CLINICAL RESEARCH STUDY

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Errors in Diagnosis of Spinal Epidural Abscesses in the Era of Electronic Health Records

Viraj Bhise, MBBS, MPH,[a,b] Ashley N.D. Meyer, PhD,[a,b] Hardeep Singh, MD, MPH,[a,b] Li Wei, MS,[a,b] Elise Russo, MPH,[a,b] Aymer Al-Mutairi, MD,[b] Daniel R. Murphy, MD, MBA[a,b]

[a]*Houston Veterans Affairs Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center, Houston, Tex;* [b]*Department of Medicine, Baylor College of Medicine, Houston, Tex.*

ABSTRACT

PURPOSE: With this study, we set out to identify missed opportunities in diagnosis of spinal epidural abscesses to outline areas for process improvement.

METHODS: Using a large national clinical data repository, we identified all patients with a new diagnosis of spinal epidural abscess in the Department of Veterans Affairs (VA) during 2013. Two physicians independently conducted retrospective chart reviews on 250 randomly selected patients and evaluated their records for red flags (eg, unexplained weight loss, neurological deficits, and fever) 90 days prior to diagnosis. Diagnostic errors were defined as missed opportunities to evaluate red flags in a timely or appropriate manner. Reviewers gathered information about process breakdowns related to patient factors, the patient−provider encounter, test performance and interpretation, test follow-up and tracking, and the referral process. Reviewers also determined harm and time lag between red flags and definitive diagnoses.

RESULTS: Of 250 patients, 119 had a new diagnosis of spinal epidural abscess, 66 (55.5%) of which experienced diagnostic error. Median time to diagnosis in error cases was 12 days, compared with 4 days in cases without error ($P < .01$). Red flags that were frequently not evaluated in error cases included unexplained fever (n = 57; 86.4%), focal neurological deficits with progressive or disabling symptoms (n = 54; 81.8%), and active infection (n = 54; 81.8%). Most errors involved breakdowns during the patient−provider encounter (n = 60; 90.1%), including failures in information gathering/integration, and were associated with temporary harm (n = 43; 65.2%).

CONCLUSION: Despite wide availability of clinical data, errors in diagnosis of spinal epidural abscesses are common and involve inadequate history, physical examination, and test ordering. Solutions should include renewed attention to basic clinical skills.

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Requests for reprints should be addressed to Daniel R. Murphy, MD, MBA, Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC), HSR&D Center for Innovations in Quality, Effectiveness & Safety (152), 2002 Holcombe Boulevard, Houston, TX 77030.

E-mail address: drmurphy@bcm.edu

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Diagnostic evaluation of back pain in the outpatient setting can be challenging, as evaluation needs to rule out rare but serious etiologies, such as spinal epidural abscess, among the vast majority of benign causes.[1-5] Although very few patients presenting with back pain to a primary care setting eventually have epidural abscesses,[1,6,7] a missed or delayed diagnosis of spinal epidural abscess can lead to significant morbidity, such as permanent neurological damage with long-term disability.[8-11] While advanced imaging tests can confirm a spinal epidural abscess diagnosis, they are costly and offer little benefit for patients where signs and symptoms clearly indicate benign causes.[12-14] Thus, maintaining an appropriate balance between ordering imaging tests when signs and symptoms suggest serious causes while avoiding unnecessary imaging when they do not, is critical in preventing misdiagnoses of spinal epidural abscess.

CLINICAL SIGNIFICANCE

- In a retrospective evaluation of a national sample with 119 patients, we identified diagnostic errors that occurred in 66 patients (55.5%).
- Contributing factors included information gathering during history and physical examination and inadequate ordering of diagnostic tests to evaluate red flags during diagnostic evaluation.
- Our findings highlight the need for renewed attention to basic clinical skills.

