



Real-World Treatment Patterns and Gaps in Clinical Management of Lumbar Disc Herniation in the United States



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INTRODUCTION

- Lumbar disc herniation (LDH) is a common chronic condition frequently affecting lower back and legs and causing debilitating pain
- LDH affects approximately 1-3% of the population annually, primarily affecting individuals between 30 and 50 years of age¹
- Conservative treatments are the first line treatments for most newly diagnosed LDH patients
- While conservative treatments are usually effective for initial symptomatic relief, many patients will require epidural steroid injection (ESI) and some may require surgeries²
- ESI has no confirmed long-term benefits and carries the risk of neurological complications;^{3,4} surgery carries the risk of complications, risk relating to general anesthesia, along with a chance of re-herniation⁵

OBJECTIVE

- This study seeks to describe current treatment patterns and inform gaps in clinical management of patients with newly diagnosed LDH

METHODS

Study Design and Sample Selection

- A retrospective study using IQVIA PharMetrics® Plus database (01/01/2018 to 03/31/2023)
- The selection of LDH sample was described in Table 1

Table 1. Sample selection

Selection step	Description	N of patients
Step 1	≥1 inpatient diagnosis or ≥2 outpatient diagnosis codes of LDH between 01 January 2018 to 31 March 2022	2,595,743
Step 2	≥18 years old at the index date (Index date was defined as first available diagnosis of LDH)	2,560,704
Step 3	≥6 months of continuous enrollment in an insurance plan prior to and ≥12 months following the index date	1,253,562
Step 4	No ESI or LDH surgical procedures prior to the index date	1,244,758
Step 5	30-70 years old at the index date	1,086,552

Statistical Analysis

- Demographic and clinical characteristics during the 6-month baseline period were summarized and compared across subgroups defined based on treatments received. Continuous variables were compared using Wilcoxon Rank Sum Test and categorical variables were compared using Chi-squared Test
- Treatment patterns (including conservative treatments, ESI, and LDH surgery) were described over a three-year follow-up period. Conservative treatments included nonopioid analgesics (including NSAID, acetaminophen, etc.), opioids, systemic glucocorticoids, benzodiazepines and antispasmodic agents, physical/massage therapy, spinal manipulation, and acupuncture
- Time from first ESI to second ESI were described during the follow-up period among ESI-treated patients, using Kaplan-Meier (KM) analysis

KEY TAKEAWAYS

- 1 Around one quarter of newly diagnosed LDH patients received ESIs and/or surgeries after conservative treatment
- 2 Half of the patients who received ESI needed additional ESIs within one year, indicating potential lack of effectiveness
- 3 Close to one-fifth of ESI-treated patients underwent surgery including repeated surgeries
- 4 Among surgery-treated patients, close to half directly received surgery without ESI
- 5 Unmet needs exist in the current treatment options for LDH patients, highlighting the need for new effective treatment options to reduce the need for surgeries and ESIs

RESULTS

Demographic and Baseline Characteristics

Table 2. Summary of baseline patient characteristics

	Overall LDH Patients N = 1,086,552	LDH subgroups			
		Conservative Only/ No treatment N = 836,811	One ESI without Surgery N = 84,151	Multi ESIs without Surgery N = 87,533	Surgery treated N = 78,057
Demographics					
Age (years) at the index date, Mean ± SD	50.8 ± 10.0	50.4 ± 10.1	51.9 ± 9.7*	52.6 ± 9.3*	52.1 ± 9.8*
Female, n (%)	585,050 (53.8)	460,825 (55.1)	43,826 (52.1)*	45,910 (52.5)*	34,489 (44.2)*
Duration of follow-up, in months, Mean ± SD	27.1 ± 8.5	27.0 ± 8.5	26.7 ± 8.5	27.8 ± 8.3	27.8 ± 8.2
Prior conservative treatment, n (%)	720,578 (66.3)	529,162 (63.2)	63,705 (75.7)*	69,147 (79.0)*	58,564 (75.0)*
CCI score, Mean ± SD	1.2 ± 1.8	1.1 ± 1.7	1.3 ± 1.9*	1.4 ± 1.9*	1.3 ± 1.9*
Comorbidities, n (%)					
Hypertension	306,367 (28.2)	222,482 (26.6)	27,011 (32.1)*	30,983 (35.4)*	25,891 (33.2)*
Chronic pulmonary disease	281,785 (25.9)	209,369 (25.0)	23,768 (28.2)*	26,558 (30.3)*	22,090 (28.3)*
Diabetes	215,015 (19.8)	157,297 (18.8)	18,607 (22.1)*	21,035 (24.0)*	18,076 (23.2)*
Mild liver disease	157,740 (14.5)	117,147 (14.0)	13,566 (16.1)*	14,995 (17.1)*	12,032 (15.4)*
Osteoarthritis	117,649 (10.8)	81,310 (9.7)	12,059 (14.3)*	14,228 (16.3)*	10,052 (12.9)*
Obesity	115,802 (10.7)	86,708 (10.4)	9,773 (11.6)*	11,377 (13.0)*	7,944 (10.2)

Abbreviations: CCI: Charlson Comorbidity Index; SD: standard deviation. * Indicates p value < 0.001. Characteristics in each of the ESI- or surgery-treated group were compared with those in the conservative/only treatment group.

