Lumbar Disc Herniation and Central Lumbar Spinal Stenosis - Outcomes after surgery

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Title and subtitle

Lumbar disc herniation and central lumbal spinal stenosis – outcomes after surgery

Abstract

Lumbar disc herniation (LDH) is most often found in middle-aged individuals, while central lumbar spinal stenosis (CLSS) predominantly develops in older ages. The typical symptom of LDH is sciatica, with or without neurological deficits, while the classical symptom of CLSS is neurogenic claudication. The diseases may also be accompanied by back pain. The natural history of the clinical symptoms related to LDH is usually favourable, while only a third of patients with CLSS improve spontaneously. Physiotherapy and pain management are most often advocated for both conditions in cases with short duration of symptoms, while surgery becomes an option in severe cases or when patients do not respond to non-surgical treatment. Most studies that have evaluated the outcomes after LDH surgery have focused on middle-aged individuals and the improvement in leg pain and quality of life. Outcomes in the elderly, and whether back pain also improves by LDH surgery, are less often evaluated. Other studies have found that a variety of factors, such as mental health and smoking, are of importance for the outcomes of both LDH and CLSS surgery, while the importance of other factors, such as level of obesity, are less clear. Furthermore, the recovery pattern in the postoperative period after CLSS surgery to our knowledge has not previously been structurally evaluated.

In Papers I to IV we used data from the national Swedish spine register (Swespine). In Paper I we address whether elderly individuals are improved by LDH surgery, in Paper II whether back pain is improved by LDH surgery, and in Papers III and IV whether different levels of obesity are associated with the outcomes after LDH and CLSS surgery. In Paper V, in a prospective observational cohort study we identified the recovery pattern during the first two weeks after CLSS surgery.

In LDH patients aged ≥65, most were satisfied after LDH surgery; only one out of ten were dissatisfied. Shorter duration of symptoms, younger age, and better preoperative quality of life were all associated with superior outcomes. In younger patients (aged 20–64), leg pain improved more than back pain after surgery. 79% of patients with clinically relevant leg pain improved ≥MCID (minimal clinically important difference) and 60% of patients with clinically relevant back pain improved ≥MCID in back pain. Smoking, lower preoperative mental component score (MCS) and long preoperative duration of pain were associated with a lower probability of achieving improvement in back pain ≥MCID. Overweight and obese patients achieved slightly inferior outcomes after LDH surgery compared to normal-weight patients, but morbidly obese patients (grade III obese patients according to World Health Organisation) achieved similar outcomes compared to grade I obese patients. Similar results were found for patients with CLSS surgery. However, morbidly obese patients with CLSS surgery experienced more complications than patients with less severe obesity. Finally, decompression due to CLSS (without fusion) was followed by improvement in leg pain within a day of surgery, back pain from day 1 to 14 after surgery and improved quality of life from preoperative to day 7 after surgery.

In summary, only one out of ten elderly patients is dissatisfied with the outcome after LDH surgery; also, back pain is improved in most patients by LDH surgery; surgery should continue to be a treatment option in morbidly obese patients with LDH and CLSS, and decompression without fusion due to CLSS are usually followed within 2 weeks by clinically relevant improvement in leg and back pain, and quality of life.

Key words: Lumbar disc herniation, Central lumbar spinal stenosis, PROMs, obesity, surgery

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To Nurshin, Ronya and Rebin

"The only true wisdom is in knowing that you know nothing" – Socrates

Table of Contents

Abstract

Lumbar disc herniation (LDH) is most often found in middle-aged individuals, while central lumbar spinal stenosis (CLSS) predominantly develops in older ages. The typical symptom of LDH is sciatica, with or without neurological deficits, while the classical symptom of CLSS is neurogenic claudication. The diseases may also be accompanied by back pain. The natural history of the clinical symptoms related to LDH is usually favourable, while only a third of patients with CLSS improve spontaneously. Physiotherapy and pain management are most often advocated for both conditions in cases with short duration of symptoms, while surgery becomes an option in severe cases or when patients do not respond to non-surgical treatment. Most studies that have evaluated the outcomes after LDH surgery have focused on middle-aged individuals and the improvement in leg pain and quality of life. Outcomes in the elderly, and whether back pain also improves by LDH surgery, are less often evaluated. Other studies have found that a variety of factors, such as mental health and smoking, are of importance for the outcomes of both LDH and CLSS surgery, while the importance of other factors, such as level of obesity, are less clear. Furthermore, the recovery pattern in the postoperative period after CLSS surgery to our knowledge has not previously been structurally evaluated.

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back pain from day 1 to 14 after surgery and improved quality of life preoperative to day 7 after the operation.

In summary, only one out of ten elderly patients is dissatisfied with the outcome after LDH surgery; also, back pain is improved in most patients by LDH surgery; surgery should continue to be a treatment option in morbidly obese patients with LDH and CLSS, and decompression without fusion due to CLSS are usually followed within 2 weeks by clinically relevant improvement in leg and back pain, and quality of life.

Populärvetenskaplig sammanfattning

Ryggraden består av kotor med mellanliggande stötdämpande diskar. Det är tack vare dessa diskar som vi kan böja och sträcka i ryggraden. Redan i unga år kan man se förändringar i diskarna som är sammankopplade med åldrande. Med tiden kan vissa personer utveckla diskbråck. Med detta menar vi att en bit av disken buktar utanför sin vanliga plats. Om denna buktning trycker mot nervstrukturer som i eller omkring ryggradskanalen kan det uppkomma symptom i form av smärta i ben (ischias) samt eventuellt känselbortfall och svaghet i benen. En utveckling av diskbråck sker vanligen först i arbetsför ålder. Senare i livet kan förändringarna i diskar och andra strukturer i och kring kotpelaren medföra att det blir allt mindre utrymme i ryggradskanalen, något som i sin tur kan medföra att nervstrukturerna i ryggradskanalen blir klämda. Detta tillstånd som oftast uppkommer hos äldre kallas för spinal stenos ("ryggradsförträngning"), där de mest typiska symptomen är smärta och/eller svaghet/stumhet i benen när man gått en viss sträcka. Såväl patienter med diskbråck som ryggradsförträngning i ländryggen har ofta också ryggsmärta.

Diskbråck är i regel självläkande. Ibland sker denna förbättring inte alls eller väldigt långsamt och någon gång medför diskbråck så svåra besvär och symtom att patienten måste opereras omgående. Förloppet vid ryggradsförträngning är mer oförutsägbart. Man kan inte förvänta att mer än en tredjedel av alla patienter med besvär av en ryggradsförträngning förbättras spontant, något som gör att avlastande kirurgi lyfts fram som ett behandlingsalternativ vid stationära och svåra besvär. Som regel börjar man dock, både vid diskbråck och ryggradsförträngning, med icke-kirurgisk behandling med smärtlindring och sjukgymnastik.

Vanligtvis visar studier av de som opererats för diskbråck, respektive ryggradsförträngning, på goda kirurgiska resultat. Däremot debatteras om äldre personer får lika bra resultat efter lumbal diskbråckskirurgi som yngre, samt om inte bara bensmärta utan även ryggsmärta blir bättre efter kirurgi. Det är även ifrågasatt om långtidsresultaten av en operation är bättre än icke-kirurgisk behandling. Detta beror delvis på att det är svårt att genomföra studier som svarar på dessa frågor, då många patienter med icke kirurgisk behandling väljer att avbryta deltagandet för att bli opererade när de inte förbättras i önskad omfattning. När man diskuterar kirurgi är det även viktigt att ta hänsyn till faktorer som kan påverka utfallet av ett ingrepp. Rökning och mental hälsa är exempel på faktorer som är kopplade till ett sämre kirurgiskt utfall, medan betydelsen av andra faktorer som graden av fetma är omdebatterad.