The American College of Radiology offers guidelines based on the presence of "red flags" to determine which imaging tests to pursue.[15,16] Despite the widespread availability of such guidelines, instances of missed spinal epidural abscess diagnoses continue to occur, even when documentation of initial symptoms suggest a need for further work-up.[6,17-19] Previous estimates from a single institution retrospective chart review study suggest that most patients (75%-84%) with spinal epidural abscess experienced diagnostic delays after initial assessments in the emergency department.[17,20] However, factors responsible for such delays in diagnostic assessment have not been discussed in detail and are not well understood.[4,20,21] Unrecognized red flag signs and symptoms during diagnostic evaluation, failure to consider spinal epidural abscess in the differential diagnosis, and atypical and subtle presentations of back pain (vs classic presentations) have been suggested as potential reasons.[22-27] Advancing the understanding of contributory factors for misdiagnosis of spinal epidural abscess can enable the development of interventions to prevent patient harm from delays in care.

A recent Institute of Medicine report, *Improving Diagnosis in Healthcare*,[28] calls for better approaches to understand and measure diagnostic errors. However, most systems lack availability of longitudinal clinical patient data to enable accurate assessment of the diagnostic process.[29] In integrated systems, such as the Department of Veterans Affairs (VA), that use comprehensive electronic health records (EHRs), accessibility of large amounts of diagnostic data (such as visit notes, lab tests, imaging tests, pathology, and procedures) makes it possible to understand the patient's diagnostic process as it evolves over time. Our study objective was to evaluate the diagnostic process in patients presenting with back pain who were subsequently diagnosed with spinal epidural abscess. We used predefined criteria to identify missed opportunities in the diagnostic process in order to understand factors contributing to the diagnostic errors.

METHODS

Study Setting

To identify patients with spinal epidural abscess diagnosis, we accessed a VA database that contains clinical EHR data from over 1700 VA outpatient and inpatient facilities, serving over 8 million veterans across the US annually. The local institutional review board approved the study.

Design

We used an electronic query to identify all instances of spinal epidural abscess diagnosis during any outpatient or inpatient visit between January 1 and December 31, 2013 in the national database. The query was based on the presence of the International Classification of Diseases, Ninth Revision code 324.1. From this cohort, 2 physicians independently reviewed 250 randomly selected records to identify instances of errors in diagnostic assessment of spinal epidural abscess. Because our primary objective was to understand details of the evolving diagnostic process, we excluded patients with spinal epidural abscess diagnosed outside the VA system (ie, patients who transferred care to the VA only once treatment was needed). We defined diagnostic errors as "missed opportunities to make the correct or timely diagnosis of spinal epidural abscess based on available evidence regardless of whether the patients experienced harm." This definition is similar to what we have used in our previous work.[30,31] To operationalize this definition, reviewers first identified whether red flag signs or symptoms were documented in any outpatient clinic or emergency department visit note during the 90 days prior to the new spinal epidural abscess diagnoses (ie, the date the International Classification of Diseases, Ninth Revision code was identified). We chose the 90-day period based on expert input in order to capture all diagnosis-related activity during the evolution and progress of spinal epidural abscess.

Red flags were based on signs and symptoms from the American College of Radiology's Appropriateness Criteria for patients presenting with chronic back pain[15,16]. All documentation in the chart, including notes from other providers, such as nursing and triage notes, was reviewed for the presence of red flags. Reviewers then assessed whether providers took subsequent action to evaluate documented red flag signs or symptoms (eg, appropriate

Table 1 Factors Analyzed as Potential Contributors to Diagnostic Errors in the Evaluation of Spinal Epidural Abscesses

Factors	Error Cases (n = 66)	Non-error Cases (n = 53)	*P*-Value
Age (mean, SD)	63.5 (11.9)	63.3 (10.6)	.95 (*t*-test)
Charlson Comorbidity Index (mean, SD)	2.6 (2.7)	2.9 (2.3)	.56 (*t*-test)
Sex			.07
Male	61 (92.4%)	53 (100.0%)	
Female	5 (7.6%)	0 (0.0%)	
Race			.23
African American	20 (30.3%)	11 (20.8%)	
American Indian	1 (1.5%)	0 (0.0%)	
Asian	3 (4.5%)	0 (0.0%)	
Native Hawaiian/Pacific Islander	0 (0.0%)	1 (1.9%)	
White	39 (59.1%)	36 (67.9%)	
Unknown	3 (4.5%)	5 (9.4%)	

imaging tests, referrals, or close follow-up). Absence of evaluation of red flags denoted presence of missed opportunities and constituted a diagnostic error.

