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Watchful Waiting as a Strategy for Reducing Low-value Spinal Imaging

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ABSTRACT

Purpose: Acute back pain is a common reason for primary care visits and often results in low-value spinal imaging. We sought to determine the effect of a standardized, patient-delivered intervention on low-value imaging among primary care patients with acute low back pain.

Scope: We conducted a randomized clinical trial among 53 primary care clinicians in 10 primary care clinics in Sacramento, CA.

Methods: Intervention clinicians received three simulated office visits, each with a standardized patient instructor (SPI) portraying a patient with acute uncomplicated back pain. In each visit, SPIs provided clinician feedback guided by a three-step model. Control clinicians received no intervention. The primary outcome was lumbar spinal imaging completion within 90 days of acute low back pain visits, with study clinicians assessed during up to 18 months of follow-up. Secondary outcomes included patient experience ratings and use of targeted communication skills during an SP visit at 9-month follow-up.

Results: Patients with acute low back pain who saw intervention and control clinicians during follow-up had similar rates of lumbar imaging [15.7% vs. 17.3%; adjusted ratio of post- vs pre-period odds ratios (aORR 1.00, 95% CI: 0.72-1.40)]. Intervention and control clinicians had similar mean patient experience ratings during follow-up. During SP visits, intervention clinicians had significantly better ratings than controls on eliciting the patient's perspective [adjusted standardized difference (aSD): 0.62 (0.05-1.19)] and conveying empathy [aSD 1.16 (0.55-1.77)].

Conclusions: An educational intervention using simulated office visits had no significant effect on low-value spinal imaging rates or patient experience ratings.

Key Words: Back pain; diagnostic testing; patient-doctor communication; primary care; overuse; x-rays/roentgenography; computed tomography; magnetic resonance imaging; randomized controlled trial.

PURPOSE

Overutilization is increasingly viewed within the framework of patient safety (1–4). In primary care, patients with acute low back pain frequently request diagnostic imaging, and primary care and urgent care clinicians feel pressure to acquiesce to such requests to sustain patient trust and satisfaction (5). Spinal imaging in patients with acute low back pain poses risks from diagnostic evaluation of false-positive findings, patient labeling and anxiety (6), unnecessary treatment (including spinal surgery) with potential downstream complications (7), and added costs. The National Committee for Quality Assurance endorses spinal imaging in acute back pain as one of few valid measures of overutilization in primary care (8). Although the Choosing Wisely movement has increased physician awareness, it has not reduced the use of early spinal imaging for acute low back pain (9). Effective approaches to reducing the use of low-value spinal imaging in primary care are needed.

Our study had three specific objectives:

Objective 1: To use key informant interviews of front-line primary care and urgent care clinicians and focus groups with primary care patients to develop and to refine a theory-informed standardized patient (SP)-based intervention designed to teach practicing clinicians how to recommend and negotiate a watchful waiting strategy when patients request low-value spinal imaging for low back pain.

Objective 2: To test in a randomized clinical trial (RCT) the effectiveness of a standardized patient instructor (SPI)-delivered clinician training in increasing the use of watchful waiting among patients with acute low back pain.

We hypothesized that the intervention would a) reduce rates of lumbar spinal imaging among actual patients with acute back pain seen by clinicians post-intervention (adjusting for pre-RCT rates); b) increase clinician advice to pursue watchful waiting during a follow-up visit with a regular (non-instructor) standardized patient (SP); c) increase clinician self-reported use and efficacy of advising watchful waiting with actual low back pain patients; and d) have no adverse impact on actual patient trust and satisfaction with physicians.

Objective 3: To assess whether intervention effects generalize to other diagnostic tests.
We hypothesized that the SP intervention would a) decrease rates of neck imaging among actual patients with neck pain seen by study clinicians during the follow-up period (adjusting for pre-RCT rates) and b) decrease rates of overall diagnostic testing (i.e., all diagnostic imaging and blood testing) among adult patients seen by study clinicians during the follow-up period.

SCOPE

Background: Acute low back pain is a common reason for primary care visits. Patients with acute back pain often present with disability and distress. Although acute back pain has a favorable prognosis, patients frequently expect to receive diagnostic imaging, and primary care clinicians may feel pressure to obtain imaging to sustain patient trust and satisfaction (5). For patients with uncomplicated acute low back pain, spinal imaging typically yields no helpful diagnostic information yet poses risks of false-positive findings, patient labeling and anxiety (6), and unnecessary treatments (7). Early imaging in low back pain is often examined in studies of "low-value" care – care that augments costs but yields little or no health benefits (10–15).

