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Review Article

Cost-effectiveness and Safety of Interspinous Process Decompression (Superion)

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Abstract

Objective. There are several treatment options for patients suffering from lumbar spinal stenosis, including surgical and conservative care. Interspinous spacer decompression using the Superion device offers a less invasive procedure for patients who fail conservative treatment before traditional decompression surgery. This review assesses the current cost-effectiveness, safety, and performance of lumbar spinal stenosis treatment modalities compared with the Superion interspinous spacer procedure. **Methods.** EMBASE and PubMed were searched to find studies reporting on the cost-effectiveness, safety, and performance of conservative treatment, including medicinal treatments, epidural injections, physical therapy, and alternative methods, as well as surgical treatment, including laminectomy, laminectomy with fusion, and interspinous spacer decompression. Results were supplemented with manual searches. **Results.** Despite substantial costs, persistent conservative treatment (>12 weeks) of lumbar spinal stenosis showed only minimal improvement in pain and functionality. When conservative treatment fails, surgery is more effective than continuing conservative treatment. Lumbar laminectomy with fusion has considerably greater cost than laminectomy alone, as the length of hospital stay increases, the costs for implants are substantial, and complications increase. Although laminectomy and the Superion have comparable outcomes, the Superion implant is positioned percutaneously. This approach may minimize the direct and indirect costs of outpatient rehabilitation and absenteeism, respectively. **Conclusions.** Superion interspinous lumbar decompression is a minimally invasive procedure for patients with lumbar spinal stenosis who have failed conservative treatment. Compared with extending conservative treatment or traditional spinal surgery, interspinous lumbar decompression reduces the direct and indirect costs associated with lumbar spinal stenosis.

Key Words: Lumbar Spinal Stenosis; Interspinous Spacers; Epidural Steroids Injections; Neurogenic Claudication; Laminectomy; Interspinous Lumbar Decompression

Introduction

Lumbar spinal stenosis is defined as narrowing of the spinal canal causing pressure on spinal nerve roots and less commonly the spinal cord. Spinal stenosis can occur at three sites: the central canal, lateral recess, and neuroforamen. Narrowing of the spinal canal manifests as a degenerative process that occurs slowly over time.

The pathophysiology of lumbar spinal stenosis often begins with lumbar degenerative disc disease, causing disc space narrowing, thereby increasing motion on facet joints with resulting facet joint arthropathy, as well as increased stress on the ligamentum flavum, causing ligamentum flavum infolding. Disc degeneration may lead to lumbar disc protrusions. Together, these changes crowd the spinal canal anteriorly, laterally, and posteriorly. This may result in compression of the spinal canal and/or spinal nerve roots.

Lumbar spinal stenosis (LSS) accounts for one of the most commonly diagnosed spinal disorders in elderly patients, with at least 200,000 adults in the United States having symptoms that require treatment; however, exact numbers are unknown [1]. The Framingham Study [2] reported a prevalence of absolute LSS of 47.2% for patients aged 60–69 years, with this number increasing with age.

Patients with LSS may experience symptoms of neurogenic claudication, including pain or discomfort that radiates to the lower leg, thigh, and/or buttocks while walking. Patients with more pronounced LSS may also develop lower extremity weakness, muscle cramping, numbness, and imbalance. Patients typically report symptoms of neurogenic claudication that abate with sitting down or leaning forward, referred to as the "shopping cart sign." When spinal stenosis predominantly affects the neuroforamen or lateral recess, patients may report radicular pain following a specific dermatomal distribution.

For diagnosis of LSS, magnetic resonance imaging (MRI) or computed tomography (CT) myelogram studies are required, as physical examination and x-ray imaging do not have a high enough sensitivity or specificity. MRI is the most common imaging modality to assess LSS [3].

There are several treatment options for patients suffering from LSS, including surgical and nonsurgical care. Conservative, nonsurgical treatment consists of medication management, epidural steroid injections (ESIs), and physical therapy (PT). Surgical options include lumbar laminectomy and lumbar laminectomy with fusion. Historically, patients who fail conservative treatment would proceed to surgical intervention.

Interspinous spacer decompression offers a less invasive procedure for patients who fail conservative treatment before traditional, more invasive surgery. This review assesses these treatment modalities to investigate the current cost-effectiveness, safety, and performance of these modalities compared with the interspinous spacer procedure. See Table 1 for an overview of benefits and risks of the treatment modalities and Table 2 for a tabulation of costs associated with the treatment modalities.

