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Clinical Study

Lumbar epidural steroid injections for herniation and stenosis: incidence and risk factors of subsequent surgery

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Abstract

BACKGROUND CONTEXT: Lumbosacral epidural steroid injections (ESIs) have increased dramatically despite a narrowing of the clinical indications for use. One potential indication is to avoid or delay surgery, yet little information exists regarding surgery rates after ESI.

PURPOSE: The purpose of this research was to determine the proportion of patients having surgery after lumbar ESI for disc herniation or stenosis and to identify the timing and factors associated with this progression.

STUDY DESIGN/SETTING: This study was a retrospective review of nationally representative administrative claims data from the Truven Health MarketScan databases from 2007 to 2014.

PATIENT SAMPLE: The study cohort was comprised of 179,025 patients (54±15 years, 48% women) having lumbar ESIs for diagnoses of stenosis and/or herniation.

OUTCOME MEASURES: The primary outcome measure was the time from ESI to surgery.

METHODS: Inclusion criteria were ESI for stenosis and/or herniation, age ≥18 years, and health plan enrollment for 1 year before ESI to screen for exclusions. Patients were followed longitudinally until they progressed to surgery or had a lapse in enrollment, at which time they were censored. Rates of surgery were assessed with the Kaplan−Meier survival curves. Demographic and treatment factors associated with surgery were assessed with multivariable Cox proportional hazard models. No external funding was procured for this research and the authors' conflicts of interest are not pertinent to the present work.

RESULTS: Within 6 months, 12.5% of ESI patients underwent lumbar surgery. By 1 year, 16.9% had surgery, and by 5 years, 26.1% had surgery. Patients with herniation had surgery at rates of up to five-fold to seven-fold higher, with the highest rates of surgery in younger patients and those with both herniation and stenosis. Other concomitant spine diagnoses, male sex, previous tobacco use, and residence a rural areas or regions other than the Northeastern United States were associated with higher surgery rates. Medical comorbidities (previous treatment for drug use, congestive heart failure, obesity, chronic obstructive pulmonary disease, hypercholesterolemia, and other cardiac complications) were associated with lower surgery rates.

CONCLUSIONS: In the long term, more than one out of every four patients undergoing ESI for lumbar herniation or stenosis subsequently had surgery, and nearly one of six had surgery within the first year. After adjusting for other patient demographics and comorbidities, patients with herniation were more likely have surgery than those with stenosis. The improved understanding of the

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progression from lumbar ESI to surgery will help to better inform discussions regarding the value of ESI and aid in the shared decision-making process.

Keywords: Epidural steroid injection; Herniation; Lumbar; Lumbosacral; Stenosis; Survival.

Introduction

The use of lumbosacral epidural steroid injections (ESIs) for lower back conditions has increased dramatically with the improved understanding of their efficacy and proper indications for use [1,2]. Early placebo-controlled studies of ESIs produced widely varying results, likely caused by differing patient indications, heterogeneous cohorts, and a lack of precision in ESI placement without image guidance [3]. Randomized controlled trials of ESIs using modern injection techniques consistently show improvements in pain and function [4−6] and superiority to relative to placebo [7]; however, trials comparing ESIs to active controls, such as physical therapy, anesthetic injection, or intramuscular injection, have produced widely varying results [5,8−11]. Systematic reviews of the literature therefore have produced divergent conclusions depending on their study selection technique. For example, some suggest that lumbar ESIs are no more effective than active controls or provide only short-term benefits [3,5,9,12,13], whereas others claim that ESIs may be effective for some pathologies (disc herniation and to a lesser degree, stenosis) but not others (axial pain and postsurgery syndrome) [8,14].

Aside from pain reduction, one potential indication for ESIs is the ability to avoid or delay invasive lumbar spine surgery. Several randomized trials have examined rates of surgery following ESI; however, these have been considerably underpowered or hindered by other methodological limitations [15−19]. Up to 30% of patients had surgery within 1−2 years following lumbar ESI and up to 49% had surgery within 5 years [6,7,16,17,20], with roughly half of patients requiring a second ESI to achieve their surgery-sparing results [6,7,11]. These trials clearly demonstrate that ESI outcomes differ according to patients' symptoms and underlying pathologies and suggest that long-term surgery rates range anywhere from 17% to 49%. However, treatment outcomes in clinical practice often do not match those measured in randomized controlled trials. Thus, the timing and factors associated with progression to surgery after lumbar ESI remain unclear.

