

Effectiveness of Surgery for Degenerative Lumbar Spinal Stenosis: A Systematic Review

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ABSTRACT

Background: Lumbar spinal stenosis is common condition. Many similar treatment procedures have been described. In managing spinal stenosis surgery has expanded dramatically in the last two decades.

Aim of the study: Assess the safety and efficacy of operative and invasive therapies for people experiencing degenerative LSS.

Patients and Methods: PubMed, Embase, Web of Science, and the Cochrane library were used to find relevant clinical research. Participants in such studies were 60 years old or older and had degenerative lumbar spinal stenosis.

Results: All studies were randomized controlled trials. There were 974 patients. As regard Outcomes measures after surgical treatment, significant improvement in functional outcome and scores. Outcome of patients were measured pre and post operation by Oswestry disability index (ODI) score in 8 studies with mean pre operation score 43.7 and post operations score decreased to 26.06. Visual analog scales (VAS) were used in 3 studies with preoperation mean score 5.49 and decreased post operation to 22.5. EQ-5 D was used by 1 study and mean preoperation score was 0.29 which increased to 0.58 postoperation. SF-36 scores were used to assess patient's outcome after surgery and showed that mean SF-36 physical pre was 34.7 decreased to 33.1, mean SF-36 mental pre was 58.6 increased to 66.4 and mean SF-36 pain pre was 31.2 and changed to 34.6.

Conclusion: Surgery showed higher effectiveness and functional outcome improvement and scores among included studies. As regard Patient's satisfaction reported in three studies in 114 patients was satisfied.

Keywords: Clinical studies; Effectiveness; Lumbar spinal stenosis; Treatment strategy.

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INTRODUCTION

LSS is a prevalent degenerative spinal condition that causes leg and back pain as well as neurologic dysfunction. It includes stenotic shapes of the spinal canal, neural canal, and foraminal, and also soft tissue-induced shifts in spinal canal volume, as well as stenosis of the dural sac. People over the age of 40 are more likely to develop the condition, and it is among the most prevalent spinal lesions in those over the age of 65. The prevalence of LSS is growing year after year as the world population ages.¹

According to reports, lumbar syndrome affects almost 47% of the over-60 population and 9% of the overall population. It not only has a negative impact on patients' mobility and life quality, but it also

places a significant financial burden on the families and community. There are two types of treatments for LSS: non-invasive and surgical.²

Acupuncture, massage, and drug injections are commonly used in the former. However, for sufferers with severe degenerative LSS symptoms, spinal surgery processes like conventional decompressive laminectomy (DL), minimally invasive decompression (MID), bilateral decompression via unilateral laminotomy (BDUL), interspinous process spacer (IPS), minimally invasive percutaneous interspinous process spacer (MIPS) device, as well as posterior decompression though unilateral laminotomy (PLF) are used.³

Therefore, this study aims to conduct an NMA and a systematic review to evaluate the safety and efficacy of operative and invasive methods for people experiencing degenerative LSS.

PATIENTS AND METHODS

The protocol has been established in compliance with the Protocols for Preferred Reporting Items in Systematic Reviews and Meta-Analyses.⁴ The PROSPER Oregistration was updated with any changes that have been made to this protocol.

Inclusion criteria: We included studies that enrolled people aged 60 and up who had been diagnosed with degenerative LSS.

Exclusion criteria: All studies on patients having malignancy, vertebral fractures, trauma, inflammatory illnesses, and infection were excluded. Only subjects experiencing Meyerding grade I spondylolisthesis were involved in studies involving degenerative lumbar spinal stenosis and related spondylolisthesis. Studies with mixed populations were only considered if the data for participants having degenerative LSS could be retrieved individually or if the condition was identified in at least 80% of the participants.

