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# Patient Priority Weighting of the Roland Morris Disability Questionnaire Does Not Change Results of the Lumbar Epidural Steroid Injections for Spinal Stenosis Trial

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## Abstract

**Study Design—**Secondary analysis of Lumbar Epidural steroid injections for Spinal Stenosis randomized controlled trial data.

**Objective—**To re-evaluate whether outcomes for older adults receiving epidural steroid injections with or without corticosteroid improve after using patient-prioritized Roland-Morris Disability Questionnaire (RDQ) items.

**Summary of Background Data—**Epidural corticosteroid injections are commonly used to treat lumbar spinal stenosis symptoms, despite limited evidence for their effectiveness in clinical trials. It is unclear whether evaluating patient-prioritized outcomes would alter results of a large clinical trial.

**Methods—**Outcomes from the LESS trial were re-analyzed using RDQ, Sickness Impact Profile-SIP weights assigned to the RDQ items, and patient-prioritized RDQ items. Differences between

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Level of Evidence: 2

corticosteroid+lidocaine versus lidocaine-alone groups and 95% confidence intervals (CI) were calculated using analysis of covariance with adjustment for baseline values of the RDQ and recruitment site.

**Results—**At 6 weeks, both the corticosteroid+lidocaine group and the lidocaine-alone group had improvement in the RDQ scores (RDQ, RDQ using SIP weights, patient-prioritized RDQ) as compared with baseline scores (corticosteroid+lidocaine: -4.2 points, -4.1 points, -4.2; lidocaine-alone: -3.1 points, -2.9 points, and -3.1 points, respectively). However, there was no significant between-group difference in the RDQ or patient-prioritized RDQ (average treatment effect -1.0 points, 95% CI -2.1 to 0.1, P = 0.07; -1.0 points, 95% CI -2.0 to 0.1, P = 0.08 respectively). While the between-group difference of RDQ using SIP weights was statistically significant (average treatment effect -1.1, 95% CI -2.2 to -0.1, P = 0.04), this was not clinically important.

**Conclusions—**Results of the LESS trial did not substantively differ based on re-analysis of data using RDQ with SIP weights or patient-prioritized RDQ outcomes. This provides additional evidence that epidural injection of corticosteroid+lidocaine offered minimal or no short-term benefit as compared with epidural injection of lidocaine-alone for older adults with lumbar spinal stenosis.

### Keywords

Patient-Centered; Lumbar Spinal Stenosis; Outcomes; Prioritization; Epidural Steroid Injections; Treatment

## Introduction

Spinal stenosis is one of the most common causes of chronic low back pain among older adults (>65 years of age) and often results in significant disability and cost.[1] Despite the prevalence of spinal stenosis and its impact on quality of life and health care utilization, it remains unclear which treatments are most effective.[2-4] Non-operative treatments are commonly attempted for management of spinal stenosis symptoms; however, many questions remain unanswered regarding both short- and long-term outcomes associated with these treatments.[5]

Epidural steroid injections (ESI) are widely used, despite lack of clear evidence for their efficacy or safety in older adults.[2] The rates and costs of ESI use have increased dramatically without evidence of improvement in patient outcomes.[6-9] The first large randomized multicenter trial of lumbar epidural corticosteroid injections for spinal stenosis (LESS trial) compared epidural corticosteroid with lidocaine to lidocaine injections alone in older adults, and found no differences between treatment groups for the primary outcomes of pain (measured by the pain numeric rating scale (NRS)) or physical function (measured by the Roland-Morris Disability Questionnaire, RDQ).[2,10] However, satisfaction with treatment measured by the Swiss Spinal Stenosis Questionnaire,[11] was higher among those who received the injections with corticosteroid and lidocaine as compared to those receiving lidocaine alone.

There is debate about what outcomes are most relevant, appropriate, and meaningful to evaluate in older adults with chronic back pain, and [lumbar] spinal stenosis specifically. It is

not clear that commonly used patient-reported outcome measures for pain and physical function (e.g., pain NRS, RDQ) used in clinical research to determine the effectiveness of back pain treatments adequately reflect the outcomes of most importance to patients, particularly older adults with spinal stenosis. Our research team has partnered with patients to help design and conduct research on spinal stenosis. A better understanding of what outcomes are important to this large and growing population of patients has potential to improve their clinical care by refocusing evaluation of the effectiveness of treatments on outcomes that matter most to this patient population as a whole as well as to individual patients. We sought to identify the outcomes of greatest importance to older adults with spinal stenosis, using the RDQ as the source instrument on which to base this conversation. We focused on the RDQ, one of the primary outcomes in the LESS trial, as it is comprehensively validated and frequently used as a low back pain specific disability measure.[12,13]

