

Observational Study

A Pilot Study Implementing a Machine Learning Algorithm to Use Artificial Intelligence to Diagnose Spinal Conditions

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Background: Chronic spinal pain is the most prevalent chronic disease, with chronic persistent spinal pain lasting longer than one-year reported in 25% to 60% of the patients. Health care expenditures have been escalating and the financial impact on the US economy is growing. Among multiple modalities of treatments available, facet joint interventions and epidural interventions are the most common ones, in addition to surgical interventions and numerous other conservative modalities of treatments. Despite these increasing costs in the diagnosis and management, disability continues to increase.

Consequently, algorithmic approaches have been described as providing a disciplined approach to the use of spinal interventional techniques in managing spinal pain. This approach includes evaluative, diagnostic, and therapeutic approaches, which avoids unnecessary care, as well as poorly documented practices.

Recently, techniques involving artificial intelligence and machine learning have been demonstrated to contribute to the improved understanding, diagnosis, and management of both acute and chronic disease in line with well-designed algorithmic approach. The use of artificial intelligence and machine-learning techniques for the diagnosis of spinal pain has not been widely investigated or adopted.

Objectives: To evaluate whether it is possible to use artificial intelligence via machine learning algorithms to analyze specific data points and to predict the most likely diagnosis related to spinal pain.

Study Design: This was a prospective, observational pilot study.

Setting: A single pain management center in the United States.

Methods: A total of 246 consecutive patients with spinal pain were enrolled. Patients were given an iPad to complete a Google form with 85 specific data points, including demographic information, type of pain, pain score, pain location, pain duration, and functional status scores. The data were then input into a decision tree machine learning software program that attempted to learn which data points were most likely to correspond to the practitioner-assigned diagnosis. These outcomes were then compared with the practitioner-assigned diagnosis in the chart.

Results: The average age of the included patients was 57.4 years (range, 18-91 years). The majority of patients were women and the average pain history was approximately 2 years. The most common practitioner-assigned diagnoses included lumbar radiculopathy and lumbar facet disease/spondylosis. Comparison of the software-predicted diagnosis based on reported symptoms with practitioner-assigned diagnosis revealed that the software was accurate approximately 72% of the time.

Limitations: Additional studies are needed to expand the data set, confirm the predictive ability of the data set, and determine whether it is broadly applicable across pain practices.

Conclusions: Software-predicted diagnoses based on the data from patients with spinal pain had an accuracy rate of 72%, suggesting promise for augmented decision making using artificial intelligence in this setting.

Key words: Algorithmic approach, artificial intelligence, facet joint pain, lumbar disc herniation, lumbar radiculopathy, lumbar spondylosis, machine learning, pain scores, post laminectomy syndrome, sacroiliitis, spinal pain

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Chronic spinal pain is the most prevalent chronic disease across the globe, negatively impacting the quality of life and function and straining the health care system as a leading cause of disability-adjusted life years (1-9). In fact, chronic persistent spinal pain lasting longer than 1-year is reported in 25% to 60% of the patients (10-12). The assessments of the impact of spinal pain in the United States (US) showed low back pain ranking number one and neck pain ranking number 3 (8). Further, Dieleman et al (5,6) evaluated the economic impact on health care in the United States and showed an estimated spending of \$134.5 billion in 2016 (an increase of 53.5% from 2013) with \$87.6 billion spent for managing spinal pain. The costs of other musculoskeletal disorders also increased by 43.5% from \$183.5 billion in 2013 to \$263.3 billion in 2016.

Among multiple modalities of treatments available, facet joint interventions and epidural interventions are the most performed procedures with interventional techniques in managing spinal pain, in addition to surgical interventions and multiple conservative modalities of treatments (1-4). Interventional techniques have been shown to increase over the years, even though they have shown flattening or some decline in recent years from 2009 to 2018 (13-21), except for spinal cord stimulation utilization and trends in expenditures have increased exponentially (22). Consequently, their utilization, indications and medical necessity have been continuously discussed with establishment of new guidance from public and private payers starting with multiple changes related to the Affordable Care Act (23-31). These questions have been raised despite overwhelming evidence in the diagnosis and treatment of spinal pain with interventional techniques (1,2,32-42). Further, the COVID-19 pandemic has reduced access to interventional techniques in conjunction with the opioid epidemic, which was under control until 2018 and has been intensifying since 2019 with exploding patterns of opioid deaths in 2020 (1,2,43-47). To provide optimal care, multiple measures have been developed to continue interventional pain management to chronic pain patients, with optimal utilization of interventional techniques and conservative management (48-51), including avoidance of steroids and assessment of patients with telehealth (51).

