

Longitudinal Analysis of the Care Pathway of Patients with Lumbar Spinal Stenosis in the US

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Background: Evidence regarding the frequency and timing of treatment for lumbar spinal stenosis (LSS) fails to offer clear consensus. We describe the LSS care journey from initial diagnosis to first surgical intervention.

Methods: Using Medicare claims database from 2009 through 2020, we identified patients who were diagnosed with LSS. The use and timing of conservative and surgical treatments during the entire follow-up from the initial diagnosis were reported.

Results: Of the 143,849 patients identified, 68% received conservative care within 8.4 months and 25.3% received a surgical or minimally invasive intervention over 5.7 years following initial diagnosis, with 12.6% undergoing open decompression alone, 10.2% undergoing open decompression with fusion, and 5.1% undergoing fusion surgery alone. Fewer than 1% were provided with interspinous spacers or a percutaneous image-guided lumbar decompression.

Conclusion: Approximately three-quarters of patients in the study received no surgical or non-invasive interventions for approximately six years following diagnosis with LSS.

Keywords: lumbar spinal stenosis, interspinous spacer, lumbar decompression, chronic pain

Introduction

Lumbar spinal stenosis (LSS) represents a narrowing of the spinal canal to the point that the neurovascular structures of the spine are compressed.^{1,2} In addition to congenital causes, LSS may stem from degenerative diseases or conditions such as spondylolisthesis and disc herniation.² While patients with LSS can be asymptomatic,³ for many patients, LSS imposes a significant decrement on health-related quality of life,⁴ commonly due to neurogenic intermittent claudication (NIC) that manifests as pain, discomfort, and/or weakness in the back and legs, as well as difficulty walking.² LSS is estimated to affect 11% of the general population and 39% of those in primary and secondary care, with prevalence increasing with age.^{5,6} As a result, global prevalence will invariably rise as the duration of global life expectancy grows.

First-line treatment for LSS typically begins with non-operative “conservative care” (CC), which typically consists of pain medications, physical therapy, and epidural spinal injections.^{7,8} When CC fails to relieve symptoms, surgical options are often considered, including the placement of interspinous spacers and direct or indirect decompression of the spinal canal with or without fusion, as well as traditional spinal surgery to decompress the spinal canal and retain stability.⁷ Minimally invasive treatments, such as interspinous spacers, can be an appropriate treatment for those with mild-to-moderate LSS,⁹ while surgical options are “indicated in patients whose symptoms persist despite conservative measures and demonstrate surgically correctable pathologies” (page 20).¹⁰ Surgical interventions such as decompression and fusion can be costly, and patients face a higher risk of surgical complications compared to minimally invasive procedures including a placement of an interspinous spacer.^{11–15} Algorithms and recommendations exist for consideration of these procedures,⁸ but there are limited data elucidating how many (and when) patients receive an initial surgical intervention in routine clinical practice.³

Given the variety of available treatment options, a description of the real-world care pathways of LSS patients provides a better understanding of how often these treatments are used in clinical practice. This study examines the patient care journey from initial LSS diagnosis to first surgical intervention using healthcare claims to assess longitudinal healthcare resource utilization associated with LSS.

Material and Methods

Study Design and Data Source

This study used the Medicare 5% Standard Analytical Files (SAF) administrative claims data from 2009 through 2020 to perform a retrospective analysis of patients diagnosed with LSS. The Medicare data were drawn from a randomly selected 5% sample of all Medicare Fee-for-Service beneficiaries that allows for patients to be followed longitudinally over multiple years. The International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification (ICD-9-CM and ICD-10-CM) and Procedure Coding System (ICD-9-PCS and ICD-10-PCS) codes, and Current Procedural Terminology 4th edition (CPT®) codes were used to identify diagnoses and procedures. Patient reported outcomes, including pain-related symptomology (eg, a visual analogue scale, etc.), are not captured in the Medicare data. All analyses were performed using the Instant Health Data (IHD) software (Panalgo, Boston MA, USA) and R, version 3.2.1 (R Foundation for Statistical Computing, Vienna, Austria). The Centers for Medicare and Medicaid Services (CMS) authorized the access and utilization of data from the Medicare 5% SAF database through the data use agreement (<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms-r-0235L.pdf>). These data are available to any entity who can meet CMS's criteria regarding the study purpose and the ability to house and manage the fully de-identified data. Informed consent was not obtained in this study. This study received an exemption determination from the Sterling Institutional Review Board pursuant to the terms of the US Department of Health and Human Service's Policy for Protection of Human Research Subjects at 45 C.F.R. 46.104(d).

