Red Flags for Low Back Pain Are Not Always Really Red

A Prospective Evaluation of the Clinical Utility of Commonly Used Screening Questions for Low Back Pain

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Background: Low back pain has a high prevalence and morbidity, and is a source of substantial health-care spending. Numerous published guidelines support the use of so-called red flag questions to screen for serious pathology in patients with low back pain. This paper examines the effectiveness of red flag questions as a screening tool for patients presenting with low back pain to a multidisciplinary academic spine center.

Methods: We conducted a retrospective review of the cases of 9,940 patients with a chief complaint of low back pain. The patients completed a questionnaire that included several red flag questions during their first physician visit. Diagnostic data for the same clinical episode were collected from medical records and were corroborated with imaging reports. Patients who were diagnosed as having a vertebral fracture, malignancy, infection, or cauda equina syndrome were classified as having a red flag diagnosis.

Results: Specific individual red flags and combinations of red flags were associated with an increased probability of underlying serious spinal pathology, e.g., recent trauma and an age of >50 years were associated with vertebral fracture. The presence or absence of other red flags, such as night pain, was unrelated to any particular diagnosis. For instance, for patients with no recent history of infection and no fever, chills, or sweating, the presence of night pain was a false-positive finding for infection >96% of the time. In general, the absence of red flag responses did not meaningfully decrease the likelihood of a red flag diagnosis; 64% of patients with spinal malignancy had no associated red flags.

Conclusions: While a positive response to a red flag question may indicate the presence of serious disease, a negative response to 1 or 2 red flag questions does not meaningfully decrease the likelihood of a red flag diagnosis. Clinicians should use caution when utilizing red flag questions as screening tools.

Low back pain is a major cause of disability worldwide[1,2]. In the United States, low back pain has a lifetime prevalence approaching 85%, is the most common cause of activity limitation in people younger than 45 years, and is a leading driver of physician visits and hospital admissions[3-7].

While a substantial burden on our health-care system, low back pain is typically self-limited, with most cases resolving after conservative management in 6 to 8 weeks[8]. While most low back pain is nonspecific, patients with low back pain may have neurologic impairments (e.g., radiculopathy or spinal stenosis) or a serious underlying pathology (e.g., malignancy or infection) that requires timely and accurate diagnosis[9-11]. Low back pain that is due to serious pathology occurs between 1% and 4% of the time, and has been generally classified as related to 4 etiologies: fracture, malignancy, infection, and cauda equina syndrome[10-12]. While they are rare, appropriate identification of these diagnoses and specialist consultation for their management are essential. Imaging for low back pain can be costly, and there is a high prevalence of abnormal findings in asymptomatic patients[12-14]. Due to the prevalence, burden, and associated health-care cost of low back pain, it is paramount to utilize noninvasive and inexpensive screening tools to detect serious disease.

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TABLE I Patient Characteristics and Positive Responses to Red Flag Questions

Demographic data	
No. of patients	9,940
Mean age (and stand. dev.) *(yr)*	56.8 ± 15.0
Female sex *(no. [%])*	4,838 (48.7)
Family history of cancer *(no. [%])*	3,827 (38.5)
Red flags *(no. [%])*	
Age of >50 yr	6,710 (67.5)
Pain awakens from sleep	5,780 (58.1)
Age of >70 yr	2,046 (20.6)
Persistent sweating at night	1,387 (14.0)
Trauma	1,204 (12.1)
Recent loss of bladder (urination) control	960 (9.7)
Fever, chills, or sweating	685 (6.9)
Recent loss of bowel control (other than diarrhea)	500 (5.0)
Cancer	466 (4.7)
Unexplained weight loss	441 (4.4)
Recent infection	284 (2.9)
None	737 (7.4)

Within this context, red flag screening questions were developed and encouraged for use in the detection of serious spine pathology in the primary care or multidisciplinary setting[15]. These red flag symptoms are widely believed to indicate specific underlying pathology, and multiple practice guidelines for the management of low back pain recommend against diagnostic imaging or procedures for low back pain unless such red flag symptoms are present[9,16-18]. Specific red flag questions are not consistent between guidelines, and there is a paucity of evidence to support their inclusion aside from consensus decision[13,15,19-21].