Syftet med denna avhandling är att ta reda på hur det går för äldre patienter (65 år eller äldre) som opereras för diskbråck i ländryggen (studie 1), om även ryggsmärta förbättras vid diskbråckskirurgi i ländryggen (studie 2), om patienter med grav fetma förbättras sämre vid diskbråckskirurgi i ländryggen (studie 3), och vid

operation av ryggradsförträngning i ländryggen (studie 4), än patienter med lägre vikt. För att i framtiden kunna ge bättre information vid det samtal som föregår en operation, studerade vi även förbättringen under de första veckorna efter en operation av ryggradsförträngning i ländryggen (studie 5). I studie 1 till 4 hämtade vi data från det svenska nationella kvalitetsregistret för ländryggskirurgi (Swespine), medan vi i studie 5 följde en grupp personer som skulle opereras för ryggradsförträngning i ländryggen från före till 2 veckor efter operationen.

Vi fann att, även om resultaten efter diskbråckskirurgi i ländryggen hos de som är 65 år eller äldre är något sämre än vad som beskrivits i litteraturen hos de som är under 65 år, så är de flesta äldre patienter ändå nöjda med resultatet. Endast en av tio är missnöjd. Hos personer i åldrarna 20 till 64 år som opererats för diskbråck i ländryggen minskar ryggsmärtan, om än i mindre omfattning än smärtan i benet. Av de med ryggsmärta av klinisk betydelse före operationen, uppger 60% ryggsmärtan förbättras så mycket att det anses av klinisk betydelse. Patienter med fetma hade något sämre utfall efter kirurgi vid diskbråck och ryggradsförträngning i ländryggen jämfört med normalviktiga personer, men skillnaderna var så små att det knappast hade någon klinisk betydelse. Personer med sjuklig fetma (enligt världshälsoorganisationen (WHO) patienter med BMI (bodymassindex) 40 kg/m^2 eller mer, också kallad grad 3 fetma eller sjuklig fetma) hade liknande utfall som de med mindre allvarlig fetma (grad 1 fetma). Däremot drabbades de med sjuklig fetma av fler komplikationer vid operation av ryggradsförträngning än de med mindre allvarlig fetma. De flesta patienter, även de med sjuklig fetma, var nöjda med resultatet efter såväl lumbal diskbråckskirurgi som vid operation av lumbal ryggradsförträngning. Slutligen, efter operation av lumbal ryggradsförträngning förbättras bensmärtan märkbart redan till dag 1 efter operationen, ryggsmärtan förbättras dag 1 till 14 efter operationen, och patientens livskvalitet gradvis från före till 1 vecka efter operationen.

List of Papers

Paper I
Hareni N, Strömqvist F, Strömqvist B, Rosengren BE, Karlsson MK. Predictors of satisfaction after lumbar disc herniation surgery in elderly. *BMC MusculoskeletDisord*. **2019** Dec 9;20(1):594. doi:10.1186/s12891-019-2975-4

Paper II
Hareni N, Strömqvist F, Strömqvist B, Sigmundsson FG, Rosengren BE, Karlsson MK. Back pain is also improved by lumbar disc herniation surgery. *Acta Orthop*. **2021** Feb;92(1):4-8. doi:10.1080/17453674.2020.1815981. Epub 2020 Sep 8.PMID: 32896198

Paper III
Hareni N, Strömqvist F, Rosengren BE, Karlsson MK. A study comparing outcomes between obese and nonobese patients with lumbar disc herniation undergoing surgery: a study of the Swedish National Quality Registry of 9979 patients. *BMC MusculoskeletDisord.* **2022** Oct 22;23(1):931. doi: 10.1186/s12891-022-05884-8.PMID: 36273136

Paper IV
Hareni N, Gudlaugsson K, Strömqvist F, Rosengren BE, Karlsson MK. A comparison study on patient-reported outcome between obese and non-obese patients with central lumbar spinal stenosis undergoing surgical decompression: 14,984 patients in the National Swedish Quality Registry for Spine Surgery. *Acta Orthop.* **2022** Nov 28;93:880-886. doi:10.2340/17453674.2022.5254.PMID: 36445071

Paper V
Hareni N, Ebrahimnia S, Rosengren BE, Karlsson MK. Recovery Pattern after Decompression of Central Lumbar Spinal Stenosis – a Prospective Observational Cohort Study. *Submitted.*

Abbreviations

ALL	Anterior longitudinal ligament
CI	Confidence Interval
CLSS	Central lumbar spinal stenosis
CT	Computed tomography
CES	Cauda equina syndrome
EQ-5D	The 5-dimensional scale of the EuroQol
DDD	Disc degeneration disease
DS	Degenerative spondylolisthesis
EMG	Electromyography
ENG	Electroneurography
FELD	Full-Endoscopic Lumbar Discectomy
FS	Foraminal stenosis
GH	General Health (SF-36)
HRQoL	Health-related quality of life
L	Lumbar
LDH	Lumbar disc herniation
LSS	Lumbar spinal stenosis
MCID	Minimal clinically important difference
MCS	Mental Component Summary (SF-36)
MRI	Magnetic resonance imaging
NRS	Numeric Rating Scale
ODI	Oswestry Disability Index
PCS	Physical Component Summary (SF-36)
PF	Physical Functioning (SF-36)
PLL	Posterior longitudinal ligament
PROM	Patient-reported outcome measure
QALY	Quality-adjusted life years
RCT	Randomised controlled trial

RPA	Robotic Process automation
S	Sacrum
SD	Standard deviation
SEWD	Self-estimated walking distance
SF	Social Functioning (SF-36)
SFR	Swedish Fracture Register
SF-36	Medical outcomes study short form survey, 36 items
SKR	Swedish Association of Local Authorities and Regions
SPORT	The Spine Outcome Research Trial
SS	Spinal stenosis
SLR	Straight Leg Raise Test
Th	Thoracic
VAS	Visual analogue scale
VT	Vitality (SF-36)

History

Lumbar disc herniation

Throughout history, 'sciatica' has been referred to with several eponyms. In ancient times, the phenomenon was attributed to supernatural or evil forces, resulting in such names as the British '*elf's arrow'*, or the German '*hexenschuß*' (witch-shot). The reasons why these symptoms emerged were unknown. It was probably Hippocrates who suggested a connection between sciatica, claudication, and an antalgic posture. The pathophysiologic explanation at that time was that sciatica was more prevalent during warm months, as the sun dried up the necessary joint fluid [1].

Further works by Galen in the second century, and Caelius Aurelianus in the fourth, shed light on sciatica. The former enhanced our knowledge about different spinal pathoanatomical conditions, and the latter provided a detailed description of the clinical condition rhizopathy. Aurelianus also asserted that sciatica was more common in the middle-aged than in young and old individuals. Paul of Aegina in the seventh century described sciatica in detail, also in relation to spine trauma [1]. In the 15th century, Sabuncuoğlu described medical heat and heat cauterisation as a treatment for sciatica [2], and in 1543 Andreas Vesalius' work *De Humani Corpos Fabrica* reached another milestone, broadening our understanding by probably being the first to describe the intervertebral disc [1, 3].

Further knowledge of the condition was gathered in the 18th and 19th centuries when Domenico Cotugno linked radicular pain to the sciatic nerve. Following this report, sciatica became generally known as *Cotugno's disease*. When in 1857 Rudolf Virchow described disc pathology as a reason for radicular pain, a herniated disc became known as *Virchow's Tumour*. A few years later, Ernest-Charles Lasègue published a paper that described the association between back pain and sciatica, and also described the *Lasègue manoeuvre* as an excellent test for diagnosing sciatica. A couple of years later, a German pathologist named Schmorl, after studying thousands of spines, reported protrusion of the disc into the spinal canal as a pathological entity, however without drawing conclusions regarding the clinical relevance of the finding.

Several other surgeons then initiated the description of the most common cause of sciatica. Among them was Walter Dandy, who reported two cases of lumbar surgery for back and leg pain in 1929, as did Alajouanine and Petit-Dutaillis in 1930 when

they proposed that what was formerly defined as a tumour, might actually be herniation of nucleus pulposus from the intervertebral disc [1, 3].