The date of the initial claim with an LSS diagnosis between January 1, 2010 and June 30, 2020 was used as the index date, with the baseline period defined as the 12 months prior to index. Patients were followed from their index date until the earliest of the end of study period, the end of continuous enrollment, or death. Demographic and clinical characteristics were measured during the baseline period.

Study Population

Patients were identified using the ICD-9 and ICD-10 diagnosis codes for LSS (724.02, 724.03, M48.061, or M48.062) on Medicare claims. Eligible patients were those with at least 2 inpatient (IP) or outpatient (OP) claims (at least 30 days apart) for LSS between 1/1/2010 and 6/30/2020. Eligible patients were ≥ 18 years old on the index date with ≥ 12 months of continuous enrollment with medical coverage prior to the index date (baseline period) and ≥ 6 months of continuous enrollment with medical coverage on and after the index date. Six months represented the minimum follow-up period. Individuals with a prior diagnosis of LSS during the baseline period or any prior decompressive spine surgeries in the baseline period were excluded.

Primary and Secondary Outcomes

Nonoperative CC, surgical, and minimally invasive treatments for LSS were identified through ICD-9-PCS procedure codes from 2009 to 2015 and ICD-10-PCS procedure codes from 2016 to 2020 for procedures performed in an IP setting, and CPT codes for the entire study period for procedures performed in an OP setting. CC was identified as physical therapy with a diagnosis claim for LSS or epidural spinal injections. Surgical and minimally invasive treatments identified included surgical decompression (eg, laminectomy/laminotomy), surgical decompression with fusion (ie, laminectomy + fusion), interspinous spacer without surgical decompression (eg, Superion, X-Stop), interspinous spacer with surgical decompression (eg, CoFlex), and minimally invasive lumbar decompression (MILD). Outcomes for treatments during the entire follow-up period included the time to the initial treatment from the index date in months and all-cause and LSS-related (defined as occurring with a diagnosis of LSS or dorsalgia) healthcare resource utilization. The latter included IP admissions or visits to an emergency department (ED), OP hospital, physician office, rehabilitation

facility, or skilled nursing facility. These were identified using the location codes on claims. Additionally, the type of physician seen at index and during follow-up was also identified using the physician specialty code on claims.

Statistical Analysis

Demographics and comorbidity burden were identified during the 12-month baseline period. Comorbidity burden included the Deyo-Charlson Comorbidity Index¹⁶ and several selected comorbidities. Categorical variables are presented as count and percent of patients in each category, while continuous variables are presented as mean and standard deviation (SD).

Results

Patient Characteristics

A total of 143,849 patients met the inclusion and exclusion criteria (Figure 1). The mean (SD) age was 71.71 (0.10) years, and the majority of patients were female (57.7%) and Caucasian (87.7%, Table 1). The most represented geographic region was the South (41.3%), followed by the Midwest (24.0%). Mean (SD) follow-up was 5.7 (3.1) years. The most commonly identified comorbidities included hypertension (77.7%), disorders of lipoprotein metabolism and other lipidemias (72.6%), dorsalgia (68.2%), osteoarthritis (47.9%), and respiratory symptoms (43.6%, Table 1).