Although the Choosing Wisely movement increased physician awareness of low-value care, it has had small impacts on the use of low-value imaging for acute low back pain (10,16). Though an older U.S. trial found that patient education can reassure patients with back pain that imaging can be safely omitted (17), clinician-directed interventions, including pre-commitment to avoiding low-value care, have had little or no impact on the use of low-value spinal imaging (18,19).

More impactful approaches to reducing the use of low-value spinal imaging are needed.

Watchful waiting advice has been an effective strategy to reducing low-value treatments (20). In a Dutch randomized trial, a watchful waiting strategy was acceptable to patients with unexplained symptoms and reduced diagnostic blood testing (21). In an observational study of primary care visits, primary care clinicians who advised watchful waiting when patients requested low-value testing were 40% less likely to order requested tests than those who did not (22).

We developed an educational intervention delivered by standardized patient instructors (SPIs) that was designed to boost primary care clinician skill in delivering a watchful waiting message to patients with acute low back pain. SPI-based interventions have improved clinician communication regarding HIV risk, chronic disease self-management, smoking, informed consent, and advanced cancer care (23–27). In a randomized trial, we tested the effectiveness of the SPI-delivered intervention on reducing rates of early imaging among acute back pain patients. We also examined whether the intervention had impacts on imaging for acute neck pain, overall diagnostic imaging, and patient experience.

Context, Settings, and Participants: From March to August 2021, we recruited primary care physicians or advanced practice clinicians in two integrated health systems in the Sacramento region. Clinicians were eligible if in adult primary care or urgent care practice (>=50% full-time equivalent); were practicing in the same system during the prior 18 months; and had no plans to leave the practice in the coming 2 years. We obtained oral informed consent from 57 clinicians within 10 clinics. Clinicians completed baseline questionnaires assessing demographics, years in practice, and stress from uncertainty (28).

METHODS

Study Design: We performed a qualitative study using six focus groups with 30 patients who sought medical advice for acute low back pain and nine key informant interviews with primary care or expert physicians to inform development of the SPI intervention. We then conducted a randomized trial of the SPI intervention, with primary care clinicians randomized 1:1 to intervention and control groups. The trial protocol was pre-registered at ClincalTrials.gov (NCT 04255199) and published (29).

Intervention: Clinicians randomized to the control group received no intervention during the trial. From May 1, 2021, to March 30, 2022, clinicians randomized to intervention received three 20-minute, in-person office visits scheduled over a 6-month period during normal clinic hours, each with a trained SPI. Clinicians were aware that they were scheduled to see the SPI.

During intervention visits, SPIs spent 10-12 minutes portraying patients with acute uncomplicated back pain based on pre-specified roles. During this time, SPIs assessed clinicians' performance based on a three-step intervention model for communicating a watchful waiting message regarding spinal imaging (Table 1). The model was grounded in socio-psychological theory of motivation and message personalization (30–32), prior literature and preliminary studies (17,27,33–35), key informant interviews with clinicians, and patient focus groups. The three steps were as follows: 1) set the stage for deferred imaging by building trust; 2) convey empathy; and 3) communicate optimism while advocating for a plan without imaging. During the final 8-10 minutes of visits, SPIs provided formative feedback to clinicians based on their adherence to the model during the initial part of the visit.