Conservative Treatments

Nonsurgical treatments, while less invasive than surgery, can incur substantial costs for patients with lumbar spinal stenosis. These treatments include medication management, ESIs, and PT. Aichmair et al. [4] found the mean costs for patients treated with conservative treatment to be $14,183 USD in a study evaluating a cohort of 264 patients. Of all the patients in this study, 0.8% of patients with LSS did not respond to nonsurgical treatment, and surgical intervention was needed. Despite substantial costs, conservative treatment of lumbar spinal stenosis showed only minimal improvement in pain and functionality [5].

Adogwa et al. [5] investigated the cost and utilization of long-term maximal nonoperative therapy over five years in patients suffering LSS. The study included 4,133 patients with lumbar stenosis or spondylolisthesis who were continuously active within the insurance system for at least five years before the lumbar operation. Of these patients, 66.7% used nonsteroidal anti-inflammatory drugs (NSAIDs), 84.4% used opioids, 58.6% used muscle relaxants, 65.5% received lumbar ESIs, 66.6% attended PT, and 24.9% received chiropractic treatment. Adogwa et al. [5] reported 7,466 PT, 8,258 emergency department (ED), and 20,197 chiropractor visit units billed before index spinal fusion in 4,133 patients. This accounted for a total cost of, respectively, $438,338 USD, $602,909 USD, and $528,697 USD for PT, ED, and chiropractor visits. The normalized total annual dollars spent on medical therapy per patient was, respectively, $81.19 USD, $706.32 USD, and $292.94 USD in 2015 for PT, ED visits, and chiropractor visits.

Adogwa et al. [5] also found that the use of opioids in patients suffering from LSS doubled between 2007 and 2015. These are alarming numbers, considering the opioid epidemic in the United States [6]. Peters et al. [7] found that hospitalization due to overdose of patients taking opioids for chronic pain contributes to a large part of opioid overdose hospitalizations in the United States (24.5% in 2013). There are few to no data that demonstrate efficacy of opioids for lumbar spinal stenosis. Therefore, long-term prescription of opioids should be minimized in patients with spinal stenosis. Depending on the type of opioid prescribed, medication costs can be substantial, with the average cost of opioids in chronic lower back pain being $2,508 USD per year for opioids alone and up to $30,994 USD when direct costs (medication and hospital costs) and indirect costs (productivity loss, e.g., missed work days) are considered [8]. A study by Ashaye et al. [9] reported annual prescription costs between £3 and £4,844 for opioids used for chronic musculoskeletal pain, whereas Shah et al. [10] reported an average annual cost of $8,982.28 USD for patients treated for chronic back pain with opioids.

NSAIDs, on the other hand, are both less expensive and pose substantially fewer addictive risks. However, chronic use of NSAIDs can cause gastrointestinal bleeds, liver failure, and renal compromise. These may be life-threatening and can increase health care costs dramatically. Shah et al. [10] found average annual costs of $6,137.41 USD for patients treated with NSAIDs for chronic back pain, which was slightly less than for opioids. They also reported a cost-effectiveness slightly in favor of NSAIDs compared with opioids (QALY of 0.661 and 0.663 for NSAIDs and opioids, respectively).

Neuropathic meds are expensive and are used as palliative treatment and require long-term usage. Muscle relaxants and anxiolytic medications also are occasionally

Table 1. Summary of benefits and risks of treatment modalities for lumbar spinal stenosis

Treatment Modality	Benefits	Risks
Conservative treatment		
Physical therapy	Noninvasive Low costs	Less effective when treatment fails
Chiropractor	Noninvasive Low costs	Less effective when treatment fails
NSAIDS	Noninvasive	Gastrointestinal bleeds
	Low costs	Liver failure
	Nonaddictive	Renal compromise
Opioids	Noninvasive Low costs	Highly addictive Overdose
Neuropathics	Noninvasive	High costs
Epidural steroid injections	Short-term effective	Long-term effectiveness not established Often need more than 1 injection
Surgical treatment		
Lumbar laminectomy	Resolves the stenosis	Complication associated with surgery Reinterventions High costs Long rehabilitation time
Lumbar laminectomy with fusion	Resolves the stenosis	Complication associated with surgery Reinterventions High costs Long rehabilitation time
Percutaneous image-guided lumbar decompression	Minimally invasive, decompression of the ligamentum flavum	Previous hardware Limited efficacy for foraminal stenosis
Interspinous spacers		
X-STOP	Minimally invasive Resolves the stenosis	No longer commercially available
Coflex	Resolves the stenosis	In addition to lumbar decompression
Superion	Minimally invasive Resolves the stenosis Less expensive than other surgical treatments Short rehabilitation time	Complications associated with minimally invasive surgery