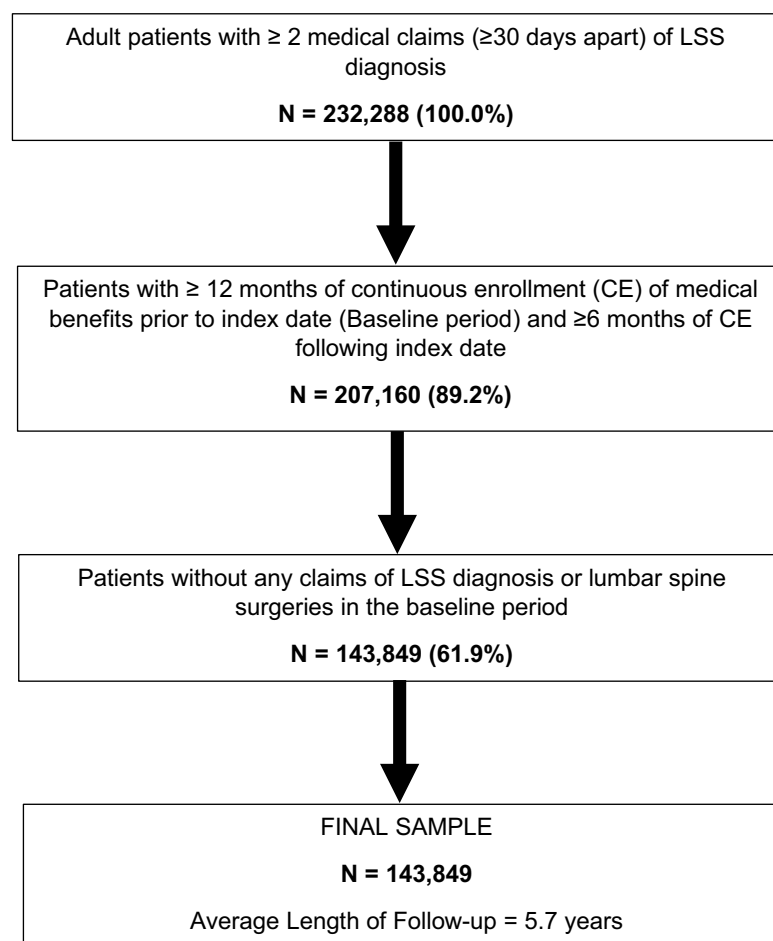


Figure 1 Patient Selection.

Table I Demographic and Clinical Characteristics

Follow-up length in years (Mean, SD)	5.7 (3.1)
Age at index (Mean, SD)	71.7 (0.10)
Sex (N, %)	
Male	61,139 (42.5%)
Female	82,710 (57.5%)
Region (N, %)	
Midwest	34,452 (24.0%)
Northeast	25,426 (17.7%)
South	59,455 (41.3%)
West	24,232 (16.8%)
Race (N, %)	
Caucasian	126,110 (87.7%)
Black	10,959 (7.6%)
Asian	1,611 (1.1%)
Charlson Comorbidity Index (Mean, SD) - Assessment of comorbidities (N, %)	1.4 (1.8)
Dorsalgia (N, %)	98,145 (68.2%)
Disc hernia (N, %)	51,301 (35.7%)
Osteoarthritis (N, %)	68,840 (47.9%)
Asthma (N, %)	27,333 (19.0%)
Atrial fibrillation (N, %)	23,362 (16.2%)
Back syndrome (ie, post laminectomy syndrome) (N, %)	4,829 (3.4%)
Chronic obstructive pulmonary disease (N, %)	23,522 (16.4%)
Chronic ischemic heart disease (N, %)	41,081 (28.6%)
Congestive heart failure (N, %)	16,548 (11.5%)
Diabetes (N, %)	48,646 (33.8%)
Hypertension (N, %)	111,833 (77.7%)
Disorders of lipoprotein metabolism and other lipidemias (N, %)	104,486 (72.6%)
Obesity (N, %)	21,555 (15.0%)
Osteoporosis (N, %)	20,969 (14.6%)
Respiratory symptoms (N, %)	62,701 (43.6%)
Vascular claudication (N, %)	9,321 (6.5%)
Pathological or closed spinal, vertebral, or hip fracture (N, %)	3,246 (2.3%)
Spondylolisthesis (N, %)	11,266 (7.8%)

Abbreviation: SD, standard deviation.

Table 2 LSS-Related Treatments During Follow-Up

	N (%)	Time (months), Mean (SD)
Non-pharmacologic Conservative Care		
Either epidural spinal injection or physical therapy	98,216 (68.3%)	9.4 (18.9)
Epidural spinal injection	84,269 (58.6%)	11.1 (20.4)
Physical therapy	34,731 (24.1%)	14.3 (24.6)
Surgical Interventions		
Open decompression only	18,174 (12.6%)	17.4 (24.1)
Open decompression with fusion surgery	14,741 (10.2%)	19.2 (24.7)
Fusion only	7,344 (5.1%)	22.6 (26.2)
Interspinous spacer	782 (0.5%)	29.9 (34.5)
Percutaneous image-guided lumbar decompression	493 (0.3%)	27.7 (32.7)

Abbreviation: SD, standard deviation.