For all patient records with identifiable diagnostic error, reviewers collected information about process breakdowns using the 5 diagnostic process dimensions described in the Safer Dx framework (patient factors, patient–provider encounter, test performance and interpretation, test follow-up and tracking, or the referral process).[30,32,33] Reviewers also identified harm associated with diagnostic errors using the Agency for Healthcare Research and Quality Common Format Harm Scale v.1.2[34] and calculated the Charlson Comorbidity index[35] based on EHR documentation during the 1-year period prior to the spinal epidural abscess diagnosis. We compared assessments from each reviewer regarding the presence of diagnostic error. Disagreements were discussed and resolved by consensus prior to analysis.

Sample Size

We selected a sample size of 250 patients in order to maintain sufficient statistical power ($\beta > .80$, $\alpha = .05$) to detect univariate differences between the error and nonerror groups on various patient characteristics. Each reviewer independently evaluated 150 charts, such that there was a 33% overlap to enable calculation of interrater reliability.

Statistical Analysis

We used SPSS (v22; IBM Corp, Armonk, NY) for our analysis. First, initial review agreement was assessed using Cohen's kappa. Then, we compared cohorts with and without diagnostic errors to assess differences in demographic characteristics and comorbidity, using *t*-tests, Fisher's exact tests, and chi-squared analyses, where appropriate. The nonparametric Wilcoxon rank-sum test was used to compare median times to pathological diagnosis. Additionally, we used descriptive statistics to describe commonly missed red flags, the Safer Dx dimensions of diagnostic errors, and levels of harm experienced for diagnostic errors.

RESULTS

In a national VA cohort, we identified 446 patients with a new spinal epidural abscess diagnosis between January 1 and December 31, 2013 and then randomly selected 250 records for manual chart review. After excluding 131 patients where diagnosis was made outside the VA, 119 patient records with newly diagnosed spinal epidural abscess were analyzed in detail. Of these, 66 (55.5%) patients were determined to have experienced a diagnostic error. The median time from when the red flag was first apparent to the subsequent definitive diagnosis of spinal epidural abscess was 12 days (interquartile range, 5-26 days) in patients with diagnostic error, compared with 4 days (interquartile range, 1-17 days) in patients without diagnostic error ($P = .004$). Agreement between the reviewers was 81.5% (Cohen's kappa = 0.63). **Table 1** summarizes the characteristics of patients with and without diagnostic errors. We found no differences in age, sex, race, or Charlson Comorbidity Index between these patient groups.

Most patients (n = 116; 97.5%) presented to the provider with multiple red flags (mean 4.6, SD 1.7). The mean number of red flags present was greater in patients who experienced a diagnostic error (mean: 4.9 vs 4.3 for the nonerror group, $P = .03$). Among the 66 patients who experienced a diagnostic error, unexplained fever was the most commonly missed red flag (n = 57; 86.4%), followed by focal neurological deficits with progressive or disabling symptoms (n = 54; 81.8%) and active infection (n = 54; 81.8%). Other missed red flags are listed in **Table 2**. In most cases (57.6%), the provider documented the red flag during the diagnostic assessment, but did not act upon it. For example, providers recorded red flags, such as history of prolonged corticosteroid use or focal neurological symptoms, in their visit, but did not take appropriate action on them. In other instances (33.3%), providers missed red flags during the initial diagnostic assessment (history/examination). Here, reviewers found lack of red-flag documentation on providers' visit notes even when recent notes from other providers prior to the visit confirmed these red flags to be present. In one example, the treating

Table 2 Red Flags Found to Be Missed Within 90 Days Prior to Spinal Epidural Abscess Diagnosis

Red Flag Missed	Error Cases (n = 66)
Unexplained fever	57 (86.4%)
Focal neurologic deficit with progressive or disabling symptoms	54 (81.8%)
Active infection	54 (81.8%)
Immunosuppression	36 (54.5%)
Intravenous drug use	20 (30.3%)
Prolonged use of corticosteroids	16 (24.2%)
Unexplained weight loss	13 (19.7%)
Back pain duration longer than 6 weeks	13 (19.7%)
History of cancer	9 (13.6%)

nurse documented unexplained fever in the EHR, but it was not mentioned or followed-up by the provider. Similarly, a history of intravenous drug use was missed during the diagnostic assessment despite documentation highlighting it in a previous primary care visit.