Table 2. Summary of costs per treatment modality

Treatment Modality	Costs, $ USD	Interpretation of Costs
Conservative treatment		
Physical therapy	4,010	Per patient
Emergency department visits	706	Annual per patient
Chiropractor	293	Annual per patient
NSAIDs	6,137	Annual costs
Opioids	2508	Direct annual costs per patient
	30,994	Indirect annual costs per patient
Neuropathics	7,747	Over 2 years per patient, incl. indirect costs
Epidural steroid injections	2,961	1-year improvement in QALY
Alternative treatments	33.9 billion	Overall costs USA in 2007
Surgical treatment		
Lumbar laminectomy	9,349	Direct costs surgery
	23,724	Overall hospital costs
Lumbar laminectomy with fusion	28,029	Costs after 1 year
	58,511	Simple fusion incl. total hospital costs
	80,088	Complex fusion incl. total hospital costs
Revision surgery after fusion	49,431	Surgery costs, outpatient resources, indirect costs
Interspinous spacers		
X-STOP	9,757	Costs after 2-year follow-up
Superion	13,947	Surgery costs

NSAID = nonsteroidal anti-inflammatory drug; QALY = quality-adjusted life-year.

prescribed to help with symptoms of muscle spasm, but they are costly and can increase the risk of falls, which can also substantially increase health care costs. Parker et al. [11] reported that the overall medical management costs for LSS were $7,747 USD over two years, including indirect costs. There was a significant improvement in back pain and physical disability; however, there was no improvement in mental and physical quality of life or depression scores. Therefore, from a societal and payer perspective, medical management was associated with low effectiveness and high cost, resulting in low value.

PT is commonly described as a treatment method for LSS; however, little evidence is available that reports the long-term effectiveness of PT [12–16]. Adogwa et al. [5] showed the average cost per patient utilizing therapy to be $4,010 USD. Sixty-seven percent of patients with LSS undergo PT, mostly combined with other medical management [5]. Patients typically require four to six weeks of PT, attending two to three times a week. Patients undergoing PT often have additional durable medical equipment (DME) costs such as lumbosacral orthoses, transcutaneous electrical nerve stimulation units, and electronic stimulation units. Patients' failure in compliance with continuing to do home exercises after being discharged may also account for suboptimal outcomes [14]. As a result, patients frequently repeat PT yearly, further increasing costs.

ESIs are the most commonly performed nonsurgical spinal procedure, with 65.5% of patients with lumbar spinal stenosis undergoing at least one ESI. Adogwa et al. [5] reported 18,494 ESIs in a subgroup of adults with a degenerative spinal diagnosis who underwent an index one-, two-, or three-level decompression and fusion between 2007 and 2016 and were continuously active in the Humana insurance system for five or more years before index surgery. However, there are few data demonstrating long-term efficacy. Manchikanti et al. [17] showed that ESIs provided short-term relief of low back and lower extremity pain for patients with LSS; however, less evidence is available for long-term efficacy. Bresnahan et al. [18] also showed a short-term improvement after ESI; however, these effects diminished over time. In addition, costs for ESIs both are substantial and vary considerably depending on the site of service, for example, physician's office, ambulatory surgery center, or hospital outpatient department. In 2010, the average reimbursement for an ESI was $637 USD. As many patients require more than one ESI, Aichmair et al. [4] reported the average cost for a successful ESI to be $2,105 USD. In this study, after conservative treatment including ESIs, 72.4% of patients ultimately required surgery. Manchikanti et al. [19] reported the total cost for one-year improvement of quality of life to be $2,961 USD for the use of ESI, when other conservative treatments failed.

Rarely, ESIs have complications, including dural leaks, significant elevations in blood sugars in diabetics that cause hospitalizations, and severe reactions to contrast dye. These complications can further increase costs. Cohen et al. [20] report that despite the lack of comparative effectiveness studies, consensus guidelines recommend that the number of ESIs be tailored based on individual response. This also further potentially increases costs depending on provider protocols.

Alternative treatments have ballooned into a multi-billion-dollar industry. In 2007, a total of $33.9 billion USD was spent out of the pocket on visits to complementary and alternative medicine practitioners and purchases of products, classes, and materials [21]. Despite minimal data demonstrating efficacy, patients with LSS spend considerable money out of pocket for medical massage, acupuncture, Chinese medicine, and over-the-counter DME. These costs are hard to objectively measure given that a substantial proportion of these costs are paid out of pocket.