Prior studies examining the utility of red flag questions are hampered by small numbers[13,15]. Recent Cochrane reviews have indicated a need for more robust data and have noted that it is currently challenging to provide strong recommendations for or against the clinical application of these questions[13,20].

In the present study, we analyzed records for individuals seen with a chief complaint of low back pain at a large academic multidisciplinary spine center. We sought to evaluate the utility of red flag questions in uncovering their classically associated diagnoses. We hypothesized that the use of red flag questions would improve detection and aid in the workup and management of infection, malignancy, fracture, and cauda equina syndrome.

Materials and Methods

Participants

Institutional review board approval was granted for this study. Patients completed a questionnaire that included red flag questions during their first visit, before seeing their surgeon. Diagnostic information was drawn directly from the physician entry and was corroborated by imaging reports, if the patient had received imaging. Information on the diagnosis was also confirmed by reviewing the International Classification of Diseases categories for each patient.

All unique patients who presented as a new patient with a chief complaint of low back pain with or without leg pain, between July 2005 and February 2016, to 1 of 6 fellowship-trained spine surgeons at our institution were identified. Patients seen because of a chief complaint of deformity rather than pain were excluded from the analysis, as were patients with a chief complaint of neck pain. All 9,940 patients identified by the criteria described above were included in our analysis.

Variables of Interest

The hypothesized red flag questions for spinal pathology in our questionnaire have been advocated for use in this context in

TABLE II Frequency of Red Flag Diagnoses Among 9,940 Patients

Diagnosis	No. (%)
Fracture	554 (5.6)
Malignancy	159 (1.6)
Infection	120 (1.2)
Cauda equina syndrome	36 (0.4)

TABLE III Red Flags and Diagnostic Associations*

Fracture
Trauma
Age of >50 yr
Age of >70 yr
Malignancy
Cancer
Unexplained weight loss
Pain awakens from sleep
Age of >50 yr
Age of >70 yr
Infection
Fever, chills, or sweating
Recent infection
Pain awakens from sleep
Persistent sweating at night
Cauda equina syndrome
Recent loss of bowel control
Recent loss of bladder control

*The associations of red flags with a particular diagnosis in the setting of low back pain are based on published literature and guidelines[15,23-26].

TABLE IV Diagnostic Accuracy of Red Flag Questions*

	No. (%)	Sens. (%)	Spec. (%)	PPV†	NPV†	PLR†	NLR†	Probability of Diagnosis (%)
Fracture	554 (5.6)							
Age of >50 yr	410 (4.1)	74	32.9	6.1 (5.6-6.7)	95.5 (94.8-96.2)	1.1 (1.05-1.16)†	0.79 (0.69-0.91)†	6.1
Age of >70 yr	171 (1.7)	3.9	80	8.4 (7.2-9.7)	95.2 (94.7-95.6)	1.55 (1.36-1.76)†	0.86 (0.82-0.91)†	8.4
Trauma	137 (1.4)	24.7	88.6	11.3 (9.7-13.3)	95.2 (94.8-95.7)	2.17 (1.86-2.54)†	0.84 (0.81-0.89)†	11.4
Malignancy	159 (1.6)							
Age of >50 yr	114 (1.2)	71.7	32.6	1.7 (1.4-2.1)	98.6 (98.1-99.0)	1.06 (0.96-1.17)	0.87 (0.68-1.11)	1.7
Age of >70 yr	36 (0.4)	22.6	79.5	1.8 (1.3-2.5)	98.4 (98.1-98.7)	1.1 (0.82-1.47)	0.97 (0.9-1.06)	1.8
Pain awakens from sleep	88 (0.9)	55.4	41.8	1.5 (1.2-1.9)	98.3 (97.8-98.7)	0.85 (0.83-1.1)	1.07 (0.9-1.27)	1.4
Unexplained weight loss	13 (0.1)	8.2	95.6	3 (1.7-5.1)	98.5 (98.2-98.7)	1.87 (1.1-3.17)†	0.96 (0.92-1.01)	3.0
Cancer	49 (0.5)	32	95.6	10.5 (8-13.8)	98.9 (98.6-99.1)	7.25 (5.65-9.3)†	0.71 (0.64-0.79)†	10.6
Infection	120 (1.2)							
Fever, chills, or sweating	14 (0.1)	11.7	93.2	2 (1.2-3.5)	98.9 (98.6-99.1)	1.71 (1.04-2.81)†	0.95 (0.89-1.01)	2.0
Pain awakens from sleep	69 (0.7)	57.5	41.8	1.2 (0.9-1.5)	98.8 (98.4-99.1)	0.99 (0.85-1.15)	1.02 (0.82-1.25)	1.2
Persistent sweating at night	21 (0.2)	17.5	86.1	1.5 (1-2.4)	98.8 (98.6-99.1)	1.26 (0.85-1.86)	0.96 (0.88-1.04)	1.5
Recent infection	29 (0.3)	24.2	97.4	10.2 (7.1-14.5)	99.1 (98.8-99.2)	9.31 (6.63-13.07)†	0.78 (0.7-0.86)†	10.2
Cauda equina syndrome	36 (0.4)							
Recent loss of bladder control	8 (0.1)	22.2	90.4	0.8 (0.4-1.7)	99.7 (99.5-99.8)	2.31 (1.25-4.27)†	0.86 (0.72-1.03)	0.9
Recent loss of bowel control	5 (0.1)	13.9	95	1 (0.4-2.5)	99.7 (99.5-99.8)	2.78 (1.23-6.3)†	0.91 (0.8-1.03)	1.1