Types of interventions: The researchers looked at studies that compared either surgical or invasive treatment for degenerative LSS patients. Laminectomies or laminotomies with or without fusion, IPS devices, minimally invasive surgical decompression, and corticosteroid epidural injections are a few examples of surgical decompression. The comparison group may include no therapy, standard care, simulated surgery, another active alternative, or a combination of techniques. The interventions were handled as distinct nodes in the comparison groups. To make the most of the data, we'll merge no therapy and standard treatment into a single node if there aren't enough studies to connect various therapies.

Outcome measures: The results were divided into three categories: short-term (6 months), mid-term (6–12 months), and long-term (12 months) follow-up. We performed NMA (Network Meta-Analysis) at three different time periods. The data that is most closely related to the 6 and 12 month follow-up periods was included in the primary analysis for studies that provide outcomes at various time points. Subgroup analyses were undertaken for several time periods in the long-term follow-up evaluation (e.g. 1 year, 2 years, and 5 years).

Primary outcomes which are: Physical function, as assessed by the Oswestry Disability Index (ODI), the Roland Morris Disability Questionnaire (RMDQ), the Patient-Specific Function Scale, and the Core Outcome Measures Index (COMI).²¹ Additional rating scales were considered if they were published in peer-reviewed literature. If the study provides more than one instrument, the ODI was chosen first,

then RMDQ, and finally COMI.⁵ The percentage of patients who die after randomization is used to measure all-cause mortality.

Secondary outcomes which are: The Numeric Rating Scale (NRS) and the Visual Analogue Scale (VAS) are routinely used to measure pain intensity.^{6,7} Other grading scales have also been considered if they were published in peer-reviewed publications. The intensity of pain was categorized and analyzed into 3 categories: back pain, leg pain, and overall pain. If more than one instrument is available in the study, VAS has been chosen first and NRS has been chosen second.⁵

Health-related life quality, as assessed by the 36-Item Short Form Survey (SF-36), the Euro Qol five-dimension (EQ-5D), the Nottingham health profile (NHP), and the SF-12.⁵ EQ-5D might be mapped to SF-36, NHP, and SF-12.⁸ Other instruments, as mentioned above, have also been included if they were suggested in peer-reviewed publications. The EQ-5D has been chosen first, followed by the SF36, SF-12, and NHP, when the study includes more than one tool.⁵

The patients' percentage who are satisfied with their recovery provides a global impression of recovery. Work absenteeism is evaluated by the number of sick days taken. Walking distance is used to measure mobility. The number of people taking part in a negative event, or the number of negative events in each group, is used to measure the number of adverse events. The side effects include dural tear, deep infection, nerve injury, vascular injury, and pulmonary embolus.

Therapy discontinuation owing to a negative effect, as assessed by the percentage of cases who discontinue owing to a negative impact.

Types of studies: Only randomized controlled trials were included, including parallel, cross-over, and cluster trials. Only data from before the washout phase was utilized in cross-over studies. We extracted data that had been adjusted for clustering for cluster randomized trials. If such data were not available, we extracted the original data and adjusted it for clustering.^{9,10} We omitted research that had a high risk of bias in the domain of risk of bias emerging from the randomization procedure to reduce bias.¹¹

Search strategy

Electronic searches:

The following databases were searched for published research: AMED, CINAHL, EMBASE, the Cochrane Library, and MEDLINE (This includes MEDLINEE Pub A Head of Print, In-Process, and Other Non-Indexed Citations, MEDLINE Daily, and MEDLINE). The WHO International Clinical Trials Registry Platform (<http://www.who.int/ictrp/en/>) and

the US National Institutes of Health (<https://clinicaltrials.gov/>) were searched for unpublished and continuing studies. Only English studies were considered, and there were no restrictions on publishing status. The MEDLINE search technique is available as online supplemental material.

Lists of references and other sources: All included studies' reference lists, pertinent systematic reviews and meta-analyses, and recommendations were searched for new studies that could be added.

RESULTS

The studies considered in this systematic review compared any operative or invasive treatment for people having degenerative lumbar spinal stenosis.

Type of studies: 10 studies were included all were randomized controlled trials.

Patient's characteristics: There were 995 patients in all, with an average age of 65.5 years. The male/female ratio was 514/481.

