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ORIGINAL RESEARCH

Longitudinal Comparative Analysis of Complications and Subsequent Interventions Following Stand-Alone Interspinous Spacers, Open Decompression, or Fusion for Lumbar Stenosis

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ABSTRACT

Introduction: For individuals with lumbar spinal stenosis (LSS), minimally invasive procedures such as an interspinous spacer device without decompression or fusion (ISD) or open surgery (i.e., open decompression or fusion) may relieve symptoms and improve functions when patients fail to respond to conservative therapies. This research compares longitudinal postoperative outcomes and rates of subsequent interventions between LSS patients treated with ISD and those with open decompression or fusion as their first surgical intervention.

Methods: This retrospective, comparative claims analysis identified patients age ≥ 50 years with LSS diagnosis and with a qualifying procedure during 2017–2021 in the Medicare database which includes healthcare encounters in inpatient and outpatient settings. Patients were followed from the qualifying procedure until end of data availability. The outcomes assessed during the follow-up included subsequent surgical interventions, including subsequent fusion and lumbar spine surgeries, long-term complications, and short-term life-threatening events. Additionally, the costs to Medicare during a 3-year follow-up were calculated. Cox proportional hazards, logistic regression, and generalized linear models were used to compare outcomes and costs, adjusted for baseline characteristics.

Results: A total of 400,685 patients who received a qualifying procedure were identified (mean age 71.5 years, 50.7% male). Compared to ISD patients, patients receiving open surgery (i.e., decompression and/or fusion) were more likely to have a subsequent fusion [hazard ratio (HR), 95% confidence intervals (CI): 1.49 (1.17, 1.89)–2.54 (2.00, 3.23)] or other lumbar spine surgery [HR (CI): 3.05 (2.18, 4.27)–5.72 (4.08, 8.02)]. Short-term life-threatening events [odds ratio (CI): 2.42 (2.03, 2.88)–6.36 (5.33, 7.57)] and long-term complications [HR (CI): 1:31 (1.13, 1.52)–2.38 (2.05, 2.75)] were more likely among the open surgery cohorts. Adjusted mean index costs were lowest for decompression alone (US$7001) and highest for fusion alone ($33,868). ISD patients had significantly lower 1-year complication-related costs than all surgery cohorts and lower 3-year all-cause costs than fusion cohorts.

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Conclusions: ISD resulted in lower risks of short- and long-term complications and lower long-term costs than open decompression and fusion surgeries as a first surgical intervention for LSS.

Keywords: Lumbar spinal stenosis; Interspinous spacer; Surgical decompression; Laminectomy; Fusion; Postoperative complication; Cost comparison

Key Summary Points

Why carry out this study?

Multiple treatments are available for patients with symptomatic lumbar spinal stenosis, ranging from minimally invasive procedures to more invasive surgical options; however, few investigations have compared the postoperative outcomes of procedures in a real-world setting.

This study sought to longitudinally compare the rates of safety events and subsequent spinal surgeries of patients who received interspinous devices (without decompression or fusion) versus patients treated with either open decompression or fusion as their first surgical intervention.

What was learned from the study?

Compared with patients who received open surgery, those treated with interspinous devices were less likely to have a subsequent fusion or other lumbar spine surgery.

Patients who were treated with interspinous devices had lower rates of short- and long-term complications than open decompression or fusion surgery as well as lower long-term costs than fusion surgery.

INTRODUCTION

Lumbar spinal stenosis (LSS) is a condition that affects 1 out of 10 people in the general population and nearly half of those over the age of 60 years [1, 2]. A common presentation of LSS is neurogenic intermittent claudication (NIC), manifesting as pain, numbness, and/or subjective weakness in the back and legs with difficulty walking [3]. The goal of treatment is to relieve symptoms and improve function, where the first-line treatment for these symptoms is typically categorized as being "conservative" and includes physical therapy, pain medication, and/or epidural injections [3].

Patients who fail to respond to these modalities may be appropriate candidates for minimally invasive procedures such as the placement of stand-alone interspinous devices (ISD) without a direct decompression or fusion [4]. These spacers are inserted posteriorly between the spinous processes and bring about an "indirect" decompression of the neural elements by limiting lumbar extension, a position known to decrease the cross-sectional area of the spinal canal, and which can exacerbate symptoms of neurogenic claudication. Studies have shown patients receiving ISDs exhibit reductions in pain and improvements in both function and quality of life [4–7]. In addition, minimally invasive strategies such as ISDs may be a good option for patients with medical comorbidities or other contraindications for surgery [8].