Therefore, the goal of the current study is to use a large national claims database to determine the proportion of patients undergoing lumbar ESI for disc herniation or stenosis who subsequently progress to surgery. Furthermore, we seek to better understand the typical timing of this progression and to examine factors associated with surgery. We hypothesize that a considerable proportion of lumbar ESI patients will subsequently undergo lumbar spine surgery, with the majority of these progressing to surgery within the first year following their ESI.

Materials and methods

A retrospective longitudinal analysis of ESIs for lumbar disc herniation and/or stenosis was performed using the Truven Health MarketScan outpatient and inpatient databases from 2007 to 2014. This large, nationally representative, administrative claims resource includes deidentified data on 149 million unique patients during this time frame from more than 100 large employers, managed care organizations, hospitals, electronic medical record (EMR) providers, Medicare, and Medicaid [21]. The data contain unique patient identifiers allowing longitudinal patient tracking for assessment of patient comorbidities and outcomes.

Patients were identified through *International Classification of Diseases-9th revision* (ICD-9-CM) and *Current Procedural Terminology* (CPT) codes (Table) [22,23]. For inclusion, patients had to have an epidural injection (CPT codes 62311, 64483, and/or 64484) with a diagnosis of stenosis (ICD-9-CM codes 724.02, 724.03) or herniation (ICD-9-C code 722.1). Whereas lumbar disc herniation and stenosis could be coded in a few other ways; these codes are those specific to these pathologies in the lumbar region and therefore these diagnoses and were used to select a cohort that was as unambiguous and homogeneous as possible. Additionally, patients were required to have at least 1 year of continuous health plan enrollment before their ESI to allow for screening

Table
Lumbar ESI cohort details

Basic demographics & ESI details		
Age (years)		53.0±14.9
Female sex		97,124 (47.8%)
Region	Northeast	33,646 (16.6%)
	North Central	58,152 (28.6%)
	South	75,886 (37.4%)
	West	30,012 (14.8%)
Rural residence		34,654 (17.1%)
Diagnosis:	Herniation	125,564 (61.9%)
	Stenosis	57,169 (28.2%)
	Herniation and stenosis	20,268 (10.0%)
Fluoroscopic guidance		167,398 (82.5%)
Multiple levels Injected		42,837 (21.1%)
# ESI treatments:	1	127,149 (62.6%)
	2	37,582 (18.5%)
	3	22,435 (11.1%)
	4	6,822 (3.4%)
	5+	9,013 (4.4%)

ESI, epidural steroid injection.

of inclusion criteria and comorbidities. Paravertebral facet injections and sacroiliac joint injections were excluded, as were patients under 18 years of age. Patients who had a previous ESI or lumbar spine surgery within the year prior were excluded, as were those with any diagnoses of pregnancy, neoplasms, intraspinal abscesses, osteomyelitis, discitis, fracture, dislocation, vehicular accidents, inflammatory spondyloarthropathies, or rheumatoid arthritis (Supplementary Data, Table 1) [24]. Comorbidities were identified by ICD-9-CM codes, as published previously by Ratliff et al. for spine surgery based on comorbidity measures developed by Elixhauser et al. and Deyo et al. (Supplementary Data, Table 1) [25−27]. The use of fluoroscopic guidance was identified through CPT codes 77003 and 72275. Code 64483 was also used from 2011 to 2014, as the code description changed to specifically indicate ESI with fluoroscopy in 2011 [28].

Patients were followed longitudinally from the time of their first captured ESI until they either progressed to surgery or had a lapse in health plan enrollment, at which time they were censored. Lumbar spine surgery was identified based on a well-validated, highly sensitive and specific coding algorithm developed previously by Gray et al. [24]. Rates of lumbar surgery after ESI were assessed with the Kaplan−Meier survival curves and 99% confidence intervals (99% CIs). Univariate relationships between demographic and treatment factors and the progression from ESI to surgery were first assessed with stratified Kaplan−Meier survival curves with 99% CIs and log-rank tests. Factors assessed included age, sex, diagnoses, comorbidities, region of the United States (Northeast, Central, South, or West), patient residence in a rural or urban area (based on their metropolitan statistical area), single- or multiple-level injection, and the number of ESI treatments (between the index ESI and either surgery or censorship). The proportional hazards assumption for the univariate models was assessed visually through the stratified Kaplan−Meier survival curves.