The first time surgery was performed for a 'ruptured intervertebral disc' was in 1932, when neurosurgeon Mixter, and Orthopaedic surgeon Barr, performed a laminectomy from the second lumbar vertebra (L2) to the first sacral vertebra (S1) on a patient with signs of nerve root compression, where the histopathological analysis found no signs of tumour in the mass that was removed from the spinal canal. They presented the findings 1934 in the New England Journal of Medicine (Figure 1), and after this they are usually credited for introducing discectomy surgery as a treatment option for herniated intervertebral discs [4], even if others find that this credit ought to be given to Dandy.

Figure 1. Mixter and Barr's publication in New England Surgical Society 1934. Reproduced with permission from NEJM, Copyright Massachusetts Medical Society

After these first reports, surgery soon became a popular treatment option for lumbar disc herniation (LDH). Love described an intralaminar and extradural technique in 1938 that could be used when operating on patients with LDH. This technique was gradually modified, until 1977 when Caspar recommended that medial facetectomy, extradural dissection, and discectomy should be used as an excellent surgical technique with a good outcome when operating on patients with LDH. The initially proposed large surgical exposures in the skin had then shrunken to no more than 5 cm [1, 5].

Lumbar spinal stenosis

Lumbar spinal stenosis (LSS) can present as LDH with radiating leg pain. Therefore, it is difficult to assess whether the ancient physicians were referring to LDH or LSS when describing their patients. However, both ancient Greek and Egyptian physicians suspected that lower extremity symptoms might have a relation to spinal disorders [1].

It was not until the 19th and 20th centuries that the pathophysiology of neurogenic claudication became better understood. Half a decade after Cotugno linked radicular pain to the sciatic nerve, a French physician named Antoine Portal described that narrowing of the spinal canal may lead to numbness, weakness and paralysis of the legs [6]. Dejerine et al. later postulated that it was syphilitic vasculitis that caused the intermittent claudication of the spinal cord, while Oppenheim and Kause described cauda equina syndrome (CES) in the early 20th century. Another major contribution to understanding the pathophysiology of LSS comes from Sarpyener et al. who, in 1945, described that a congenital spinal stenosis was one anatomical condition that could be of clinical relevance for this type of symptom [7].

The physician who nowadays is the most credited for the term spinal stenosis is the neurosurgeon Henk Verbiest, who in 1949 published a paper in French and years later in English in the *Journal of Bone and Joint Surgery* (Figure 2), where he described in detail several cases with narrow spinal canals and classic LSS symptoms [8]. Verbiest also included myelograms in his research to demonstrate anatomical deviations that could exist when having these symptoms.

Case 2. *Narrowing of the spinal canal at L.4 and 5, with narrowing of the dural sheath*—A man aged forty-four complained of pain in the lumbar region of two years' duration. When standing he suffered from paraesthesiae in the legs and buttocks, then lost power in the legs and fell down.
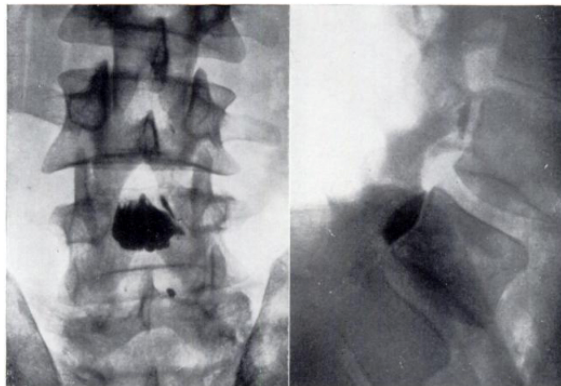
FIG. 1   FIG. 2

Case 1—Myelograms. Obstruction to upward flow of opaque fluid at the upper border of L.4. (Patient in Trendelenburg position.) Note in the lateral radiograph the pointed apex of the advancing fluid. The anterior border of the fluid lies close to the vertebral body; the posterior border slopes towards the anterior.

Figure 2. From Verbiest's publication 'A radicular syndrome from developmental narrowing of the lumbar vertebral canal'. J Bone Joint Surg Br, 1954. Vol 36B. No. 2. Page 231

Modern aspects

Lumbar disk herniation

Nowadays, symptomatic LDH is usually reported with a prevalence of 1–3% [9]. The condition constitutes significant costs to society, not only due to health care costs, but also because of sick leave due to its high prevalence among individuals of working age [10, 11]. Further, LDH is one of the most usual causes for radiculopathy (pain in a dermatome distribution area), with or without sensory and/or motor disturbances. In the literature, the term sciatica is often used as synonymous with LDH radiculopathy, since the most commonly affected segments include the distribution area of the sciatic nerve (L4–S3). However, it should be emphasised that herniation in the upper lumbar region (L2–L4) does not usually affect the nerve roots to the sciatic nerve, but to the femoral nerve.

Saal et al. is one of the authors who postulated that LDH with clinical symptoms usually has a favourable natural history [12]. Surgery becomes an option first when non-surgical treatment (physiotherapy, and/or epidural injections and pain management) results in unsatisfactory outcomes. Another surgical indication includes cauda equina syndrome (CES). CES appears when the sacral nerves are affected, often due to a large, slipped disc, which in turn results in symptoms from the bladder, genital area, anus, and/or perineum. This condition should be handled with haste, as irreversible impairment may occur within a relatively short time. Other relative indications for surgery are morphine-resistant hyperalgia, progressive neurology, and/or paralysing sciatica [13].

Several randomised controlled trials (RCTs) have reported favourable outcomes after LDH surgery [14-16]. Weber (1983) showed that after one year, surgically treated patients had superior outcomes compared with non-surgical patients [17]. However, these differences diminished with time so that after 4 years there were no statistically significant group differences [17]. It is difficult to interpret this study as approximately a third of the patients were operated on immediately due to severe acute symptoms. However, other RCTs and prospective cohort studies have come to similar conclusions [14-16], even if these studies were also associated with either high cross-over rates between the groups, or group differences in patient selection. The current consensus is that surgery is likely to shorten the period of pain and disability in patients where the first months of non-surgical treatment have been unsuccessful, then excluding patients with emergent indications for a surgical

intervention. Despite this consensus, surgical rates vary four to fivefold between different countries and between different regions in the same country [18].

Lumbar spinal stenosis

LSS is the most common indication for spine surgery in the elderly and in Sweden today the most common lumbar spine surgical procedure [19]. More than 5,000 operations were registered in 2019 in the national quality registry for spine surgery (Swespine), where 4,607 patients were operated on due to central lumbar spinal stenosis (CLSS) [19].

Due to degenerative spine alterations, such as disc protrusion, facet joint osteophytes, and/or hypertrophy of the ligamentum flavum, the narrowing of the spinal canal can affect nerve structures/nerve roots and/or local circulation, leading to neurogenic claudication. It should be noted that these changes must be regarded in a clinical perspective. Around 20% of patients above age 60 have radiographic evidence of LSS, most of them without clinical symptoms. Congenital spinal stenosis is another, less common, condition behind LSS symptoms [20]. Other spinal conditions, such as infection and metastasis, can also be associated with clinical symptoms resembling degenerative LSS.

There is no commonly accepted definition of spinal canal reduction, and/or anatomic abnormality for LSS. As a result, there exist several radiological classifications [21, 22], with no gold standard [23]. The classic symptoms of LSS include neurogenic claudication in both legs that are precipitated by standing and/or walking, symptoms that are relieved by sitting and/or bending forward [24]. Patients can also experience problems with balance, sensory loss and/or weakening. A spinal canal stenosis often affects the entire spinal canal, in which case it is referred to as central lumbar spinal stenosis (CLSS). A spinal canal stenosis can also specifically affect the lateral recess or the intervertebral foramen (or a combination). In these cases, the symptoms can resemble a unilateral radiculopathy [20]. Such conditions are often referred to as lateral lumbar spinal stenosis (LLSS) or foraminal spinal stenosis (FSS), depending on where the compression is found.

