# Injection Treatment and Back Pain Associated with Degenerative Lumbar Spinal Stenosis in Older Adults

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Free full manuscript: www.painphysicianjournal.com **Background:** Lower back pain is one of the most common health-related complaints in the adult population. Thirty percent of Americans 65 years and older reported symptoms of lower back pain in 2004 (NCHS, 2006). Injection treatment is a commonly used non-surgical procedure to alleviate lower back pain in older adults. However, the effectiveness of injection treatment, particularly in older adults, has not been well documented.

**Objective:** This study quantified the effectiveness of injection treatment on pain relief among adults 60 years and over who were diagnosed with degenerative lumbar spinal stenosis, a common cause of lower back pain in older adults. The variations of the effectiveness were examined by selected patient attributes.

Study Design: Prospective, non-randomized, observational human study.

Setting: Single institution spine clinic.

**Methods:** Patients scheduled for lumbar injection treatment between January 1 and July 1, 2008 were prospectively selected from the study spine clinic. Selection criteria included patients age 60 and over, diagnosed with degenerative lumbar spinal stenosis and no previous lumbar injection within 6 months or lumbar surgery within 2 years. The pain sub-score of the SF-36 questionnaire was used to measure pain at baseline and at one and 3 months post injection. Variations in longitudinal changes in pain scores by patient characteristics were analyzed in both unadjusted (univariate) analyses using one-way analysis of variance (ANOVA), and adjusted (multiple regression) analyses using linear mixed effects models.

Limitations: This study is limited by its sample size and observational design.

**Results:** Of 62 patients receiving epidural steroid injections, the mean Pain score at baseline was 27.4 (SD =1 3.6), 41.7 (SD = 22.0) at one month and 35.8 (SD = 19.0) at 3 months. Mean Pain scores improved significantly from baseline to one month (14.1 points), and from baseline to 3 months (8.3 points). Post injection changes in pain scores varied by body mass index (BMI) and baseline emotional health. Based on a linear mixed effects model analysis, higher baseline emotional health, as measured by the SF-36 Mental Component Score (MCS>50), was associated with greater reduction in pain over 3 months when compared to lower emotional health (MCS <50). In patients with higher emotional health, pain scores improved by 14.1 (P < .05: 95% CI 6.9, 21.3). Patients who were obese also showed significant improvement in pain scores over 3 months compared to non-obese patients. In obese patients, pain scores increased by 7.9 (P <.05; 95% CI:1.0, 14.8) points.

**Conclusion:** Lower back pain in older adults with degenerative lumbar spinal stenosis might be clinically significantly alleviated after injection treatment. Pain relief varies by a patient's personal and clinical characteristics. Healthier emotional status and obesity appears to be associated with more pain relief experienced over 3 months following injection.

**Key words:** Degenerative lumbar spinal stenosis, low back pain, older adults, epidural steroid injection, MRI, SF-36, Pain sub-score.

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ower back pain is one of the most common healthrelated complaints in the adult population. Thirty percent of Americans 65 years and older reported symptoms of lower back pain in 2004 (1). With an aging population, the proportion of people over the age of 65 is expected to reach 20% by the year 2030. Because of this increase in older adults, lumbar spinal stenosis (LSS) associated with arthritic changes will also likely increase. In older adults, lower back pain is most often caused by degenerative lumbar spinal stenosis. Stenosis is the narrowing of the spinal canal, causing pressure on the nerve roots, and is frequently treated surgically. LSS is one of the most common reasons for back surgery in patients 65 years and older (2). However, risks associated with surgery increase with age (3-5) and older patients might choose non-surgical treatment for their lower back pain, including injection treatment.

Injection treatment, usually consisting of anti-inflammatory medications and analgesics, has improved since the mid 1990s when fluoroscopic guidance was developed (6). Information about injection treatment for lower back pain is limited, especially in the older population. An extensive review of published literature regarding injection treatment revealed a paucity of information about older adults diagnosed with degenerative LSS (6-13). In this study, pain relief following injection treatment has been examined in patients over age 60, diagnosed with degenerative LSS primarily caused by degenerative changes. Variations in pain relief according to patient attributes were also assessed. To our knowledge, such results have not been reported in the literature.