Subsequently, the relationships between demographic and treatment factors, considered simultaneously, and the incidence of lumbar surgery after ESI were assessed with multivariable Cox proportional hazard models. Further evaluation of the proportional hazard assumption was assessed with plots of Schoenfeld residuals, log-negative log plots of the survival function, and through tests of interaction terms with time. Results of the multivariable models are presented as hazard ratios and their 99% CIs. Descriptive statistics are presented as means and 99% CIs for continuous variables and frequencies and percentages for categorical variables. Due to the large sample size, a more stringent criterion for statistical significance was employed (two-sided α=0.001). All analyses were performed in SAS version 9.4.

Results

A total of 179,025 unique patients having lumbar ESI for stenosis and/or herniation and meeting the inclusion and exclusion criteria were identified. The average follow-up time was 2.2±1.8 years (range 0.0−7.0 years). The average age of the cohort was 53.6±15.3 years, and 48.3% were women (Table). Fluoroscopic guidance was used in 89.9% of the ESIs, with this number remaining relatively constant from 2007 to 2014.

Most patients proceeded to surgery within the first 6 months to 1 year following lumbar ESI, as demonstrated by the initial drop in the survival curves (Fig. 1), which subsequently leveled off by this time frame. Within 6 months, 12.5% (99% CI: 12.2%, 12.7%) of ESI patients underwent lumbar surgery. By 1 year, this increased to 16.9% (99% CI: 16.6%, 17.3%) and by 5 years, this reached 26.1% (99% CI: 25.6%, 26.6%). In univariate tests, surgery rates differed by diagnosis ($p < .001$), with only 6.6% (99% CI: 6.3%, 7.1%) of stenosis patients but 13.5% (99% CI: 13.2%, 13.9%) of herniation patients having surgery within the first 6 months (Fig. 1). Patients with both herniation and stenosis were the most likely to have surgery, with 23.6% (99% CI: 22.6%, 24.7%) doing so within 6 months. Almost half (49.6%) of subsequent surgeries were performed in an inpatient setting, whereas the rest were performed at outpatient or ambulatory facilities. Of all surgeries, 92.4% had a diagnosis of stenosis and/or herniation. The few surgeries without a diagnosis of stenosis and/or herniation typically had diagnoses of spondylosis, instability, spondylolisthesis, and/or lumbago. Excluding surgeries that did not have a diagnosis of stenosis and/or herniation (ie, censoring these patients at the time of their surgery) changed the survival results by less than 1% at 6 months and 1 year and less than 2% at 5 years.

The most common procedure following ESI was a discectomy (56.8), followed by laminectomy (37.6%), and fusion (18.2%), with 37.0% of surgeries involving two or more of these procedures. Of patients having surgery after ESI for disc herniation, 70.3% had a discectomy, 26.5%

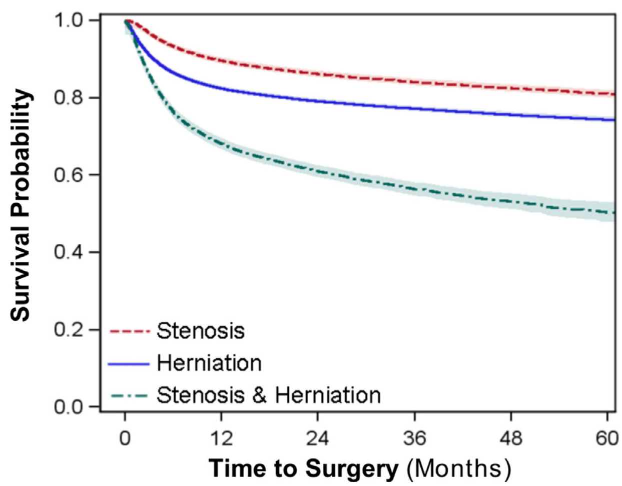

Fig. 1. Univariate Kaplan−Meier survival curves and 99% confidence intervals stratified by diagnosis. Survival is defined as the time from the index ESI to surgery; therefore, lower survival indicates a higher rate of surgery (1-survival). Rates of surgery differed by diagnosis ($p < .001$).