The natural course of LSS has been studied in several studies [20, 25, 26]. Up to a third of all patients in these studies have been reported to experience a spontaneous regression of the clinical symptoms, around one fourth deterioration, while the rest have predominantly unaltered symptomatology with small fluctuations in their disability [20].

Treatments for LSS include physiotherapy, pain medication and/or epidural injection, while decompressive surgery is recommended for patients with more severe associated disability. Several studies, including RCTs, have reported that surgery results in favourable outcomes compared to non-surgical treatments [27-31]. Some surgeons also recommend the decompression to be accompanied by

segmental fusion of the degenerated spine segment(s), especially when the patient has an additional degenerative spondylolisthesis (DS). In the United States, approximately half of the registered lumbar operations in patients over age 45 are decompression surgery with fusion [32], while the corresponding proportion in Sweden is 9% [19].

Two recent RCTs compared decompression surgery versus decompression and fusion surgery for LSS. Ghogawala et al. reported that the addition of fusion gives slightly better Short Form (SF-36) physical component outcomes two years after the operation, but no significant difference in the Oswestry Disability Index (ODI) [33]. However, this study had substantially higher reoperation rates in the decompression group, which may affect the SF-36 assessment. Forsth et al. reported that decompression alone was not followed by inferior outcomes when compared to decompression with fusion, both in LSS patients with and without associated DS [29]. However, the latter surgical technique was associated with a significantly higher hospital cost. Recently, Austevoll et al. investigated decompression with or without fusion in degenerative lumbar spondylolisthesis, showing that decompression was non-inferior to decompression with fusion [34].

Finally, a recent Cochrane review, which included five RCTs, stated that based on published research, surgery could not be recommended over conservative treatment for LSS [35]. Nevertheless, there are great difficulties when randomising patients with debilitating pain, whether evaluating surgical outcome versus conservative treatment or comparing different surgical techniques. The reason is that the cross-over rate between groups is usually high due to dissatisfied patients. The conclusions in cited reviews are therefore controversial due to the substantial heterogeneity in the treatment arms, heterogeneity in the different interventions, and high cross-over rates [36]. Many of the RCTs were also performed in specialised spine units with narrowly defined groups of patients and skilled surgeons, where the studies then show what is possible to achieve, more than what outcomes are typical in general health care.

With such problems in RCTs, national registries like Swespine could be one approach in general health care when identifying the surgical outcomes of different procedures in different diseases. National registries also have an advantage when evaluating the outcomes in rare subgroups where it is difficult to include a sufficient sample size in individual centres. A third advantage is that surgical national registries may be used when trying to identify factors that are associated with superior and inferior outcomes in the general population.

Anatomy

The spinal column

The human spine typically consists of 7 cervical (C1–C7), 12 thoracic (Th1–Th12) and 5 lumbar vertebrae (L1–L5) (Figure 3).
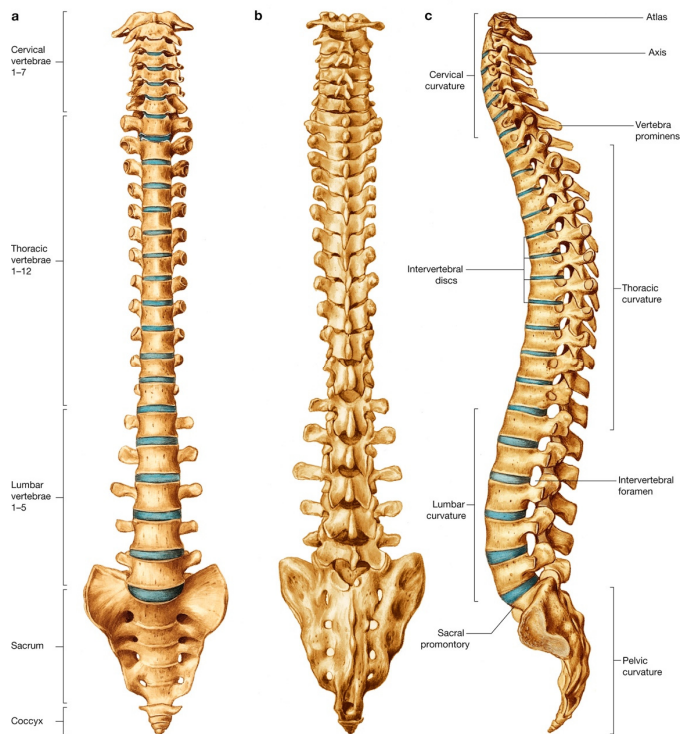
Figure 3. Human spine in anterior, posterior and lateral view. From "Anatomy of the vertebral column" Vishy Mahedan. Surgery (Oxford) Vol 36, 2018

Below the second cervical vertebra (C2), all vertebral bodies are separated by an intervertebral disc. The inner structure of the disc, the nucleus pulposus, is delimited by a lamellar structure called the annulus fibrosus.

Anterior to the vertebral body and discs, the anterior longitudinal ligament (ALL) lies on the surface of the vertebral body as a stabiliser of the spinal column. Posterior to the vertebral body, the vertebrae form a vertebral arch where the laminae are attached to the vertebral body through the pedicles (Figure 4). The articular processes are attached to this arch, where the upper and lower articular processes form the facet joint. The joints with the joint capsules are important stabilisers of the spinal complex. Inside the spinal canal, the posterior longitudinal ligament (PLL) lies on the posterior surface of the vertebral body as another stabiliser of the spinal column. The ligamentum flavum, another stabiliser, connects the posterior part of the lamina within the spinal canal. Posterior from the lamina extends the spinous process, a bony extension from the lamina. The interspinal and supraspinal ligaments are also important stabilisers of the spinal column (Figure 5).
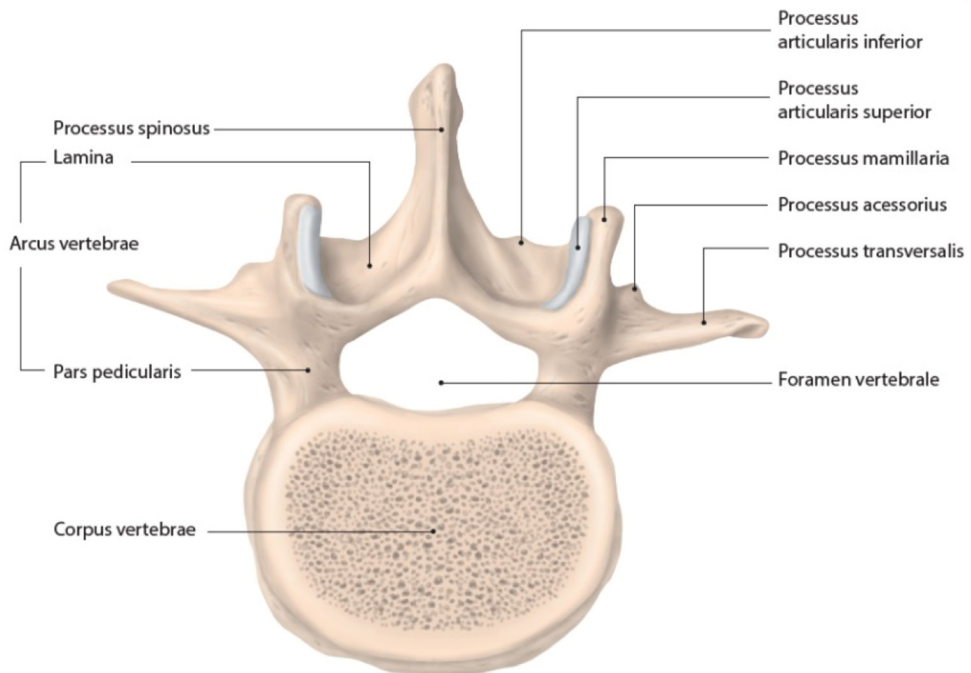
Figure 4. A lumbar vertebral body seen from above
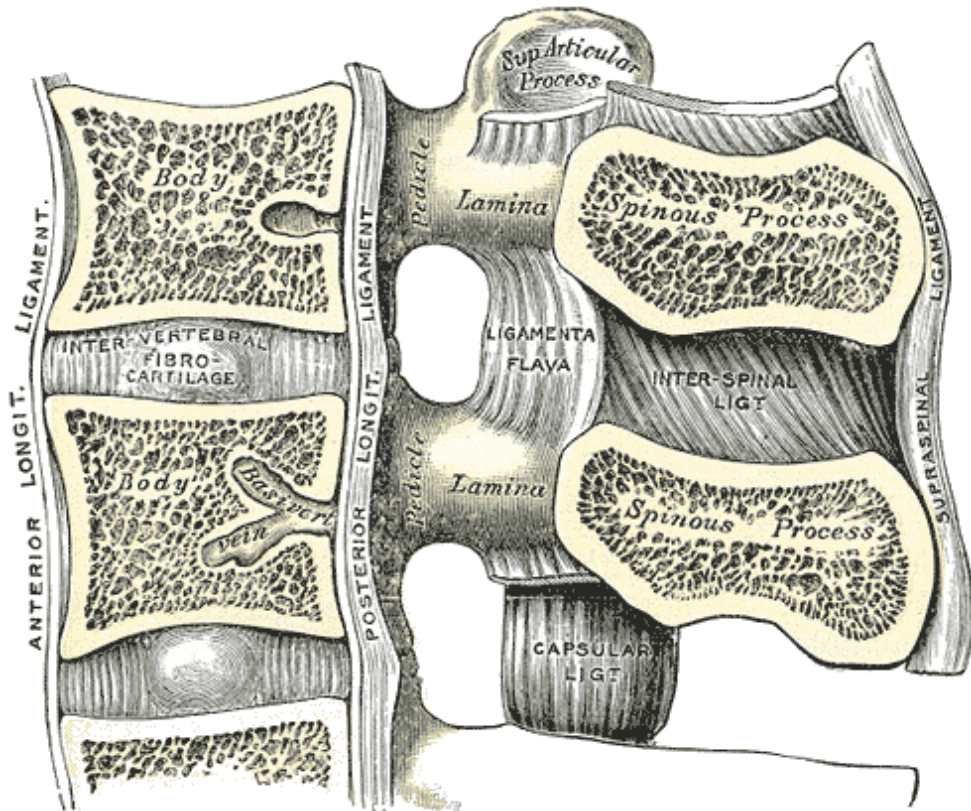
Figure 5, Median sagittal section of two lumbar vertebrae. From "Anatomy of the human body" Gray's Anatomy 1918