Treatment Patterns and Sequences

- Almost all patients (98.4%) were treated with conservative treatment during the follow-up period and 23.0% of patients required ESI and/or surgery to manage their LDH
- The group of patients who received ESI and/or surgery were on average 1-2 years older and had a slightly lower percentage of female patients compared to patients who received conservative treatments only (Table 2)

Utilization of ESI

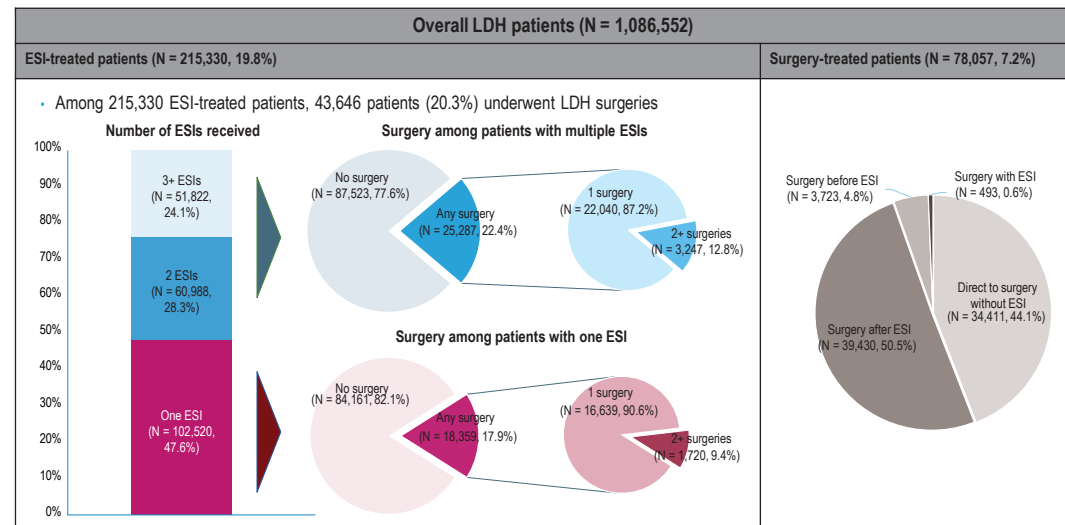
- Overall, 19.8% of LDH patients received at least one ESI with or without surgery; more than half of ESI-treated patients (52.4%) received multiple ESIs (Figure 1)
- Among ESI-treated patients, the average duration from LDH diagnosis to first ESI was 6.2 months, with 53.4% and 82.3% received first ESI within 3 months and one year, respectively
- 50.0% of the patients who received first ESI also received second ESI within 1 year (Figure 3)

Utilization of surgery

- Overall, 7.2% of LDH patients underwent LDH surgeries with or without ESI; one in ten surgery-treated patients (9.6%) received multiple surgeries
- Among surgery-treated patients, the average duration from LDH diagnosis to first surgery was 8.4 months, with 53.5% and 74.7% received first surgery within 6 months and one year, respectively

