56 (−13.77 to 2.65)	.23
12 mo	−2.12	2.98	−5.10 (−13.31 to 3.11)	.27

* PT in conjunction with ESI.
† ESI+PT minus ESI values.
‡ A lower score (with negative difference) indicates improvement in the outcome favoring ESI only.
§ $P \leq .05$.
‖ $P \leq .01$.
¶ A greater score (with negative difference) indicates improvement in outcome favoring ESI+PT.

Intention-to-treat analysis

Results of the intention-to-treat analysis for interventions are listed in table 3. Group by time interactions on ODI were similar and nonsignificant for ESI and ESI+PT (fig 2). Statistically significant lower scores were found in ESI for pain at 6 months (mean difference [MD], −1.99; 95% confidence interval [CI], −3.38 to −.60; $P=.04$) and 1 year (MD, −2.44; 95% CI, −3.80 to −1.08; $P=.004$) (fig 3). Group by time interactions revealed statistically significant worse scores for ESI at 10 weeks for SF-36 in emotional role functioning (MD, −28.53; 95% CI, −49.05 to −8.01; $P=.03$), emotional well-being (MD, −11.26; 95% CI, −19.52 to −2.99; $P=.02$), and general health perceptions (MD, −8.99; 95% CI, −17.20 to −0.78; $P=.05$) (fig 4). There were no other significant differences between ESI and ESI+PT.

For the main effects (table 4), all participants in the study significantly reduced disability of −11.76% at 10 weeks (95% CI, −18.01 to −5.51; $P=.001$) and −8.3% at 1 year (95% CI, −14.57 to −2.03; $P=.01$) meeting MCID of 5% for ODI in LSS. Participants in ESI had statistically significant group main effects for pain (95% CI, 0.50-2.96; $P=.01$) with ESI 1.73 points higher (6.37) than ESI+PT (4.64). For the main effects of SF-36, participants across both groups had statistically significant quality of life changes, indicating improved bodily pain,

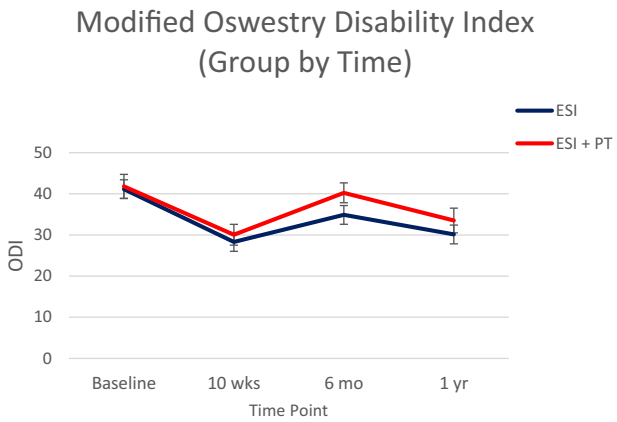

Fig 2 Self-reported modified ODI adjusted mean scores.

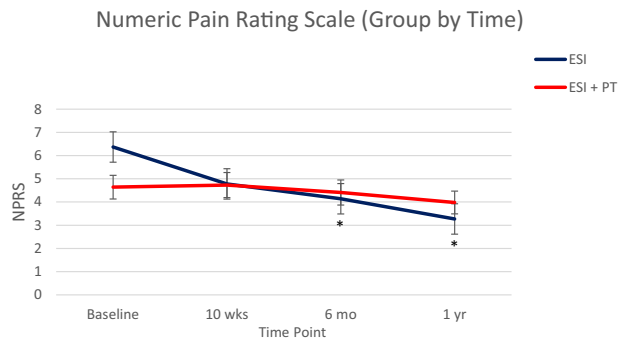

Fig 3 Self-reported NPRS adjusted mean scores.