In patients who experienced diagnostic errors, specific laboratory tests such as erythrocyte sedimentation rate or C-reactive protein were ordered at the first visit in less than a third of patients (n = 18, 27.3%). While in most error cases (n = 58; 87.9%), providers ordered imaging, the test of choice (MRI) was ordered in less than half (n = 24; 41.4%). In all of these 24 cases, the MRI was not marked as urgent, which resulted in a median delay of 6 days (interquartile range, 3.5-27 days) from ordering to completion (vs median time of 1 day in patients without diagnostic error, $P < .001$). None of this delay was attributable to patient factors (refusal or no-shows).

For the 66 error cases, most common breakdowns of the diagnostic process involved the patient–provider clinical encounter (n = 60; 90.9%). For example, clinicians missed red flags during history and physical examination or failed to order appropriate imaging tests (MRI) urgently. Process breakdowns also involved referrals (n = 51; 77.3%), patient actions or inactions (n = 17; 25.8%), follow-up and tracking of diagnostic tests (n = 11; 16.7%), and performance and interpretation of diagnostic tests (n = 5; 7.6%) (**Table 3**). Most diagnostic errors were associated with temporary harm lasting <1 year (n = 43; 65.2%; **Table 4**); however, the magnitude of harm reported was serious (n = 40, 60.6%) and contributed to death in 8 (12.1%) patients.

DISCUSSION

Diagnostic errors occurred in over half of the patients with newly diagnosed spinal epidural abscesses in a national sample. Multiple red-flag symptoms were either missed or not appropriately acted upon during the patient–provider encounter, resulting in a median diagnostic delay of 12 days. About 60% of the diagnostic errors had potential for severe harm or death. The prevalence of diagnostic errors in spinal epidural abscess is thus high and warrants increased attention to prevent patient harm, especially because the incidence of spinal epidural abscess has doubled over the last 2 decades in clinical practice.[4,36]

Our findings build on previous estimates of diagnostic delays in patients from non-EHR-based settings.[17,20] Unlike previous studies, which used paper-based medical records, where there is often missing diagnostic information, we used an integrated EHR, which provides comprehensive access to diagnostic information (eg, documentation of abnormal findings, reports, information about multiple provider visits) and facilitates information exchange.[37] It is therefore likely that our study provides a more accurate estimate of diagnostic delays in spinal epidural abscess. Additionally, we were able to achieve a high interrater reliability in identifying the presence of diagnostic errors, when compared with other studies measuring diagnostic error in primary care.[30,38] We recommend that future work use similar objective criteria (identification of a clear red flag followed by lack of follow-up action) for diagnostic error measurement.[39]

Our study found striking evidence of deficiencies in the diagnostic evaluation of spinal epidural abscess in back pain patients. First, lack of meticulous information gathering

Table 3 Dimensions of the Diagnostic Process Where Diagnostic Error Occurred (for Error Cases Only; n = 66)

Dimensions of Diagnostic Process Where Error Occurred*	n (%)	Examples
Provider-patient encounter	60 (90.9%)	• Missed red flags (information not gathered during history and physical examination) • Appropriate action (ordering tests) not taken after identifying red flags
Performance and interpretation of diagnostic tests	5 (7.6%)	• The MRI report was not read accurately and was believed to be nonserious
Follow-up of patients and diagnostic tests	11 (16.7%)	• Provider took too much time to follow-up test result
Subspecialty consultation	51 (77.3%)	• Did not believe referral was required • Appropriate expert was not consulted
Patient-related issues	17 (25.8%)	• Patient no-shows for the outpatient visit

MRI = magnetic resonance imaging.
*Not mutually exclusive.

