2-17-2021

Providing Epidemiologic Data in Lumbar Spine Imaging Reports Did Not Affect Subsequent Utilization of Spine Procedures: Secondary Outcomes from a Stepped-Wedge Randomized Controlled Trial

Pradeep Suri

Eric N. Meier

Laura S. Gold

Zachary A. Marcum

Sandra K. Johnston

See next page for additional authors

Recommended Citation

Suri P, Meier EN, Gold LS, Marcum ZA, Johnston SK, James KT, Bresnahan BW, O'Reilly M, Turner JA, Kallmes DF, Sherman KJ, Deyo RA, Luetmer PH, Avins AL, Griffith B, Heagerty PJ, Rundell SD, Jarvik JG, and Friedly JL. Providing Epidemiologic Data in Lumbar Spine Imaging Reports Did Not Affect Subsequent Utilization of Spine Procedures: Secondary Outcomes from a Stepped-Wedge Randomized Controlled Trial. Pain Med 2021.

Authors

Pradeep Suri, Eric N. Meier, Laura S. Gold, Zachary A. Marcum, Sandra K. Johnston, Kathryn T. James, Brian W. Bresnahan, Michael O'Reilly, Judith A. Turner, David F. Kallmes, Karen J. Sherman, Richard A. Deyo, Patrick H. Luetmer, Andrew L. Avins, Brent Griffith, Patrick J. Heagerty, Sean D. Rundell, Jeffrey G. Jarvik, and Janna L. Friedly

Providing Epidemiologic Data in Lumbar Spine Imaging Reports Did Not Affect Subsequent Utilization of Spine Procedures: Secondary Outcomes from a Stepped-Wedge Randomized Controlled Trial

Pradeep Suri, MD[1-4] ; Eric N. Meier[1,5]; MS; Laura S. Gold, PhD[1,6]; Zachary A. Marcum, PharmD, PhD[7]; Sandra K Johnston PhD, RN[1,6]; Kathryn T. James, PA, MPH[1,6]; Brian W. Bresnahan, PhD[6]; Michael O'Reilly MD,MSc;[1,6] Judith A. Turner, PhD;[1,2,8] David F. Kallmes, MD;[9] Karen J. Sherman, PhD; [10] ;Richard A. Deyo, MD, MPH;[11] Patrick H. Luetmer, MD;[9] Andrew L. Avins, MD, MPH;[12] Brent Griffith, MD;[13] Patrick J. Heagerty, PhD;[1,5] Sean D. Rundell, PT, PhD[1,2]; Jeffrey G. Jarvik, MD, MPH[1,6,14] Janna L. Friedly, MD, MPH;[1,2]

[1]Clinical Learning, Evidence, and Research Center, University of Washington, Seattle, WA;

[2]Department of Rehabilitation Medicine, University of Washington, Seattle, WA

[3]Seattle Epidemiologic Research and Information Center, VA Puget Sound Health Care System, Seattle, WA

[4]Rehabilitation Care Services, VA Puget Sound Health Care System, Seattle, WA.

[5]Department of Biostatistics, University of Washington, Seattle, WA

[6]Department of Radiology, School of Medicine, University of Washington, Seattle, WA;

[7]Department of Pharmacy, School of Pharmacy, University of Washington, Seattle, WA;

[8]Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, WA

[9]Department of Radiology Mayo Clinic, Rochester, MN

[10]Kaiser Permanente Washington

[11]Departments of Family Medicine and Internal Medicine, Oregon Health & Science University, Portland, OR, USA

[12]Division of Research (ALA), Kaiser Permanente Northern California, Oakland, CA, USA.

[13]Department of Radiology Henry Ford Hospital, Detroit, MI, USA

[14]Department of Neurological Surgery, University of Washington, Seattle, WA

Corresponding Author: Pradeep Suri, MD, MS

Mailing Address: Rehabilitation Care Services, VA Puget Sound Health Care System, S-RCS-117, 1660 S. Columbian Way, Seattle, WA, 98108; email: pradeep.suri@va.gov; phone 206-764-2673; fax 206-716-5977

Funding Source: This work was supported within the National Institutes of Health (NIH) Health Care Systems Research Collaboratory by the NIH Common Fund through cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director and cooperative agreements UH2AT007766 and UH3AR066795 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). It was also supported by the UW Clinical Learning, Evidence and Research (CLEAR) Center for Musculoskeletal Disorders funded by NIH/NIAMS P30AR072572. This content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Dr. Suri is a Staff Physician at the VA Puget Sound Health Care System and was funded by the VA Puget Sound Health Care System. The contents of this work do not represent the views of the US Department of Veterans Affairs or the US Government.

Registration: Clinicaltrials.gov NCT02015455

Potential Conflicts of Interest: Dr Jarvik reported receiving royalties from Springer Publishing and Wolters/ Kluwer/*UpToDate* and receiving travel reimbursement from GE–Association of University Radiologists outside the submitted work. Dr Deyo reported having an endowed professorship funded by Kaiser Permanente and receiving personal fees from *UpToDate* outside the submitted work. Dr Friedly reported receiving grants from the Department of Defense and salary support from the

American Academy of Physical Medicine and Rehabilitation for serving as editor in chief outside the submitted work. None of the other authors has potential conflicts of interest to report.