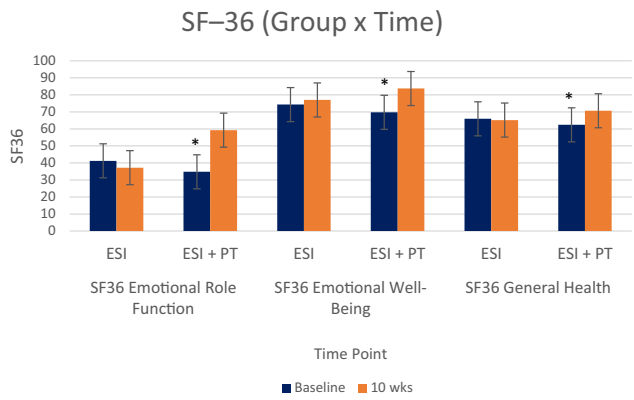

Fig 4 Self-reported SF-36 adjusted mean scores.

physical function, energy, emotional role function, emotional well-being, social functioning, and general health perceptions (see table 4).

Secondary analyses using Fisher exact test indicated that the proportion of participants reporting success on the GRC by time point (ESI 16.4, 14.2, and 13.6; ESI+PT 6.4, 7, and 5.6, respectively) did not differ between groups ($P = .347$). Cross tabulations demonstrated that 23 (54%) participants reported a successful recovery outcome on the GRC after 10 weeks, 21 (50%) after 6 months, and 19 (44%) after 12 months.

Discussion

Older individuals with LBP and leg pain can be challenging to manage, and the optimal conservative interventions for individuals with LSS is unknown.[9,13] This study examined the value of adding PT in combination with ESI compared with ESI alone. There have been few prior reports about the combination of ESI and PT,[32,34] although reports of ESI[19,20] and PT[26-28,31] alone support the use of each separately. Analysis of the primary outcome, physical disability on ODI, suggests that both ESI and ESI+PT improved short- and long-term outcomes. However, we were unable to meet our a priori power calculations based on ODI at 6 months. If there was difference in ODI scores between intervention groups, it is possible we were unable to detect this because of the small sample size. Therefore, conclusions related to disability when combining PT with ESI should not be made until a larger, more robust study can evaluate these nonsurgical options.

Pain is often a reason individuals with LSS seek health care, and this study showed significant decreases over time for both ESI and ESI+PT. This was supported by the significant reduction in bodily pain on the SF-36 at each time point. However, group by time analysis revealed that ESI significantly lowered pain at 6 months and 1 year, meeting MCID (1.9 and 2.4, respectively). There may not be benefit in combining ESI and PT related to pain outcomes in the long term. One explanation is those in the ESI+PT group may have increased their physical activity long term, which could have elevated their low-back–specific pain scores. Wood et al[51] identified that patients with LSS have higher fear of reinjury and activity avoidance. If adding PT reduced fear of activity and heightened an individual's expectation and participation in activities that in turn resulted in increased pain, it could explain this discrepancy.

Quality of life is often identified as important in the biopsychosocial model for management of many conditions. Both ESI and ESI+PT resulted in individuals with LSS experiencing a significantly greater quality of life in physical function, emotional function, energy, emotional well-being, social functioning, and general health. Uniquely, the ESI+PT group had significantly

Table 4 Main effects: adjusted estimated change in outcome scores for all participants by time and by group