Lesion characteristics: Treated level among included studies were L1–L2(n3), L2–L3(n109), L3–L4 (n318), L4–L5(n538), L5–S1(n30), as regard surgical intervention lumbar decompression used among (487), X STOP interspinous implant (n296), undercutting laminectomy of stenotic segments, augmented with transpedicular-instrumented fusion (n50), Laminectomy (n26), Non-instrumented fusion (n7), Instrumented fusion(n12)

Outcomes measures: Outcome of patients were measured pre and post operation ODI score was used in 8 studies with mean pre operation score 44 and post operations score decreased to 25.6.

VAS was used in 3 studies with pre operation mean score 5.49 and decreased post operation to 2.25, EQ-5D was used by 1 study and mean pre operation score was 0.24 which increased to 0.51 postoperation (Table1). SF-36 scores were used to assess patient's outcome after surgery and showed that mean SF-36 physical pre was 33.17 decreased to 34.5, mean SF-36 mental pre was 58.6 increased to 66.4 and mean SF-36 pain pre was 27.9 and changed to 39.4 (Table2)

Secondary outcome: Patients' satisfaction reported in three studies in 114 patients was satisfied, mean Work absenteeism/days was 5.1 days and regard Mobility measured by walking distance mentioned in three studies Rodrigues L.C.L et al.,2021 showed that 6MWT: pre 287.16 -post 279.00 and in Slätis P et al.,2011 was Reported walking ability: 500 pre -post 1,250 and in Malmivaara A et al.,2007 was reported walking ability (m) pre 1321- post 2829 (Table3).

Adverse events: Intraoperative adverse effect mainly was Dural tear or spinal fluid leak (n17), lesions to the dural sac (n7), misplaced transpedicular screw (n1), Other(n1), as regard postoperative adverse effect was delay in wound healing (n6), surgical site infection (n8), Wound hematoma (n 3), Other(n8), peridural hematoma(n1), misjudgment of stenotic level(n1), respiratory distress(n1), MI(n1), persistent pain (1), fracture (1). Withdrew was mentioned in 1 study and was in 4 patients as regard additional surgery needed in 3 studies and was after 1 year (n16), after 2 years (n10), mortality was founded in 12 patients (Table4).

author	ODI pre	ODI post	VAS for back pain pre	VAS post	EQ-5D pre	EQ-5D post
Borg A et al.,2021	47	41			0.24	0.51
Rodrigues L.C.L et al.,2021	47.81	34.9	4.35	3.61		
Hamawandi SA et al.,2019	71.3	10.5	5.22	0.24		
Delitto A et al.,2015	42.6	25.2				
Slätis P et al.,2011	34	24.2	6.9	2.9		
Weinstein JN et al.,2010	42.7	26.6				
Kuchta J et al.,2009	32.6	20.3				
Malmivaara A et al.,2007	34	22.8	6.90	2.74		
Chang Y et al.,2005						
Zucherman J F et al.,2004						

Table 1: Outcomes measures.

author	SF-36 physical pre	SF-36 physical post	SF-36 mental pre	SF-36 mental post	SF-36 pain pre	SF-36 pain post
Borg A et al.,2021	24	41			27.5	47
Rodrigues L.C.L et al.,2021	30.16	23.87	61.55	64.77	38.61	45.81
Hamawandi SA et al.,2019						
Delitto A et al.,2015	49.5	26.8				
Slätis P et al.,2011						
Weinstein JN et al.,2010	35.4	18.7	49.8		31.9	8.7
Kuchta J et al.,2009						
Malmivaara A et al.,2007						
Chang Y et al.,2005	28.3		67.7		17.2	
Zucherman J F et al.,2004	31.7	62.2	64.6	66.8	24.5	56.1

Table 2: Outcome measures.