Running Title: Epidemiologic Data and Spine Procedure Outcomes

Key Words: Epidural injections; zygapophyseal joint; injection, injections; radiofrequency ablation; radiology; spine; lumbar

AUTHOR'S CONTRIBUTIONS

Study concept and design: PS, EM, KT, JAT, RAD, ALA, PJH, JGJ, JLF

Acquisition of data: EM, KT, DFK, KJS, PHL, ALA, BG, KTJ, SDR, JGJ

Analysis and interpretation of data: EM, PS, LSG, ZAM, SKJ, BWB, MOR, JAT, DFK, RAD, KJS, PHL, ALA, BG, PJH, SDR, JGH, JLF

Drafting/revision the manuscript, and approval of final version: all authors

ABSTRACT current word count:247, limit: 250

Objective: To evaluate the effect of inserting epidemiologic information into lumbar spine imaging reports on subsequent non-surgical and surgical procedures involving the thoracolumbosacral spine and sacroiliac (SI) joints.

Design: Analysis of secondary outcomes from the Lumbar Imaging with Reporting of Epidemiology (LIRE) pragmatic stepped-wedge randomized trial.

Setting: Primary care clinics within four integrated healthcare systems in the United States.

Subjects: 238,886 patients aged ≥18 years who received lumbar diagnostic imaging between 2013-2016.

Methods: Clinics were randomized to receive text containing age- and modality-specific epidemiologic benchmarks indicating the prevalence of common spine imaging findings in people without low back pain, inserted into lumbar spine imaging reports (the "LIRE intervention"). The study outcomes were receiving (1) any non-surgical lumbosacral or sacroiliac spine procedure (lumbosacral epidural steroid injection, facet joint injection, or facet joint radiofrequency ablation; or sacroiliac joint injection) or (2) any surgical procedure involving the lumbar, sacral, or thoracic spine (decompression surgery or spinal fusion or other spine surgery).

Results: The LIRE intervention was not significantly associated with subsequent utilization of non-surgical lumbosacral or sacroiliac spine procedures (odds ratio [OR]=1.01, 95% confidence interval [CI] 0.93-1.09; p=0.79) or any surgical procedure (OR=0.99, 95 CI 0.91-1.07; p=0.74) involving the lumbar, sacral, or thoracic spine. The intervention was also not significantly associated with any individual spine procedure.

Conclusions: Inserting epidemiologic text into spine imaging reports had no effect on non-surgical or surgical procedure utilization among patients receiving lumbar diagnostic imaging.

SUMMARY

Using a stepped-wedge randomized trial design, primary care clinics were randomized to receive text containing epidemiologic benchmarks indicating the prevalence of common spine imaging findings in people without low back pain, inserted into lumbar diagnostic imaging reports. Among 238,886 patients, this intervention had no effect on the subsequent occurrence of any non-surgical lumbosacral or sacroiliac spine procedure, or any surgical procedure involving the lumbar, sacral, or thoracic spine.

INTRODUCTION

Low back pain (LBP) has been the leading contributor to years lived with disability in the United States (US) over the past 25 years.(1) LBP is also a major contributor to health-related spending in the US.(2) Despite considerable increases in expenditures for LBP over time,(2) there is a lack of evidence of a corresponding improvement in health status for US adults.(3) Indeed, there is concern that more treatment increases costs without leading to better health outcomes.(3, 4) Procedural treatments for LBP or conditions associated with LBP, such as lumbosacral radiculopathy and symptomatic lumbar spinal stenosis, include both surgical (e.g., spinal fusion or laminectomy) and non-surgical (e.g., epidural corticosteroid injections or other non-surgical percutaneous procedures) invasive treatments, often performed on an elective basis.(5, 6) For the purposes of this study, we define “procedural treatments for LBP” as including both surgical and non-surgical percutaneous procedures, either for LBP itself or for the treatment of specific spine-related pain syndromes (e.g. lumbosacral radiculopathy or symptomatic lumbar spinal stenosis) that may be associated with LBP. Surgical procedures for conditions associated with LBP are commonly used in the US and comprise a substantial component of LBP-related health spending (7). Non-surgical percutaneous procedures for conditions associated with LBP are also commonly used(8-12). Decreasing procedural treatments for LBP may be one way to decrease LBP-related healthcare spending in the US.

Procedural treatments for LBP are typically directed at correcting an underlying structural or anatomic problem, or eliminating pain attributed to such a problem. A fundamental issue in spine care is that many of the commonly noted anatomic or structural “findings” described on lumbar spinal imaging reports (e.g., intervertebral disc height loss or facet degeneration) are highly prevalent even among those without LBP and therefore lack specificity, making it problematic to attribute individual cases of LBP to these findings. (13, 14) However, certain spine imaging findings of lower prevalence (e.g. nerve root displacement/compression or disc extrusion) are less commonly found in

asymptomatic individuals and may be more strongly associated with LBP or specific spine syndromes such as lumbosacral radiculopathy. (15-17)

Providing patients and providers with epidemiologic information to educate them about the high prevalence of common imaging findings even in those without LBP may increase awareness that certain imaging findings are unlikely to pinpoint the cause of pain for a given patient.(18) This may reduce potentially unnecessary subsequent procedural treatments for LBP. The Lumbar Imaging with Reporting of Epidemiology (LIRE) randomized controlled trial examined the effect of inserting epidemiologic "benchmark" information regarding the prevalence of common imaging findings among individuals without LBP into lumbar spine imaging reports, as compared to the usual practice of not providing such information.(19) Importantly, the LIRE benchmark epidemiologic information does not include less common imaging findings that may have stronger links to spine-related symptoms (e.g. nerve root displacement/compression, disc extrusions, etc). The LIRE trial found that providing epidemiologic information did not reduce overall subsequent spine-related costs as reflected by relative value units (RVUs).(19) However, providing epidemiologic information in lumbar spine imaging reports resulted in a slightly lower likelihood of patients receiving a subsequent opioid prescription (odds ratio [OR]=0.95, 95% confidence interval [CI] 0.91-1.00), as compared to not providing such information.(20) A pre-specified analysis of procedural treatments (non-surgical percutaneous spine procedures and spine surgeries) for LBP and conditions associated with LBP was originally planned as an examination of secondary outcomes in the LIRE trial protocol.(21) The aims of the current study were to examine the effects of inserting epidemiologic text into lumbar spine imaging reports on (1) the likelihood of subsequent non-surgical lumbosacral or sacroiliac spine procedures and (2) the likelihood of subsequent spine surgery involving the lumbar, sacral, or thoracic spine. We hypothesized that inserting epidemiologic text into spine imaging reports would