*Sens. = sensitivity, Spec. = specificity, PPV = positive predictive value, NPV = negative predictive value, PLR = positive likelihood ratio, and NLR = negative likelihood ratio. †The values are given as the percentage, with the 95% confidence interval in parentheses. ‡Significant likelihood ratios.

published clinical practice guidelines[9,15-18]. Table I shows the specific red flags in our questionnaire and their associated diagnoses. Each questionnaire answer was assessed categorically as 1 of 2 responses: "Yes" or "No."

Outcomes

The primary dependent variable of interest was the presence of spinal fracture, malignancy, infection, or cauda equina syndrome. We identified these 4 diagnoses as "red flag diagnoses," as they have been previously categorized in this manner in the literature[12,15,21].

If a patient had >1 of these diagnoses, we treated each diagnosis as a separate entity for analysis. For example, a patient with both a diagnosed malignancy and a fracture was evaluated with other patients diagnosed with a malignancy, as well as with other patients who had a fracture.

Statistical Analysis

Statistical analysis was performed using the SAS software package (version 9.4; SAS Institute). Student t tests were performed for continuous data, and chi-square or Fisher exact tests were performed for categorical data, as appropriate. The sensitivity, specificity, positive likelihood ratio (PLR), and negative likelihood ratio (NLR) were reported with their corresponding 95% confidence intervals (CIs) using Wilson scoring methods[22]. Two-tailed p values of <0.05 were considered significant.

Results

As shown in Table I, the patients in our cohort had an average age (and standard deviation) of 56.8 ± 15.0 years, and 48.7% were women. Most patients (92.6%) possessed at least 1 listed red flag symptom at the time of their new-patient visit. The most commonly endorsed red flag symptom was that of night pain (58.1%). Eight hundred and twenty-eight patients (8.3%) were identified as having a red flag diagnosis. Fracture was by far the most common red flag diagnosis, followed by tumor and infection. Cauda equina syndrome was the least common red flag diagnosis (Table II). Table III outlines which red flag questions have been classically associated with which diagnosis in the setting of low back pain, as stated in prior practice guidelines[8,13,15,23,24].

TABLE V Analysis of Combinations of Red Flags*

	Sens. (%)	Spec. (%)	PPV†	NPV†	PLR†	NLR†	Probability of Diagnosis (%)
Fracture							
Combination 1: trauma and age of >50 yr	14.8	94.2	13.1 (10.6-16.0)	94.9 (94.4-95.4)	2.54 (2.05-3.16)†	0.90 (0.87-0.94)†	13.1
Combination 2: trauma and age of >70 yr	5.2	98.7	20.4 (14.3-28.1)	94.6 (94.2-95.1)	4.35 (2.92-6.48)†	0.96 (0.94-0.98)†	20.5
Malignancy							
Combination: unexplained weight loss and cancer	2.5	99.8	14.3 (4.7-33.6)	98.4 (98.2-98.7)	10.25 (3.6-29.21)†	0.98 (0.95-1)	14.3
Infection							
Combination: fever, chills, or sweating, and a recent infection	7.5	99.4	13.8 (6.9-25.2)	98.9 (98.6-99.1)	13.15 (6.66-25.97)†	0.93 (0.88-0.98)†	13.8
Cauda equina syndrome							
Combination: recent loss of bladder control and recent loss of bowel control	8.3	97.2	1.1 (0.3-3.4)	99.7 (99.5-99.8)	3 (1.01-8.92)†	0.94 (0.85-1.04)	1.2