Depending upon the pathology, the surgical treatment for patients with LSS may involve decompression to remove bony or soft tissue structures that may be contributing to the stenosis , a fusion to stabilize the spine, or both procedures [3]. However, lumbar fusion is a more invasive operation that may not result in better outcomes relative to decompression alone, and is associated with an increased risk of complications and adverse events [9]. ISDs are indicated to treat skeletally mature patients with NIC who have undergone at least 6 months of non-operative treatment, and are implanted at one or two adjacent lumbar levels from L1 to L5 [10]. The minimally-invasive

nature of ISDs may reduce rehabilitation time compared to more invasive surgical procedures [11], although some have reported higher re-operation rates for ISDs compared with traditional decompression surgery [12].

While there are previous studies that utilize large databases or prospective studies to compare outcomes between decompression and fusion [13, 14], there is currently a paucity of real-world data directly comparing the outcomes of patients treated with ISDs without decompression or fusion with patients treated with conventional surgical options for lumbar stenosis. Previous works have compared decompression/fusion surgery to an ISD that requires decompression [15] and to an ISD that is no longer available for use [16, 17]. However, controlled trials require strict inclusion and exclusion criteria, potentially limiting their generalizability to wider use in real-world practice. Additionally, while the safety and efficacy of the most recently approved ISD have previously been established [18, 19], no studies have directly compared postoperative outcomes and subsequent interventions between patients treated with the currently approved ISD and those treated with either open decompression and/or fusion as their first surgical treatment for LSS. Thus, the primary objectives of this longitudinal study were to compare the rates of safety events and rates of subsequent spinal surgeries of patients who received an ISD compared to either open decompression (with or without concomitant fusion) or fusion alone as their first operative intervention, using the most recent real-world claims data available.

METHODS

Study Design and Data Source

This study is a retrospective cohort analysis comparing postoperative complications, rates of subsequent interventions, and costs between patients receiving an implant of ISD and patients treated with open decompression without fusion, open decompression with fusion, and fusion surgeries as their first surgical intervention. This analysis used claims data from the 100% Medicare Standard Analytical Files (SAFs), which include enrollment, demographic, and encounter data for Medicare beneficiaries. Specifically, these data reflect encounters that occur in either the inpatient or outpatient setting such as an inpatient hospital, outpatient hospital, skilled nursing facility, and home health services, but the SAFs do not include pharmacy data, even for beneficiaries with Medicare medication coverage. Sample selection and the creation of analytic variables were performed using the Instant Health Data software (Panalgo, Boston, MA, USA). Statistical analyses were generated using StataCorp 2021 (College Station, TX, USA). This study does not involve human participants, so neither independent review board approval nor patient consent was required. We had permission to access and analyze the data used in this study through the CMS Data Use Agreement.

The study was longitudinal in nature such that an index date was created for each patient when they were first treated with placement of an ISD, decompression, or fusion between January 1, 2017 and December 31, 2021. Patients were followed from their index date until the end of the study period, the end of their Medicare coverage, or death, whichever occurred first. Patient demographic and clinical characteristics were identified during a baseline period of 12 months prior to the index date.

Study Population and Outcome Measures

Health encounters in the SAFs include patient diagnoses and procedures that are documented using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) or Procedure Coding System (ICD-10-PC) codes and Current Procedural Terminology 4th edition (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, respectively. These data reflect information from beneficiaries with Part A/B coverage but not those covered by Medicare Part C (MA).

Patients were included if they had at least one claim for an ISD, open decompression, or spinal fusion during the study period (codes included in Supplementary Material Table 1);

were at least 50 years of age as of the index date with at least 12 months of continuous enrollment with Medicare coverage during the baseline period; and had a diagnosis of LSS during the study period. However, individuals who had undergone prior lumbar spine surgeries during the baseline period were excluded from the analysis.

During the follow-up period, subsequent spinal interventions specific to LSS were evaluated as well as those related to other spinal conditions. Subsequent surgical interventions for LSS included ISD, minimally invasive lumbar decompression (i.e., MILD), open decompression with or without fusion, fusion alone, and placement of an interspinous spacer with an open decompression. Other surgical interventions included removal of implants from the lumbar spine (whether or not they were related to the index procedure), insertion of a spinal cord stimulator or drug delivery device, and other lumbar spine surgeries consisting of disc procedures, endoscopic decompressions, repair of a cerebrospinal fluid leak, vertebral excision, and cement augmentation of vertebral bodies (i.e., vertebroplasty, kyphoplasty). Furthermore, a re-operation was defined as having an open decompression, fusion, and or device removal within 3 months of the index procedure [11].