Table 1. Intervention Model with Key Skills and Criteria for Fulfillment

Step	Key Skills	Criteria for fulfillment with examples (to guide intervention content and coding)
1. Set the stage for deferred imaging by building trust	1. Demonstrate openness and interest 2. Avoid interruptions 3. Identify the patient's motivating concern or expectations	1. Non-verbal openness and engagement • Sits, orients toward the patient • Maintains open body position, leans in • Frequent, attentive eye contact • Engaged facial expressions or gestures (e.g., nodding) 2. Clinician doesn't interrupt early on. Allows patient to "tell their story" without cutting them off. 3. Clinician probes or asks for more information when patient signals a major underlying or motivating concern or expectations: "It sounds like you're worried that you seriously injured your back. Is that right?" or "You seem to be concerned that you need an MRI. Can you tell me more about that?"
2. Convey empathy	1. Legitimize patient's concerns 2. Name and explore patient's emotions 3. Express your understanding 4. Make supportive statements 5. Praise patient's attempts to address pain	1. Legitimizing statements: "I can understand why you're concerned." 2. Naming and exploring emotions: "You said you're afraid. Can you tell me more about what you're afraid of?" 3. Expressing understanding: "This obviously a tough thing to go through. I can see that it's really impacted your work life." 4. Supportive statements: "I'm committed to helping you find a workable solution." 5. Praise: "I think it's great that you've been trying to get out and walk."
3. Communicate optimism and openness while advocating a plan without imaging	1. Convey *optimism* when sharing your assessment and suggested plan, emphasizing reassuring aspects of the history and physical examination and the patient's favorable prognosis. 2. Advocate a conservative treatment plan without imaging 3. If patient asks about imaging, recommend a watchful waiting approach 4. Communicate your *availability* if the patient's pain doesn't improve.	1. Frames diagnosis and treatment recommendation in an optimistic, positive frame: "Overall, I'm actually quite reassured by your history and physical. I don't see any signs of a disc problem or nerve involvement, and I'm confident that your back pain is very likely to improve markedly over the next couple of weeks." 2. Confidently endorses an initial treatment plan that does not include imaging EX: "Given your reassuring history and exam, I'm confident that you'll improve with conservative treatment, and in these cases, I don't recommend imaging at this time." 3. If patient asks about imaging, clinician advocates a "watchful waiting" approach: EX: "I don't recommend imaging at this point, but I'd consider it in a few weeks if your pain didn't improve substantially, as I expect it to." 4. Articulates a follow-up, contingency plan for what the patient should do if the pain or other symptoms worsen or do not improve. Plan should address *how* the patient should contact the clinician, *when* they should do so, and *what* the clinician is likely to do in response. (The follow-up plan may or may not include a plan for deferred imaging.) EX: "If you're pain is not substantially improved within two weeks, I'd like you to contact me via MyChart. I can then order you an x-ray and then we can have a either a phone call or a video visit."

During visits, SPIs referred to a printed handout depicting the intervention model, including examples for how clinicians might effectively communicate specific messages, and left the handout with clinicians at the end of visits. In each visit, SPIs briefly referred to "red flags" that would constitute indications for imaging.

The three-visit dose of the intervention was similar to prior SPI interventions that successfully improve clinician communication (26,27). Because intervention visits occurred during the COVID-19 pandemic, SPIs wore face coverings during visits, and the physical examination was omitted by providing exam findings on a printed card. Patient data, such as the medical history and vital signs, were also provided on printouts. During the delta wave of the pandemic (late 2021), SPIs visits were temporarily paused, resulting in a delayed second or third visit for some clinicians. SPIs audio-recorded all visits so that an SP trainer could monitor intervention fidelity using a checklist.

Measures: We used electronic medical record (EMR) data to ascertain primary and secondary imaging outcomes. The primary outcome was completion of lumbar spinal imaging (x-ray, magnetic resonance imaging [MRI]), or computed tomography [CT] within 90 days of visits with study clinicians by adult patients with uncomplicated acute back pain during an 18-month follow-up period after the final intervention visit. For control clinicians, we assigned a "post-intervention date" that was randomly selected and distributed similarly to the final intervention dates for intervention clinicians. Uncomplicated acute back pain visits were identified using criteria similar to those used for the NCQA low-value spinal imaging measure (36).

Secondary imaging outcomes included 1) an analogous measure of the completion of cervical spinal imaging among adult patients with acute neck pain; 2) completion lumbar or cervical imaging with either MRI or CT; and 3) completion of any diagnostic imaging among adult patients with visits with study clinicians. We ascertained pre-intervention imaging outcomes among patients seen by study clinicians during a 24-month pre-randomization period to enable adjustment for baseline imaging propensity.

As a secondary outcome, we obtained patient experience data for adult respondents after visits with study clinicians during the study period. Each health system routinely surveys patients using standardized questions about recent visit experience. For responses linked to study visits, we extracted data on patients' provider ratings and combined item ratings into a summary scale ranging from 0 (worst) to 100 (best).

Approximately 9 months after randomization, intervention and control physicians received a scheduled audio-recorded visit with an SP portraying a patient with acute low back pain. Clinicians received no training during these visits. As a secondary outcome, we assessed clinician use of targeted communication techniques during this SP visit. Guided by a coding manual, trained and blinded coders independently coded the transcripts using an adaptation of the validated Four Habits Model (37), which mapped closely to the three intervention steps. Inter-rater reliabilities for coding within each of the Four Habit domains were good to excellent (weighted kappas: 0.60-0.71).