LSS Treatments

During follow-up, 98,216 patients (68.3%) received non-pharmacologic CC, including 84,269 (58.6%) with an epidural spinal injection and 34,731 (24.1%) with physical therapy. On average, patients waited 9.4 months from diagnosis until the initial provision of CC (Table 2). The most common surgical or minimally invasive treatments included open decompression, either with (10.2%) or without (12.6%) fusion; 5.1% of patients received fusion-only surgery, and fewer than 1% were provided with either an interspinous spacer or a percutaneous image-guided lumbar decompression. The remaining 74.7% of patients underwent no surgical or minimally invasive interventions during the follow-up period. Of those undergoing a surgical/minimally invasive intervention, the mean time until treatment was longer for the less common procedures (Figure 2).

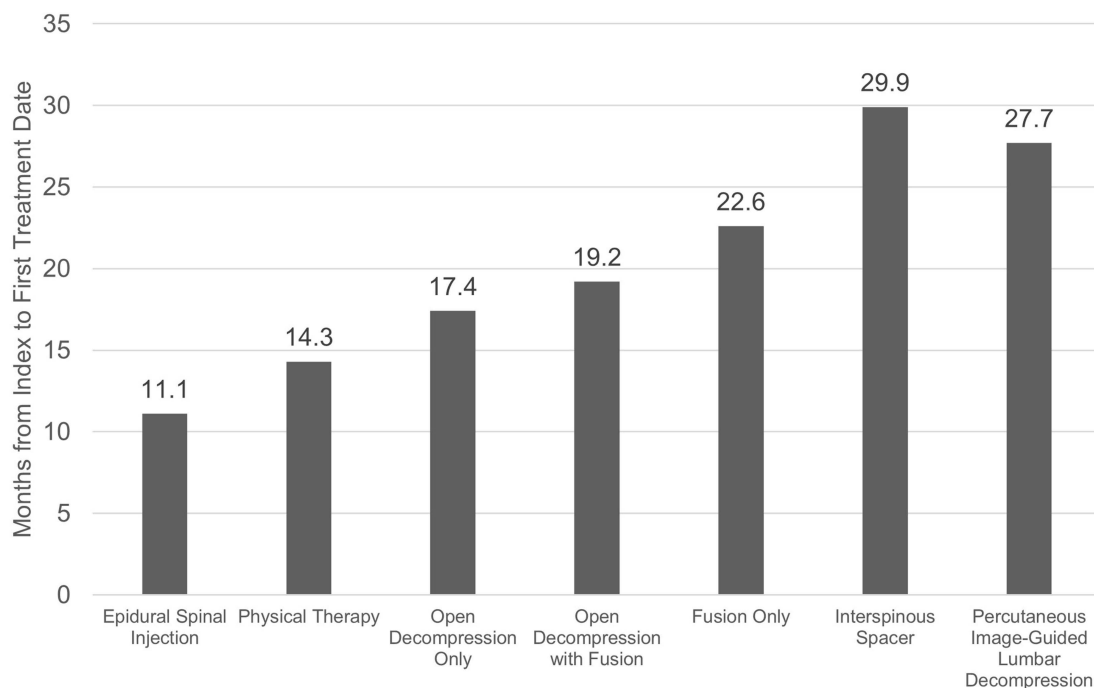


Figure 2 Time from index diagnosis to first treatment (months).