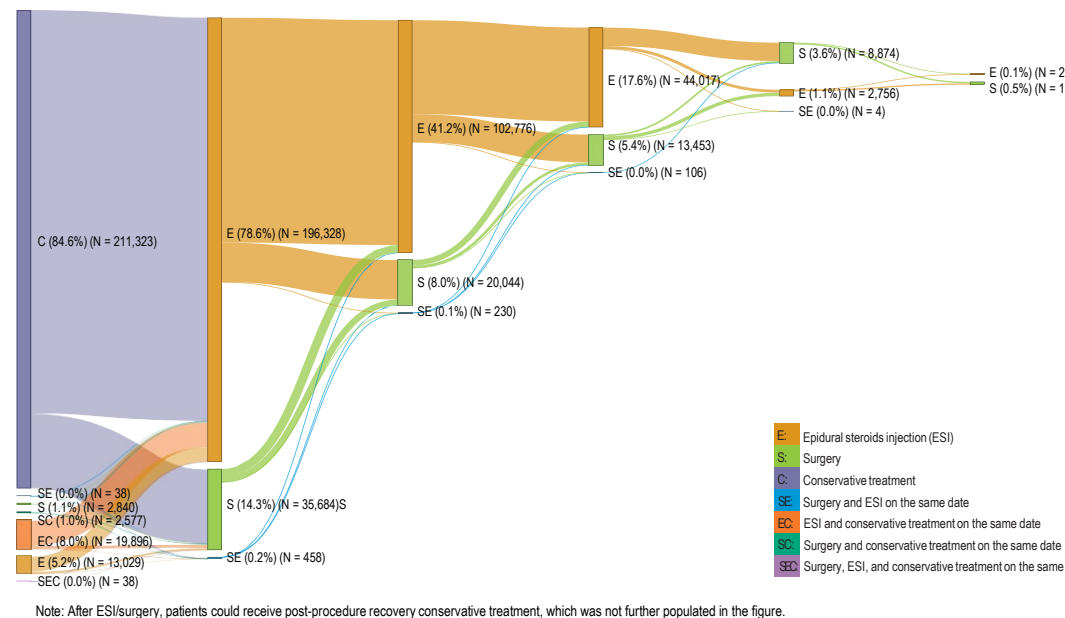
- A total of 1,086,552 LDH patients were included for analyses with a mean age of 50.8 years and a mean Charlson Comorbidity Index (CCI) score of 1.2. Patients on average had more than two years of follow-up data (27.1 ± 8.5 months)
- The most common comorbidities included hypertension (28.2%), chronic pulmonary disease (25.9%), and diabetes (19.8%)

Figure 1. Treatments among LDH patients during the follow-up period



Abbreviations: ESI: Epidural steroid injection; LDH: lumbar disc herniation.

Figure 2. Sankey Diagram for patients with any ESI and/or surgery (n=249,741, 23.0% of entire LDH sample)

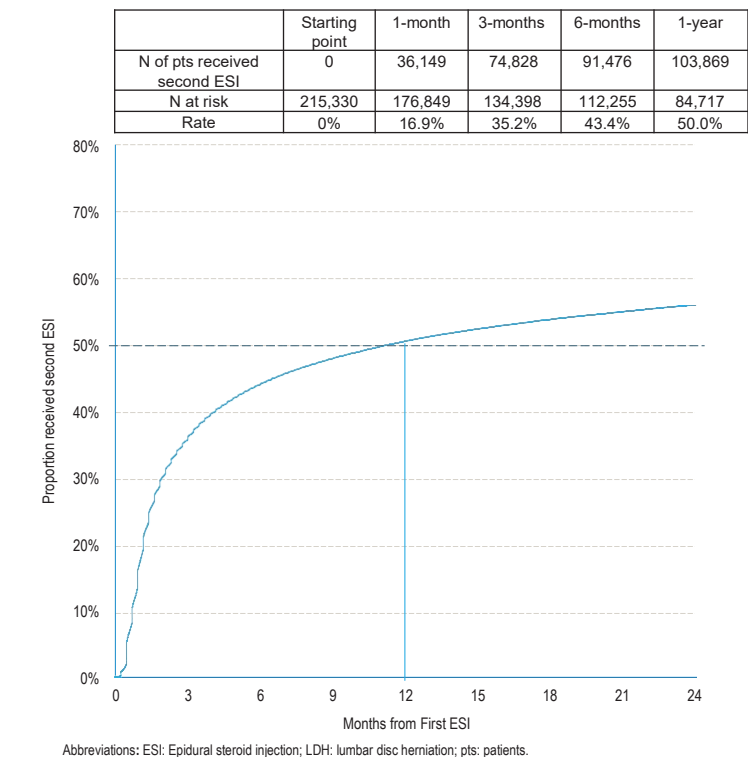


Note: After ESI/surgery, patients could receive post-procedure recovery conservative treatment, which was not further populated in the figure.

Table 3. Common treatment sequences (n=249,741, 23.0% of entire LDH sample)

Common treatment sequences	N (%)
ESI	
Conservative treatments followed by one ESI	71,454 (28.6%)
Conservative treatments followed by two ESIs	40,331 (16.1%)
Conservative treatments followed by three or more ESIs	32,683 (13.1%)
Surgery	
Conservative treatments followed by one LDH surgery directly	27,391 (11.0%)
ESI and surgery	
Conservative treatments followed by one ESI and one LDH surgery	12,774 (5.1%)
Conservative treatment followed by two ESIs and one LDH surgery	8,442 (3.4%)

Figure 3. Time from first ESI to second ESI among ESI-treated patients



Acknowledgments

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Disclosures

AB: consultant for 4WEB Medical, Corelink/Zavation, and Ferring Pharmaceuticals; KC, AG: employees of Ferring Pharmaceuticals; MY, QL, YG, JL, SL: employees of Analysis Group, Inc., which received payment from Ferring Pharmaceuticals for participating in this research.

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