Safety events included any postoperative complications and/or life-threatening events. Long-term complications were evaluated during the follow-up period, including mechanical complications of a device, allergic reaction to an implant, injury to the lumbosacral spine or nerve root, cerebrospinal fluid leak, wound infection or dehiscence, hematoma, thrombophlebitis, and closed/collapsed lumbar fracture, including those involving the spinous process. Life-threatening events relevant to surgical operations [20–23] were evaluated within 30 days of the index procedure, and included sepsis, pneumonia, cardiac arrest, pulmonary embolism, deep venous thrombosis, ischemic stroke, acute myocardial infarction, blood transfusions related to blood loss, and inpatient re-admission. Readmission due to postoperative or life-threatening complications occurring up to 3 months after the index procedure was also reported (codes included in Supplementary Material Table 1).

Healthcare costs included the costs associated with the index procedure, all-cause (i.e., those incurred from all medical services) for up to 3 years, and any complications for up to 1 year after the index procedure. The costs were adjusted for inflation using the medical care component of the Consumer Price Index and standardized to 2021 US dollars [24].

Statistical Analysis

The baseline characteristics available for each patient included demographics (i.e., age, gender, race, geographic region), Elixhauser comorbidity index score [25], and relevant clinical conditions (codes included in S1). Categorical variables are presented as the count and percent of patients in each category, while continuous variables are recorded as mean and standard deviation (SD). Cox proportional hazards regression was used to examine the times to several events, including subsequent open surgery (decompression and/or fusion), and any long-term complication, adjusted for baseline characteristics. Logistic regression was used to examine the likelihood of suffering a life-threatening event within 30 days of the index procedure, a 90-day re-admission due to a complication, and a 90-day re-operation, adjusted for the baseline characteristics. Generalized linear models with a gamma log-link were employed to compare costs between cohorts. An alpha of 0.05 was used to signal statistical significance.

RESULTS

Study Population

A total of 400,685 subjects were identified, including 4183 (1.0%) who received placement of an ISD, 211,014 (52.7%) treated with decompression alone, 76,935 (19.2%) treated with decompression with a concomitant fusion, and 108,553 (27.1%) who received a fusion alone. The average length of follow-up was