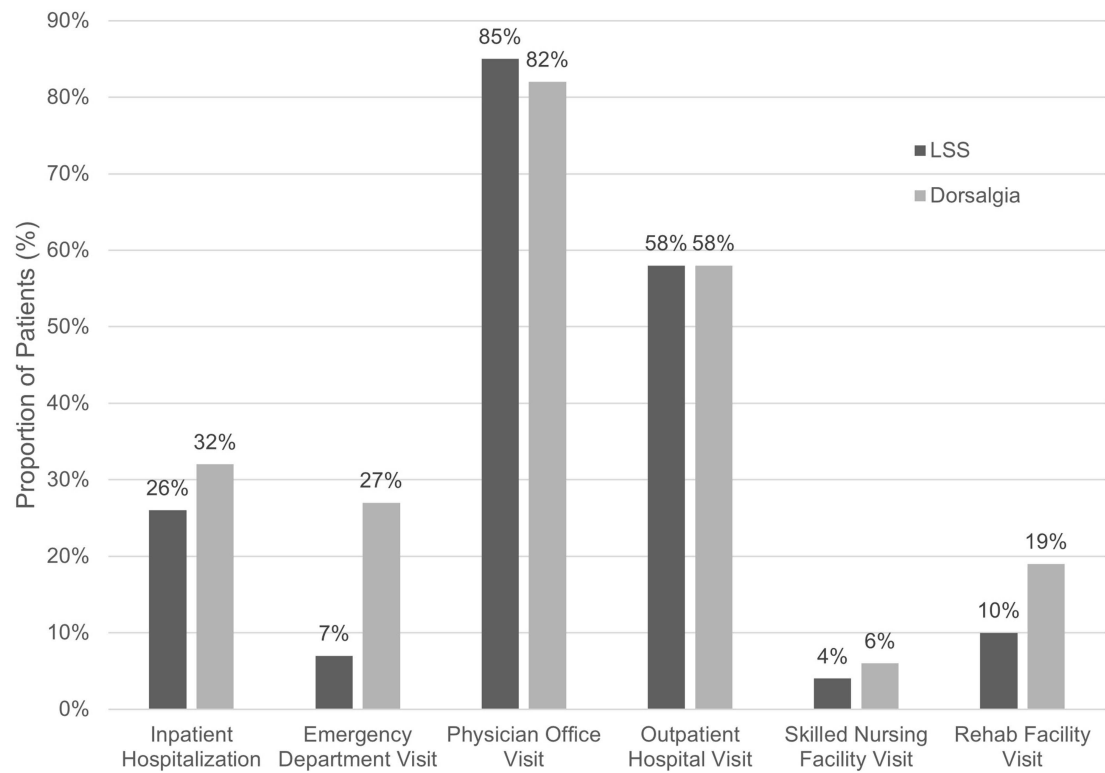


Figure 3 Patients with at least one LSS/dorsalgia-related healthcare resource visit.

Healthcare Resource Use

The most common type of LSS- or dorsalgia-related healthcare visit during follow-up was a physician office visit, which occurred in 84.8% and 81.9% of patients, respectively (Figure 3). Approximately 58% of patients had an OP hospital visit, and between one-fourth and one-third (25.8% to 31.5%) had an IP hospital stay. Notably, 27% and 19% had dorsalgia-related ED and rehabilitation facility visits, respectively. Those values were 7% and 10% for LSS-related visits (Figure 3).

Physician Visits

Among the 15,033 whose index diagnosis claim contained a physician specialty code, 36.8% were provided with their initial LSS diagnosis by a family practice or internal medicine physician, and 11.5% were provided with their initial LSS diagnosis by an orthopedic surgeon. Only 2.5% of patients were initially diagnosed by an interventional pain or pain management physician (Table 3). During follow-up, patients continued to see family practice or internal medicine physicians most often, with 31.7% having an LSS-related visit with either specialty. Visits with interventional pain or pain management physicians continued to be rare; only 2.8% of patients with an indication of an LSS had a visit with an interventional pain or pain management physician during follow-up.

Table 3 Physician Visits at Index Diagnosis and During Follow-Up

Provider Specialty	At Index		During Follow up	
	N	%	N	%
Patients with specialty data (N,%)	15,033	100.0%	131,006	100.0%
Family practice	2,966	19.7%	19,878	15.2%
Internal medicine	2,562	17.0%	21,673	16.5%
Orthopedic surgery	1,727	11.5%	14,633	11.2%
Physical medicine and rehabilitation	695	4.6%	6,581	5.0%

(Continued)

Table 3 (Continued).

Provider Specialty	At Index		During Follow up	
Neurosurgery	688	4.6%	13,090	10.0%
Emergency medicine	644	4.3%	2,745	2.1%
Neurology	477	3.2%	2,509	1.9%
Pain or interventional pain management	380	2.5%	2,953	2.8%

Discussion

This study presents an examination of the care pathway of patients diagnosed with LSS from their initial diagnosis through several years of follow-up. Nearly three-quarters of patients received non-surgical CC within less than a year after being newly diagnosed. Given that CC is generally accepted as the most appropriate first-line therapy, this is not surprising, and it may have been effective for many of these patients. Non-surgical treatment can result in symptom improvement and maintenance of physical function for several years.^{17,18}