ESI, epidural steroid injection.

had a laminectomy, and 12.8% had a fusion, with 29.2% of these patients having two or more these procedures. Of those having surgery after ESI for stenosis, 19.8% had a discectomy, 64.5% had a laminectomy, and 33.9% had a fusion, with 52.3% of these patients having two or more of these procedures (all but 6.1% of the fusion patients also had either a discectomy or laminectomy, and all patients with stenosis that had a fusion had either spondylolisthesis and/or instability as a concomitant diagnosis).

Roughly half of lumbar ESI patients had a second epidural, and the vast majority of these occurred within 3 months of the index ESI (Fig. 2). Within just 1 month, 20.4% (20.2%, 20.8%) had a second ESI, and this number increased to 29.4% (99% CI: 29.1%, 29.8%) by 3 months, 34.3% (99% CI: 33.9%, 34.7%) by 6 months, 39.3% (99% CI: 38.9%, 39.7%) by 1 year, and 44.4% (99% CI: 43.9%, 44.9%) by 5 years. The rate of second ESI for patients with herniation or both stenosis and herniation differed from those with stenosis, alone ($p < .001$ for each comparison); however, this difference was <3% at 5 years and may not be clinically relevant (Fig. 2).

In multivariable models, the diagnoses associated with the index ESI were most predictive of subsequent surgery. Patients with herniation or herniation and stenosis progressed to surgery at higher rates than those with stenosis, alone, and the difference in surgery rates was more pronounced with younger age (Fig. 3). Patients aged 45−54 years with herniation had surgery at 1.68 (1.51, 1.86) times the rate of those with stenosis, alone; patients aged 35−44 years with herniation had surgery at 2.78 (2.28, 3.43) times the rate of those with stenosis, alone; and patients aged 18−34 years with herniation had surgery at 5.78 (3.76, 9.56) times the rate of those with stenosis, alone. Of the concomitant spine diagnoses, a diagnosis of neuritis, radiculitis, or radiculopathy was associated with the greatest increase in subsequent surgery rates

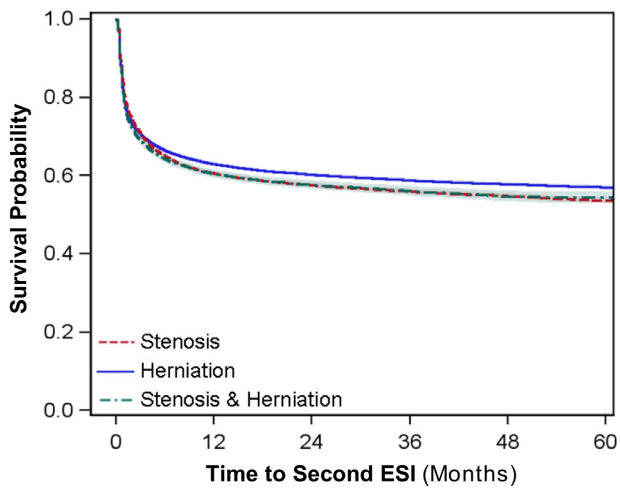

Fig. 2. Kaplan−Meier survival curves and 99% confidence intervals for the time to second ESI stratified by diagnosis. Lower survival in these figures indicates a higher rate of second ESI (1-survival).

ESI, epidural steroid injection.