The lumbar region in the spinal column usually consists of five lumbar vertebrae (L1–L5), where the fifth lumbar vertebra connects to the sacrum. In some individuals the first sacral segment is lumbarised and a radiograph will then reveal 6 lumbar vertebrae (L1–L6). The fifth lumbar vertebra can also be sacralised. A radiograph will then reveal 4 lumbar vertebrae (L1–L4).

The spinal column protects the spinal cord, below the conus medullaris, the nerve structures, and finally the nerve roots extending from the spinal canal. The spinal cord is the structure between the medulla oblongata and the conus medullaris. The conus medullaris usually ends between Th12 to L2. Nerve root elements continue from the conus medullaris distally within the dural sack in a structure called the cauda equina. This is a Latin expression that means 'horse's tail'. The nerve elements then form the lumbar nerve roots, which exit the spinal canal pairwise at each segment below the pedicle in the nerve root foramina (Figure 6). Several different nerve roots then form the peripheral nerves as the femoral and sciatic nerves.
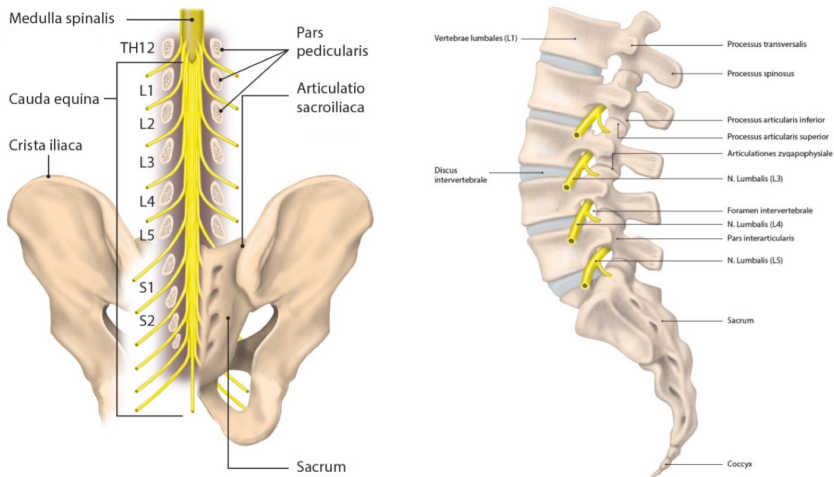
Figure 6. Left: The medulla spinalis ends in the conus medullaris. Distal from this point, the nerve structures continue in the cauda equina. On each level, paired nerve roots branch out under the pedicula. Right: Lateral view with nerve roots exiting the nerve root foramina

The intervertebral disc

The intervertebral disc comprises an outer fibrous ring called *anulus fibrosus* and an inner gel-like mass called *nucleus pulposus* (Figure 7). The disc is situated between two adjacent vertebrae where it meets the endplates and forms a fibrocartilaginous joint. Together with two vertebrae it forms a motion segment, allowing movement between the vertebrae. The anulus fibrosus consists of around 20 concentric lamellae of type I and type II collagen. The type I collagen is stiff and concentrated outwards in the anulus fibrosus while the type II collagen is more elastic and concentrated inwards. The nucleus pulposus is a gel-like tissue that maintains an intradiscal pressure, thereby providing tension to the anulus fibrosus and allowing the disc to act as a shock absorber. The nucleus pulposus is highly hydrated and rich in proteoglycans [37].
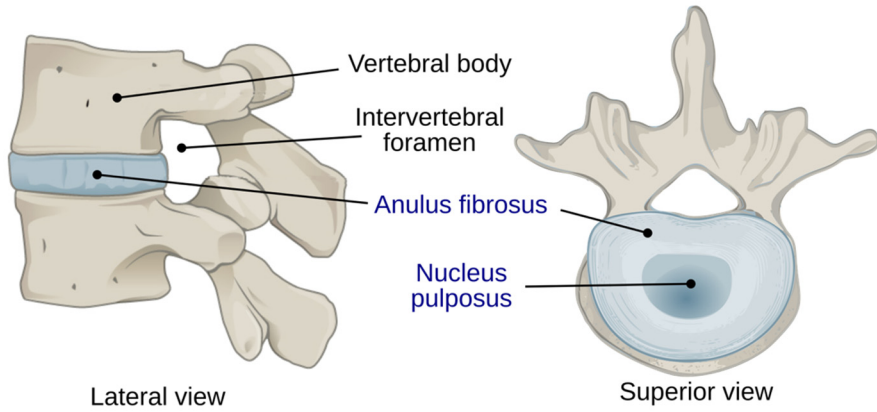
Figure 7. Lateral and superior view of intervertebral disc. By: Jmarchn. Wiki Common media CC BY-SA 3.0

Pathophysiology

Lumbar disc herniation

The spinal column is formed from the mesoderm during the embryogenic period, with the exception of the nucleus pulposus, which arises from the endoderm. The intervertebral disc is vascularised during the embryogenic period but soon after birth this structure becomes avascularised [38]. The discs then receive their nutritional supply via diffusion through the vertebral endplates and the outer layer of the anulus fibrosus [39, 40]. The intervertebral disc is the largest avascular structure in the human body, probably explaining why degenerative changes are often found earlier in these discs than in other organs. Major histological changes are found in the discs by the end of the first decade of life, with histological changes continuing over a lifetime [41]. With ageing, macroscopic, radiological and biochemical changes, such as loss of glycosaminoglycans, water content, loss of height, and impaired function occur successively, with the changes being found in individuals with back symptoms and in asymptomatic individuals [38, 42].