Thus, the importance of an algorithmic approach has increased. The purpose of an algorithmic approach is to provide a disciplined approach to the use of spinal interventional techniques in managing spinal pain,

as described in multiple publications (1,2,52). This approach includes evaluative, diagnostic, and therapeutic approaches, which in turn avoid unnecessary care as well as poorly documented practices. Among the various components of algorithmic approach, accurate diagnosis of underlying causes is prerequisite for successful therapy of spinal pain (1-3,32-37,52). Assessment of a patient with spinal pain starts with patient self-report questionnaire items and history taking, followed by physical examination to help clinicians generate a probable hypothesis which may differentiate those patients with pain of spinal origin or non-spinal origin, with or without serious pathology (53). While this paradigm has been shown to be valid in other areas of medicine (54), in spinal pain, the reliability of history and physical examination in detecting sources of spinal pain is less certain. Consequently, expensive modalities with imaging or diagnostic blockade are performed to improve the accurate diagnosis to provide appropriate treatment (1,2,32-37,52).

It is possible that an improved method for objectively diagnosing spinal pain will improve the success of clinical decision-making and subsequent interventions. Clinicians who manage spinal pain may tend to recommend the therapies, which they themselves deliver (eg, interventional pain specialists might recommend medications, while spine surgeons might recommend surgery) (55-59). Indeed, there is substantial evidence from both within the pain field and from other medical fields that this is the case (55-59). Even for clinicians from the same specialties, treatment recommendations can vary based on practice location, type, and various other factors (60). Together, these findings suggest that there is a need for objective measures of spinal pain, including improved diagnostic approaches.

Because of the heterogeneity of low back pain presentations across patho-anatomical etiologies, diagnostic standardization has been a challenge. In a recent systematic review of diagnostic accuracy studies, researchers attempted to develop best-evidence, clinical diagnostic rules for the most common disorders of the lumbar spine (e.g., intervertebral discs, sacroiliac joints, etc); however, the researchers reported that clinical diagnostic rules could only be recommended for selected lumbar spine disorders. Furthermore, the researchers emphasized that single clinical tests were generally not useful for making diagnostic conclusions, and instead, clusters of tests performed with sequential, algorithmic, or staged approaches may be used to improve accurate clinical diagnosis of specific disorders (61).

Techniques involving artificial intelligence and machine learning have been shown to contribute to the improved understanding, diagnosis, and management of both acute and chronic diseases (62). Furthermore, machine-learning algorithms facilitate pattern recognition and have been shown to lead to the successful classification of patients with heart failure and other chronic conditions, and there may be more broad applicability in a heterogeneous medical field such as pain (62-66). However, the use of artificial intelligence and machine-learning techniques for the diagnosis of spinal pain is not currently well understood.

Therefore, a pilot study was developed within the principles of established algorithmic approach to spinal pain (1,2,52), at a single pain management center, to evaluate whether it is possible to use artificial intelligence/machine learning to analyze specific data points and to predict the most likely diagnosis related to spinal pain.

METHODS

The pilot study was conducted utilizing Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) guidance (67). In addition, we also utilized essential principles of a pilot study (68) with feasibility of the study protocol, recruitment of subjects, testing and measurement instruments, and data entry and analysis. Institutional Review Board (IRB) approval was not sought as this was part of the patient assessment, with consent following the principles of confidentiality with Health Insurance Portability and Accountability Act (HIPAA).

STUDY DESIGN/SETTING

To assess the differences in outcomes for patients provided with patient navigator services, a pilot study was conducted at a pain management center, The Ohio Pain Clinic (Centerville, Ohio, USA).