Table 1 Demographic and baseline clinical characteristics

Demographics at index diagnosis	ISD (n = 4183)	Decomp alone (n = 211,014)		Decom + fusion (n = 76,935)		Fusion (n = 108,553)	
	n/mean (%/SD)	n/mean (%/SD)	p value vs. ISD	n/mean (%/SD)	p value vs. ISD	n/mean (%/SD)	p value vs. ISD
Age at index, mean (SD)	74.2 (7.9)	72.3 (7.0)	< 0.001	71.1 (6.7)	< 0.001	70.3 (6.9)	< 0.001
Female, n (%)	2317 (55.4)	89,065 (42.2)	< 0.001	43,147 (56.1)	0.380	63,082 (58.1)	< 0.001
Region, n (%)							
Midwest	1246 (29.8)	50,981 (24.2)	< 0.001	19,431 (25.3)	< 0.001	25,509 (23.5)	< 0.001
Northeast	490 (11.7)	29,609 (14.0)	< 0.001	12,444 (16.2)	< 0.001	13,212 (12.2)	0.375
South	1823 (43.6)	87,708 (41.6)	0.009	30,204 (39.3)	< 0.001	46,713 (43.0)	0.482
West	622 (14.9)	42,392 (20.1)	< 0.001	14,708 (19.1)	< 0.001	22,890 (21.1)	< 0.001
Race, n (%)							
Caucasian	3823 (91.4)	192,028 (91.0)	0.381	68,540 (89.1)	< 0.001	96,851 (89.2)	< 0.001
Black	191 (4.6)	8522 (4.0)	0.087	4222 (5.5)	0.010	6301 (5.8)	0.001
Other/unknown	169 (4.0)	10,464 (5.0)	0.007	4173 (5.4)	< 0.001	5401 (5.0)	0.006
Follow up length in months, mean (SD)	19.4 (12.8)	28.8 (16.1)	< 0.001	24.9 (15.7)	< 0.001	31.4 (15.9)	< 0.001
Elixhauser Comorbidity Index during baseline, mean (SD)	3.5 (2.9)	2.7 (2.6)	< 0.001	2.8 (2.6)	< 0.001	2.8 (2.7)	< 0.001
Clinical comorbid conditions during baseline, n (%)							
Hypertension	2712 (64.8)	121,668 (57.7)	< 0.001	44,328 (57.6)	< 0.001	63,459 (58.5)	< 0.001
Osteoarthritis	1536 (36.7)	55,331 (26.2)	< 0.001	21,128 (27.5)	< 0.001	30,502 (28.1)	< 0.001
Intervertebral disc disorders	1463 (35.0)	58,418 (27.7)	< 0.001	22,884 (29.7)	< 0.001	33,471 (30.8)	< 0.001
Diabetes	1187 (28.4)	51,456 (24.4)	< 0.001	18,313 (23.8)	< 0.001	25,866 (23.8)	< 0.001
Obesity	674 (16.1)	27,836 (13.2)	< 0.001	11,309 (14.7)	0.012	16,056 (14.8)	0.018
Chronic obstructive pulmonary disease	628 (15.0)	19,259 (9.1)	< 0.001	6926 (9.0)	< 0.001	10,895 (10.0)	< 0.001
Atrial fibrillation	608 (14.5)	22,234 (10.5)	< 0.001	7068 (9.2)	< 0.001	9596 (8.8)	< 0.001
Osteoporosis	548 (13.1)	14,647 (6.9)	< 0.001	7584 (9.9)	< 0.001	11,063 (10.2)	< 0.001
Lumbar spondylolisthesis	532 (12.7)	22,682 (10.7)	< 0.001	22,709 (29.5)	< 0.001	29,419 (27.1)	< 0.001

Table 1 continued

Demographics at index diagnosis	ISD ($n = 4183$)	Decomp alone ($n = 211,014$)		Decom + fusion ($n = 76,935$)		Fusion ($n = 108,553$)	
	n/mean (%/SD)	*n*/mean (%/SD)	*p* value vs. ISD	*n*/mean (%/SD)	*p* value vs. ISD	*n*/mean (%/SD)	*p* value vs. ISD
Congestive heart failure	457 (10.9)	13,365 (6.3)	< 0.001	4621 (6.0)	< 0.001	6379 (5.9)	< 0.001
Asthma	392 (9.4)	12,850 (6.1)	< 0.001	5678 (7.4)	< 0.001	8659 (8.0)	0.001
Diabetic neuropathy	296 (7.1)	11,843 (5.6)	< 0.001	4400 (5.7)	< 0.001	6135 (5.7)	< 0.001
Back syndrome	170 (4.1)	4514 (2.1)	< 0.001	2601 (3.4)	0.018	4963 (4.6)	0.122
Spondylolisthesis in other spinal regions	155 (3.7)	8375 (4.0)	0.387	8403 (10.9)	< 0.001	11,587 (10.7)	< 0.001
Vascular claudication	83 (2.0)	3007 (1.4)	0.003	872 (1.1)	< 0.001	1221 (1.1)	< 0.001
Closed hip, vertebral, lumbar or spinal fracture	58 (1.4)	2938 (1.4)	0.975	1033 (1.3)	0.810	1883 (1.7)	0.089

ISD stand-alone interspinous device, *SD* standard deviation

19.4 months for the ISD patients and 24.9–-31.4 months for the decompression and/or fusion patients. Compared with the decompression and/or fusion patients, patients who received ISD were older ($p < 0.0001$ vs. all three surgery groups) with a higher comorbidity burden as evidenced by a higher Elixhauser score ($p < 0.0001$ vs. all groups) and increased prevalence of several comorbidities including hypertension, osteoarthritis, diabetes, obesity, chronic obstructive pulmonary disease, atrial fibrillation, osteoporosis, and congestive heart failure (Table 1).