The multifactorial aetiology behind the changes is not fully understood, and there is no consensus as to what constitutes pathological disc degeneration [43]. Pfirmann et al. described the degenerative stages with magnetic resonance imaging (MRI) of the intervertebral disc [44]. They proposed a five-graded scale that relies on assessing the signal intensity/structure of the nucleus pulposus, the distinction between anulus and nucleus pulposus, and the disc height. A normal disc (Grade I) displays homogenous hyperintense and bright white nucleus pulposus, with a clear distinction between the anulus fibrosus and the nucleus pulposus and a normal disc height. A completely degenerated disc (Grade V) displays a black signal, with lost distinction and a collapsed disc space (Figures 8 and 9).

Grade	Structure	Distinction of Nucleus and Anulus	Signal Intensity	Height of Intervertebral Disc
I	Homogeneous, bright white	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
II	Inhomogeneous with or without horizontal bands	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
III	Inhomogeneous, gray	Unclear	Intermediate	Normal to slightly decreased
IV	Inhomogeneous, gray to black	Lost	Intermediate to hypointense	Normal to moderately decreased
V	Inhomogeneous, black	Lost	Hypointense	Collapsed disc space

* Modified from Pearce (cited by Eyre et al[9]).

Figure 8. Classification of disc degeneration, from A: Grade I to E: Grade V. From: Magnetic Resonance Classification of Lumbar Intervertebral Disc Degeneration. Pfirrmann et al, Spine, 2001, vol 26, 17-1873-1878
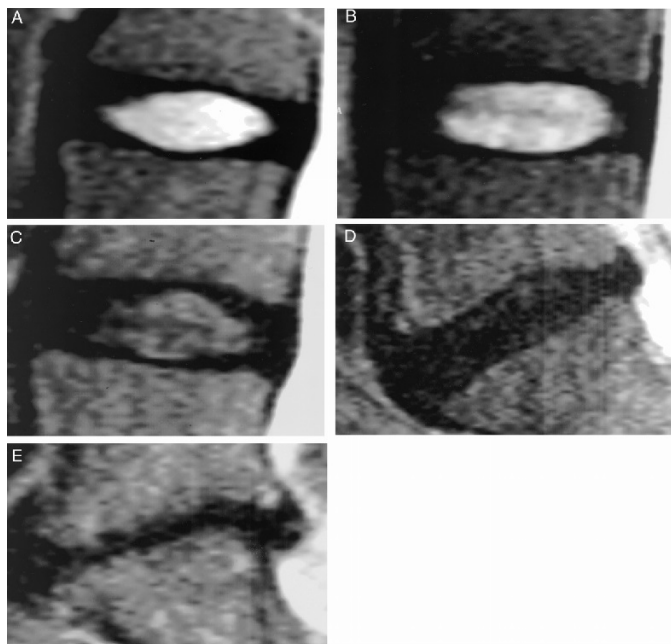
Figure 9. Classification of disc degeneration, from A: Grade I to E: Grade V. From: Magnetic Resonance Classification of Lumbar Intervertebral Disc Degeneration. Pfirrmann et al, Spine, 2001, vol 26, 17-1873-1878

Lumbar spinal stenosis

The path that leads to narrowing of the spinal canal in patients with LSS is not entirely clarified. One common hypothesis is that the degeneration starts in the intervertebral disc. When the biomechanics of the motion segment become altered and the movement in the segment increases, this results in stress on the facet joints and buckling of the flaval ligaments [45, 46]. These changes stimulate a cascade of events that lead to the formation of osteophytes. The relationship between disc

degeneration and the degenerative cascade is not thought to be linear, as increased movement in the segment is shown in the early stages of disc degeneration, and less in advanced stages [47, 48]. Further, it is not possible to directly correlate the histologic and anatomic findings with clinical symptoms.

Aetiology

Lumbar disc herniation

Several aetiological factors have been proposed to be associated with degenerative disc disease (DDD). Some studies have shown a genetic predisposition [49-51]. In addition, environmental and occupational factors are thought to be linked to LDH [52, 53]. For example, a Swedish study of 265,529 individuals found higher than normal hospitalisation rates due to lumbar disc disease in construction workers, individuals of tall stature and smokers [54]. Athletes, especially in full contact sports such as American football, have also been shown to have a higher incidence of DDD and LDH compared to controls, likely because of repeated excessive load [55, 56]. Disc degenerative changes are also found with a higher incidence than expected by sex and age in obese individuals, and the degenerative changes become more and more obvious with increasing obesity [57]. Sagittal alignment of the spine is also postulated to have an association to LDH, as there is a higher prevalence of hypo-lordosis in lumbar spines in patients with LDH than in patients without LDH [58-60]. The hypothesis in these cases is that a low lumbar lordosis shifts the axial load distribution, thus increasing the mechanical stress on the discs [60]. In this context, it should also be noted that reports addressing these questions are virtually all association studies with lower levels of evidence. Also, age and sex seem to be of importance, as LDH is most common in middle-aged individuals than in adolescents [61-63] and elderly [64-67], and twice as common in men as in women [9]

Lumbar spinal stenosis

In acquired LSS, ageing is considered the most important factor due to degenerative changes that come with increasing age. However, there are also other conditions that may lead to symptomatic narrowing of the spinal canal, such as congenital stenosis, malignancies, calcium metabolism disorders (Pagets) and/or inflammatory disorders (rheumatoid arthritis) [32, 68]. As LSS in most cases is a degenerative condition, the narrowing of the spinal canal is often accompanied by degenerative spondylolisthesis (DS), even if distinct pathophysiological and aetiological factors also exist that distinguish DS from LSS [69]. However, DS must be taken into account when treating LSS with surgery, as the translation of the vertebrae may

contribute to the narrowing of the spinal canal [69]. Overweight and obese patients are thought to have higher incidences of LSS [70].

Pain mechanisms

Lumbar disc herniation

The physiological mechanisms that cause radiculopathy in patients with LDH is not fully understood [20, 71]. One theory is that the disc material induces mechanical compression on the nerve root. However, as asymptomatic patients may also have disc compression on MRI examination, compression alone seems not enough to induce pain. A common view is that chemical inflammation also plays a role in the pain cascade. For example, a Swedish research group demonstrated decades ago in animal models that the nucleus pulposus has inflammatory capabilities on the nerve root [72-74], and in human studies that mediators of inflammation can be found in the cerebrospinal fluid in patients with symptomatic LDH [75].

Lumbar spinal stenosis

One of the most advocated hypotheses relates symptoms to ischemia [76, 77]. This hypothesis infers that a mechanical compression leads to ischemia in the neural elements. Another commonly postulated hypothesis suggests that a venous pooling leads to accumulation of metabolites due to insufficient oxygenation [78, 79]. A third hypothesis is that the intradural pressure rises with the spine becoming extended, which leads to clinical symptoms [80, 81]. It should also be noted that the role of inflammation in neurogenic claudication seems of less significance as compared to symptomatic LDH. This makes sense, as in contrast to LDH where the disc is ruptured, putting the nucleus pulposus in direct contact with the nerve roots, such pathoanatomical findings are usually not prevalent in patients with symptomatic LSS.