decrease the likelihood of non-surgical lumbosacral or sacroiliac spine procedures, and decrease the likelihood of subsequent spine surgery involving the lumbar, sacral, or thoracic spine.

METHODS

Study Design

The LIRE trial was a pragmatic, multi-center, stepped-wedge, cluster-randomized trial conducted within four large integrated healthcare systems. Primary care clinics were randomly assigned to different start dates for receiving imaging reports containing several additional lines of text describing age- and imaging modality-appropriate epidemiologic benchmarks for the prevalence of common degenerative imaging findings in adults without LBP, such that all primary care providers (PCPs) within a clinic would begin receiving the intervention at approximately the same time. Clinics received standard imaging reports (without the addition of epidemiologic benchmarks) prior to their assigned intervention date. We used clinic-level cluster randomization to minimize potential contamination that might result from having some providers receiving epidemiologic benchmark information and others not receiving epidemiologic benchmark information within the same clinic. We used a stepped-wedge randomization scheme to facilitate implementation of the intervention within all clinics by the end of the study; the design permitted both within-cluster and between-cluster comparisons. We reported previously a detailed description of the LIRE trial protocol.(21)

Study Participants

We enrolled clinics and their patients from four integrated health care systems: Kaiser Permanente, Northern California; Henry Ford Health System, Detroit, MI; Kaiser Permanente Washington (formerly Group Health Cooperative), Seattle, WA; and Mayo Clinic Health System, Rochester, MN. These health care systems have comprehensive electronic health record (EHR) systems allowing capture of health care utilization data, including procedural care. Within each health care system, we identified adult primary care clinics and associated PCPs. We defined “LIRE providers” as PCPs who were primarily based at a single primary care clinic and who ordered at least one lumbar imaging examination during the study period.(19) When a provider ordered a lumbar

imaging examination, an automated screening process determined whether the PCP, patient, and clinic were eligible for our study. PCPs in the participating health care systems were able to order x-rays (XR), MRI, and CTs (i.e., MRI/CT did not have to be ordered by a specialist). We enrolled participants from the population of eligible patients ≥ 18 years old whose PCP ordered a diagnostic imaging study of the lumbar spine between October 1, 2013 and September 30, 2016. Exclusion criteria included patients who had received spine imaging within the 12 months prior to the lumbar diagnostic imaging study and those who had opted out of research study participation. The institutional review boards for the participating health systems determined that the study was minimal risk and granted waivers of consent and Health Insurance Portability and Accountability Act (HIPAA) authorizations.

Randomization

We used a stepped-wedge cluster randomization study design, randomly assigning clinics from each health care system to begin receiving the intervention at one of five calendar times, separated by 6-month intervals, between April 2014 and April 2016. Clinics were classified into tertiles of clinic size based on the number of PCPs within each clinic. The randomization was stratified by clinic size tertile and health care system, so that health care systems and clinics of similar size were represented similarly in each randomization wave. Because of the stepped-wedge temporal randomization scheme, we labelled clinics as “control” clinics if insertion of the intervention text into spine imaging reports had not yet started and as “intervention” clinics after insertion of the intervention text had begun. Because the intervention text was visible to providers, blinding of the participating clinics was infeasible. The study investigators at the data coordinating center were blinded to clinic and participant randomization status, except for the biostatistician (E.M.) who received and cleaned the data.

Intervention

The "intervention text" consisted of age- and modality-specific epidemiologic benchmark information regarding the prevalence of common findings in adults without LBP (Supplemental File 1) (12-14). Using a fully automated approach through the radiology information system or EHR, we inserted the intervention text into thoracic or lumbar spine imaging reports at intervention clinics. PCPs in control clinics continued to receive their usual imaging reports without the intervention text.

Baseline Measures

As a key design feature of our pragmatic approach, we collected all measures passively through the EHR. EHR data were obtained for patients beginning 12 months prior to their index imaging, continuing up to 24 months after the index imaging. This included International Classification of Diseases (ICD), Ninth Revision, Clinical Modification (ICD-9-CM) and Tenth Revision [ICD-10-CM] diagnostic and procedure codes; Current Procedural Terminology (CPT) procedure codes; and site-specific procedure codes. At study baseline, we collected data on patient age (categorized as 18-39, 40-60, and ≥61 years); sex; insurance type (Medicare, Medicaid/state-subsidized, commercial, Veterans Affairs (VA), self-pay, and unknown/not reported); study site; and clinic size. The Charlson comorbidity index (categorized as 0, 1, 2, and ≥3 conditions)(22-24) was calculated using diagnostic codes present in the 12 months prior to the index imaging. The index imaging modality (x-ray, CT, or MRI) was determined using CPT and site-specific codes.