Outcome Variable (N = 54)	Time 10 wk*	Time 6 mo*	Time 12 mo*	Group (Overall)†
ODI total (0-100)‡	−11.76 (−18.01 to −5.51)§	−1.57 (−7.83 to 4.69)	−8.30 (−14.57 to −2.03)‖	−0.67 (−7.69 to 6.35)
NPRS (0-10)‡	−6.67 (−13.68 to 15.40)	−2.39 (−16.56 to 11.78)	0.86 (−20.01 to 6.67)	1.73 (.50-2.96)‖
SF-36 (0-100)				
SF-36 Physical Functioning	10.45 (1.0-19.91)¶	3.20 (−6.21 to 12.60)	11.78 (2.36-21.20)‖	−0.14 (−10.15 to 9.86)
SF-36 Emotional Role Function	24.49 (5.03-43.95)‖	14.72 (−4.67 to 34.10)	17.13 (−2.30 to 36.57)	6.46 (−14.10 to 27.00)
SF-36 Energy/Fatigue	19.84 (11.81-27.87)§	5.78 (−2.23 to 13.78)	12.02 (4.07-19.98)‖	5.84 (−4.08 to 15.76)
SF-36 Emotional Well-Being	13.97 (6.66-21.29)§	1.33 (−5.97 to 8.63)	6.52 (−0.79 to 13.83)	4.54 (−3.72 to 12.79)
SF-36 Social Functioning	22.34 (11.12-33.56)§	1.41 (−9.77 to 12.59)	−4.45 (−15.63 to 6.73)	0.23 (−11.84 to 12.30)
SF-36 Bodily Pain	20.33 (11.64-29.01)§	10.41 (1.75-19.10)¶	16.52 (7.83-25.21)§	−0.63 (−9.85 to 8.59)
SF-36 General Health Perceptions	8.27 (1.37-15.17)¶	−6.33 (−13.17 to 0.51)	2.98 (−3.93 to 9.89)	3.52 (−4.68 to 11.73)

NOTE. Fixed effects analysis by time and by group. All scores reported as change score (95% CI).

* Change score main effects analyses with missing data imputed. Values are mean change in outcome score after controlling for baseline score.

† Change score main effect analyses with missing data imputed. Main effects by group reported for ESI as difference from reference group ESI+PT.

‡ Lower score is better. In all other scales, higher score is better.

§ $P \leq .001$.

‖ $P \leq .01$.

¶ $P \leq .05$.

greater improvements in emotional function, emotional well-being, and general health perception short term. Psychosocial factors such as emotional distress have been found to be stronger predictors of LBP outcomes when compared with physical examination findings or severity of pain alone.[52] The findings in this study of improved perceptions of emotional and general heath with the combination of ESI+PT may be an important aspect of patient management in LSS that warrants further exploration.

Study limitations

The largest limitation of this study was a small sample size. There may be differences between the nonsurgical intervention strategies that were not been captured. Both ESI and ESI+PT resulted in improvement across primary and secondary outcomes. However, because we did not include a control group, these improvements might have been simply related to the passage of time. Compared with only a few previous studies,[23,32,34] this study evaluates the effectiveness of combining ESI+PT interventions in the largest cohort of individuals with LSS. Generalizability is a limitation because the inclusion criteria required living within 1 hour of the clinic, speaking English, and being able to attend 10 PT appointments over 10 weeks. It is likely that older adults with limited transportation and accessibility were not included. The MCID used for pain determined in Cleland et al[41] used a receiver operating curve method that can overestimate the true value. In addition, long-term conclusions from this study are limited by the large loss to follow-up at 6 months and 1 year. Data collection at these time points was exclusively by mail packets. Previous literature has noted the difficulty in retaining older adults in a study[53] plus issues with return of mail packets even when incentive programs are added.[54,55] In response, robust statistical analyses accounting for missing data were used to compare intervention effects. Importantly, minimal loss to follow-up was noted at 10 weeks upon completion of ESI or ESI+PT. Comparisons at this time point likely represent true change with intervention identifying significant main effects for both groups.

Conclusions

This study found that ESI+PT was not superior to ESI alone for reducing disability. The addition of multimodal PT interventions added short-term benefit related to emotional function, emotional well-being, and general health perceptions, suggesting these interventions should be considered by clinicians striving to manage individuals with LSS. Although both groups had improved outcomes in the short and long term, we are unable to conclude that the interventions alone contributed to these results. This study serves to provide a basis for future high-quality research to further understand nonsurgical options for LSS.

Supplier

a. SPSS, version 24.0; IBM Corporation.