# METHODS

# Participants

All patients  $\geq$  60 years old, who had been diagnosed with degenerative LSS and were scheduled to receive any lumbar injection for lower back pain at a single institution spine clinic were eligible for review. Diagnosis of LSS was confirmed using magnetic resonance imaging (MRI) reports and clinical notes. Potential study participants were identified by reviewing injection room schedules 2 weeks in advance. Exclusion criteria were receipt of a previous injection in the lumbar region within the past 6 months; lumbar surgery within the past 2 years; history of lumbar fracture; acute disc herniation; malignancy or infection; inability to provide informed consent due to dementia or cognitive impairment; coexisting musculoskeletal conditions that would negate functional improvement with injection (e.g., severe Parkinson disease, or hemiparesis) or amputation of any lower extremity. All patients who agreed to participate provided signed consent forms and completed one general health questionnaire and one questionnaire specific to back pain before their scheduled injections. Eighty-nine patients were approached to participate in the study and 86 (96%) agreed and completed baseline questionnaires.

Approximately 3 weeks following baseline injection, participants were mailed one-month follow-up questionnaires. If the questionnaires were not returned within 2 weeks, the participants were contacted by phone. Two additional calls were made if the surveys were still not returned. The process was repeated for the 3-month follow-up period (Fig. 1).

#### **Epidural Steroid Injection Procedure**

Patients of 2 physiatrists were included in the study. One physiatrist administered injections to 93.5% of patients (n = 58). In the procedure room, the patient was placed in a prone position. The skin over the intended interlaminar target site was marked and prepped in the usual sterile fashion. The skin and subcutaneous tissue were anesthetized with 1% lidocaine mixed with sodium bicarbonate 8.4% (10:1). The tip of a 20-gauge, 3.5-inch Tuohy spinal needle was advanced under intermittent fluoroscopic guidance toward the target. Loss of resistance with air was used to identify the epidural space. After negative aspiration for blood and cerebrospinal fluid, Isovue (Bracco Diagnostics, Prineton, NJ) was injected to confirm epidural placement. Subsequently, 5 mL of injectate (1 mL triamcinolone acetonide [40 mg/mL] and 4 mL 0.5% preservative-free Xylocaine [AstraZeneca, Wilmington, DE]) was administered. The needle was removed. For multiple levels, 5 mL of injectate was distributed equally between levels injected. For caudal injections, 10mL of injectate (1 mL triamcinolone acetonide [40 mg/mL], 5 mL preservativefree normal saline, and 4 mL preservative-free 0.5% Xylocaine) was slowly administered without resistance.

# **Outcome Measure**

The primary outcome measure used for this study was the paper and pencil version of the Short Form-36 (SF-36 version 2) (14). The SF-36 Questionnaire is a multi-purpose 36-item questionnaire used to assess functional health and well-being of adults. It is one of the most frequently used questionnaires to assess health related quality of life in patients with back pain

#### Fig. 1. Patient enrollment



(15) and has been used in large-scale studies examining musculoskeletal issues, including a prospective study by Zanoli (15) examining 451 patients with degenerative lumbar spine disorders. The SF-36 was also used by Vogt et al (16), in the evaluation of 5,995 men 65 years and older in the Osteoporotic Fractures in Men Study.

The questionnaire represents multiple indicators of health including 8 components. Four of these components relate to physical health and produce the measure Physical Component Summary (PCS). The remaining 4 components relate to mental health and produce the Mental Component Summary (MCS). In this study, 2 components were used; the Pain sub-score of the PCS (as a primary outcome for long-term pain) and the MCS (as a covariate).

The SF-36 surveys were scored using QualityMetric SF-36 scoring software (QualityMetric, Inc., Lincoln, RI) by a research assistant. Training to use the scoring software was given by the orthopedics department research coordinator. All survey scores were manually entered into an ACCESS database form by the research assistant and every fifth record was checked for accuracy by the primary investigator.

# Covariates

To assess physical attributes that could affect the response to treatment for pain and function, information about gender, age, body mass index (BMI), hip or knee replacement surgery history and co-morbidities was collected. Co-morbidities were scored using the Charlson Comorbidity Index (CCI) (17). The CCI includes 19 co-morbidities, selected based on their association with mortality. It includes conditions related to cancer, diabetes, heart disease, liver disease, renal disease, chronic pulmonary disease and others. Following retrieval of diagnostic histories using electronic medical files, medical conditions relevant to the Charlson Index were recorded and the Index was computed by the first author. Results were verified by a dedicated orthopedic research resident. Medical records were also used to collect information on patient history of hip or knee replacement surgery to adjust for other lower extremity arthritic changes common in this age group and were included in the analysis.