Outcome Measures

Outcomes were evaluated over an 18-month follow-up, due to some missing EHR data between 18 and 24 months of follow-up. The primary outcome for aim 1 of the current study was the occurrence of any non-surgical lumbosacral or sacroiliac spine procedure from among the four types of non-surgical procedures considered in this analysis (epidural steroid injections [ESI], facet joint

injections (including both intraarticular joint injections and medial branch blocks), facet joint radiofrequency ablation (RFA), and sacroiliac (SI) joint injections) during the 18-month follow-up. In other words, this was a single primary outcome reflecting the occurrence of any one of the four major types of non-surgical lumbosacral or sacroiliac spine procedures. The CPT codes and site-specific codes used to identify these non-surgical lumbosacral or sacroiliac spine procedures are provided in **Supplemental File 2**. Other non-surgical lumbosacral or sacroiliac spine procedures were not considered, due to their lower frequency of utilization. In exploratory secondary analyses, we examined the same four non-surgical procedures separately. These four analyses examined the outcomes of (1) any lumbosacral ESI, (2) any lumbosacral facet joint injection, (3) any lumbosacral facet joint RFA, and (4) any sacroiliac joint injections during the 18-month follow-up. These four exploratory secondary analyses were conducted because changes relevant to specific procedures might be obscured in the primary analysis grouping various procedures together. To account for the fact that non-surgical lumbosacral and sacroiliac procedures are often repeated, secondary analyses were also conducted for each outcome examining the number of procedures (as a count) conducted during the 18-month follow-up. The primary outcome for aim 2 of the current study was the occurrence of any lumbar, sacral, or thoracic spine surgery (spinal fusion or proxies for fusion such as disc arthroplasty; decompression surgery; or other spine surgeries) during the 18-month follow-up. We used ICD-9, ICD-10, CPT, and site-specific codes to identify surgical spine procedures, including algorithms with ≥98% sensitivity and specificity for identifying decompression surgery and spinal fusion; (25) these codes are provided in **Supplemental File 2**. There were two exploratory secondary spine surgery outcomes for aim 2: the occurrence of (1) any spinal fusion or proxy for fusion and (2) any decompression surgery.

Statistical Analysis

We used descriptive statistics to compare baseline characteristics of the intervention and control groups. To evaluate the effect of the LIRE epidemiologic benchmark intervention on binary outcomes, we used generalized linear models that clustered on clinic and then provider within clinic, using robust standard errors. Models included fixed effects (site, clinic size by tertile, CT [vs. MR], Charlson Comorbidity category [0, 1, 2, 3+], site-specific time [linear], sex, age range [<40, 40-60, >60)] and random effects for clinic (intercept and treatment) and provider (intercept only). Models for non-surgical lumbosacral or sacroiliac spine procedures also included prior non-surgical procedural utilization in the 1 year preceding the index image as a fixed effect. Because there were very few patients with surgical procedures involving the lumbar, sacral, or thoracic spine in the 1 year preceding the index image (n=90 [0.1%] in controls not receiving the LIRE intervention, n=89 [0.1%] in those receiving the LIRE intervention) relative to the total sample size, prior surgical procedure utilization was not included in the models for surgical spine procedures. Secondary analyses examined the *number* of non-surgical spinal procedures using negative binomial regression where possible and Poisson regression where negative binomial regression models did not converge. Statistical significance was determined by a p-value <0.05 for each of the two primary outcomes (any non-surgical procedure, and any spine surgery). A Bonferroni correction was used to determine the threshold for statistical significance for exploratory secondary outcomes examining individual non-surgical lumbosacral or sacroiliac spine procedures (0.05/4 individual procedures=0.0125) and surgical procedures involving the lumbar, sacral, or thoracic spine (0.05/2 individual procedures=0.025). Analyses used the intention-to-treat method. SAS software version 9.4 (Cary, NC USA) was used for all analyses.

RESULTS

Study Sample

The study sample included 238,886 patients (**Figure 1**). Baseline characteristics were generally comparable between patients in the intervention and control groups (**Table 1**).

Table 2 shows the frequencies and proportions of patients who received non-surgical lumbosacral or sacroiliac spine procedures and surgical procedures involving the lumbar, sacral, or thoracic spine over the 18-month follow-up. Nearly 12% of patients received at least one non-surgical lumbosacral or sacroiliac spine procedure. ESIs were by far the most common non-surgical procedure (received by 10% of patients), with much lower proportions of patients receiving facet joint injections (2%), sacroiliac joint injections (1%), and facet joint RFA (1%). A minority of those receiving non-surgical procedures had repeat procedures, with 3% receiving 2 procedures, and 2% receiving 3 or more procedures over 18 months. Repeat procedures consisted mainly of repeat ESIs (**Table 2**).

The results of generalized linear models to evaluate the effect of the LIRE intervention on non-surgical lumbosacral or sacroiliac spine procedures are presented in **Table 3**. Inserting epidemiologic text into lumbar spine imaging reports did not have a significant effect on the occurrence of any non-surgical lumbosacral or sacroiliac spine procedure over the subsequent 18 months (odds ratio [OR]=1.01, 95% confidence interval [CI] 0.93-1.09; p=0.79), the primary outcome for aim 1. Similarly, there were no significant effects on the four exploratory secondary outcomes for aim 1 (the four specific procedure types: ESIs, facet joint injections, facet joint RFA, and sacroiliac joint injections), after accounting for multiple statistical comparisons (**Table 3**). Results were also similar when outcomes were treated as counts of procedures, showing no significant effects on non-surgical lumbosacral or sacroiliac spine procedure utilization (**Table 3**).