Subsequent Spinal Surgeries

Adjusted Cox models revealed that patients in the surgery cohorts were 1.5–2.5 times more likely to have a subsequent fusion [hazard ratio (HR) 95% confidence intervals (CI): 1.49 (1.17, 1.89)–2.54 (2.00, 3.23), all $p \leq 0.001$] compared to those who had been treated with an ISD (Table 2). The patients in the surgery cohorts were also more likely to have undergone other lumbar spine surgeries [HR (CI): 3.05 (2.18, 4.27)–5.72 (4.08, 8.02), all $p < 0.001$], but less likely to have a drug delivery implant [HR (CI): 0.41 (0.28, 0.61)–0.44 (0.30, 0.66), all $p < 0.001$]. The patients in the decompression without fusion cohort was 1.3 times more likely to have a subsequent decompression [HR (CI): 1.26 (1.05, 1.50), $p = 0.011$], but those in the fusion cohorts were less likely to have had a subsequent decompression [HR (CI): 0.47 (0.39, 0.57)–0.56 (0.47, 0.67), $p < 0.001$] compared to patients who received an ISD. Patients in the fusion cohorts were also 6.4–6.5 times more likely to have undergone a subsequent surgery for removal of an implant [HR (CI): 6.37 (4.64, 8.73)–6.54 (4.77–8.96), $p < 0.001$].

Among patients with ≥ 3 months of follow-up, the re-operation rates at 3 months were 1.7%, 1.6%, and 2.5% for the decompression, decompression with fusion, and fusion cohorts, respectively, which were significantly higher than the 0.6% re-operation rate observed for the ISD cohort (all $p < 0.001$) (Table 3). Adjusted logistic regression confirmed the patients in the decompression cohorts (with or without fusion) were 2.6–2.8 times more likely to have a re-operation at 3 months than those in the ISD cohort [odds ratio (OR) (CI): 2.62 (1.74, 3.93)–2.77 (1.85, 4.15), all $p < 0.001$], whereas the re-operation rate for the fusion cohort was 3.9 times greater [OR (CI): 3.90 (2.60, 5.84), $p < 0.001$] (Fig. 1). Full model results are presented in Supplementary Material Table 2.

Table 2 Incidence rate and hazard ratio of subsequent spinal surgeries during follow-up

	Unadjusted incidence rate per 10,000 person-years				Estimated hazard ratio from adjusted cox model (reference = ISD)					
	ISD	Decomp alone	Decomp + fusion	Fusion alone	Decomp alone		Decomp + fusion		Fusion alone	
					HR (95% CI)	*p*	HR (95% CI)	*p*	HR (95% CI)	*p*
Subsequent lumbar spine surgical intervention										
Open decompression alone	187.6	227.5	84.4	97.2	1.26 (1.05, 1.50)	0.011	0.47 (0.39, 0.57)	< 0.001	0.56 (0.47, 0.67)	< 0.001
Open decompression with fusion	107.6	93.2	125.7	110.9	0.80 (0.64, 1.02)	0.068	1.06 (0.84, 1.34)	0.623	0.91 (0.72, 1.15)	0.436
Fusion alone	100.4	142.8	179.0	257.3	1.49 (1.17, 1.89)	0.001	1.78 (1.40, 2.27)	< 0.001	2.54 (2.00, 3.23)	< 0.001
MILD	28.2	[a]	[a]	[a]	N/A	N/A	N/A	N/A	N/A	N/A
ISD	257.4	[a]	[a]	[a]	N/A	N/A	N/A	N/A	N/A	N/A
Spacer with open decompression	[a]	[a]	[a]	[a]	N/A	N/A	N/A	N/A	N/A	N/A
Other surgical intervention										
Removal of an implant in the spine region	58.1	30.5	315.7	300.2	0.69 (0.50, 0.94)	0.021	6.37 (4.64, 8.73)	< 0.001	6.54 (4.77, 8.96)	< 0.001
Drug delivery implant	38.7	14.2	15.5	16.6	0.41 (0.28, 0.61)	< 0.001	0.43 (0.29, 0.64)	< 0.001	0.44 (0.30, 0.66)	< 0.001
Spinal cord stimulation	206.0	50.4	44.6	50.0	0.26 (0.22, 0.31)	< 0.001	0.23 (0.19, 0.28)	< 0.001	0.24 (0.20, 0.29)	< 0.001
Other lumbar spine surgeries[b]	50.5	103.4	205.5	161.1	3.05 (2.18, 4.27)	< 0.001	5.72 (4.08, 8.02)	< 0.001	5.14 (3.66, 7.20)	< 0.001

CI confidence interval, *Decomp* decompression, *ISD* stand-alone interspinous device, *MILD* minimally invasive lumbar decompression, *N/A* not applicable, *HR* Hazard ratio