Keywords

Exercise; Injections, epidural; Low back pain; Musculoskeletal manipulations; Rehabilitation; Spinal stenosis; Therapeutics

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Appendix 1 Physician epidural steroid injection treatment algorithm for lumbar spinal stenosis trial

The patient will receive maximum of 2-3 epidural steroid injections during the randomized controlled trial for lumbar spinal stenosis following the algorithm listed below:

Epidural Steroid Injections	
Assessment	Treatment
1. Make verbal confirmation	• Before starting treatment, make verbal confirmation that the patient (1) does not have any allergies and (2) is not on any blood thinning medications.
2. 1st Injection	• Identify the level of greatest stenosis pathology according to MRI or CT scan that correlates to symptoms. • Use a transforaminal approach at the level identified. • Determine if bilateral sites (2 injections at both sides of the level identified) or unilateral site (1 injection on only 1 side of the level identified). If >90% of the patient's symptoms are one only 1 side, perform unilateral site injection. Otherwise, perform bilateral site injection. • Use exactly 1.5 mL of steroid at each site injected.
3. Reassess 3-4 weeks for possible 2nd injection	• If patient reports >90% improvement in back/buttock/leg pain, discontinue injections • If patient reports 50%-90% improvement in back/buttock/leg pain, repeat injection #1 procedure at the same level indicated.

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Epidural Steroid Injections	
Assessment	Treatment
4. Reassess 3-4 weeks for possible 3rd injection	• If patient reports <50% improvement in back/buttock/leg pain, change levels to above or below 1st injection determined by stenosis pathology indicated at other levels on MRI or CT scan. • If patient reports >90% improvement in back/buttock/leg pain; discontinue injections. • If patient reports 50-90% improvement in back/buttock/leg pain; repeat injection #1 procedure at the same level indicated. • If patient reports <50% improvement in back/buttock/leg pain; change levels to above or below 1st and 2nd injection determined by stenosis pathology indicated at other levels on MRI or CT scan.
5. Reassess 3-4 weeks after 3rd injection	• Determine the level of patient reported improvements in back/buttock/leg pain at this time. • No further epidural steroid injections at this time.

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging.

Appendix 2 Physical therapy treatment algorithm for lumbar spinal stenosis trial

The patient will receive interventions targeting lumbopelvic impairments on day 1. Other interventions indicated based on the following tables and will be provided no later than the end of the third visit. Prioritization is as follows: (1) lumbopelvic spine, (2) hips/hip flexors, (3) abdominal muscles/stabilization exercise, (4) thoracic spine mobility.

Manual Interventions **If thrust manipulation is contraindicated for a particular patient, all thrust manipulations will be omitted from the program.	
Assessment	Treatment
1. Clinicians assess lumbar spine mobility and range of motion (including overpressure, quadrant testing and repeated movements, if indicated).	• If hypomobility or limited range of motion of the lumbar is identified, the therapist will use lumbopelvic thrust manipulation and/or lumbar rotation thrust and nonthrust manipulation (may include rotation, central, and unilateral posterior-anterior techniques). Thrust manipulation used unless contraindications noted or lower extremity symptoms reproduced with patient positioning. • Thrust manipulations may be repeated up to 2 times if reassessment of the patient shows improvements in range of motion, mobility, and/or pain. • Nonthrust manipulations generally performed 2-3×30 repetitions at each hypomobile level. • If improvements in pain and/or movement after the above interventions, the same interventions may be repeated a second time.
2. Clinicians assess thoracic spine mobility and range of motion.	• If hypomobility or limited range of motion is identified in the thoracic spine, the therapist will use thoracic thrust manipulation and/or and nonthrust manipulation (may include central and

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Manual Interventions

**If thrust manipulation is contraindicated for a particular patient, all thrust manipulations will be omitted from the program.