More than 3% of patients received spine surgery, with 3% receiving decompression surgery and 1% receiving spinal fusion or a proxy for fusion such as disc arthroplasty over 18 months of follow-up (**Table 2**). Inserting epidemiologic text into lumbar spine imaging reports did not have a significant effect on the occurrence of any spine surgery over 18 months of follow-up (OR=0.99, 95 CI 0.91-1.07; p=0.74) (**Table 4**), the primary outcome for aim 1. Similarly, there were no significant effects on the occurrence of decompression surgery or the occurrence of spinal fusion over 18 months of follow-up (**Table 4**), the two exploratory secondary outcomes for aim 2.

DISCUSSION

In this pre-specified secondary analysis of the LIRE stepped-wedge, cluster randomized trial, 12% of study patients who received lumbar spine imaging also received one or more non-surgical lumbosacral or sacroiliac spine procedures over the 18 months after the index image report. Inserting epidemiologic text into spine imaging reports had no significant effect on the subsequent occurrence or frequency of non-surgical lumbosacral or sacroiliac spine procedures. Similarly, although 3% of patients who received lumbar spine imaging also received thoracolumbar spine surgery over 18 months of follow-up, there was no significant effect of inserting epidemiologic text into spine imaging reports on subsequent spine surgery involving the lumbar, sacral, or thoracic spine.

The findings of our study are consistent with the main results of the LIRE trial, in which there was no statistically significant impact of the insertion of epidemiologic text into spine imaging reports on spine-related RVUs.(19) Because spine procedures are associated with substantial direct health care costs,(3, 8, 12) it is perhaps unsurprising that we found no effect of the intervention on such procedures. The decision of whether or not to offer spine procedures is largely made by clinical spine specialists such as spine surgeons, pain medicine physicians, or other non-surgical specialists. Spine specialists are likely already aware of the high prevalence of incidental and non-clinically meaningful findings on spine imaging, and such knowledge may already be incorporated into their clinical decision-making regarding the suitability of spine procedures for a given patient. Thus, while providing benchmark epidemiologic information in spine imaging reports to non-specialists (such as primary providers) may offer new information or a useful reminder of information previously learned, this is likely not the case for spine specialists. This may explain the null effect of the LIRE intervention on non-surgical lumbosacral or sacroiliac spine procedures or spine surgery involving the lumbar, sacral, or thoracic spine in the current study.

The LIRE intervention consisted of short segments of text that could easily be inserted into electronic lumbar spine radiology report templates, making it an intervention that is very low-cost and relatively simple to implement in many health care contexts. Given the LIRE trial's finding of significantly lower opioid prescription rates in those randomized to receive the LIRE intervention text, a case could be made for widespread adoption of the LIRE intervention text. A potential limitation of such an approach might be if the intervention text led treating clinicians to devalue the importance of all spine conditions and "undertreat" conditions that might otherwise have benefitted from treatment. In this sense, the lack of any significant effects of the LIRE intervention on spine procedural utilization seen in the current study is reassuring. In particular, decompressive spine surgery may be performed non-electively for progressive neurologic deficits or cauda equina syndrome, and rates of decompression did not appear to be affected by the LIRE intervention in our study. Therefore, our findings add to the strength of the case for broader adoption of the LIRE intervention and routine incorporation into lumbar imaging reports, beyond the evidence we have reported previously.(19)

This study has some limitations. First, our study examined the effects of the LIRE intervention in a broad sample of participants receiving lumbar spine imaging. This imaging may have been for patients with LBP, or for specific spine diagnoses that are often (but not necessarily) associated with LBP, such as lumbosacral radiculopathy or symptomatic lumbar spinal stenosis. Our approach did not restrict analyses according to specific diagnostic subgroups that may be more appropriate clinical candidates for a given procedure (such as analyses of surgical decompression performed only in those with lumbosacral radiculopathy). Second, while the LIRE trial was intentionally designed such that all study outcomes could be evaluated through the EHR, patient-reported outcomes (PROs) such as pain and back pain-related functional limitations were not collected. PROs may have added an element of depth to the current findings. On the other hand, the current study's outcomes are high-cost spine procedures, which are generally accepted to be accurate in EHR documentation due to

their high costs, and the EHR-based algorithms used for identifying spine surgeries in the current study have been validated.(25) Another potential limitation of the study is that we did not have access to data that would have enabled us to examine whether the LIRE intervention affected PCPs' recommendations for spine procedures or referrals to spine specialists, which might have been impacted without manifesting as an overall change in procedural outcomes given that final procedural eligibility is ultimately determined by the treating specialist. Nevertheless, our results are likely to represent the overall effect that could be expected from applying the LIRE intervention in usual clinical practice.

In summary, in this secondary analysis of a stepped-wedge randomized controlled trial, inserting epidemiologic text into spine imaging reports did not affect use of non-surgical lumbosacral or sacroiliac spine procedures, or surgical procedures involving the lumbar, sacral, or thoracic spine.

ACKNOWLEDGEMENTS

Funding Source: This work was supported within the National Institutes of Health (NIH) Health Care Systems Research Collaboratory by the NIH Common Fund through cooperative agreement U24AT009676 from the Office of Strategic Coordination within the Office of the NIH Director and cooperative agreements UH2AT007766 and UH3AR066795 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). It was also supported by the UW Clinical Learning, Evidence and Research (CLEAR) Center for Musculoskeletal Disorders funded by NIH/NIAMS P30AR072572. This content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. Dr. Suri is a Staff Physician at the VA Puget Sound Health Care System and was funded by the VA Puget Sound Health Care System. The contents of this work do not represent the views of the US Department of Veterans Affairs or the US Government.

Registration: Clinicaltrials.gov NCT02015455

Prior presentation: None.