Nonsurgical treatment may seem preferable but may be less effective in patients whose symptoms have not resolved within 12 weeks [15]. Moreover, when conservative treatment fails, surgery is more effective than continuing conservative treatment [22]. Long-term medical costs for nonsurgical treatments may even surpass one-time costs for surgical treatments. When patients have chronic pain from LSS, they also require ongoing imaging studies like MRIs, CT myelograms, lab work, etc. These additional diagnostic tests can be performed as often as yearly or every couple of years depending on providers' preferences.

Surgical treatments, on the other hand, have additional costs associated with risk of complications, including costs of repeat operations and aftercare. Less invasive procedures such as interspinous spacers offer a less costly treatment option with significantly less risk to the patient. Moreover, community costs may be lower, as patients' recovery is considerably shorter compared with laminectomy and laminectomy with fusion.

Surgical Treatment

The purpose of surgery in patients with lumbar spinal stenosis is to decompress the spinal canal while maintaining spinal stability. Although fusion adds additional costs and risks to the patient, sometimes it is necessary in cases of unstable spondylolisthesis or multilevel decompression, where the surgery itself can create instability. Before surgical treatment, patients undergo additional diagnostic tests, including electrocardiogram, chest x-ray, lab work, and in some cases costly diagnostic cardiac tests, to ensure patient safety to withstand the stress of the operation itself. Harrop et al. [23] reported that surgical treatments had a greater overall financial cost than nonoperative care; $26,035 vs $5,883, respectively, in patients with lumbar spinal stenosis. The cost for surgical intervention does not include costs not directly related to the surgery, including follow-up care, care at skilled nursing facilities, PT, costs for revision surgery, etc.

The average hospital charge for a lumbar laminectomy as reported by Deyo et al. [24] was $23,724 USD, with an average length of stay of 2.7 days, cardiopulmonary complication rate of 2.1%, and 30-day mortality of 0.3%. After surgery, 9.6% of patients were discharged to nursing homes and 7.8% to rehabilitation homes. Burnett et al. [25], in 2010, reported laminectomy costs of $9,349.03 USD.

Lumbar laminectomy with fusion has considerably greater cost than laminectomy alone as the length of hospital stay increases, the costs for implants are substantial, and complications also increase. Fujimori et al. [26] reported that the cost-effectiveness of posterior lumbar interbody fusion one year after surgery was $28,029 USD, resulting in a cost per QALY of $26,975 USD. This is regarded as a cost-effective health care intervention. Deyo et al. [24] reported a cardiopulmonary and stroke complication rate for decompression with complex fusion of 5.2% and 4.7% for simple fusion. The 30-day mortality was 0.6% and 0.5% for complex and simple fusion. Length of hospital stay was 4.6 and 4.3, respectively. Hospital charges for complex and simple fusion were $80,888 USD and $58,511 USD; 19.9% and 20.7% were discharged to nursing homes, and 13.0% and 11.1% were discharged to rehabilitation homes for complex and simple fusion, respectively. These numbers do not include the significant costs of skilled nursing facilities, postop PT, postop physician office visits, postop pain medications, and additional diagnostic tests such as x-rays that evaluate implant position.

Between 8% and 10% of patients per year who undergo spinal decompression ultimately require a revision surgery [27]. Fusion at the index procedure does not protect against subsequent readmission. Risks of revision surgery increase exponentially depending on the number of levels involved. Adogwa et al. [28] reported the cost of same-level recurrence of lumbar spinal stenosis, including two-year related medical resource utilization, missed work, and health state values. The mean interval between surgery and revision surgery was four years. A total of 0.84 QALYs were gained over two years. The cost of revision fusion was $49,431 USD (surgery cost: $21,060 USD; outpatient resource utilization: $9,748 USD [health care visits, diagnostic imaging, medications, injections]; indirect costs: $18,623 USD [missed work]). Revision decompression and extension of fusion were associated with a mean two-year cost per QALY of $58,846 USD.

Andersen et al. [29] reported the spine-related health care use of patients after laminectomy and fusion. In the longer term, it normalizes to a level that is lower than before surgery. The general health care use of these patients compares well to that of the general population in terms of specialized care, but not in terms of primary care, where the fused patients end up consuming relatively more care.

Percutaneous lumbar decompression is also a surgical treatment method for treating LSS. It may reduce cost and hospitalization duration for patients. However, there were limited data available on the cost-effectiveness on percutaneous lumbar decompression alone. Percutaneous lumbar decompression may be combined with placement of interspinous spacers.