The RDQ was developed from the original Sickness Impact Profile (SIP) a measure of sickness-related behavioral dysfunction consisting of 136 items in 12 topic categories. The SIP measures underwent several scaling and validation studies[14,15] in which “patients, individuals caring for patients, the apparently healthy, and health care professionals” were recruited to judge each item with respect to how dysfunctional each behavior was considered. The judges, in another round of scaling, included physicians, nurses and health administration students, and were asked to rate the severity of the dysfunction described in an item without additional information about what might be causing it. In 1975, a random sample of 173 persons enrolled in the Group Health Cooperative participated in a “consumer scaling” study. Of note, this sample was not necessarily focused on chronic spine conditions; it was stratified by age group with the oldest group including participants between ages 65 and 74. Ultimately, the final SIP items were given weights. It is unclear if the scaling results would have differed if an even older population were included or if the focus had been exclusively on back pain. Several modifications to the RDQ have been introduced since its inception – the number of items were reduced or individual items were removed/ changed. Since these modifications resulted in only modest psychometric improvements, or were insufficiently validated, the use of the original version has been recommended in order to guarantee homogeneity between studies and to allow for comparisons between trials.[1312,16,17]

While several expert sources recommend using the RDQ or the Oswestry Disability Index in a standard set of outcome measures for back pain,[18,19] it is possible that the concepts and domains included in commonly used patient reported outcome measures do not fully capture the experiences and priorities most valued by older adults and in particular, patients with spinal stenosis.[20-22] The experience of spinal stenosis may be different from other etiologies of back pain; symptoms of spinal stenosis may include lower extremity numbness/sensory changes, impairments in balance and weakness in addition to lower extremity pain and back pain. Leg pain is one of the most common symptoms of spinal stenosis. It is possible that the RDQ doesn't adequately capture disability from these symptoms well enough. Currently, we assume that each item of the RDQ has equal value to the individual, however, it is possible that older adults with spinal stenosis place higher priority or emphasis on specific RDQ items. For example, older adults may place higher priority on balance and weakness as such

issues can lead to falls and potential loss of independence. Given the discrepancy between satisfaction with treatment and pain and physical function in the LESS trial, we conducted a subsequent study that sought to determine what outcomes are most important to older adults with spinal stenosis. Using structured individual sorting and ranking exercises and focus group discussions, we obtained patient-selected importance prioritizations of RDQ items.[22]

The purpose of this study was to re-analyze the LESS trial outcome data using the RDQ with SIP weights and the patient-prioritized RDQ items. We hypothesized that the primary outcome data would be different from the original trial outcome results based on prioritization of items in the outcome variable (RDQ).

## Methods

The analysis was based on data from the LESS trial, described in detail elsewhere.[2,5] In brief, LESS is a multicenter randomized clinical trial of 400 patients with symptoms related to lumbar central canal stenosis. Patients were randomized to receive either a fluoroscopically guided epidural injection with corticosteroid + lidocaine or an epidural injection with lidocaine alone. The primary outcomes included average leg pain (one of the most frequently reported symptoms of spinal stenosis) experienced over the previous 7 days (pain NRS) as well as disability measured by the RDQ at 6 weeks.

Prioritization of the RDQ items was based on a previous study (Lumbar Epidural Steroid Injections for Spinal Stenosis-Extended Research- LESSER) in which a mixed-methods approach combining a quantitative sorting exercise with qualitative focus group discussions was used to identify problem areas prioritized as most important to participants and to enumerate the specific reasons why these areas were considered important.[22] The University of Washington's Institutional Review Board approved this study prior to contact with study participants.

### Prioritization of the RDQ

**Participant Population to Determine Patient-Prioritized RDQ—**In brief, study participants ≥ 50 years of age who reported low back and/or leg pain consistent with lumbar spinal stenosis were recruited for the LESSER prioritization study[22] from clinics in the University of Washington system (these participants were not part of the LESS trial) as well as senior centers, physical therapy clinics, and patient advocacy organizations in the Greater Seattle region. All participants signed informed consent and completed a brief questionnaire over the telephone at the time of screening on duration of pain symptoms, pain intensity, RDQ, treatment history, and demographics.