Conflicts of Interest: Dr Jarvik reported receiving royalties from Springer Publishing and Wolters/Kluwer/*UpToDate* and receiving travel reimbursement from GE–Association of University Radiologists outside the submitted work. Dr Deyo reported having an endowed professorship funded by Kaiser Permanente and receiving personal fees from *UpToDate* outside the submitted work. Dr Friedly reported receiving grants from the Department of Defense and salary support from the American Academy of Physical Medicine and Rehabilitation for serving as editor in chief outside the submitted work. None of the other authors has potential conflicts of interest to report.

REFERENCES

1. Mokdad AH, Ballestros K, Echko M, Glenn S, Olsen HE, Mullany E, et al. The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States. JAMA. 2018;319(14):1444-72.
2. Dieleman JL, Baral R, Birger M, Bui AL, Bulchis A, Chapin A, et al. US Spending on Personal Health Care and Public Health, 1996-2013. JAMA. 2016;316(24):2627-46.
3. Martin BI, Deyo RA, Mirza SK, Turner JA, Comstock BA, Hollingworth W, et al. Expenditures and health status among adults with back and neck problems. Jama. 2008;299(6):656-64.
4. Deyo RA, Mirza SK, Turner JA, Martin BI. Overtreating chronic back pain: time to back off? J Am Board Fam Med. 2009;22(1):62-8.
5. Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine (Phila Pa 1976). 2009;34(10):1066-77.
6. Bernstein DN, Brodell D, Li Y, Rubery PT, Mesfin A. Impact of the Economic Downturn on Elective Lumbar Spine Surgery in the United States: A National Trend Analysis, 2003 to 2013. Global Spine J. 2017;7(3):213-9.
7. Kim LH, Vail D, Azad TD, Bentley JP, Zhang Y, Ho AL, et al. Expenditures and Health Care Utilization Among Adults With Newly Diagnosed Low Back and Lower Extremity Pain. JAMA Netw Open. 2019;2(5):e193676.
8. Starr JB, Gold L, McCormick Z, Suri P, Friedly J. Trends in lumbar radiofrequency ablation utilization from 2007 to 2016. Spine J. 2019;19(6):1019-28.
9. Starr JB, Gold LS, McCormick Z, Suri P, Friedly J. Repeat procedures and prescription opioid use after lumbar medial branch nerve radiofrequency ablation in commercially insured patients. Spine J. 2019.
10. Abbott ZI, Nair KV, Allen RR, Akuthota VR. Utilization characteristics of spinal interventions. Spine J. 2012;12(1):35-43.
11. Friedly J, Chan L, Deyo R. Geographic variation in epidural steroid injection use in medicare patients. J Bone Joint Surg Am. 2008;90(8):1730-7.
12. Friedly J, Chan L, Deyo R. Increases in lumbosacral injections in the Medicare population: 1994 to 2001. Spine. 2007;32(16):1754-60.
13. Brinjikji W, Luetmer PH, Comstock B, Bresnahan BW, Chen LE, Deyo RA, et al. Systematic literature review of imaging features of spinal degeneration in asymptomatic populations. AJNR Am J Neuroradiol. 2015;36(4):811-6.
14. Endean A, Palmer KT, Coggon D. Potential of magnetic resonance imaging findings to refine case definition for mechanical low back pain in epidemiological studies: a systematic review. Spine (Phila Pa 1976). 2011;36(2):160-9.
15. Suri P, Boyko EJ, Goldberg J, Forsberg CW, Jarvik JG. Longitudinal associations between incident lumbar spine MRI findings and chronic low back pain or radicular symptoms: retrospective analysis of data from the longitudinal assessment of imaging and disability of the back (LAIDBACK). BMC musculoskeletal disorders. 2014;15:152.
16. Jarvik JJ, Hollingworth W, Heagerty P, Haynor DR, Deyo RA. The Longitudinal Assessment of Imaging and Disability of the Back (LAIDBack) Study: baseline data. Spine. 2001;26(10):1158-66.
17. Herlin C, Kjaer P, Espeland A, Skouen JS, Leboeuf-Yde C, Karppinen J, et al. Modic changes-Their associations with low back pain and activity limitation: A systematic literature review and meta-analysis. PLoS One. 2018;13(8):e0200677.
18. Roland M, van Tulder M. Should radiologists change the way they report plain radiography of the spine? Lancet. 1998;352(9123):229-30.
19. Jarvik JG. The Effect of Including Benchmark Prevalence Data of Common Imaging Findings in Spine Image Reports: A Stepped-Wedge, Pragmatic Randomized Trial. JAMA Network Open. 2020;Accepted manuscript.

20. Jarvik JG, Meier EN, James KT, Gold LS, Tan KW, Kessler LG, et al. The Effect of Including Benchmark Prevalence Data of Common Imaging Findings in Spine Image Reports on Health Care Utilization Among Adults Undergoing Spine Imaging: A Stepped-Wedge Randomized Clinical Trial. JAMA Netw Open. 2020;3(9):e2015713.
21. Jarvik JG, Comstock BA, James KT, Avins AL, Bresnahan BW, Deyo RA, et al. Lumbar Imaging With Reporting Of Epidemiology (LIRE)--Protocol for a pragmatic cluster randomized trial. Contemporary clinical trials. 2015;45(Pt B):157-63.
22. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40(5):373-83.
23. Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. J Clin Epidemiol. 1994;47(11):1245-51.
24. Quan H, Li B, Couris CM, Fushimi K, Graham P, Hider P, et al. Updating and validating the Charlson comorbidity index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. Am J Epidemiol. 2011;173(6):676-82.
25. Kazberouk A, Martin BI, Stevens JP, McGuire KJ. Validation of an administrative coding algorithm for classifying surgical indication and operative features of spine surgery. Spine (Phila Pa 1976). 2015;40(2):114-20.