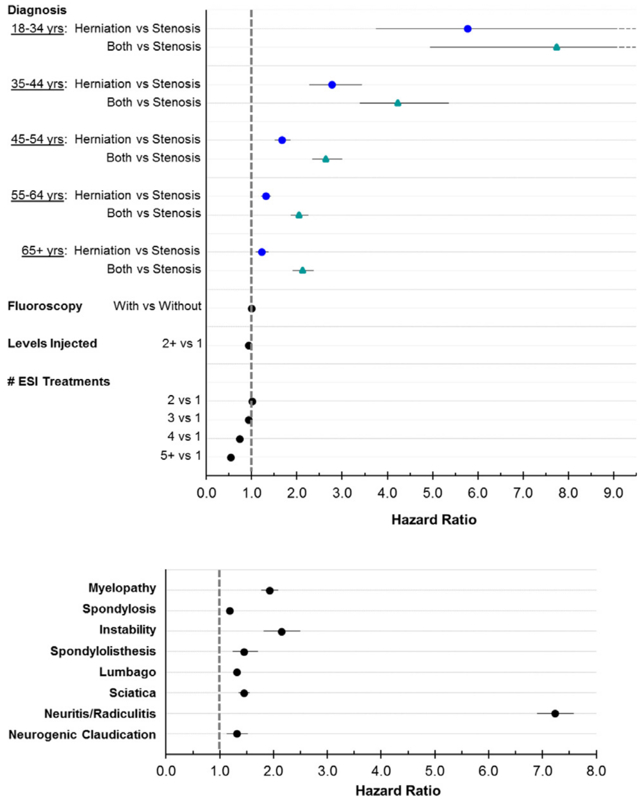

Fig. 3. Hazard ratios and 99% confidence intervals for the rate of surgery following lumbar ESI for the (Top) ESI treatment details and (Bottom) concomitant spine diagnosis included in the multivariable Cox proportional hazard model. Factors with confidence intervals not overlapping the lines indicating hazard ratios of 1 are significant at $p < .001$.

ESI, epidural steroid injection.

(hazard ratio: 7.23 [99% CI: 6.90, 7.58], $p < .001$; Fig. 3). The increase in surgery rates with other concomitant spine diagnoses ranged from an 18% increase with spondylosis (hazard ratio: 1.18 [99% CI: 1.13, 1.22], $p < .001$), to a 214% increase with instability (hazard ratio: 2.14 [99% CI: 1.82, 2.50], $p < .001$). Neurogenic claudication was associated with a 31% increase in surgery rates (hazard ratio: 1.31 [99% CI: 1.13, 1.52]).

Age was associated with surgery rates following ESI; however, this result depended upon the diagnosis (Fig. 4). Younger age was associated with increased rates of surgery after ESI for herniation, with patients aged 18−34 years having the highest rates of surgery (hazard ratio: 1.47 [99% CI: 1.31, 1.64]) relative to those aged 65 and above ($p < .001$). Conversely, younger age was associated with decreased rates of surgery after ESI for stenosis, with patients aged 18−34 years having the lowest rates of surgery (hazard ratio: 0.31 [99% CI: 0.19, 0.48]) relative to those aged 65 and above ($p < .001$). Female sex was also associated with lower rates of surgery (hazard ratio: 0.83 [99% CI: 0.80, 0.86], $p < .001$). Patients residing in areas other than the Northeastern United States were more likely to have surgery ($p < .001$ for each). The North Central United States was 14% more likely to have surgery (hazard