Patients

A total of 246 consecutive patients with chronic low back pain were enrolled. Baseline data collected included patient demographics, type of pain, pain score, pain location, pain duration, and functional status scores.

Data Collection Procedure

Consecutive patients were given an iPad with a Google Form to complete. The form contained 85 specific data points (Appendix 1). Data points collected included: demographic information (gender, age, height, weight), presenting complaints (chief complaint, history of present illness, pain location), and pain characteristics (radiation, multiple measures of quality and severity of pain, aggravating factors, associated symptoms). An example of the patient pain diagram provided to patients in the Google Form is shown in Fig. 1A. Pain radiation locations evaluated included: left/right buttock, hip, thigh, shin, calf, and foot. Furthermore, pain referral from lumbar interspinal ligaments (lumbar facet pain) was assessed (Fig. 1B) along with investigation of a dermatome map evaluating L3-L5 and S1 (Fig. 1C).

Variables

Other data points that were evaluated included: pain visual analog scale score; muscle quality; gluteus minimus trigger point; gluteus medius trigger point; multifidi trigger point; quadratus lumborum trigger point; piriformis trigger point; iliolumbar ligament; sacroiliac ligament pain referral pattern; hip pain; sacroiliac pain; radiation of symptoms; modifying factors;

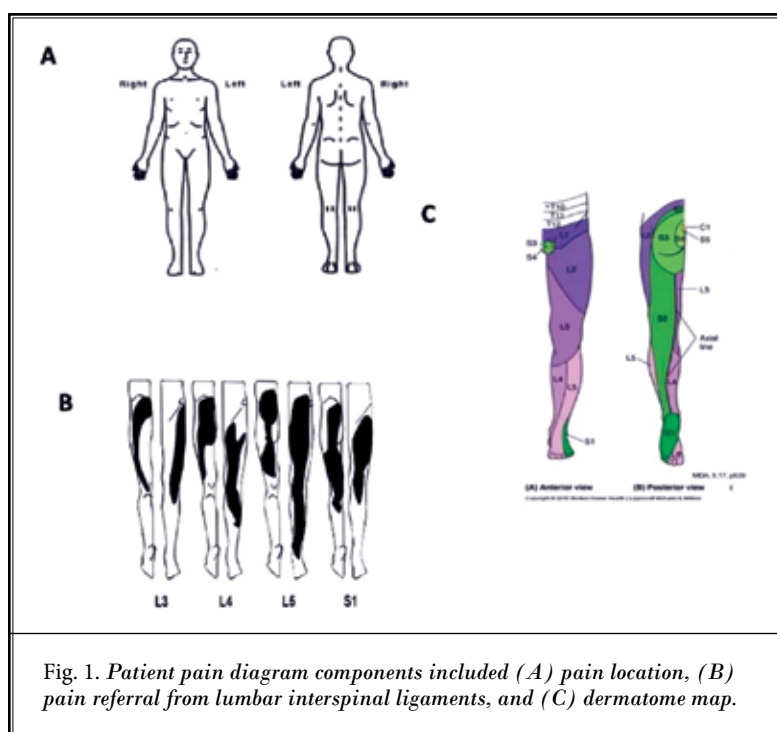


Fig. 1. Patient pain diagram components included (A) pain location, (B) pain referral from lumbar interspinal ligaments, and (C) dermatome map.

time of day; and associated symptoms. Patients were separated into the following practitioner-assigned diagnoses: lumbar radiculopathy, lumbar spondylosis without myelopathy, post-laminectomy syndrome, and sacroiliitis. Various interventions, such as physical therapy, injections, or surgery, were also tracked.

Data Sources/Measurement

The entire data set was then inputted into a software program that attempted to learn which data points were most likely to correspond to the practitioner-assigned diagnosis using a decision-tree machine learning algorithm. The system then tried to predict which diagnoses belonged to which patients using the data set. For example, if someone entered "pain in the back that radiates down the leg" on the data capture form, it was likely they may have had lumbar radiculopathy. In contrast, if they marked "pain in the low back with no radiation," it was likely that they did not have radiculopathy. We then compared the accuracy of the software-predicted diagnoses with the practitioner-assigned diagnoses using simple averages. No statistical evaluation of the data was performed.