Only a quarter of patients received any LSS-related surgical or minimally invasive intervention over a timeframe of nearly 6 years, even though such interventions have been established to be effective for improving short- and long-term pain relief.^{7,8} Given that surgical treatments are typically elective and pursued only if symptoms are sufficiently bothersome, it is possible that some patients chose to eschew surgery even if some symptoms persisted following CC. Furthermore, a substantial portion of those receiving a surgical or minimally invasive intervention underwent fusion surgery (either with or without open decompression) as their initial surgical intervention. Previous studies have observed that decompression surgeries with fusion are significantly more costly than those without fusion,^{7,12,14,19} and often result in more post-operative complications.⁷ Additionally, fusion, when accompanied by decompression, may not confer better clinical outcomes than decompression alone.^{19,20} Fusion is most appropriate when there is instability, degenerative scoliosis/kyphosis, or spondylolisthesis, or if decompression is extensive.¹⁰ This would indicate that fusion may be appropriate for moderate-to-severe cases, so for those receiving fusion as part of an initial surgical intervention, it could reflect either a delay in appropriate treatment until LSS degenerates to the point where fusion is appropriate, or an inappropriate treatment performed on those with mild-to-moderate LSS. Given the dramatic increase in fusion surgeries over the past several years, and the associated increase in hospital costs,²¹ ensuring the appropriateness of fusion is critical to ease both clinical and financial burdens.

In addition to the low rate of surgical treatment (particularly for less invasive procedures), a relatively high healthcare resource utilization rate was observed, with 26%–32% of patients experiencing an IP hospital stay related to LSS/dorsalgia. Further, 27% experienced a dorsalgia-related ED visit. This suggests that there exist missed opportunities to improve health outcomes among these patients earlier in the patient care pathway. Interspinous spacers have been demonstrated to be safe and effective in relieving LSS-related pain²² and improving quality of life,²³ but were used as a surgical option in fewer than 1% of patients. Notably, 2.5% of patients were initially provided with an LSS diagnosis by an interventional pain management or pain management physician, and fewer than 3% of patients visited a pain management physician over the course of treatment. When appropriate, referral to physician specialties most experienced with LSS treatment could reduce the use of more costly, more invasive, and riskier surgical procedures while providing safe and effective treatment to LSS patients on a timely basis.

This study has a number of strengths, including the large, geographically diverse sample of patients, and a long-term follow-up that provides one of the first examinations of patients' care pathway from LSS diagnosis to the end of their follow-up. The limitations of this study include those inherent in any retrospective claims analysis. The Medicare data rely on administrative claims data for clinical details, and these data are subject to data coding limitations and data entry error. Additionally, while the severity and location of LSS may inform treatment decisions, these data are not available from claims. As such, administrative claims data do not capture all aspects of a patient's circumstance that might determine the appropriate care. Furthermore, the availability of all interspinous spacers varied during the study period.

The X-Stop²⁴ was available in 2005 but discontinued in 2015, while the Superion²⁵ Indirect Decompression System (Vertiflex) became available in 2017. The primary results in this study are limited to individuals with Medicare coverage, and consequently, results of this analysis may not be generalizable to patients with other insurance or without health insurance coverage. However, this is less of a concern because almost all adults 65 years and older in whom LSS prevalence is mostly concentrated have Medicare coverage in the US. This study also includes patients younger than 65 who are Medicare eligible, meaning that they are either disabled or have end-stage renal disease, which may not be reflective of all LSS patients in that age group.

Conclusion

Approximately three-quarters of patients received no surgical or minimally invasive interventions approximately 6 years after being diagnosed with LSS. While CC may have been effective for some of these patients, it is likely that for many, a surgical or minimally invasive intervention could have eased symptom burden and improved quality of life. In order to ensure all patients have access to appropriate therapy, a strategy to increase the likelihood that LSS patients will see physician specialties such as interventional pain specialists or orthopedic spine surgeons who are familiar with the variety of treatments, including surgical options, can help patients determine and access the best intervention to treat their LSS. Future studies should aim to examine how severity of LSS impacts the pharmacologic, minimally invasive or open surgical treatment recommendations, or referral pathways to appropriate physician specialties by primary care providers.

Abbreviations

CC, conservative care; CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology; ICD-9/10-CM, International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification; ICD-9/10-PCS, International Classification of Diseases, Ninth and Tenth Revision, Procedure Coding System; ED, emergency department; IHD, Instant Health Data; IP, inpatient; LSS, lumbar spinal stenosis; MILD, minimally invasive lumbar decompression; NIC, neurogenic intermittent claudication; OP, outpatient; SAF, standard analytical files; SD, standard deviation.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Ramana Naidu reports personal fees from Boston Scientific and Vertos, during the conduct of the study; personal fees from Boston Scientific and Vertos, outside the submitted work. Oth V Tran was a full-time employee of Boston Scientific at the time when this study was conducted. Michael Schatman is a research consultant for Modoscript and an AdComm member for Syneos Health, outside the submitted work.

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