**Outcomes Used in this Analysis—**The RDQ was a primary outcome for the original LESS trial.[2] The RDQ is a self-report generic back pain functional status questionnaire adapted from the SIP[15] and consists of 24 yes/no items representing common limitations in daily activities experienced by people with low back pain.[12] A single score is derived by summing the 24 individual items that are equally weighted, (scores range from 0 (no disability) to 24 (maximum disability)). In our study we used the version of the RDQ that contains the original 24 items with slight modification to the terminal phrase of each

statement: ‘because of my back’ is changed to ‘because of my back or leg problem (sciatica)’. This makes the questionnaire more suitable for use in a population with sciatica/lower extremity pain, and is an acceptable modification.[23] The second outcome we evaluated included SIP weights assigned to the RDQ items.[15] The third outcome included in this secondary data analysis included the patient-prioritized RDQ from the LESSER study. See Appendix A for the SIP weights and the patient-prioritized [LESSER] weights that were used in this analysis.

**Prioritization of RDQ Items From LESSER—**As reported previously, patient focus group participants were provided with responses to the RDQ questionnaire that they completed over the telephone during screening and were asked to mark which of the items they had previously endorsed (experienced) would need to improve in order for them to consider trying or continuing (as appropriate) ESI treatment. This was considered to be a clinically relevant threshold for “prioritization” as it required participants to anticipate future medical decision-making that involved a procedure.

We tabulated the number of times participants endorsed each RDQ item (i.e., experienced the disability associated with it), and for those who did, the percentage who rated each as sufficiently important to change in order to make trying or having additional ESIs worthwhile to them. These percentages were used to weight the RDQ items in the current analysis (see Appendix A).

## Statistical Analysis

### Re-Analysis of LESS: RDQ using SIP Weights and Patient-Prioritized RDQ

As in the analysis of LESS primary outcomes,[2] differences and 95% confidence intervals (CI) were calculated using analysis of covariance (ANCOVA) with adjustment for baseline values of the RDQ and recruitment site. An indicator of treatment group was coded such that negative differences indicate greater improvement in the corticosteroid plus lidocaine group. Using the SIP weights assigned to the RDQ[14,15] and LESSER priority scores[22] for each item, we derived alternatively weighted RDQ scores for each patient and standardized each scale to a range from 0 to 24. We then re-assessed the effect of corticosteroids using each alternatively weighted RDQ in separate ANCOVA and qualitatively compared the resulting differences in both statistical significance and clinical importance. For this analysis, a clinically important result is defined as a difference of 2.25 points or more in the RDQ score[10,24-26] between the corticosteroid+lidocaine and lidocaine only groups; this conservative estimate of the minimal clinically important difference was used in the original LESS trial. Per the original LESS trial, $P<0.05$ was considered to indicate statistical significance.

## Results

### Description of the LESS sample and the RDQ prioritization study sample

The LESS trial sample (n=400)[2] as well as the LESSER participants (n=33)[22] have been described in detail in other reports. Baseline participant characteristics for LESS and LESSER are included in Table 1. For the LESS trial, the subjects had an average age of 68

years, were predominantly Caucasian (70%), the majority were highly educated (66% reporting at least some college) and had experienced chronic pain (21% reporting pain duration for 1-5 years, 28% reporting pain duration greater than 5 years). For LESSER, we conducted six focus groups with a total of 33 participants.[22] The participants had an average age of 73 years, were predominantly Caucasian (78.8%), were highly educated (>95% reporting at least some college), with the majority having experienced chronic pain (62.5% reporting pain duration greater than 5 years), and the majority had engaged in physical therapy (88%) and had ESI treatment (64%) for back pain prior to participating in the study.

### Re-Analysis of LESS trial data: RDQ using SIP Weights and Patient-Prioritized RDQ

Table 2 reports results from the LESS trial evaluating the overall RDQ score, RDQ using SIP weights, and patient-prioritized RDQ from the LESSER study. At 6 weeks, both the corticosteroid+lidocaine group and the lidocaine-alone group had improvement in the RDQ scores (RDQ, RDQ using SIP weights, patient-prioritized RDQ) as compared with baseline scores (corticosteroid+lidocaine: −4.2 points, −4.1 points, -4.2; lidocaine alone: -3.1 points, -2.9 points, and -3.1 points). However, there was no significant between-group difference in the RDQ or patient-prioritized RDQ (adjusted difference in the average treatment effect between the corticosteroid + lidocaine group and the lidocaine alone group, −1.0 points, 95% confidence interval [CI], −2.1 to 0.1, P = 0.07; -1.0 points, 95% CI -2.0 to 0.1, P = 0.08 respectively). While the between-group difference in the RDQ using SIP weights was statistically significant at 6 weeks (average treatment effect -1.1, 95% CI -2.2 to -0.1, P = 0.04), this is not within the pre-specified clinically significant range.