Table 1. Baseline Characteristics

Table 2. Frequencies of spine procedures performed over 18-month follow-up

Table 3. Effects of the LIRE intervention on utilization of non-surgical lumbosacral or sacroiliac spine procedures over 18-month follow-up

Table 4. Effects of the LIRE intervention on utilization of lumbar, sacral, or thoracic spine surgery over 18-month follow-up

FIGURE LEGENDS

Figure 1. Stepped-Wedge Allocation of Trial Subjects.

Patients were excluded for any of the following reasons: a prior lumbar spine image within 12 months (n=11,149; 97% of exclusions), an imaging report finalization date more than 4 days after image completion date (n=354; 3%), an image completion date prior to report finalization date (n=3), and not having a link to utilization data (n=9). For clinics under the control condition, "Intervention" indicates the intervention text was mistakenly included in the image report. For clinics under the intervention condition, "Intervention" indicates that the intervention text was successfully included in the image report and "No intervention" indicates that the intervention text was not included.

Table 1. Baseline Characteristics

Characteristic	Control (N = 117,455)	Intervention (N = 121,431)
Site, No. (%)		
A	6,950 (6)	7,388 (6)
B	96,275 (82)	100,729 (83)
C	7,846 (7)	7,726 (6)
D	6,384 (5)	5,588 (5)
Age in years, No. (%)		
18-39	21,237 (18)	22,105 (18)
40-60	45,032 (38)	44,995 (37)
>60	51,186 (44)	54,331 (45)
Sex[a], No. (%)		
Female	67,915 (58)	69,458 (57)
Male	49,534 (42)	51,965 (43)
Charlson Comorbidity Index, No. (%)		
0	75,106 (64)	77,973 (64)
1	20,675 (18)	21,193 (17)
2	11,451 (10)	11,760 (10)
3+	10,223 (9)	10,505 (9)
Primary insurance at index, No. (%)		
Medicare	44,362 (38)	46,479 (38)
Medicaid/state-subsidized	5,546 (5)	6,510 (5)
Commercial	65,375 (56)	66,368 (55)
VA	117 (0)	131 (0)
Self-pay	731 (1)	570 (0)
Unknown or Not Reported	1,324 (1)	1,373 (1)
Socioeconomic index[b], mean (SD)	57 (6)	57 (7)
Prior injection, No. (%)	1,399 (1)	966 (1)
Prior surgery, No. (%)	90 (0.1)	89 (0.1)

a. Does not include 14 patients with other or unknown sex.
b. Does not include 6,810 (3%) patients with unknown socioeconomic index

Table 2. Frequencies of spine procedures performed over 18-month follow-up

	Number of procedures			
	Any	**1**	**2**	**3 or more**
Non-surgical lumbosacral or sacroiliac spine procedures				
Primary outcome (Aim 1)				
Any type of non-surgical procedure[a]	28,339 (12%)	15,422 (6%)	7,921 (3%)	4,996 (2%)
Secondary outcomes (Aim 1)				
Any ESI	24,450 (10%)	14,060 (6%)	6,850 (3%)	3,540 (1%)
Any facet joint injection	3,905 (2%)	2,842 (1%)	837 (0%)	226 (0%)
Any facet joint RFA	1,420 (1%)	1,074 (0%)	290 (0%)	56 (0%)
Any sacroiliac joint injection	1,722 (1%)	1,309 (1%)	327 (0%)	86 (0%)
Surgical procedures involving the lumbar, sacral, or thoracic spine				
Primary outcome (Aim 2)				
Any spine surgery[b]	7,538 (3%)	4,719 (2%)	2,186 (1%)	633 (0%)
Secondary outcomes (Aim 2)				
Fusion[c]	2,629 (1%)	2,490 (1%)	129 (0%)	10 (0%)
Decompression	6,734 (3%)	6,223 (3%)	458 (0%)	53 (0%)

ESI= epidural steroid injection, RFA=radiofrequency ablation

[a]including lumbosacral ESI, facet joint injection (medial branch blocks or intra-articular injections), or facet joint RFA; or sacroiliac joint injection (the occurrence of any one of these types of procedures)

[b]Any spine surgery includes decompression surgery, spinal fusion or proxies for spine fusion, or other surgeries involving the lumbar, sacral, or thoracic spine (the occurrence of any one of these types of surgeries)

[c]Spinal fusion or proxies for spinal fusion (e.g disc arthroplasty). Fusion may or may not have also involved decompression.

Table 3. Effects of the LIRE intervention on utilization of non-surgical lumbosacral or sacroiliac spine procedures over 18-month follow-up

	Any				Count			
	Adjusted proportions				Adjusted rate			
	Control (n=117,455)	Intervention (n=121,431)	Odd ratio* (95% CI)	P	Control (n=117,455)	Intervention (n=121,431)	IRR* (95% CI)	P
Non-surgical lumbosacral or sacroiliac spine procedures								
Primary outcome (Aim 1)								
Any type of non-surgical procedure[a]	11.8%	11.9%	1.01 (0.93, 1.09)	0.79[b]	0.205	0.207	1.01 (0.93, 1.10)	0.86[c]
Secondary outcomes (Aim 1)								
Any ESI	10.1%	10.4%	1.03 (0.95, 1.12)	0.46[d]	0.166	0.169	1.02 (0.93, 1.11)	0.67[c]
Any facet joint injection	1.7%	1.5%	0.89 (0.78, 1.02)	0.09[d]	0.023	0.021	0.94 (0.80, 1.10)	0.44[c]
Any facet joint RFA	0.6%	0.6%	0.99 (0.81, 1.20)	0.89[d]	0.008	0.008	1.03 (0.80, 1.34)	0.81[c]
Any sacroiliac joint injection	0.7%	0.8%	1.13 (0.93, 1.37)	0.22[d]	0.009	0.010	1.08 (0.87, 1.34)	0.50[ce]