*Results from analysis of combinations of 2 red flags for each diagnosis of interest based on symptoms that are commonly associated with the same diagnosis in the medical literature. Sens. = sensitivity, Spec. = specificity, PPV = positive predictive value, NPV = negative predictive value, PLR = positive likelihood ratio, and NLR = negative likelihood ratio. †The values are given as the percentage, with the 95% confidence interval in parentheses. ‡Significant likelihood ratios.

Analysis of Red Flag Questions and Individual Red Flag Diagnoses

Univariate analysis examining each red flag question and its associated diagnosis identified several significant findings. The sensitivities, specificities, and positive and negative likelihood ratios for each red flag question are detailed in Table IV.

Fracture

An age of >50 years (PLR of 1.10 [95% CI, 1.05 to 1.16] and NLR of 0.79 [95% CI, 0.69 to 0.91]), an age of >70 years (PLR of 1.55 [95% CI, 1.36 to 1.76] and NLR of 0.86 [95% CI, 0.82 to 0.91]), and a history of recent trauma (PLR of 2.17 [95% CI, 1.86 to 2.54] and NLR of 0.84 [95% CI, 0.81 to 0.89]) were all associated with a significantly increased probability of vertebral fracture when present and a significantly decreased probability of vertebral fracture when absent.

Malignancy

Unexplained weight loss (PLR of 1.87 [95% CI, 1.10 to 3.17]) and personal history of cancer (PLR of 7.25 [95% CI, 5.65 to 9.30] and NLR of 0.71 [95% CI, 0.64 to 0.79]) both significantly increased the probability of malignancy when present; however, the absence of unexplained weight loss was not significantly associated with decreased probability of spinal malignancy (NLR of 0.96 [95% CI, 0.92 to 1.01]).

In addition, an age of >50 years (PLR of 1.06 [95% CI, 0.96 to 1.17] and NLR of 0.87 [95% CI, 0.68 to 1.11]), an age of >70 years (PLR of 1.1 [95% CI, 0.82 to 1.47] and NLR of 0.97 [95% CI, 0.9 to 1.06]), and night pain (PLR of 0.85 [95% CI, 0.83 to 1.10] and NLR of 1.07 [95% CI, 0.90 to 1.27]) did not significantly change the probability of spinal malignancy when present or absent. Sixty-four percent of patients with spinal malignancy had no associated red flags.

Infection

Fever, chills, or sweating (PLR of 1.71 [95% CI, 1.04 to 2.81]) and recent infection (PLR of 9.31 [95% CI, 6.63 to 13.07] and NLR of 0.78 [95% CI, 0.70 to 0.86]) both significantly increased the probability of a spinal infection when present. The absence of fever, chills, or sweating was not associated with a lower probability of spinal infection (NLR of 0.95 [95% CI, 0.89 to 1.01]).

In addition, night pain (PLR of 0.99 [95% CI, 0.85 to 1.15] and NLR of 1.02 [95% CI, 0.82 to 1.25) did not significantly change the probability of spinal infection when present or absent.

Cauda Equina Syndrome

Recent loss of bladder (urination) control (PLR of 2.31 [95% CI, 1.25 to 4.27]) and recent loss of bowel control other than diarrhea (PLR of 2.78 [95% CI, 1.23 to 6.30]) both significantly increased the probability of cauda equina syndrome when present; however, the absence of either of these symptoms did not significantly decrease the probability of cauda equina syndrome.