## Discussion

Measuring patient-centered outcomes in research involves the selection of outcomes about which the population of interest cares.[27] Traditional weighting of the RDQ may not capture outcomes most important to older adults with spinal stenosis, the population assessed in the LESS trial. This study provides additional evidence that there are no significant differences at 6 weeks between older adults assigned to corticosteroid + lidocaine and those assigned to lidocaine alone despite re-evaluating the LESS data using SIP weights assigned to RDQ or patient prioritization of RDQ items. At 3 weeks, the corticosteroid + lidocaine group had greater improvement than the lidocaine-alone group using all 3 RDQ derived outcomes, but the differences were small and clinically unimportant. Similarly, at 6 weeks there was a statistically significant difference between groups for the SIP-weighted RDQ outcome, however, this also was not considered clinically important (the observed difference was 1.1, whereas the pre-specified minimally important difference was 2.25 or greater). Additional research is warranted to evaluate how incorporating outcomes of most value to patients impacts clinical trials.

We know from prior work that not all items on the RDQ are uniformly rated as being important outcomes needing to improve in order for patients to consider receiving ESIs.[22] This suggested that the individual RDQ items may be more predictive of outcomes from the perspective of the patient than the total RDQ score. While we used three versions of RDQ that are weighted differently, we acknowledge that the RDQ using SIP weights and patient-

prioritized RDQs are linear re-combinations of the original RDQ items. Remapping the original RDQ to the SIP and LESSER versions yielded reweighted scores that respectively ranged between +/-1.5 and +/-2.5 points from the original RDQ (see Appendix A). Even when reweighted, important items were not differentially endorsed enough between treatment groups to change the inference regarding the effectiveness of epidural corticosteroids. Despite evaluating patient-prioritized RDQ we found no significant differences at 3 weeks or 6 weeks. Further research is needed to determine how to translate patient-level preferences to generalizable findings from randomized controlled trials evaluating effectiveness of an intervention. It is still unclear how researchers (and clinicians) can implement patient prioritized outcomes and decisions to inform practice. Future research is also needed to better understand the connection between patient satisfaction with a treatment and patient reported outcomes such as pain and physical function. A prior study sought to evaluate mediators of effects of epidural injections on patient satisfaction with treatment of lumbar spinal stenosis.[28] These authors found that small improvements in RDQ at three weeks was a significant mediator of the effects of lumbar epidural corticosteroid injections on patient satisfaction at 6 weeks.[28] While the authors did not find other intermediate variables to be mediators of patient satisfaction, we suspect there may be psychosocial or behavioral variables not accounted for that may influence this association.

Several limitations of this study are important to mention. The patient-prioritized RDQ scores were obtained from a limited number of focus group participants and then used to re-analyze data from a larger sample. Prioritization from these focus groups may not be translatable to other populations as the demographics of the Northwest differ from the LESS population. It will be important to evaluate whether certain prioritized outcomes differ according to race/ethnicity and socio-economic factors. LESSER participants had reported a greater percentage of pain duration > 5 years than the LESS trial participants which may have impacted the RDQ prioritization results.

Strengths of this study include a large multicenter, double-blind trial of fluoroscopically guided epidural injections for lumbar spinal stenosis recruited from 16 geographically diverse clinical sites. The focus of this study was on older adults, a population that is often excluded from clinical trials for back pain,[29,30] and for which we need high quality data to inform clinical decision making. Hearing directly from patients on what outcomes are of greatest importance is central to patient-centered research. Conducting focus groups with older adults provided an opportunity to learn what outcomes are prioritized when seeking treatment. Data from the focus groups allowed for a reanalysis of the LESS trial data using new patient-prioritized outcomes.