[a]The following events had fewer than 11 patients and therefore cannot be displayed per the data use agreement with the Centers for Medicare and Medicaid Services

[b]Other lumbar spine surgeries include disc procedure, endoscopic decompression, repair of dura or cerebrospinal fluid leak, vertebral excision/corpectomy, discectomy, vertebroplasty, and kyphoplasty

Table 3 Short-term safety outcomes

	ISD $n = 4183$		Decomp alone $n = 211{,}014$			Decomp + fusion $n = 76{,}935$			Fusion $n = 108{,}533$		
	n	%	*n*	%	p^b	*n*	%	p^b	*n*	%	p^b
Life threatening events within 30 days of index procedure	132	3.2%	13,196	6.3%	< 0.001	10,400	13.5%	< 0.001	15,552	14.3%	< 0.001
Pneumonia	[a]	N/A	19	0.0%	N/A	12	0.0%	N/A	28	0.0%	N/A
Acute myocardial infarction	[a]	N/A	848	0.4%	N/A	504	0.7%	N/A	741	0.7%	N/A
Cardiac arrest	[a]	N/A	126	0.1%	N/A	97	0.1%	N/A	147	0.1%	N/A
Pulmonary embolism	11	0.3%	1053	0.5%	0.031	750	1.0%	< 0.001	1097	1.0%	< 0.001
Deep venous thrombosis	[a]	N/A	550	0.3%	N/A	414	0.5%	N/A	656	0.6%	N/A
Ischemic stroke	[a]	N/A	668	0.3%	N/A	377	0.5%	N/A	521	0.5%	N/A
Sepsis	[a]	N/A	680	0.3%	N/A	465	0.6%	N/A	673	0.6%	N/A
Blood transfusion indication of blood loss	17	0.4%	1800	0.9%	0.002	5119	6.7%	< 0.001	7438	6.9%	< 0.001
Inpatient re-admission	102	2.4%	10,189	4.8%	< 0.001	4,971	6.5%	< 0.001	7748	7.1%	< 0.001
Patients with ≥ 3 months of follow-up	$n = 3850$		$n = 200{,}409$		N/A	$n = 71{,}715$		N/A	$n = 104{,}014$		N/A
90-day complication related- re-admission	51	1.3%	4351	2.2%	< 0.001	2664	3.7%	< 0.001	4117	4.0%	< 0.001
90-day re-operation	24	0.6%	3432	1.7%	< 0.001	1169	1.6%	< 0.001	2567	2.5%	< 0.001

Decomp decompression, *ISD* stand-alone interspinous device

[a] $n < 11$ patients cannot be displayed per the data use agreement with the Centers for Medicare and Medicaid Services

[b] Versus ISD

Safety Outcomes

Adjusted logistic regression showed patients that received decompression and fusion were 2.4–6.4 times more likely to experience a life-threatening complication within 30 days compared with those who received ISD [OR (CI): 2.42 (2.03, 2.88)–6.36 (5.33, 7.57), all $p < 0.001$] (Fig. 1), driven primarily by re-admission and blood loss associated with fusion procedures (Table 3). The long-term unadjusted incidence rates of any complication (per 10,000 person-years) were 280.3 for ISD versus 264.4 for decompression alone, 489.1 for decompression with fusion, and 469.6 for fusion alone. The rates of closed/collapsed lumbar vertebra fractures including those specifically involving the spinous process fracture were 94.2, 98.8, 173.3, and 174.5 for ISD, decompression alone and with fusion, and fusion alone, respectively. Patients in the decompression and fusion cohorts were 1.3–2.4 times more likely to have a long-term complication [OR (CI): 1.31 (1.13, 1.52)–2.38 (2.05, 2.75), all $p < 0.001$] and 1.6–3.0 times more likely to have sustained a spinous process fracture [OR (CI): 1.61 (1.25, 2.06)–3.03 (2.36, 3.89), all $p < 0.001$] (Fig. 1).