IRR = incidence rate ratio, ESI= epidural steroid injection, RFA=radiofrequency ablation, SI=sacroiliac

*Models adjusting for fixed effects (site, clinic size tertile, computed tomography vs. magnetic resonance imaging, Charlson Comorbidity category [0, 1, 2, 3+], site-specific time [linear], gender, age range [<40, 40-60, >60] , and prior injection) and random effects: (clinic [intercept and treatment] and provider [intercept only])

[a]lumbosacral ESI, facet joint injection, or facet joint RFA; or sacroiliac joint injection (the occurrence of any one of these types of procedures)

[b]Statistical significance defined as p<0.05

[c]Poisson regression

[d]Statistical significance defined as p<0.0125 (with Bonferroni correction accounting for 4 individual non-surgical spine procedures)

[e]Due to lack of model convergence, the clinic-level treatment random effects term was dropped from this model.

Table 4. Effects of the LIRE intervention on utilization of lumbar, sacral, or thoracic spine surgery over 18-month follow-up

	Any			
	Adjusted proportions			
	Control (n=117,455)	Intervention (n=121,431)	Odd ratio* (95% CI)	P
Primary outcome (Aim 2)				
Any spine surgery[a]	3.2%	3.1%	0.99 (0.91, 1.07)	0.74[b]
Secondary outcomes (Aim 2)				
Fusion[c]	1.1%	1.1%	1.01 (0.89, 1.14)	0.85[d]
Decompression	2.9%	2.8%	0.97 (0.88,1.06)	0.47[d]

*Models adjusting for fixed effects (site, clinic size tertile, computed tomography vs. magnetic resonance imaging, Charlson Comorbidity category [0, 1, 2, 3+], site-specific time [linear], gender, age range [<40, 40-60, >60]) and random effects: (clinic [intercept and treatment] and provider [intercept only])

[a]Any spine surgery includes decompression surgery, spinal fusion or proxies for spine fusion, or other surgeries involving the lumbar, sacral, or thoracic spine

[b]Statistical significance defined as p<0.05

[c]Spinal fusion or proxies for spinal fusion (e.g disc arthroplasty). Fusion may or may not have also involved decompression.

[d]Statistical significance defined as p<0.025 (with Bonferroni correction accounting for 2 individual surgical spine procedures)

FIGURE LEGENDS

Figure 1. Stepped-Wedge Allocation of Trial Subjects.

Patients were excluded for any of the following reasons: a prior lumbar spine image within 12 months (n=11,149; 97% of exclusions), an imaging report finalization date more than 4 days after image completion date (n=354; 3%), an image completion date prior to report finalization date (n=3), and not having a link to utilization data (n=9). For clinics under the control condition, "Intervention" indicates the intervention text was mistakenly included in the image report. For clinics under the intervention condition, "Intervention" indicates that the intervention text was successfully included in the image report and "No intervention" indicates that the intervention text was not included.

Clinic Group (# of clinics*)	Step 0 ** Oct 2013 - Mar 2014	Step 1 ** Apr 2014 - Sep 2014	Step 2 Oct 2014 - Mar 2015	Step 3 Apr 2015 - Sep 2015	Step 4 Oct 2015 - Mar 2016	Step 5 Apr 2016 - Sep 2016	Total
1 (n=19)	**10,630** Analyzed **78 (1%)** Interv. **970** Excluded	**41,558** Analyzed **34,219 (82%)** Intervention **7,339 (18%)** No intervention **1,424** Excluded					**52,188** Analyzed **2,394** Excluded
2 (n=20)	**15,605** Analyzed **4 (0%)** Intervention **1,134** Excluded	**31,611** Analyzed **29,167 (92%)** Intervention **2,444 (8%)** No intervention **1,024** Excluded					**47,216** Analyzed **2,158** Excluded
3 (n=20)	**29,628** Analyzed **394 (1%)** Intervention **1,788** Excluded		**30,157** Analyzed **25,313 (84%)** Intervention **4,844 (16%)** No intervention **978** Excluded				**59,785** Analyzed **2,766** Excluded
4 (n=18)	**21,970** Analyzed **194 (1%)** Intervention **1,428** Excluded			**10,277** Analyzed **9,433 (92%)** Intervention **844 (8%)** No intervention **459** Excluded			**32,247** Analyzed **1,887** Excluded
5 (n=21)	**39,622** Analyzed **114 (0%)** Intervention **2,037** Excluded				**7,828** Analyzed **7,411 (95%)** Interv. **417 (5%)** No interv. **273** Excluded		**47,450** Analyzed **2,310** Excluded

* Two small clinics randomized to clinic groups 2 and 5 were dropped prior to the first data submission due to clinic closure and are not included in clinic counts.

** By pre-trial design, Step 0 extended through May 2014 and Step 1 began Jun 2014 for one healthcare system.

Clinics under control condition

Clinics under intervention condition

Totals

All (n=98)	**117,455** Analyzed **784 (1%)** Intervention **7,357** Excluded		**121,431** Analyzed **105,543 (87%)** Intervention **15,888 (13%)** No intervention **4,158** Excluded				**238,886** Analyzed **11,515** Excluded