In conclusion, this study provides further evidence showing that at 6 weeks corticosteroid + lidocaine injections are no more effective than lidocaine alone for lumbar spinal stenosis in older adults. How we seek outcome prioritization and apply priority outcomes to clinical trials and clinical settings has yet to be fully understood and appreciated. Given recent literature providing high quality evidence that corticosteroid epidural injections are not more effective than epidural lidocaine injections,[2,31] it will be critical to evaluate how these data impact clinical care. More research is needed to identify interventions that are effective, safe,

and that appropriately target outcomes of interest to older adults with this common disabling condition.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Table 1**
**Baseline Characteristics of Participants in LESS and LESSER**

| Participant Characteristics | LESS (n=400) | LESSER (n=33) |
|---|---|---|
| Age - mean yrs (sd) | 68.0 (10.0) | 71.9 (9.8) |
| median (min - max) | 68 (50 – 96) | 73 (56 – 85) |
| Female - no. (%) | 221 (55.3%) | 15 (46.9%) |
| Race - no. (%) | | |
| Caucasian | 275 (69.5%) | 26 (78.8%) |
| Black / African American | 105 (26.0%) | 2 (6.1%) |
| Other | 20 (4.5%) | 5 (15.2%) |
| Hispanic ethnicity - no. (%) | 17 (3.0%) | 3 (9.4%) |
| Education - no. (%) | | |
| High school, GED, or less | 127 (33.5%) | 1 (3.1%) |
| Some college, voc. tech | 128 (28.0%) | 6 (18.8%) |
| College graduate or beyond | 65 (16.0%) | 13 (40.6%) |
| Professional or graduate degree | 80 (22.5%) | 12 (37.5%) |
| Married or living with other - no. (%) | 237 (55.5%) | 18 (56.3%) |
| Employment - no. (%) | | |
| Full/Part Time | 128 (35.5%) | 6 (18.2%) |
| Retired, not disabled | 181 (44.0%) | 19 (57.6%) |
| Retired, disabled | 54 (11.5%) | 7 (21.2%) |
| Other | 37 (9.0%) | 1 (3.1%) |
| Pain duration - no. (%) | | |
| < 3 months | 64 (20.1%) | 0 (0%) |
| 3 – 12 months | 121 (31.2%) | 2 (6.2%) |
| 1 – 5 years | 109 (21.1%) | 9 (28.1%) |
| > 5 years | 105 (27.6%) | 20 (62.5%) |
| Roland Morris (0-24), mean (SD) | 15.8 (4.4) | 13.2 (5.1) |
| Leg Pain NRS (0-10), mean (SD) | 7.2 (1.8) | 4.8 (2.3) |
| Back Pain NRS (0-10), mean (SD) | 6.7 (2.5) | 4.5 (2.3) |

**Table 2**

**Outcomes (RDQ, RDQ Using SIP Weights, and Patient-Prioritized RDQ) According to Treatment Group**

| | Lidocaine Alone | | | Corticosteroid + Lidocaine | | | Treatment Comparison | |
|---|---|---|---|---|---|---|---|---|
| **Outcomes** | **N** | **Mean (SD)** | **Mean change (SD)** | **N** | **Mean (SD)** | **Mean change (SD)** | **Coef (95% CI)** | **P-value** |
| ***Overall*** | | | | | | | | |
| RDQ | | | | | | | | |
| Baseline | 200 | 15.7 (4.3) | - | 200 | 16.1 (4.5) | - | - | - |
| 3 Weeks | 189 | 13.1 (5.7) | -2.6 (4.4) | 195 | 11.7 (6.1) | -4.4 (5.7) | -1.8 (-2.8, -0.9) | <0.001 |
| 6 Weeks | 193 | 12.5 (6.4) | -3.1 (5.3) | 193 | 11.8 (6.3) | -4.2 (5.8) | -1.0 (-2.1, 0.1) | 0.07 |
| RDQ using SIP Weights | | | | | | | | |
| Baseline | 200 | 14.6 (4.4) | - | 200 | 15.1 (4.7) | - | - | - |
| 3 Weeks | 189 | 12.2 (5.7) | -2.5 (4.3) | 195 | 10.7 (6.0) | -4.4 (5.6) | -1.9 (-2.9, -0.7) | <0.001 |
| 6 Weeks | 193 | 11.7 (6.3) | -2.9 (5.1) | 193 | 11.0 (6.1) | -4.1 (5.6) | -1.1 (-2.2, -0.1) | 0.04 |
| RDQ Patient-Prioritized (LESSER) | | | | | | | | |
| Baseline | 200 | 15.2 (4.3) | - | 200 | 15.7 (4.5) | - | - | - |
| 3 Weeks | 189 | 12.7 (5.8) | -2.7 (4.5) | 195 | 11.2 (6.1) | -4.5 (5.9) | -1.8 (-2.8, -0.8) | <0.001 |
| 6 Weeks | 193 | 12.0 (6.5) | -3.1 (5.3) | 193 | 11.5 (6.2) | -4.2 (5.8) | -1.0 (-2.0, 0.1) | 0.08 |