The rates of re-admission due to any complication at 3 months was 1.3% for the ISD cohort, which was lower than that of the

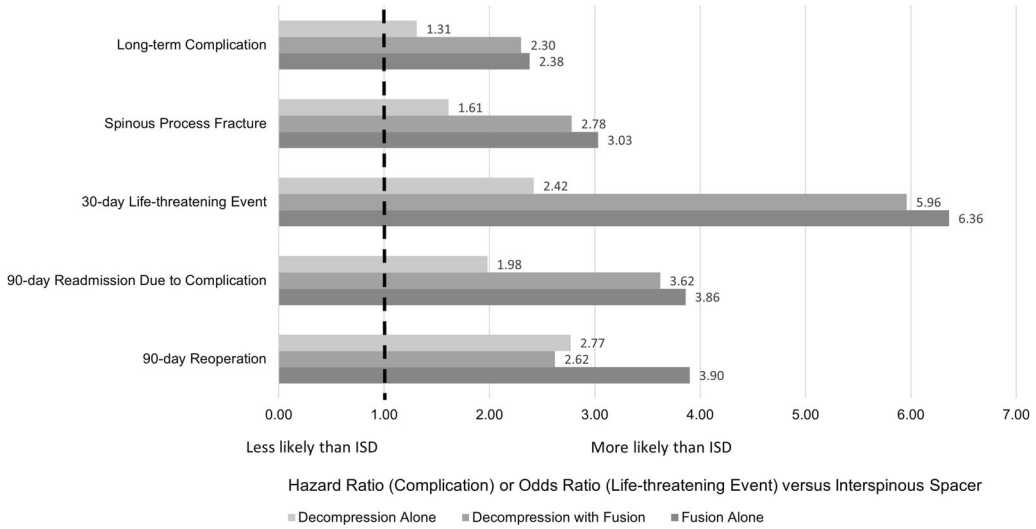

Fig. 1 Adjusted hazard ratios of a long-term complication and a spinous process fracture and odds ratios of a life-threatening event, a re-admission, and a re-operation compared to ISD. *ISD* stand-alone interspinous device

surgery cohorts (2.2% for decompression, 3.7% for decompression with fusion, and 4.0% for fusion, Table 3). Adjusted logistic regression also revealed that compared to ISD cohort, patients who received decompression were 2.0 times [OR (CI): 1.98 (1.50, 2.62), $p < 0.001$] and those receiving decompression with fusion and only fusion were 3.6–3.9 times [OR (CI): 3.62 (2.73, 4.79)–3.86 (2.92, 5.10), all $p < 0.001$] more likely to have a re-admission due to a complication (Fig. 1; Supplementary Material Table 3).

Cost Outcomes

Adjusted mean index costs [standard deviation (SD)] ranged from \$7001 (\$1105) for decompression alone to \$33,868 (\$5392) for fusion alone, with ISD [\$12,742 (\$2069)] and decompression plus fusion [\$32,488 (\$5102)] falling within that range. The average 1-year costs of decompression plus fusion [\$17,039 (\$8762)] and fusion alone [\$18,506 (\$9534)] were statistically significantly higher than that recorded for the ISD cohort [\$14,232 (\$7681)] (both $p < 0.001$, Table 4 and Supplementary Material Table 4); however, the average 1-year costs for patients who received decompression alone [\$12,344 (\$6200)] were not statistically different from those who received ISD ($p = 0.760$). A similar pattern was also observed for the 3-year costs. The complication-related costs for the first year were lowest in ISD patients [mean \$655 (\$282)] and significantly higher for all three surgical cohorts (means ranging from \$1487 (\$714) to \$7888 (\$4051), $p < 0.001$].

DISCUSSION

Compared with patients who received open surgery (i.e., decompression and/or fusion) as a treatment for symptomatic LSS, patients who received ISD were less likely to receive a subsequent fusion or other lumbar spine operation, but were more likely to be treated with an ISD/MILD procedure. Not surprisingly, both short- and long-term complications were more frequently observed among the open surgery cohorts. The costs of the index procedure were highest for surgeries involving a fusion and lowest for decompression alone. Placement of an ISD was associated with lower 1-year complication-related and 3-year all-cause costs. Given the large sample size and geographically diverse sample over a lengthy follow-up period, these results represent meaningful findings, given the heterogeneity observed in the approaches adopted by clinicians to treat LSS.