Bias

Potential sources of bias were addressed by random selection of patients included without identification of source of pain.

Study Size

For a pilot study, a total of 246 consecutive patients were selected, which was considered adequate based on previous pilot studies which included much smaller number of patients.

RESULTS

Patients/Descriptive Data

A total of 246 consecutive patients were enrolled in this prospective, single-site, pilot study. The average age of the included patients was 57.4 (range, 18-91) years. The majority of patients were women and the average pain history was approximately 2 years (Table 1). The most common practitioner-assigned diagnoses included lumbar radiculopathy, post-laminectomy syndrome, and sacroiliitis.

Outcome Data/Main Results

Comparison of the software-predicted diagnosis

based on reported symptoms with practitioner-assigned diagnosis revealed that the software was accurate approximately 72% of the time; therefore, the end result is a data set that, through machine learning, may allow computer algorithms to provide the treating physician with guidance to which potential therapeutic option would give the greatest likelihood of success based on objective and patient-reported data. This may result in enhanced decision making by the physician, allowing them to choose a therapy that could be more beneficial to the patient while eliminating options that may be more costly and ineffective.

DISCUSSION

We have developed an initial data set that can be used to help predict spinal diagnoses using a machine-learning algorithm, which may ultimately contribute to augmented clinical decision making, in an algorithmic approach to management of spinal pain. Using 85 data points, software-predicted diagnoses were accurate approximately 72% of the time, when compared with practitioner-assigned diagnoses.

In the last decade, artificial intelligence use, particularly related to machine learning technologies, has greatly increased across a variety of health care applications, including the investigation of issues related to the spine and spinal pain (66). Notably, the use of machine learning has the promise to increase the avoidance of biases in diagnosis and treatment by objectively incorporating and interpreting data (69).

The results of the present study are similar to the previously published algorithmic approach (70-74) of results in managing chronic low back pain. Manchikanti, et al (70), evaluated 120 patients with a chief complaint of chronic low back pain to evaluate relative contributions of various structures in chronic low back pain. They showed prevalence of facet joint pain of 40% with a false-positive rate of 47%, discogenic pain of 26%, and sacroiliac joint pain of 2% of the patients with comparative local anesthetic blocks. They also showed pain of nerve root origin in 13% of the total population. Consequently, the authors were able to identify a pain generator in 81% of the population. Pang, et al (71), applied spinal pain mapping in the diagnosis of low back pain utilizing diagnostic nerve blocks. They showed sacroiliac joint pain in 6%, lumbar nerve root in 20%, facet joint in 24%, combined lumbar nerve root and facet disease in 24%, internal disc disorder in 7%, combined facet and sacroiliac joint in 4%, and lumbar sympathetic dystrophy in 2% of the

patients. Schwarzer et al (72,73), in a series of manuscripts, attributed origins of chronic low back pain to intervertebral discs in 39% of patients, to facet joints in 15% of 40%, and to sacroiliac joints in 30%. DePalma et al (74), assessed the source of chronic low back pain and identified internal disc disruption, facet joint pain, and sacroiliac joint pain in 42%, 31%, and 18%, respectively. Traditionally, clinical features in imaging or neurophysiologic studies have been claimed not to permit the accurate diagnosis of causation of low back pain in 85% of patients in the absence of disc herniation and neurological deficit (70). Overall, studies show similar patterns in the cervical spine and more recent studies also confirm the prevalence of lumbar facet joint pain with controlled diagnostic blocks utilizing a philosophical paradigm shift from an acute to a chronic pain model in low back pain, showed prevalence and false positive rates of 34.1% and 49.8% in the low back, and 49.3% prevalence and 25.6% prevalence in chronic neck pain (32,33). Thus, the results of this pilot study are similar to published results with controlled diagnostic blocks. The next step would be to confirm these impressions with diagnostic blocks.