MRI reports were reviewed for information about LSS diagnosis. Reports that indicated acute disc herniation in the lumbar region as being the primary diag-

Characteristic	N	%	SF-36 Pain Score Baseline Mean (SD)				
Total	65	100	27.4 (1.7)				
Age							
Mean	74	-	-				
SD	8.1	-	-				
Range	60-90	-	-				
Gender							
Male	21	32	28.8 (14.2)				
Female	44	68	26.7 (13.3)				
SF-36/MCS *							
Low (< 50)	26	40	21.3 (10.5)				
High (≥50)	39	60	31.4 (13.9)				
Body Mass Index							
Normal Weight (<25)	14	21	28.5 (13.2)				
Overweight (25-29.9)	17	26	26.4 (14.0)				
Obese (30-34.9)	12	18	30.8 (16.4)				
Morbidly Obese (≥35)	12	18	27.6 (7.7)				
Comorbidities *							
0	31	48	28.0 (14.7)				
1	10	15	22.3 (12.3)				
2	11	17	30.7 (13.4)				
≥3	13	20	26.9 (11.9)				
Narcotic Use *							
Yes	16	25	22.1 (12.6)				
No	38	58	29.4 (14.1)				
Hip or Knee Replacement							
Yes	11	17	30.2 (15.8)				
No	43	66	26.5 (13.6)				

Table 1. Patien	t characteristics	at	baseline
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Note: Mean SF-36 Pain score for the general population = 75.2 (SD=23.7) (22)

Baseline scores between group categories compared: \* P <.05 (t-test); \*\* P <.05 (chi-square)

noses were not included in the study. When available, images were reviewed to determine LSS severity. A mid sagittal diameter of  $\geq$  13 mm was classified as "mild," 11mm to 12 mm was classified as "moderate" and  $\leq$  11 mm was classified as "severe" (18,19).

To adjust for other pain control medications that might interfere with injection treatment, information about narcotic use was also collected. Medication lists were reviewed using electronic records and noted as "yes" or "no" regardless of dosage or medications. Narcotic use was defined as being used or reported within three months of baseline injection. To adjust for other lower extremity joint arthritis common in this age group, information was collected on history of total hip or knee replacement surgery using medical records. Demographic and anthropometric information was collected using hospital administrative data and medical records. Information was also collected on body mass index (BMI) and demographic variables (gender, age and race). Information about race was not consistently reported in patient files and was not included in the analysis.

# **Data Collection**

Demographic information was collected using hospital administrative data and medical records. Survey scoring was accomplished using Quality Metrics scoring software for the SF-36 survey. A standard form was created and a corresponding data management program was developed using Microsoft ACCESS (20). Data collected on paper forms were entered by a trained research assistant and the first author. Quality of data entry was verified by reviewing every fifth record. AC-CESS files were then exported using StataTransfer. All statistical analyses were completed using Intercooled STATA 9.0 (21).

# **Statistical Analysis**

Descriptive statistics summarize patient characteristics such as gender, baseline emotional status (MCS), BMI, co-morbidities, narcotic use and history of total hip or knee replacement surgery (THKR) (Table 1). Baseline MCS and BMI were transformed to categorical variables. For categorical variables (gender, baseline MCS, BMI, co-morbidities, narcotics and THKR), numbers and percentages were presented. Age was presented as a continuous variable with mean, standard deviation and range. T-tests compared physical function between baseline and one month and between baseline and 3 months for each patient characteristic category (i.e. gender, age 60-69, age 70+, etc.) (Table 2). Differences in pain score changes among patient categories (i.e. BMI groups) were assessed using analysis of variance tests. Significant variables in the univariate analysis were entered into a multiple regression model. Change in pain was examined in a series of linear mixed effects models. The mixed effects model assumes that repeated measurements in the same individual are not independent and allows individuals to have unequal numbers of observations. In this study, the outcome measure included function at baseline, one month and 3 months and the covariates