Table 4 Adjusted healthcare costs

	ISD	Decomp alone	p^a	Decomp + fusion	p^a	Fusion alone	p^a
Index event							
n	4183	211,014		76,935		108,553	
Index cost	$12,742 ($2069)	$7001 ($1105)	< 0.001	$32,488 ($5102)	< 0.001	$33,868 ($5392)	< 0.001
Those with ≥ 1 year of follow-up							
n	2761	168,852		56,417		90,900	
Year 1 costs	$14, 232 ($7681)	$12,344 ($6200)	0.760	$17,039 ($8762)	< 0.001	$18,506 ($9534)	< 0.001
Those with ≥ 3 years of follow-up							
n	484	77,855		20,765		48,204	
Year 2 costs	$11,935 ($4921)	$9599 ($4088)	0.150	$10,117 ($4442)	0.408	$10,899 ($4853)	0.839
Year 3 costs	$8610 ($3690)	$9238 ($4027)	0.147	$10,100 ($4545)	0.012	$10,586 ($4812)	0.004
Total 3-year costs	$32,390 ($12,886)	$31,050 ($13,039)	0.501	$37,319 ($16,146)	< 0.001	$39,953 ($17,392)	< 0.001
Year 1 comp-related costs	$655 ($282)	$1487 ($714)	< 0.001	$6959 ($3502)	< 0.001	$7888 ($4051)	< 0.001

Cost values are mean (SD) from adjusted GLM with gamma log-link
Comp-related complication-related, *Decomp* decompression, *ISD* interspinous device
[a]Versus ISD

Few published studies in the literature have directly compared the use of ISD to lumbar decompression and/or fusion for LSS. A retrospective cohort analysis of LSS patients treated with decompression surgery with or without fusion documented 90-day re-operation and re-admission rates of 4.7% and 7.2%, respectively [26]. Similarly, a Medicare claims study of subjects who had undergone a lumbar fusion between 2005 and 2009 reported that 10.9% had a re-operation at 3 months and the re-admission rate for complications during that period was 11.1% [27]. In contrast, the current analysis revealed lower 3-month re-operation and re-admission rates for patients who received open surgery and ISD. The incidence of re-operation at 3 months was 0.6% for ISD patients, which was lower than the 1.6–2.5% observed for patients who received decompression and/or fusion surgery. These rates reflect re-operations on the same or a different level of the spine, which cannot be separated due to the lack of clinical information in claims data; thus, the true re-operation rate on the index level is at most 2.5% and may be lower if some of the re-operations were performed at a different level. Likewise, the re-admission rate due to a complication was also lower among the patients treated with an ISD (1.3%) compared to the surgery cohorts (2.2–4.0%).

Multiple systematic reviews and meta-analyses have attempted to compare decompression alone versus decompression with fusion. Chang et al. (2017) concluded that performing a concomitant fusion produced no clinical improvements relative to decompression alone over

2 years of follow-up but gave rise to a higher risk of complications, longer operative times, and greater blood loss [28]. Shen et al. (2022) evaluated a series of patients with LSS with degenerative spondylolisthesis and found the addition of a fusion resulted in similar clinical results compared to decompression alone but was associated with poorer safety outcomes [29].

The strengths of this study include the large and geographically diverse dataset with relatively lengthy follow-ups, as well as the use of multiple methods to compare the incidence and risk of various events. However, several limitations should be acknowledged, including those inherent to these types of claims analyses, such as the potential for coding or data entry errors and the omission of details not needed to justify payment. For instance, diagnosis codes identified in claims data lack the clinical information such as the severity of LSS or postoperative complications, so the severity of LSS at the time of index procedure could not be determined, nor could outcomes be examined by severity. Additionally, the inability of claims to capture imaging data or patient-reported outcomes, such as visual or numeric pain scores and the Zurich Claudication Questionnaire, make it impossible to assess the efficacy of the procedure. Furthermore, this analysis is limited to individuals with Medicare coverage, so they may not be generalizable to other patients; however, this may be less of a concern because the vast majority of symptomatic LSS cases are adults aged 65 years and older who generally have Medicare coverage.

CONCLUSIONS

This analysis indicates that an implantation of ISD was safer than decompression and/or fusion surgeries as a first surgical treatment for LSS, due to lower rates of short- and long-term complications. Patients who received an ISD had lower costs 3 years after intervention and were less likely to require a subsequent fusion when compared to patients who received an open decompression alone, open decompression with fusion, or fusion surgery. Future investigations on clinical data, opioid and pain-related medication use, and healthcare utilizations would provide additional understanding of how spinal procedures impact the healthcare system and patient outcomes.

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Compliance with Ethics Guidelines. This study does not involve human participants, so neither independent review board approval nor patient consent was obtained. We had permission to access and analyze the data used in this study through the CMS Data Use Agreement.

Data Availability. The datasets generated during and/or analyzed during the current study are not publicly available due to the CMS Data Use Agreement. 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.

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