Interspinous Spacer

Interspinous spacers originated with the X-STOP (Medtronic, Minneapolis, MN, USA) implant, a novel procedure to indirectly decompress the lumbar spine by placing an implant between spinous processes. It was designed to create and maintain distraction of the spinous process at the level of treatment. Early studies showed promising results [30,31]; however, long-term outcomes reported higher complication rates [32, 33]. Data on the cost-effectiveness of X-STOP are not conclusive. Skidmore et al. [34] reported lower costs for X-STOP compared with laminectomy ($7,568 USD vs $22,903 USD), whereas Burnett et al. [25] reported the X-STOP to be less cost-effective than laminectomy, considering a two-year follow-up, with a mean cost of, respectively, $9,757 USD and $9,349 USD. For various reasons, including device migration and suboptimal long-term data, the X-STOP implant is no longer commercially available.

Current options for interspinous spacers include the Superion (Vertiflex, Carlsbad, CA, USA) and Coflex (Paradigm Spine, Wurmlingen, Germany) implants and are both Food and Drug Administration (FDA) approved for mild to moderate lumbar spinal stenosis. Both implants have dynamic stability without rigidity of pedicle screw instrumentation. The Superion implant is ideally performed with the patient in a flexed position using a Wilson frame and essentially acts as an extension blocker. Coflex demonstrates improved outcomes at three-year follow-up compared with traditional decompression and fusion. In many cases, a lumbar decompression is completed before placing the Coflex device. An advantage of the Superion implant is its percutaneous placement, minimizing tissue disruption of the spinal anatomy [35]. Lauryssen et al. [36] compared Superion with decompressive laminectomy. Both treatments provide effective and durable symptom relief of neurogenic claudication symptoms. Superion patients revealed improvement in back and leg pain severity after 12 and 24 months compared with laminectomy patients. Patients with Superion implants showed comparable disability, physical function, and symptoms outcomes and had a slightly higher improvement by outcome measurement compared with laminectomy. Superion is minimally invasive, with a shorter procedure time, significantly less blood loss, and significantly fewer complications. Therefore, rehabilitation is shorter, with patients being able to return to a higher level of function in a shorter period of time compared with laminectomy.

Loguidice et al. [37] reported data from two unpublished studies. One study reported improvement of back function (64% improvement) at one-year follow-up (N = 121). Extremity pain decreased from 6.6 to 2.8 (53% overall improvement). Axial pain improved from 6.9 to 3.4 (49% improvement), and Physical Composite Score (PCS) and Mental Composite Score (MCS) improved by 41% and 22%, respectively. One patient underwent revision, and four patients had a device explant (0.8% and 3.3%, respectively). The second study reported the two-year post-treatment results of 53 patients. Extremity pain decreased from 8.7 to 4.1. This was an improvement of 54%. Axial pain decreased from 8.9 to 4.1 (54%). The Zurich Claudication Questionnaire (ZCQ) symptom severity score improved by 43%, and physical function improved by 44%. Back function improved by 50%, and PCS and MCS each showed improvement of 40%. No device infection, breakage migration, or pull-out was observed. Two (3.8%) devices were explanted.

Miller et al. [31] showed a ZCQ score improvement in 30% of the patients treated with Superion (N = 80), and physical function increased by 32%. A total of 75% of the patients achieved at least two of the three ZCQ clinical success criteria at six months. Axial pain decreased from 55 mm to 22 mm at six months. Extremity pain decreased from 61 mm to 18 mm at six months, and back function improved from 38% to 21%. Seven complications were reported through six months; four device explants were due to persistent pain and two to revisions (foraminotomy and a left-sided decompression with the device left in situ). One spinal process fracture was noted in one subject. Nunley et al. [38] reported similar outcomes when evaluating the five-year clinical outcome for Superion from a randomized controlled FDA noninferiority trial. They showed clinical success on at least two of the three ZCQ domains in 84% (74 out of 88 patients). There were no reoperations, and there was revision of supplemental fixation in 75% of the patients.

They concluded that after five years of follow-up, IPD with a stand-alone spacer provides sustained clinical benefit.

Parker et al. [39] investigated the cost-effectiveness of conservative care, laminectomy, and Superion. Although conservative care had the lowest costs ($10,540 USD), it was also less effective (with a QALY gain of 0.06). Laminectomy and Superion had a QALY gain of, respectively, 0.29 and 0.27, whereas costs were $13,958 USD and $13,947 respectively. The indirect cost of outpatient rehabilitation, missed work days, etc., were not accounted for. Therefore, laminectomy indirect costs would be expected to be higher given the more invasive nature of the operation.

Conclusions

Superion interspinous lumbar decompression is a minimally invasive procedure for patients with lumbar spinal stenosis who have failed conservative treatment. Compared with extending conservative treatment or traditional spinal surgery, interspinous lumbar decompression reduces the direct and indirect cost associated with lumbar spinal stenosis.

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