Assessment	Treatment
	unilateral posterior-anterior techniques to the thoracic spine and ribs). • Thrust manipulation will be used unless contraindications noted (history or self-report of osteopenia/osteoporosis, etc) or lower extremity symptoms are reproduced with patient positioning. • Thrust manipulations may be repeated up to 2 times if reassessment of the patient shows improvements in range of motion, mobility, and/or pain. • Nonthrust manipulations generally performed 2-3×30 repetitions at each hypomobile level and may be repeated again (2-3×30 repetitions) if the patient shows improvements in range of motion, mobility, and/or pain.
3. Clinician assesses hip range of motion and joint mobility, including quadrant testing.	• If hypomobility of the hip is identified, the therapist will utilize thrust and non-thrust manipulations. Manipulation applied in the direction of identified restriction for joint assessment. All patients receive 2-5 long axis distraction thrust manipulations and (3) 30-second bouts of caudal glide nonthrust manipulations to each hip. The positioning of the hip for the caudal glide nonthrust mobilizations will start in a 90 degree flexed position and will be progressed into positions of joint restriction as tolerated by the patient. • If patient is limited in flexion or internal rotation in a flexed position, they will receive 2-3x30-second bouts of anterior-posterior nonthrust manipulations. If the patient shows improvement in pain and/or mobility after this treatment, the manipulations may be repeated. If patient is limited in hip extension they will receive 2-3x30-second bouts of posterior-anterior nonthrust manipulations. The positioning of the hip will start in a neutral position but will progress into greater degrees of hip extension and other combined positions of joint restriction as tolerated by the patient. If the patient shows improvement in pain and/or mobility after this treatment, the manipulations may be repeated.
4. Clinician assesses mobility of the tibiofemoral, patellofemoral, and proximal tibiofibular joints.	• If hypomobility is identified at the tibiofemoral joint, the therapist will use 2-3 30-second bouts of anterior-posterior and posterior-anterior glide non thrust manipulations as well as end-range mobilizations in flexion and extension. • If hypomobility is identified at the patellofemoral joint, the therapist will use 2-3 30-second bouts inferior and superior glide nonthrust manipulations performed 3x30 repetitions. • If hypomobility of the proximal tibiofibular joint is identified, the therapist will utilize a posterior-anterior thrust or nonthrust manipulation to the proximal tibiofibular joint.
5. Clinician assesses mobility of the talocrural and subtalar joints.	• If hypomobility of the talocrural joint is identified the therapist will use nonthrust manipulations. If the patient is restricted in plantarflexion, the therapist will use posterior-anterior glides of the talus. • If the patient is limited in dorsiflexion, the therapist will use anterior-posterior glides of the talus. • If the subtalar joint is limited, the therapist will use a rearfoot distraction thrust manipulation and (3) 30-second bouts of lateral glide nonthrust manipulations.

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(*continued*)

Manual Interventions

**If thrust manipulation is contraindicated for a particular patient, all thrust manipulations will be omitted from the program.

Assessment	Treatment
6. Clinician assesses flexibility of the iliopsoas and rectus femoris.	• If decreased flexibility is noted, manual stretching of the iliopsoas and/or rectus femoris will be performed in the prone position (pillows will be used as necessary). Stretches will be held for 30 seconds, and 2-3 repetitions will be performed.
7. Clinician assesses strength of the trunk and hip musculature.	• If strength impairments are identified, the patient will be specifically trained using neuromuscular re-education.

Exercise Interventions

Patients will begin an aerobic conditioning program on their second day in clinic. Patients are asked to take a "daily intentional walk" on 3 days per week that they are not coming in for treatment. On the days they are in clinic, they will perform up to 45 minutes per session of aerobic exercise. The patients will start their exercise on the treadmill (TM). The clinician will adjust the TM speed and angle of inclination to maximize comfort and/or minimize lower extremity symptoms. If the patient needs to stop walking because of symptoms, he/she will be encouraged to sit for a couple minutes to wait for symptoms to resolve and then attempt another session of TM walking. Once the patient and/or clinician deem further walking is not possible, the patient will complete the remaining aerobic exercise time on the stationary bicycle. If the patient has not been active in an exercise program, the initial target exercise program will be 20 minutes total (TM+stationary bicycling). If the patient has been active in an aerobic exercise program, the target exercise program will be 30 minutes in duration total (TM+bicycle). All patients will be progressed as able up to 45 minutes per session. This will be recorded on a training exercise log. Lastly, any rating of perceived exertion (RPE)>7 on a 10-point RPE scale mandates termination of the exercise session. The clinician will take this RPE into account in planning for the next exercise session (ie, the exercise intensity will be decreased).