Additional studies are needed to build on current approaches using machine learning. Future directions could include investigating the ability to categorize patients with spinal pain into subgroups using a broad range of biopsychosocial factors, including the incorporation of objective data from patient-owned devices. For example, smart phone applications, fitbits, and smart watches can provide large amounts of health data, including health trends, that may be collected and used to assist in the determination diagnosis, prognosis, or management options of chronic pain. Using various clinical factors and an artificial intelligence/machine learning approach within the context of a large set of training data may facilitate enhanced reliability, validity, predictive ability, and treatment stratification for patients with spinal pain (75). This type of approach may contribute to improved clinical outcomes and result in reduced healthcare costs. To date, only one study has employed this approach for low back pain using a limited set of physical factors. Similar to our study, researchers showed that a decision tree algorithm accurately classified low back pain at about a 53% to 71% rate; however, the study was not designed to assess outcomes and costs (76).

However, it is important to note that patients are more than just clusters of data sets and clinician decision-making needs to be preserved and maintained

Table 1. *Patient demographics.*

Characteristics	Patients (n = 246)
Age, mean	57.4 years
Gender, woman	59.2%
Initial pain score (out of 10), mean	6.0
Pain history, mean	25.5 months
Practitioner-assigned primary diagnosis	
Lumbar radiculopathy (L4 and L5)	37.8%
Post-laminectomy syndrome	10.2%
Sacroiliitis	7.6%
Spondylosis	6.5%
Sacroiliac	5.5%
Cervical radiculopathy	5.1%
Unknown/missing value	5.1%
Other	14.5%

for optimal health care delivery. Notably, only clinicians are able to understand the psychosocial context of a patient, weigh the importance of both objective and subjective information, and translate a patient's medical history into usable medical terms (77). Therefore, artificial intelligence may be used in an advisory capacity, contributing to increased diagnostic accuracy and patient safety, but cannot replace the clinician in many key clinical tasks, including delivering compassionate diagnoses, translating the implications of diagnoses for patients, and listening to and addressing patient concerns regarding management options (78). Instead, one could see an opportunity in the future for artificial intelligence-based diagnoses to be combined with clinical gestalt and other validated clinical tools for treatment decision making to create more objective—and hopefully more successful—treatment pathways for patients with low back pain. For example, the consensus-derived Nijmegen Decision Tool for Chronic Low Back Pain was developed to help pain specialists determine whether consultation with spine surgeons or nonsurgical care specialists would be the most appropriate route for patients with spinal pain (79,80). Integrating machine learning into these existing clinical decision pathways may help to improve outcomes for patients.

Our results should be viewed within the context of the limitations of the observational nature of this small pilot study. This single-center study had a small sample size of approximately 250 patients with only 85 data points investigated; therefore, the generalizability of these results to other settings is unclear. Furthermore, all data entries were not completed by

all patients, which limited the data set. Finally, the machine-learning algorithm relied on practitioner-assigned diagnoses to “learn” and therefore any inherent practitioner biases may have been absorbed into the machine-learning algorithm. Based on these limitations, rigorous statistical testing was not conducted, further limiting our ability to make conclusions regarding the broad and highly diverse population of patients with pain. This pilot study provides initial information for this investigational algorithm; however, our algorithm has not yet been validated, a process that will require millions of patients and their associated data in order to be predictive in a broad health care context. Additional studies are needed to expand the data set, confirm the predictive ability of the data set, and determine whether it is broadly applicable across pain types and practices.

CONCLUSIONS

In this single-center pilot study, collection and entry of 85 data points from approximately 250 patients with spinal pain resulted in the development of a machine-learning algorithm that accurately predicted patient diagnoses 72% of the time compared with practitioner diagnoses. Additional patient data are urgently needed to expand the current data set and to provide augmented decision-making for clinicians.