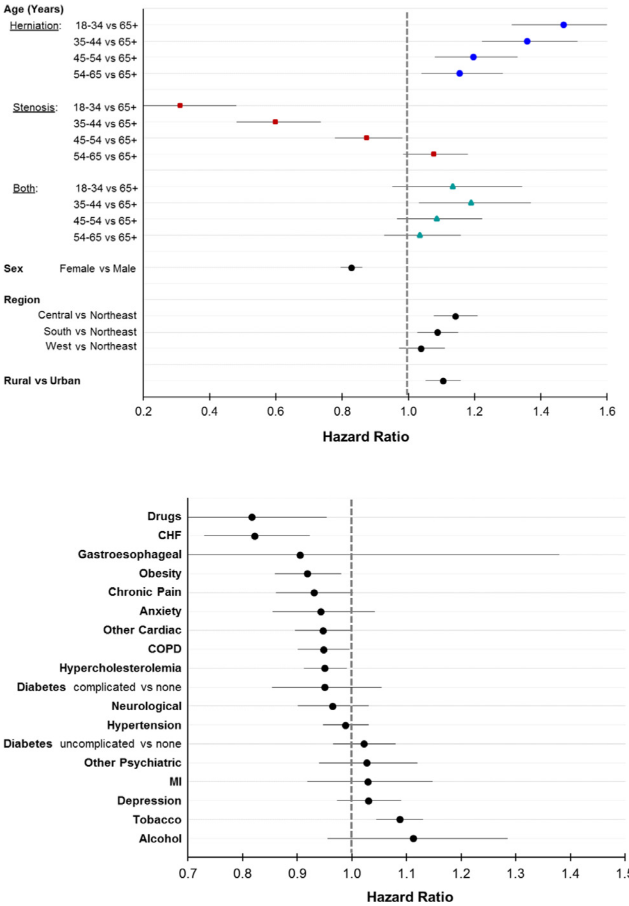

Fig. 4. Hazard ratios and 99% confidence intervals for the rate of surgery following lumbar ESI for each (Top) demographic factors and (Bottom) medical comorbidities included in the multivariable Cox proportional hazard model. Factors with confidence intervals not overlapping the lines indicating hazard ratios of 1 are significant at p < .001.

ESI, epidural steroid injection.

Ratio: 1.14 [99% CI: 1.08, 1.21]). Despite being statistically significant, differences for the South and West regions as compared with the Northeast were relatively small in magnitude (<10%). Patients living in rural areas were slightly more likely to have surgery than those in urban areas (hazard ratio: 1.10 [99% CI: 1.05, 1.16], p < .001).

Having more than one level injected was associated with slightly lower rates of surgery (Fig. 3); however, the magnitude of the difference was relatively small (hazard ratio: 0.96 [99% CI: 0.94, 0.98], p < .001). Patients having four or more ESI had significantly decreased surgery rates relative to those with only one ESI treatment (p < .001 for 4 vs 1 and 5+ vs 1); however, there was no difference in surgery rates among patients having one, two, or three ESI treatments.

Finally, a number of medical comorbidities were associated with lower surgery rates (Fig. 4). Previous treatment for drug use (hazard ratio: 0.82 [99% CI: 0.70, 0.95], p < .001) and congestive heart failure (CHF, hazard ratio: 0.82 [99% CI: 0.73, 0.92], p < .001) were associated with the lowest surgery rates. Obesity, other cardiac complications, chronic obstructive pulmonary disease (COPD), and hypercholesterolemia (p < .001 for each) were also associated with lower rates of surgery; however, despite being statistically significant, differences were less than 5%. Conversely, previous treatment for tobacco use was associated with increased rate of surgery, but the difference was less than 10% (hazard ratio: 1.09 [99% CI: 1.05, 1.13], p < .001).

Discussion

Nearly 17% of patients having a lumbar ESI for stenosis and/or herniation had surgery within 1 year, and 26% had surgery within 5 years. Over 44% of patients had a second ESI within 5 years. As hypothesized, most surgeries occurred relatively shortly after ESI, with half occurring within the first 6 months and 65% occurring within the first year. For patients having a second ESI, these happened within an even shorter time frame, with almost half occurring within the first month after the index ESI and 66% occurring within 3 months. Notably, the rate of patients having surgery after ESI strongly depended on the initial diagnosis. Patients with herniation or herniation and stenosis had surgery at higher rates than those with a diagnosis of stenosis, alone, with the magnitude of the difference increasing with decreasing age. Patients below age 45 with herniation had surgery at rates between 2.8 and 7.8 times that of those with stenosis, alone, depending on age and whether they also had a diagnosis of stenosis. Furthermore, having concomitant spine diagnoses in addition to the herniation and/or stenosis diagnosis made patients more likely to progress to surgery. In particular, patients with a concomitant diagnosis of neuritis, radiculitis, or radiculopathy had a 7.2 times higher rate of surgery than patients without these diagnoses. Younger patients with disc herniation were more likely to undergo surgery relative to those aged 65 and above, whereas younger patients with stenosis were less likely to undergo surgery. Other factors associated with higher rates of surgery included male sex, residence in rural areas or areas other than the Northeastern United States, and previous treatment for tobacco use.