Analysis of Combinations of Commonly Associated Red Flag Questions and Individual Diagnoses

Analysis of combinations of individually significant red flag questions for each diagnosis of interest was performed and

revealed several significant associations (Table V). Namely, the combination of an age of >50 years and recent trauma was significant for an increased probability of vertebral fracture (PLR of 2.54 [95% CI, 2.05 to 3.16]). The combination of an age of >70 years and recent trauma had an even stronger increase in probability of vertebral fracture (PLR of 4.35 [95% CI, 2.92 to 6.48]). The combination of unintentional weight loss and a personal history of cancer was significant for an increased likelihood of spinal tumor (PLR of 10.25 [95% CI, 3.60 to 29.21]). The combination of fever, chills, or sweating and recent infection was associated with an increased likelihood of spinal infection (PLR of 13.15 [95% CI, 6.66 to 25.97] and NLR of 0.93 [95% CI, 0.88 to 0.98]). Lastly, the combination of recent loss of bladder control and recent loss of bowel control was significant for an increased likelihood of cauda equina syndrome (PLR of 3.00 [95% CI, 1.01 to 8.92]). Of note, while each of these combinations was relatively quite specific, all of the above combinations of red flag questions were poorly sensitive in identifying their diagnoses of interest (Table V).

Discussion

Low back pain is common and is mostly self-limited, but red flag diagnoses are rare, are serious, and require urgent treatment. Because of their low prevalence, a large sample size is required to adequately study them. To our knowledge, this study contains the largest cohort of patients to date to assess the utility of red flag questions as well as combinations of red flags in the diagnosis of serious spinal pathology.

The prevalence of a red flag diagnosis for patients presenting with low back pain in our study was 8.3%, well above the published rates in primary care settings of 1% to 4% but consistent with rates in tertiary care settings[19]. As the prevalence of red flag diagnoses in this population was very low, we found traditionally calculated positive or negative predictive values to be of little relevance (e.g., all negative predictive values were very high because case prevalence was so low). Likelihood ratios, a ratio of the post-question probability of diagnosis to the pre-question probability of diagnosis, are independent of case prevalence and thus more useful markers of diagnostic utility than predictive values in this setting.

Clinical guidelines for the management of low back pain generally advocate the use of red flag questions to raise a clinician's index of suspicion concerning serious underlying spinal pathology and as an indication for further diagnostic workup, such as advanced imaging[15]. Evidence for this recommendation, however, is generally lacking, with most guidelines citing prior guidelines and unpublished data as sources[18,25]. A 2016 review of low back pain guidelines advocating for the use of red flag questions in low back pain found that of 16 recently published guidelines, only 3 presented any reference to support the use of red flag questions[15]. Of those 3, information on diagnostic accuracy was limited and, when present, referenced studies with <20 cases of a red flag diagnosis. Despite the paucity of information supporting their use, most clinical guidelines explicitly recommend the use of red flag questions as a screening tool.

A key trait of screening tests is that negative tests are very unlikely to be falsely negative, and that negative test results significantly alter the pre-test probability of a diagnosis. Therefore, characteristics of good screening tools include high sensitivity and high negative likelihood ratios. In our study, not a single red flag question had a sensitivity of >75%, and most had a sensitivity well under 60%. Similarly, not a single red flag question in our study had a meaningfully low negative likelihood ratio.

While not ideal screening tests for the aforementioned reasons, our data revealed that particular combinations of red flag questions have a high specificity and can significantly increase the probability of having certain diagnoses (Table V). These data suggest that, when used in combination, certain red flag questions can aid a clinician in ruling in a particularly serious diagnosis. For example, our data suggest that a patient with a personal history of cancer who is seen with low back pain and is experiencing unintentional weight loss should be evaluated for a spinal malignancy.

Our data also suggest that a personal history of cancer or a recent infection should raise alarm for a potential underlying serious pathological condition. Conversely, neither the presence nor the absence of night pain affected the probability of a patient having a red flag diagnosis. While this question may be of use to a clinician to gauge a patient's pain and quality of life, its use as a screening question is not supported by our data.

Over 90% of patients in this study had at least 1 positive red flag symptom during their new-patient visit. This rate is higher than, but fairly consistent with, the rate of 80% reported for the primary care population[12]. Given the high prevalence of positive red flags, indiscriminate pursuit of further imaging in the setting of a positive red flag question may lead to potentially unnecessary imaging, bringing with it increased costs and unnecessary radiation exposure[26].

Analysis of the diagnostic accuracy of individual and combinations of red flag questions, as seen in Tables IV and V, led to the development of 6 recommendations regarding the use of traditional red flag questions in patients with low back pain.