Patient characteristics	SF-36 Pain change Baseline to 1 month mean (SD) N=61	р	SF-36 Pain change Baseline to 3 months mean (SD) N=56	р
Total (n)	14.1 (9.5, 18.7)	<.05	8.3 (4.0, 12.6)	<.05
Gender				,
Male	10.9 (2.7, 19.0)	<.05	9.4 (4.0, 14.7)	<.05
Female	15.4 (9.7, 21.1)	<.05	7.7 (1.8, 13.7)	<.05
Age				
60-70	16.2 (7.7, 24.7)	<.05	7.6 (-0.12, 15.3)	<.05
>70	12.8 (7.2, 18.3)	<.05	8.7 (3.4, 14.0)	<.05
Emotional Status (SF-36/MCS)		**		
< 50	9.5 (3.9, 15.0)	<.05	8.1 (3.5, 12.7)	<.05
≥ 50	17.3 (10.5, 24.1)	<.05	8.4 (2.0, 14.8)	<.05
Body Mass Index		*		
Normal Weight (<25)	15.3 (7.6, 23.0)	<.05	3.9 (-6.6, 14.4)	0.44
Overweight (25-29.9)	1.4 (-5.3, 8.2)	0.66	6.7 (-0.68, 14.1)	0.07
Obese (30-34.9)	19.6 (7.1, 32.1)	<.05	7.9 (-5.2, 21.0)	0.21
Morbidly Obese ( ≥35)	19.9 (1.32, 38.5)	<.05	14.8 (7.0, 22.5)	<.05
Narcotics				
Yes	14.8 (5.9, 23.7)	<.05	10.7 (3.6, 17.7)	<.05
No	13.2 (7.4, 18.9)	<.05	6.7 (0.43, 13.0)	<.05
Co-morbidities				*
0	10.9 (5.3, 16.5)	<.05	7.0 (1.3, 12.7)	<.05
1	18.2 (3.7, 32.7)	<.05	17.9 (6.4, 29.4)	<.05
2	15.5 (2.4, 28.6)	<.05	-1.2 (-12.9, 10.5)	0.82
≥3	17.2(2.8, 31.5)	<.05	11.2 (0.23, 22.1)	<.05
Hip or Knee Replacement				
Yes	11.0 (-4.9, 26.8)	0.16	3.9 (-6.8, 14.5)	0.43
No	14.4 (9.8, 19.0)	<.05	9.1 (3.6, 14.5)	<.05

Table 2. Change in SF-36 Pain scores from baseline to one month and baseline to three months.

P-values represent t-test results comparing baseline and follow-up scores;

1 month change in pain = 1 month SF-36 Pain - baseline SF-36 Pain;

3 months change in pain = 3 months SF-36 Pain - baseline SF-36 Pain;

\* One way ANOVA *P*-values ≤ .05; \*\*One way ANOVA *P*-values ≤ .10. Compared variable categories (i.e. male v. female)

included MCS, BMI, gender, age and co-morbidities. The outcome measure was collected at 3 timepoints, and some of both outcome data and covariate information were missing. The fixed effects portion of the model consisted of the variables that were significant in the univariate analysis (analysis of variance). Patient level intercepts were modeled as random effects. This term accounts for between-subject variation. For example, in this study, baseline measurements of pain were analyzed as separate values for each patient, rather than as a mean. Unconditional models (fixed time) and conditional models (fixed time, BMI, MCS, age, gender) were compared to determine changes in variance after the addition of variables to the model. Akaike's information criterion was used to assess goodness-of-fit between the models.

All variables in the analysis were also tested for an interaction with time (age, gender, baseline emotional health, BMI, co-morbidities, narcotic use, hip or knee replacement). Likelihood ratio tests were used to compare models with and without time/variable interactions. Test results producing significant *P*-values (P < .05) indicated time interactions were present and were included in the final model. By adding variables into the model individually, potential interactions between variables were also evaluated and significant interactions were included in the final model. Model assumptions of linearity, normality, independence of errors, and homoscedasticity of errors were examined graphically and analytically and were adequately met. ACCESS files were exported using StatTransfer 9 for statistical analyses using Intercooled STATA 9.0. All available data from all participants were used, as long as at least one follow-up survey was returned.