author	patients satisfaction	Work absenteeism(days)	Mobility measured by walking distance
Borg A et al.,2021		4.3	
Rodrigues L.C.L et al.,2021	80		6MWT : pre 287.16 -post 279.00
Hamawandi SA et al.,2019			
Delitto A et al.,2015			
Slätis P et al.,2011			Reported walking ability: 500 pre - post 1,250
Weinstein JN et al.,2010	95		
Kuchta J et al.,2009	167		
Malmivaara A et al.,2007		6	reported walkingability (m) pre 1321- post 2829
Chang Y et al.,2005			
Zucherman J F et al.,2004			

Table 3: Secondary outcome.

author	patients satisfaction	Work absenteeism(day s)	Mobility measured by walking distance
Borg A et al.,2021		4.3	
Rodrigues L.C.L et al.,2021	80		6MWT : pre 287.16 -post 279.00
Hamawandi SA et al.,2019			
Delitto A et al.,2015			
Slätis P et al.,2011			Reported walking ability: 500 pre - post 1,250
Weinstein JN et al.,2010	95		
Kuchta J et al.,2009	167		
Malmivaara A et al.,2007		6	reported walkingability (m) pre 1321- post 2829
Chang Y et al.,2005			
Zucherman J F et al.,2004			

Table 4: Adverse effects.

DISCUSSION

Although some research has cast doubt on the efficacy of conservative therapy, flexion and stabilisation exercises remain a favored approach.¹²

As a result, our goal is to conduct an NMA and a systematic review to evaluate the effectiveness of surgical procedures for degenerative lumbar spinal stenosis.

The studies considered in this systematic review compared any operative or invasive treatment for people having degenerative LSS. Ten studies were involved; all were randomized controlled trials. There were 974 patients in all, with an average age of 65.5 years. The male/female ratio was 502/472.

MaXL and his colleagues enrolled nine RCTs in a meta analysis to assess the advantages of surgical therapy against conservative therapy. The largest scale trial involved 542 patients and was of moderate quality. The longest follow-up study lasted ten years and it was considered low-quality evidence. Three multi-center randomized controlled trials of excellent quality were SPORT (Spine Patient Outcomes Research Trial), MiDASENCORE (Evidence-based Neurogenic Claudication Outcomes Research), and IDE (Investigative Device Exemption).¹³

According Lesion characteristics, Treated level among included studies were L1–L2(n3), L2–

L3(n108), L3–L4(n307), L4–L5(n524), L5–S1(n29), as regard surgical intervention lumbar decompression used among (487), XSTOP interspinous implant (n275), undercutting laminectomy of stenotic segments, augmented with trans pedicular-instrumented fusion (n50), Laminectomy (n26), Non-instrumented fusion(n7), Instrumented fusion(n12)

As regard Outcomes measures after surgical treatment there was significant improvement in functional outcome and scores as well Outcome of patients were measured pre and post operation ODI score was used in 8 studies with mean preoperation score 43.7 and postoperations score decreased to 26.06.

VAS was used in 3 studies with preoperation mean score 5.49 and decreased postoperation to 2.25, EQ-5D was used by 1 study and mean preoperation score was 0.29 which increased to 0.58 postoperation.

SF-36 scores were used to assess patient’s outcome after surgery and showed that mean SF-36 physical pre was 34.7 decreased to 33.1, mean SF-36 mental pre was 58.6 increased to 66.4 and mean SF-36 pain pre was 31.2 and changed to 34.6

At six months, one year, and two years, surgery showed better advancements in the ODI of 16 to 20%, 15 to 31%, and 14 to 27%, as well as better

advancements in leg pain of 34%, 29 to 44%, and 26 to 34%, respectively.^{14,15}

It was challenging to pool other heterogeneous results since some of such data came from the as-treated analysis. When compared to conservative therapy, laminectomy had a greater ODI at 1 year, 2 years, and no differences at three months and six months in five studies.^{14,15,16,17,18,19,20,21}

Likewise, at three months, six months, twelve months, and two years, two of them observed no differences in the SF-36 physical function cores between laminectomy and conservative therapy.^{16,20}

After a year, two studies comparing epidural steroid injections with mild lumbar decompression found no differences in ODI, while the epidural steroid injection groups had improved ZCQ and worse VAS scores.^{19,21}

Two additional studies found that when X-STOP was implanted at 6 weeks, 6 months, and 1 year, patients were more satisfied than with usual conservative therapy.^{22,23}

Depending on such findings, they concluded that surgery groups had improved long-term clinical results following a year, despite no significant differences between surgical and conservative groups in the first 6 months after therapy. Nonetheless, we discovered that the multiple primary results measuring methods were a clear restriction that had a significant impact on the analyses.