Recommendations

1. Recent trauma in the setting of low back pain should raise a clinician's suspicion of vertebral fracture, especially in patients who are >50 years old. Suspicion should be even higher in patients who are >70 years old. The presence of both recent trauma and an age of >50 years carries a 13.1% probability of a vertebral fracture in the setting of low back pain; similarly, the presence of both recent trauma and an age of >70 years carries a 20.5% probability of vertebral fracture in the setting of low back pain.

2. A personal history of cancer in the setting of low back pain should raise suspicion of malignancy and prompt questions about constitutional symptoms such as unintentional weight

loss. Conversely, constitutional symptoms in a patient with low back pain should raise suspicion of malignancy and prompt questions about a personal history of cancer. The presence of a personal history of cancer in the setting of low back pain carries a 10.6% probability of having a spinal malignancy. A history of unintentional weight loss, alone, carries a 3% probability of having a spinal infection; however, when both red flag questions were present, the probability of having a spinal malignancy in the setting of low back pain was 14.3%, up from a baseline of 1.6%.

3. A recent history of infection in the setting of low back pain should always raise concern for the possibility of infection and should prompt questions about constitutional symptoms such as fever, chills, or sweating. A recent history of infection in the setting low back pain carries a 10.2% probability of having a spinal infection. A history of fever, chills, or sweating, alone, carries a 2% probability of having a spinal infection; however, when both red flag questions were present, the probability of having an infection in the setting of low back pain was 13.8%, up from a baseline of 1.2%.

4. A loss of bladder control (urination) and loss of bowel control (other than diarrhea) in the setting of low back pain should raise suspicion for cauda equina syndrome, but it is not highly predictive of the diagnosis. The presence of both red flag symptoms increased the probability of having cauda equina syndrome to 1.2%, up from a baseline of 0.4%.

5. Pain that awakens the patient from sleep, also known as night pain, is not a useful question to determine any diagnosis (Table IV), and its presence should not be used to justify advanced imaging. More than 55% of patients reported this symptom, and 60% of them did not have a red flag diagnosis. Classically, night pain has been associated with malignancy and infection; however, this symptom was a false positive >85% of the time for malignancy, and >96% of the time for infection when no other associated red flag symptoms were present.

6. Other than an age of >50 years and a diagnosis of vertebral fracture, the absence of any individual red flag or combination of red flags does not help to rule out a particular red flag diagnosis, as noted by the low change in probabilities, sensitivities, and NLRs of red flag questions (Tables IV and V).

Strengths

This study has several strengths. With 9,940 patients, we had the ability to examine associations between red flag questions and rare disease entities, such as cauda equina syndrome. Another strength of this study is that it was performed at a single large multidisciplinary spine center with an attached imaging suite, allowing robust diagnostic data to complement red flag question data. The study also used standardized questions, language, and protocols for administering pre-visit red flag questionnaires across providers.

Limitations

Not all red flag questions of interest, such as prolonged corticosteroid use, which is traditionally associated with vertebral fracture, were included in our questionnaire at the time of its inception in 2005. Therefore, one should use caution to avoid drawing conclusions on red flags that were not included in this analysis. Further analyses would benefit from including examination findings and a larger selection of red flags. Questions regarding red flags were delivered via a questionnaire, and it is possible that patients may respond differently when asked verbally by their physician. Another limitation of our study is that all data were collected at a large multidisciplinary spine center. Our center employs surgeons as well as physiatrists and sees primary, secondary, and tertiary-care spine patients who can self-refer or be referred by another physician. As expected, we saw a higher rate of "red flag diagnoses" in our population than the published rates in primary care populations. While this is a strength, as a high volume of patients with serious spine pathology is a requisite to study the utility of red flag questions, it also introduces inherent referral bias. Given our finding that red flag questions are not ideal screening questions in our multidisciplinary spine center, it is likely that they would be of even less benefit in a purely primary care population with a lower prevalence of cases.

Overview

While a positive response to a red flag question may indicate the presence of disease, a negative response to 1 or 2 red flag questions does not meaningfully decrease the likelihood of a red flag diagnosis. Thus, clinicians should use caution when utilizing red flag questions as screening tools. Recommendations for more efficient use of red flags are proposed in this study. Further refinements in clinical practice guidelines to improve screening for serious spinal pathology are indicated. ■

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