Classification

Lumbar disc herniation

A healthy lumbar disc does not normally extend beyond the posterior margin of the dorsal vertebrae. In LDH there are often four stages of extension beyond the posterior margin of the vertebra (Figure 10). The level of extension is then used in

one common classification of herniated discs. However, disc pathology can also be classified according to the localisation of the defect: if the LDH is central/medial/paramedial, foraminal or extraforaminal (Figure 11). The median and paramedian LDH usually affects the nerve root exiting below the compressed segment (an L5/S1 herniation affects the S1 nerve root), while a foraminal LDH usually affects the nerve root within the same segment (a foraminal L5/S1 herniation affects the L5 nerve root).
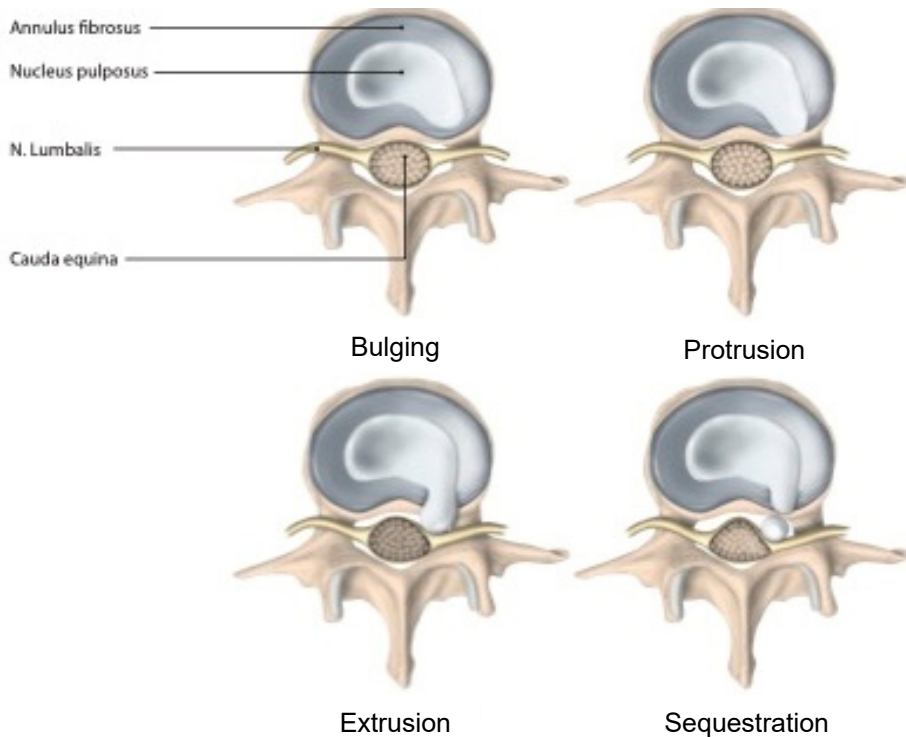
Figure 10. Upper left: Bulging disc, Upper right: Protruding disc, Lower left: Extrusion, Lower right: Sequestration. The first two are usually contained by an intact anulus and PLL

Annulus fibrosus
Nucleus pulposus
N. Lumbalis
Cauda equina
Processus transversus
Processus interarticularis superior
Processus spinosus

Central/medial/paramedian — Foraminal — Extraforaminal
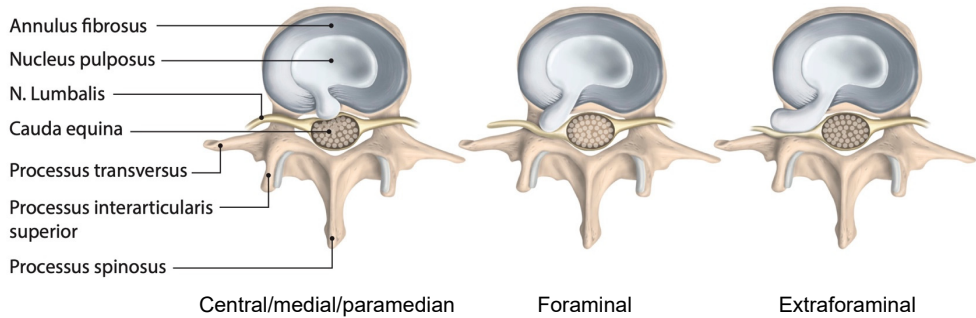
Figure 11. Localization of central/medial/paramedial disc herniations, foraminal disc herniations and extraforaminal disc herniations

Lumbar spinal stenosis

Depending on the region in the spine with the most obvious stenosis, most LSS are central (CLSS), with or without neurogenic claudication. The pathological narrowing of the spinal canal can also impinge the nerve root in the lateral recess, in which case it is usually referred to as lateral recess stenosis (LRS). Finally, the nerve root can specifically be impinged in the neuroforamen, when it is referred to as foraminal stenosis (FS).

The narrowing of the spinal canal can be described in different modes. Radiologists usually describe the degree of narrowing by measuring the cross-sectional diameter and/or the cross-sectional area of the dural sac in the affected segment(s) [82, 83]. There is no direct correlation between the dural sac diameter/area and the clinical symptoms and no specific limit in diameter or area where the clinical symptoms emerge. Neither is there any consensus when LSS should be diagnosed based on radiological imaging techniques, or when a spinal canal reduction should be regarded as being of clinical relevance [84].

One radiological qualitative classification that is often used when estimating the severity of LSS has been proposed by Schizas (Schizas classification grade A–D) [22]. This classification assesses the orientation of rootlets in the dural sac, whether or not the rootlets are individualised, whether or not cerebrospinal fluid is present in the dural sac, and whether or not the epidural fat is visible [22] (Figure 12). This classification has clinical relevance as the different classes are to some extent related to the clinical presentation. For example, patients in grades C and D are more likely to fail conservative treatment than patients in grade A and B [85]. Another classification is the nerve root *sedimentation sign,* which is positive in the absence of sedimentation of rootlets in axial MRI images [85]. However, the sensitivity for detecting surgical candidates with this sign is low [85].
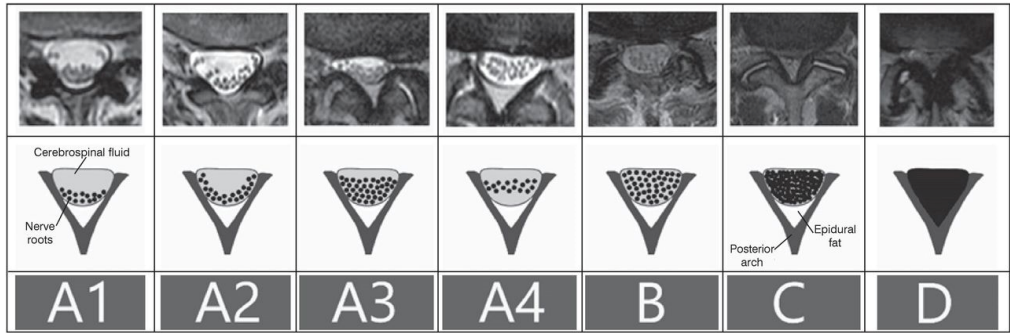
Figure 12. Schizas Classification. A1–A4: no stenosis, B: moderate stenosis, C: Severe stenosis, D: Extreme stenosis. From: Manfre et al. J Neurointerv surg 2020.