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Appendix material available at www.painphysicianjournal.com

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Appendix 1. *Data points input into the machine learning program.*

Using a Google Form, the following data points were collected:

1. Patient ID
2. Encounter ID
3. Encounter date
4. Gender (man, woman, unknown)
5. Age (in years)
6. Height (in inches)
7. Weight (in pounds)
8. Chief complaint
9. History of present illness (in months)
10. Pain location (midline lower back, referred lower back > lower extremity [leg], radicular lower back < lower extremity [leg])
11. Pain radiation (left or right buttock, hip, thigh, shin, calf, foot)
12. Muscle quality, aching (yes, no)
13. Muscle quality, crushing (yes, no)
14. Muscle quality, dull (yes, no)
15. Muscle quality, spasm (yes, no)
16. Muscle quality tightness (yes, no)
17. L&C quality, constant (yes, no)
18. L&C quality, sharp (yes, no)
19. L&C quality, stiffness (yes, no)
20. DRG quality, burning (yes, no)
21. DRG quality, shooting (yes, no)
22. NR quality, pins and needles (yes, no)
23. NR quality, stinging (yes, no)
24. NR quality, tingling (yes, no)
25. Severity, VAS score (0-10)
26. Severity, ODI scale (0-100)
27. Lumbar facet pain L3 (yes, no)
28. Lumbar facet pain L4 (yes, no)
29. Lumbar facet pain L5 (yes, no)
30. Lumbar facet pain S1 (yes, no)
31. Dermatome L1 (yes, no)
32. Dermatome L2 (yes, no)
33. Dermatome L3 (yes, no)
34. Dermatome L4 (yes, no)
35. Dermatome L5 (yes, no)
36. Dermatome S1 (yes, no)
37. Gluteus minimus trigger point (yes, no)
38. Gluteus medius trigger point (yes, no)
39. Multifidus trigger point (yes, no)
40. Quadratus lumborum trigger point (yes, no)
41. Piriformis trigger point (yes, no)
42. Iliolumbar ligament back (yes, no)
43. Iliolumbar ligament front (yes, no)
44. Iliolumbar ligament (yes, no)
45. Posterior sacroiliac ligament (yes, no)
46. Hip ligament (yes, no)
47. Sciatic nerve (yes, no)
48. Sacrospinous ligament (yes, no)
49. Hip pain (yes, no)
50. SI pain (yes, no)
51. Radiation of symptom, right leg (yes, no)
52. Radiation of symptoms, left leg (yes, no)
53. Radiation of symptoms, right arm (yes, no)
54. Radiation of symptoms, left arm (yes, no)
55. Radiation of symptoms, head (yes, no)
56. Radiation of symptoms, neck (yes, no)
57. Modifying factor, position aggravation, climbing stairs (yes, no)
58. Modifying factor, position aggravation, coughing or sneezing (yes, no)
59. Modifying factor, position aggravation, extension (yes, no)
60. Modifying factor, position aggravation, getting in and out of care (yes, no)
61. Modifying factor, position aggravation, laying down (yes, no)
62. Modifying factor, position aggravation, laying on side (yes, no)
63. Modifying factor, position aggravation, leaning forward (yes, no)
64. Modifying factor, position aggravation, sitting (yes, no)
65. Modifying factor, position aggravation, sitting to standing (yes, no)
66. Modifying factor, position aggravation, walking (yes, no)
67. Modifying factor, position aggravation, standing (yes, no)
68. Modifying factor, position relief, climbing stairs (yes, no)
69. Modifying factor, position relief, coughing or sneezing (yes, no)
70. Modifying factor, position relief, extension (yes, no)
71. Modifying factor, position relief, getting in and out of care (yes, no)
72. Modifying factor, position relief, laying down (yes, no)
73. Modifying factor, position relief, laying on side (yes, no)
74. Modifying factor, position relief, leaning forward (yes, no)
75. Modifying factor, position relief, sitting (yes, no)
76. Modifying factor, position relief, sitting to standing (yes, no)
77. Modifying factor, position relief, walking (yes, no)
78. Modifying factor, position relief, standing (yes, no)
79. Time of day worse (morning, evening, none, unknown)
80. Associated symptoms, numbness (yes, no)
81. Associated symptoms, parathesia (yes, no)
82. Associated symptoms, tingling (yes, no)
83. Primary diagnosis
84. Secondary diagnosis
85. National Provider Identifier