#### RESULTS

Eighty-six patients were initially enrolled and completed baseline SF-36 questionnaires administered by the first author from January 1, 2008 to July 1, 2008. All patients signed study consent forms approved by the Internal Review Board. Participants were followed at one month and at 3 months following baseline injection (Fig. 1). At one month, 4 participants withdrew from the study, 2 were dropped from the study (for having a second injection before follow-up (n=1) or for never having the first injection (n=1), 4 did not return the first follow-up surveys, 7 received nerve blocks, 6 received radiofrequency denervation and one died. Of the initial 86 participants, 62 were still enrolled after one month and 62 returned SF-36 surveys. At 3 months, one withdrew from the study and 4 did not return the second follow-up surveys. At the end of the second follow-up period, 61 participants were still enrolled and



56 returned 3-month surveys. All patients remaining in the study received epidural steroid injections.

Participant characteristics including gender, emotional status (MCS), BMI, co-morbidities, narcotic use and history of total hip or knee replacement surgery (THKR) are summarized and presented in Table 1. The mean age of participants was 74 (SD = 8.1, range 60 to 90), 69% were female, 60% had high emotional health (MCS  $\geq$  50) and 36% were obese to morbidly obese (BMI  $\geq$  30). Baseline scores differed significantly by patient characteristics including baseline emotional health and body mass index.

Changes in SF-36 Pain scores at one and 3 months were tabulated overall and by patient characteristics in Table 2. Overall, significant improvement was found at both one month and 3 months follow-up. SF-36 Pain scores showed a 14.1 (P < .05; 95% CI: 9.5, 18.7) point reduction in pain at one month and an 8.3 (P < .05; 95% CI:4.0, 12.6) point reduction in pain at 3 months. Significant differences (P < .05) in pain score changes from baseline to one month were found between BMI and emotional status categories. Baseline, one month and 3-month means of pain scores are presented in Fig. 2.

Results from a linear mixed effects model analysis are presented in Table 3. Variables found to have significantly different pain score changes at either one or 3 months were included in the analysis (BMI and MCS) as well as gender and age. No variable interactions or interactions with time were found or included. To account for small sample size, body mass index categories were collapsed to 2 categories, obese (BMI  $\ge$  30kg/m<sup>2</sup>) and non-obese (BMI < 30kg/m<sup>2</sup>). Comparison of covariance estimates of the conditional model showed a modest improvement in goodness of fit (0.69%, 0.93%, 0.79% and 0.64% of additional variance explained for emotional health, BMI, age and gender, respectively; *P* -value < .05) when compared to the unconditional model (time alone).

The only variables showing significance were baseline emotional health and body mass index. Pain scores were significantly improved for patients with high baseline emotional health and for patients who were obese. In patients with high baseline emotional health, Pain scores improved by 14.1 (P < .05; 95% Cl 6.9, 21.3) points over 3 months, as compared to patients with low baseline emotional health. In patients who were obese, pain scores improved by 7.9 (P < .05: 95% Cl; 1.0, 14.8) points over three months, as compared to patients who were non-obese. Mean pain scores at baseline, one month and 3 months by emotional health status and by BMI status are presented in Figs. 3 and 4.

8 ,		
Patient characteristics	SF-36 Pain change β (95%CI)	
BMI (obese vs. non-obese)	7.9 (1.0, 14.8) *	
MCS baseline (<50 vs. ≥50)	14.1 (6.9, 21.3) *	

0.25 (-6.7, 7.2)

-0.39(-8.2, 7.4)

Table 3. Predictors of change in pain over 3 months (multiple regression)

Based on linear mixed effects model analysis; \* p<.05;

#### DISCUSSION

Age (60-69, vs. 70+)

Gender (male vs. female)

This study provides new information about injection effectiveness in the older adult population. Despite the fact that degenerative LSS occurs more frequently in aging adults (23) and affects 5 of every 1,000 Americans over age 50 (24), the effectiveness of injection treatment is understudied. This study provides much needed quantitative information on the effectiveness on pain relief of injection therapy using steroids and analgesics.

There were 3 main findings of this study. First, significant pain relief was observed in older adults for up to 3 months after injection treatment. Second, patients with high emotional status experienced more pain relief than patients with low emotional status. Third, pain relief varied by body mass index.