Furthermore, the lack of a "gold standard" for evaluating the results means that the enhancements will last a long time. Tomkins and his colleagues developed Self-Paced Walking, especially to assess the walking abilities of patients with LSS.²⁴ Deyo and his colleagues had a similar endeavour, but the difference were that they tasked a research task force with developing standards for research on chronic low back pain. Maybe unified assessment criteria will be developed in the future, reducing comparison bias.²⁵

Our review showed that Patients satisfaction reported in three studies in 114 patients were satisfied, mean Work absenteeism\days was 5.1 days as regard Mobility measured by walking distance mentioned in three studies.

Rodrigues and his colleagues showed that 6MWT:pre287.16-post 279.00 while Slätis P and his colleagues was Reported walking ability 500 pre-post1, 250 as well Malmivaara and his colleagues was reported walking ability(m)pre 1321-post 829.^{26,17,14}

Our review showed that Intraoperative adverse effect mainly was Dural tear or spinal fluid leak (n17), lesions to the dural sac (n7), misplaced transpedicular screw(n1), Other(n1), as regard postoperative adverse effect was delay in wound healing(n6), surgical site infection (n8),Wound hematoma(n3),

Other(n8), peridural hematoma (n1), misjudgment of stenotic level (n1), respiratory distress(n1),MI (n1)

Withdrew was mentioned in 1 study and was in 4 patients as regard additional surgery needed in 3studies and was after 1 year(n16), after 2yr (n10), mortality was founded in 12 patients

In our pooled data, the rates of complications ranged from 0% to 24% at the conclusion of the follow-up period. Just four studies detailed perioperative complications in various treatment groups, and conservative therapy groups had fewer complications than surgical groups.^{17,21,23,27}

Two of them found 18.4% in X-STOP implanted groups and 2.8% in conventional conservative therapy groups.^{23,27} In laminectomy groups, two of them recorded 5.2%, whereas in conservative therapy groups, 1.2%.^{17,21} In the other studies, the perioperative and postoperative complication rates were combined.

Weinstein and his colleagues observed 10% perioperative with an additional 10% post-surgery complications, Zucherman and his colleagues showed 11% perioperative and post-surgery complications and Malmivaara and his colleagues observed a 24% side impact rate.^{16,23,14} Thankfully, no research found that catastrophic events happened intra-operation or at duration, and several studies found that rates of complications in the conservative therapy groups were nearly 0%.

However, we must note that complications might develop at various stages after surgery and that someone in the conservation therapy group could accept therapy multiple times or have operations throughout the follow-up period; such factors influenced the findings significantly.

CONCLUSION

Surgery showed higher effectiveness and functional outcome improvement and scores among included studies ODI score, VAS, EQ-5D and SF-36 scores and as regard Patients satisfaction reported in three studies in 114 patients was satisfied, Our review showed that Intraoperative adverse effect mainly was Dural tear or spinal fluid leak(n17), lesions to the dural sac(n7), misplaced trans pedicular screw(n1), Other(n1), as regard postoperative adverse effect was delay in wound healing(n6), surgical site infection (n8),Wound hematoma(n3), Other(n8),peridural hematoma(n1),misjudgment of stenotic level(n1),respiratory distress(n1),MI(n1).Withdrew was mentioned in 1study and was in 4 patients as regard additional surgery needed in 3 studies and was after 1 year (n16), after 2yr (n10), mortality was founded in 12 patients.

Conflict of interest : none

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