Table 4 Level of Potential for Patient Harm as a Result of the Diagnostic Delay of Spinal Epidural Abscess

	Error Cases (n = 66)
Level of harm	
Death	8 (12.1%)
Severe harm	32 (48.5%)
Moderate harm	25 (37.9%)
Mild harm	1 (1.5%)
No harm	0 (0.0%)
Unknown	0 (0.0%)
Anticipated duration of harm	
Permanent (>1 y)	18 (27.3%)
Temporary (<1 y)	43 (65.2%)
Unknown	5 (7.6%)

during history and physical examination resulted in providers missing certain red-flag symptoms. Second, inadequate action (ordering of appropriate laboratory or imaging tests, or initiating referrals) by providers regarding patients presenting with red flags led to delays in ordering definitive tests such as MRI. Third, definitive tests (eg, MRI) were not ordered or not completed in an immediate or urgent manner, resulting in delays in confirming diagnosis and initiating definitive treatment. These findings are consistent with emerging evidence from malpractice claims that suggests that diagnostic errors related to spinal epidural abscess are increasing over time.[36,40] Our findings highlight the need for attention to basic clinical skills to improve the diagnostic process.[40-42]

Most errors resulted from breakdowns of processes related to the patient−provider encounter. This is not surprising, as clinicians in outpatient settings are making complex diagnostic decisions during increasingly brief clinical encounters.[2,30] Clinicians in our study missed potentially serious red flags, such as focal neurological deficits, infections, and histories of intravenous drug abuse. Our findings highlight gaps in basic clinical skills (medical history and physical examination) and related cognitive processes (gathering of information, ordering of tests, interpretation and integration of clinical and diagnostic test information). Previous studies have also found similar gaps during the patient−provider encounter in outpatient and emergency department settings.[4,30,43] Time pressures and cognitive workload encountered by clinicians likely contribute to this problem.[2,44]

Our study suggests the need for interventions to support providers in the diagnostic evaluation of spinal epidural abscess. Knowledge of guidelines such as the American College of Radiology Appropriateness Criteria might help providers focus their attention toward identifying red-flag symptoms and confirming appropriate action. Algorithms to stratify patients as high, intermediate, or low risk based on the history and physical examination findings could also be beneficial.[45,46] Additionally, use of inflammatory markers, such as erythrocyte sedimentation rate and C-reactive protein, can help providers determine which patients are more likely to be appropriate candidates for imaging.[19,20] Use of clinical decision support tools, including checklists to support diagnostic decision-making, could also be explored.[47,48] However, use of these tools requires achieving good diagnostic calibration (ie, an improved relationship between provider's diagnostic confidence and accuracy), and information seeking continues to be a problem, as shown in recent work.[49,50] Indeed, our previous work shows that providers may not necessarily use these support tools in both vignette-based[51] and real clinical settings.[52]

One approach for improvement might involve using electronic triggers or clinical algorithms that could indicate records of patients presenting with red flags where appropriate clinical follow-up actions were not identified in the EHR (eg, patient presenting with red flag such as focal neurological symptoms, which is not followed with completion of MRI within a specific time). Similar triggers have been used effectively to ensure appropriate follow-up of patients presenting with certain clinical findings suggestive of lung, colorectal, and prostate cancers.[39,53-55] Given that several patients identified in this study experienced delays in follow-up of red flag symptoms for spinal epidural abscess, use of triggers might allow rapid identification of instances of delayed evaluation.[56]

Our study had several limitations. First, we studied diagnostic errors in one health system (VA), and hence, our findings might not be generalizable to other outpatient settings nationally. Nevertheless, to our knowledge, this is the largest study of errors in spinal epidural abscess patients. Second, we used information documented in patient charts to assess the presence or absence of a diagnostic error, and this may not represent the actual care delivered. However, care documentation is a reference standard in patient safety, and previous studies have found a good correlation between documentation and care.[30,39,55] Third, our study involved a retrospective assessment of patients who had a confirmed diagnosis of spinal epidural abscess, and the possibility of hindsight bias affecting reviewers' clinical judgment cannot be ruled out. To avoid such bias, we used objective criteria (American College of Radiology Appropriateness Criteria) and clinical guidelines while making a judgment of diagnostic errors in the diagnostic assessment of spinal epidural abscess.

In conclusion, despite wide availability of clinical data, diagnostic errors are common in the evaluation of spinal epidural abscess in EHR-based clinical settings. Most have potential to lead to severe harm and involve the patient−provider encounter, including history, physical examination, and ordering tests. Solutions to support provider cognition in busy clinical encounters, including augmentation of basic clinical skills, could improve the clinical diagnosis of spinal epidural abscess.

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