A number of studies have examined improvements in pain and symptoms with lumbar ESI [3−6,8,9,12,13,18,29,30], including several randomized controlled trials [6,7,11]. Most notably, our results are similar to those from existing randomized trials of lumbar ESI that examined rates of subsequent surgery. These trials showed rates of surgery of up to 30% within 1−2 years following ESI [7,16,17], and lower rates in patients with spinal stenosis [31]. In the present study of 203,001 patients, 17% had surgery within the first year following ESI, with the majority of these surgeries occurred within the first 6 months to 1 year. In addition, higher rates of surgery were observed in patients diagnosed with herniation relative to those with stenosis, alone, confirming results from a previous study of ESI patients in Japan [15]. Our results further demonstrate that this association depends strongly on patient age, with herniation patients having surgery at rates 1.2 times, 1.7 times, 2.8 times, and 5.8 times higher than that for stenosis patients at ages 55+, 45-54, 35-44, and 18-34, respectively. The larger differences in surgery rates at younger ages were due both to the increased rates of surgery in younger patients with herniation and the lower rates of surgery in younger patients with stenosis. Concomitant spine diagnoses, particularly neuritis, radiculitis, and/or radiculopathy, were associated with increased rates of surgery; however, whether this was due to patients' symptoms being more severe or due to surgeons being more likely to recommend surgery is unclear.

ESI injections without image guidance often fail to enter the epidural space, are inadvertently intravascular, and thus fail to reach the intended target [32−37]. For this reason, fluoroscopic guidance is often used and presumed to improve clinical outcomes. Our results did not show a difference in subsequent surgery rates with fluoroscopic guidance. Patients who had their index epidural performed without fluoroscopic guidance were more likely to have a second epidural; however, the magnitude of this difference was only 3% ($p < .001$, data not shown). Due to coding changes implemented in 2011, in which fluoroscopic guidance was bundled with the CPT epidural code 64483, coding errors due to a lag in adherence to the new coding may have hindered our ability to detect differences with fluoroscopic guidance.

Medical comorbidities, including CHF, previous treatment for drug use, chronic pain, obesity, anxiety, hypercholesterolemia, and COPD, and other cardiac complications were associated with lower rates of surgery. A number of these comorbidities likely resulted in patients being higher risk candidates for surgery, and would therefore have resulted in lower surgical rates. This highlights one notable limitation of the current study, in that we are unable to determine with the data available how many of the lumbar ESI patients were surgical candidates. It is possible that the rates of surgery in patients eligible for surgery may be higher than those reported for all lumbar ESI patients. However, our rate of surgery was similar to that seen in a smaller study where only surgical candidates were included [38].

The use of administrative claims data presents both strengths and weaknesses in the present study. As opposed to the previous studies, which were from single institutions and underpowered for the outcome of surgery after ESI, the Marketscan data provide a large, nationally representative patient cohort with more than adequate statistical power. However, clinical data regarding the patients' indications were limited, and we were not able to evaluate the patients' symptom duration or the severity and extent of neural compression. Data were also not available regarding the ESI approach and whether or not the ESI was performed for therapeutic versus diagnostic purposes, although the latter likely comprised only a small portion of all lumbar ESIs. Claims data are also known to contain coding inaccuracies. However, when compared against reviews of medical records, the current and similar algorithms used to identify spine surgery were shown to be highly sensitive and specific [39,40]. We therefore can be confident in the calculated rates of surgery. The coding for individual spine diagnoses tends to be less accurate than the coding for surgical procedures, although the specificity for these diagnoses remains high, meaning that if the diagnosis is not present the patient most likely does not have that diagnosis.

Conclusions

In conclusion, the findings of this study represent outcomes in real-world clinical practice. Over one out of every four patients undergoing ESI for lumbar disc herniation or spinal stenosis had surgery in the long term, and nearly one of six had surgery within the first year following their ESI. Frequently, the results from randomized trials are not generalizable and do not match outcomes observed in usual practice. However, the long-term surgery rates observed in the current study were well within the range observed previously in randomized trials, and our results confirm several key findings, including that nearly half of patients treated with an ESI will receive a repeat injection. After adjusting for other patient demographics and comorbidities, patients with herniation were more likely have surgery than those with a diagnosis of stenosis, and patients with additional spine diagnoses (particularly neuritis, radiculitis, or radiculopathy) were even more likely to undergo surgery. The improved understanding of the progression from lumbar ESI to surgery will help to better inform discussions regarding the value of ESI and can aid in the shared decision-making process.

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Supplementary material

Supplementary material related to this article can be found at http://dx.doi.org/10.1016/j.spinee.2018.05.034.

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