Selection of Exercise	Exercise	Progression
1. All patients	Daily walking program (In the clinic this may include incline treadmill walking or stationary biking)	Patient walks at a pace and duration that does not exacerbate lower extremity symptoms. Goal: 45 minutes
2. All patients	Pelvic tilts	Patient to perform pelvic tilts without exacerbation of symptoms. Progressed based on patient response. Goal: 3 sets of 10
3. All patients	Glute strengthening (clam exercises)	Patient to perform clam exercises without exacerbation of symptoms. Progressed based on patient response. Goal: 3 sets of 10
4. All patients	Single knee to chest	Patient draws 1 leg to chest to the point of light stretch in the low back region. This is held for 30 seconds and then repeated on the contralateral side. Goal: 2 sets
5. All patients	Double knee to chest	Patient draws both legs to chest to the point of light stretch in the low back region. This is held for 30 seconds. Goal: 2 sets
6. All patients	Self lumbar side lying-rotation mobilizations	Patient is side lying and performs self lumbar rotation for 3x30 seconds. This may be repeated again (3×30 seconds) with new positioning to target another region of the spine. Goal: 2 sets
7. All patients	Specific hip flexor stretching: 1. Rectus femoris 2. Iliopsoas	Patient to perform 3×30 second stretches for each LE. Goal: 3 sets of 30 seconds hold for each muscle
8. Patients with poor Transversus Abdominus (TrA) firing	Transversus abdominis (TrA) isometrics	Patient to exercises without exacerbation of symptoms. Progressed based on patient response.

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Exercise Interventions		
Patients will begin an aerobic conditioning program on their second day in clinic. Patients are asked to take a "daily intentional walk" on 3 days per week that they are not coming in for treatment. On the days they are in clinic, they will perform up to 45 minutes per session of aerobic exercise. The patients will start their exercise on the treadmill (TM). The clinician will adjust the TM speed and angle of inclination to maximize comfort and/or minimize lower extremity symptoms. If the patient needs to stop walking because of symptoms, he/she will be encouraged to sit for a couple minutes to wait for symptoms to resolve and then attempt another session of TM walking. Once the patient and/or clinician deem further walking is not possible, the patient will complete the remaining aerobic exercise time on the stationary bicycle. If the patient has not been active in an exercise program, the initial target exercise program will be 20 minutes total (TM+stationary bicycling). If the patient has been active in an aerobic exercise program, the target exercise program will be 30 minutes in duration total (TM+bicycle). All patients will be progressed as able up to 45 minutes per session. This will be recorded on a training exercise log. Lastly, any rating of perceived exertion (RPE)>7 on a 10-point RPE scale mandates termination of the exercise session. The clinician will take this RPE into account in planning for the next exercise session (ie, the exercise intensity will be decreased).		
Selection of Exercise	Exercise	Progression
9. Patients with thoracic mobility restrictions as identified during the manual examination	Self thoracic mobilizations	Goal: 10-second holds for 10 repetitions Patient performs self thoracic extension exercises without exacerbation of symptoms. Progressed based on patient response.
10. Patients with other muscle length, joint mobility, or muscle strength impairments may be provided up to 2 additional exercises that are patient specific.	Self-mobilization, muscle stretch, or strengthening exercise as needed by the patient	Goal: 2 sets of 15-30 repetitions As needed.

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