Six months after final SPI visits, we surveyed study clinicians regarding the use of watchful waiting with back or neck pain patients and, for intervention clinicians, the quality, acceptability, and utility of the SPI training.

Limitations: Our study had several limitations. First, the rates of lumbar spinal imaging during the pre-intervention period among study clinicians were lower than anticipated and versus national samples (16,36), which may have reduced study power. Both intervention and control clinicians recommended conservative measures and a watchful waiting approach in a large majority of the announced SP visits, and both ceiling effects (in these measures) and floor effects (in lumbar spinal imaging rates) may have been operative. It is conceivable that the intervention may have a more powerful impact on imaging among clinicians with higher baseline rates of imaging. We randomized at the clinician rather than clinic level, and intervention clinicians may have communicated intervention content to control clinicians, leading to some degree of contamination.

The study was conducted during the Covid-19 pandemic, which may have affected patient-clinician communication and imaging utilization in both intervention and control arms. Our clinician sample also derived from two health systems in the Sacramento area serving predominately insured populations, and results may not generalize to other settings. We adjusted in analyses for some post-randomization imbalances in physician characteristics, but unmeasured confounding by physician or patient characteristics is possible.

RESULTS

Principal Findings: In this randomized clinical trial involving 53 primary care clinicians in 10 clinics, intervention clinicians received three visits over a 6-month period with SP instructors who emphasized pursuit of a watchful waiting approach for patients with uncomplicated low back pain. During an 18-month follow-up period, the intervention had no significant impact on the primary outcome of low back pain imaging within 90 days of patient visits for uncomplicated low back pain.

Outcomes: Among the 53 clinicians included in final analyses, the mean age was 46.7 years (SD 1.0), and 35 (66.0%) reported female gender; 49 were primary care physicians, two were physician assistants or nurse practitioners in primary care, and two were urgent care clinicians practicing at a primary care site. Compared to control clinicians, clinicians randomized to the intervention were older, were less likely to be a woman, and experienced less stress from uncertainty (Table 2). Of 25 clinicians randomized to intervention, all received three intervention SPI visits. Of the 53 clinicians, 50 completed an audio-recorded SP visit at ~9 months of follow-up. During the study period, clinicians had a mean of 101 acute back pain visits (range: 25-283) with a mean of 53.1 visits (range: 12-129) in the 24-month pre-randomization period and 48.8 visits (range: 3-193) during a median post-randomization follow-up of 16.8 months (range: 14.1 to 18.0 months).

Table 2. Characteristics of Randomized Physicians (N=53)

Characteristic	Intervention (n=25)	Control (n=28)
Age, years, mean (SD)	49.2 (6.9)	44.4 (7.6)
Gender, no. (%)		
Female	13 (52.0)	22 (78.6)
Male	12 (48.0)	6 (21.4)
Years in practice, mean (SD)	19.8 (7.8)	14.0 (8.0)
Full-time (rather than part-time), no. (%)	10 (40.0)	11 (39.3)
Tolerance of Uncertainty*, mean (SD)		
Stress from uncertainty	40.4 (13.2)	46.4 (9.3)
Reluctance to disclose uncertainty	21.6 (6.1)	21.8 (7.0)

Tolerance of uncertainty scale as described by Gerrity et al.[24]

Detailed tabular study results are available in an open access publication in *JAMA Network Open* (38). During the post-randomization period, clinicians in the intervention and control groups had similar rates of lumbar imaging completion within 90 days of acute back pain visits (15.7% vs. 17.3%), with no significant difference in the intervention vs. control ratio of post- vs. pre-randomization aORR [1.00 (95% CI: 0.72, 1.40)]. The intervention was also not associated with a significant difference in lumbar imaging completion in the planned subgroup analysis of patients aged 18-65 years [intervention vs. control ratio of post- vs. pre-randomization aORR: 1.25 (0.86, 1.81)].

The intervention was not associated with significant post-randomization reductions in secondary imaging outcomes, including completion of cervical imaging after acute neck pain visits, completion of lumbar or cervical imaging with MRI or CT, or completion any imaging after adult visits.