Body mass index has been associated with comorbidities, including osteoarthritis and back pain, in previous literature (25). Obesity has also been associated with higher fatigue and less activity, especially in patients with knee osteoarthritis (26). In this study, patients who were obese to morbidly obese experienced more pain relief than non-obese patients. Variations in response to pain treatment could be associated with lower activity levels in obese patients, resulting in less pain. The effects of injections could also have been less effective in patients with a history of hip or knee arthritis, as noted in an earlier study by Bischoff-Ferrari (27). There are 2 possible explanations for this response: First, arthritis might be more advanced in these patients than in patients who have not had hip or knee surgery, which might have affected their response to injection medications. Second, referred hip and/or knee pain might confound pain relief due to local treatment of the lumbar stenosis. Inconsistent results found in these groups could also be due to the size of the sample, especially when distributed among sub-categories.





High emotional status was found to be strongly associated with greater improvement in pain at one month. This finding parallels findings in previous studies examining other musculoskeletal disorders, including total knee replacement (28) and total hip replacement (27). However, this is the first study on older patients diagnosed with degenerative LSS to produce these results. It is important to note that participants with low emotional health had more pain at baseline (PCS=21.3) compared to patients with high emotional health (31.4). Thus, it is not clear if greater pain preceded the lower emotional health or vice versa. This will provide clinicians with valuable information when screening their patients at baseline. If emotional status has an impact on how well patients respond to injection treatment, clinicians may discuss this association with patients. This change might maximize the benefit of injection treatment in this sub-population of aging patients.

A limitation of this study was that the effects of LSS severity could not be determined. Stenosis severity has been documented in previous studies using MRI films for measurement (13,18,19). In this study, only a minority of original MRI films were available to the study team for review and severity information could not be consistently collected. However, MRI reports were available and reviewed to confirm diagnosis. Reports that indicated disc related LSS as being the primary diagnosis were not included in the study. Future research projects examining injection treatment for degenerative LSS should determine image availability before data collection begins.

A second limitation was the study size. Enrollment of study participants was limited to one location over a relatively short period of time (6 months). The inclusion of patients from only one study center might affect the generalizability of the response to treatment found in this cohort. However, this was the first study to examine the results of injection treatment in older adults with a diagnosis of LSS specifically caused by degenerative changes. In addition, the study site was a clinic specifically designed to treat patients with back pain, serving a diverse population in a large metropolitan city in the northeast. As the only spine center in the area, the patient population is representative of the surrounding area. These results could be used in the design of future, multicenter studies.

A third limitation of this study included a lack of sufficient power to determine the differences in treatment effects within these sub-categories (BMI and emotional health), making it impossible to make recommendations according to specific conditions for potential patients. Future research should increase sample size to adequately examine the relationship between patient characteristics and injection effectiveness, especially in regard to emotional health status as a potential predictor of outcome.

Study design might also be considered a limitation. Ideally, a comparison group would have provided the best information in determining injection treatment effectiveness in this cohort. However, a randomized control design poses problems with invasive procedures such as injection treatment. Many clinicians recommend injection treatment for lower back pain as a last resort before surgery. Randomizing patients to either surgery or injection treatment could likely cause some ethical considerations in study design. Selection bias was also a potential limitation of this study. Though consideration of this potential problem was addressed in study design (by enrolling all patients who met study inclusion criteria and agreed to participate), patients who chose to participate might have had different characteristics from those who refused. However, patients who agreed to participate were compared to patients who did not agree, and had similar characteristics (age, gender).

Additional information about other patient characteristics such as socioeconomic status and lifestyle might have also been useful in assessing differences in response to injection treatment. However, in this study, patient surveys were completed within a short period of time before entering the injection room and time was limited. Future studies could benefit from collecting this information at a less sensitive time.

In general, pain scores improved substantially one month after treatment. Three months after treatment, an improvement was seen as well, but not as strong as at one month. Clearly, pain medications administered by injection did not have a lasting effect, but were still providing some pain relief even after 3 months. Though this amount of pain relief will be satisfactory for some patients, others might prefer a longer effect and could prefer surgery to injection treatment. However, this information will be useful for clinicians who consider offering injections as an option for their aging patients.

# CONCLUSION

The results of this study suggest that injection treatment might reduce lower back pain in older patients with degenerative LSS for up to 3 months or more. Treatment effects might vary by patient characteristics which should be considered when referring patients to injection treatments. To further examine potential predictors of achieving maximum pain relief, future research should increase sample size. An important finding of this study was that good baseline emotional health demonstrated a strong association with pain level following injection treatment. Future research

should take this important relationship into account in study design.

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