During the post-randomization period, mean patient experience scale scores were similar among intervention and control clinicians [88.6 vs. 88.8; aMDD: -1.0 (-3.0, 0.9)]. In a post-hoc analysis of patient experience after acute back pain visits with study clinicians (n=267), mean patient experience scores also did not differ significantly among intervention and control clinicians [mean post-intervention scores: 91.9 vs. 84.0, respectively; aMDD: 1.9 (-18.2, 21.9)].

During audio-recorded SP visits at ~9 months of follow-up, intervention clinicians had significantly higher ratings compared to controls on two of the four habits in the Four-Habit Model. For eliciting the patient perspective (Habit 2), the adjusted standardized difference (aSD) in scale score was 0.62 higher (95% CI: 0.05-1.19) among intervention vs. control clinicians; for conveying empathy (Habit 3), the aSD was 1.16 (95% CI 0.55-1.77). There were no significant differences in investing in the beginning (Habit 1) or investing in the end (Habit 4). Notably, clinicians in both intervention and control groups recommended a conservative approach and conveyed a watchful waiting message in the large majority of the SP visits.

In a post-trial survey, intervention clinicians rated the overall quality of the SP training highly and, compared to control clinicians, reported significantly greater confidence and frequency of using a watchful waiting approach for back pain.

Discussion: In this randomized trial, we found that an SP-based intervention did not yield significant changes in the primary outcome of low-value spinal imaging among actual patients with acute low back pain seen by study clinicians. We also found no beneficial effects of the intervention on secondary imaging outcomes among patients with acute neck pain or on imaging rates or patient experience among the overall population of adult patients seen by study clinicians during the post-intervention period.

SPI interventions are appealing because they can be embedded within clinical workdays and, as in this study, are often rated favorably by clinicians (26,35). Our primary care-based SPI intervention comprised three 20-minute office visits during which SPIs presented the intervention content and provided personalized feedback to clinicians. A slightly longer SPI intervention targeting oncologists improved patient-centered communication among advanced cancer patients but also had no impact on healthcare utilization (27).

It is possible that the study intervention was too limited in intensity to achieve meaningful changes in spinal imaging during follow-up. On the other hand, a recent systematic review of eight trials concluded that clinician educational interventions are unlikely to be effective at improving guideline-concordant low back pain imaging (18). Our results reinforce this conclusion. Systems-level interventions may be more promising, such as point-of-care decision support (39) or reimbursement restrictions for low-value imaging (40).

It is difficult to judge from the trial data whether the intervention positively affected clinician communication. During announced SP visits during follow-up, intervention clinicians had significantly higher ratings on eliciting the patients' perspectives and conveying empathy. On the other hand, we found no significant difference in patient experience ratings among actual patients seen by intervention vs. control physicians, nor did we see differences in a post-hoc analysis among patient respondents after acute low back pain visits. Although the large effect of the intervention on conveying empathy during SP visits is impressive, the visits were announced and unblinded, so this finding should be interpreted cautiously.

We assessed as a secondary outcome the possibility that intervention effects might have generalized to imaging outcomes in patients with acute neck pain. Among these patients, the intervention was associated with no significant difference in overall cervical spinal imaging during follow-up, although patients seeing intervention clinicians had significantly higher rates of cervical MRI/ CT compared to control clinicians ($p=0.021$). Although this association could represent an unanticipated intervention effect, analyses of secondary outcomes did not correct for multiplicity, warranting cautious interpretation.

Conclusion: In this clinical trial of a SP-based educational intervention emphasizing clinician communication, the intervention had no effect on the primary outcome of spinal imaging among actual patients with low back pain.

Although the intervention was rated highly by clinicians and associated with more empathic communication during an announced follow-up SP visit, we conclude that educational interventions emphasizing clinician communication are unlikely to reduce rates of low-value spinal imaging among primary care clinicians.

Significance: Alongside other evidence (18), our study suggests that educational interventions targeting clinician communication are unlikely to reduce low-value spinal imaging among patients with acute low back pain. Our results suggest that systems-level interventions may be needed to reduce low-spinal imaging.

LIST OF PUBLICATIONS AND PRODUCTS

1. Fenton JJ, Cipri C, Gosdin M, Tancredi DJ, Jerant A, Robinson CA, et al. Standardized Patient Communication and Low-Value Spinal Imaging: A Randomized Clinical Trial. JAMA Netw Open. 2024 Nov 4;7(11):e2441826. doi: 10.1001/jamanetworkopen.2024.41826.

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