Imaging and other diagnostic tools

Lumbar disc herniation/Lumbar spinal stenosis

When diagnosing LDH and LSS, it must be emphasised if we are referring to a clinical or a radiological diagnosis, as a radiologically diagnosed LDH or LSS may occur without clinical symptoms. As no treatment is initiated solely due to radiographic findings, clinically relevant LDH and LSS must be identified through patient history and clinical examination. In patients with an unclear diagnosis, more emergent symptoms, and/or in the need of preoperative planning, MRI is the gold standard exam [86], as MRI has high sensitivity for both LDH (Figure 13) and LSS, with or without spondylolisthesis (Figure 14) [86], but also for differential diagnoses such as malignancies and infections [86].
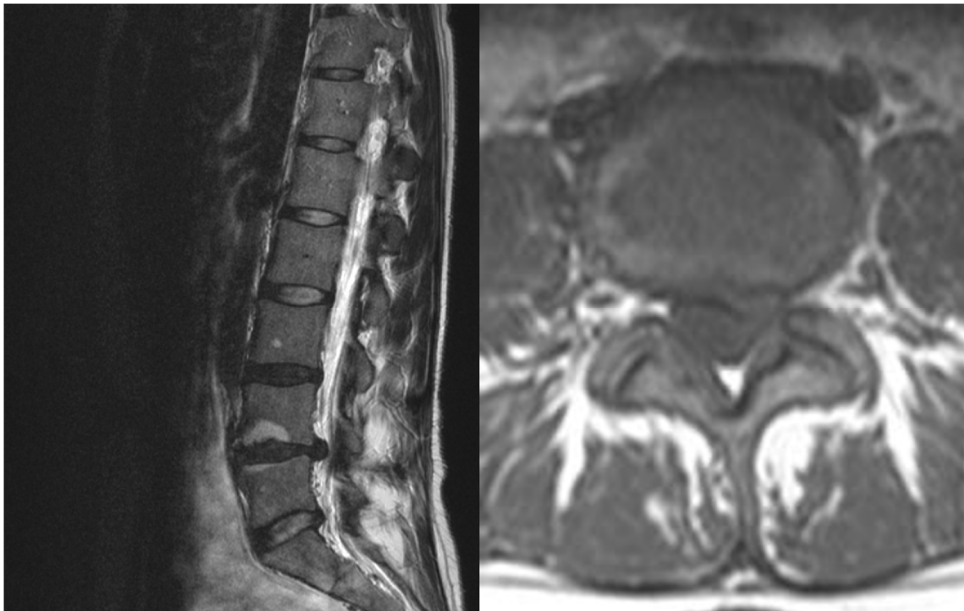
Figure 13. Lateral and axial MRI view of a herniated L4–L5 disc.

Figure 14. Lateral and axial MRI view of a very narrow spinal stenosis, spondylolisthesis where the L4 vertebra is translated forward
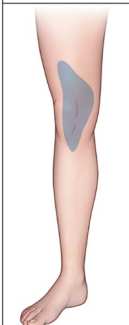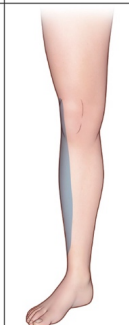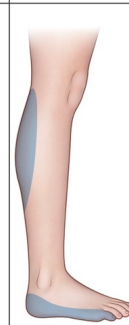
In patients where MRI is contraindicated, computer tomography (CT) or CT myelography are possible choices. The downside of these exams is the radiation exposure and inferior visualisation of soft tissues. In addition, CT myelography is an invasive examination, associated with specific complications. However, the added contrast in this technique provides good sensitivity for assessing the cross-sectional area of the dural sac. The method is also less likely to reproducing susceptibility artifacts than MRI if the patients have any surgical hardware [87]. In recent years, dual energy CT has been introduced as another method, with even higher accuracy than CT, though it has not yet been validated enough in clinical practice [88, 89].

Electro-diagnostic methods such as electromyography (EMG) and electroneurography (ENG) are other methods in use when diagnosing the disorders. EMG and ENG are usually not used as routine diagnostic tools when evaluating patients with LDH or LSS. However, these methods may be useful in assessing such differential diagnoses as neurological disorders and/or when the clinical history and imaging are inconclusive [20].

Clinical characteristics

Lumbar disc herniation

Patients with clinical symptoms due to LDH most often present with unilateral radiculopathy in the leg (ambiguously called sciatica whatever nerve root is involved). The leg pain is often described as a sharp, burning, stabbing and/or radiating pain (Figure 15). The patients may also display motor deficits, sensory deficits, limited trunk mobility and impaired neurological reflexes [90]. Lasègue's test/straight leg raise test (SLR) is the most advocated test for sciatic pain. The painful leg in this test is raised with a straight leg and with the patient lying flat on their back. The test is positive if pain is expressed in the dorsal side of the buttocks and leg at typically 30–70 degrees. The SLR test has high sensitivity but limited specificity, due to sciatica being manifested in many conditions [91]. In patients with proximal nerve root compression (L2–L4: the femoral nerve), Ely's test is the most advocated test [92].

Figure 15. Clinical presentation of common LDH levels. Reproduced with permission from (Deyo et al. Herniated Lumbar Intervertebral Disc, N Engl J Med 2016), Copyright Massachusetts Medical Society.

A specific constellation of clinical symptoms may occur after large central disc herniations that affect the cauda equina. These patients present with disturbances in the genital area, bladder function, perineum and anus, and sometimes also gait disturbances and lower limb weakness [93]. The condition is referred to as cauda equina syndrome (CES), a condition that needs to be assessed hastily as the deficits may become irreversible within days.

LDH is also often accompanied by back pain. It is not uncommon that back pain precedes the leg pain. The pathogenesis of the back pain is poorly understood. One theory is that the back pain emerges from the damage of anulus fibrosus (AF) with subsequent ingrowth of vascularised granular tissue and not from the nerve root compression [94]. This view is at least partly supported in a study that has shown that moderate disc degeneration together with a high intensity zone on MRI imaging (indicating an tear in annulus fibrosus) is associated with back pain [95]. Further studies are needed before we know the pathophysiology that explains the back pain.

Lumbar spinal stenosis

The cardinal symptom of CLSS is neurogenic claudication. Patients with clinical symptoms typically present with bilateral or unilateral pain in the buttocks and legs, and/or numbness and paraesthesia in the lower extremities. The pain often has a postural component with the clinical symptoms usually being aggravated by standing and/or walking. This is usually referred to the extension of the lumbar spine that reduces the volume in the spinal canal (Figure 16). In contrast, leaning forward alleviates the pain, as when walking slightly bending forward with a shopping cart [20, 32]. In severe form, the symptoms may progress to include balance problems and a wide-based gait.

The most important clinical differential diagnosis of CLSS is vascular claudication. If the patient describes the '*shopping cart sign*' (the individual prefers to walk leaning forward on a shopping cart), symptoms alleviated by sitting and worsened in standing, there is a greater likelihood that the symptoms arise from CLSS and not vascular claudication. Symptoms below the knees only, along with relief of symptoms when standing, indicates vascular impairment in the lower extremities [96].

Foraminal lumbar stenosis usually presents clinically with leg pain following the segment of the affected nerve root (Figure 15). The pain may be relieved in flexion and/or bending to the opposite side. Finally, lateral recess stenosis without CLSS often presents with a clinical picture mimicking LDH with well-defined radiculopathy (Figure 15).

LSS may also be accompanied by back pain, and as in LDH, the pathogenesis behind the back pain is poorly understood, as there is low correlation between degree of compression in the spinal canal and level of back pain.
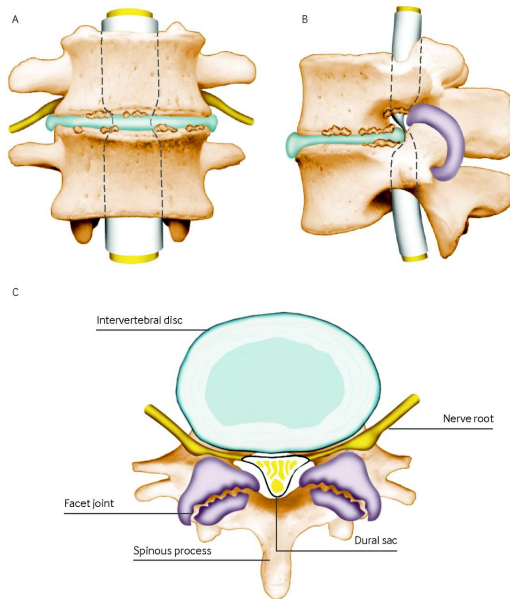
Figure 16. Lumbar spinal stenosis, frontal (A), sagittal (B) and axial (C). Thickening facet joints shown in purple. With permission from: Lurie et al. BMJ. 2016:352:h6234

Treatment

Non-operative treatment

In most cases, the natural course of LDH is benign with spontaneous recovery within a period of 6 weeks [97]. Among patients with LSS, less than one third of the patients deteriorate over time, and around one fourth improve spontaneously [20]. During the early period with clinical symptoms, non-operative treatments are an important part in care for both LDH and also LSS, where studies have shown that physiotherapy has a promising effect in the short term [98]. Patients with LDH and LSS are instructed to stay as active as possible, use analgesics if needed, and in severe cases rest for as short a period as possible. Cycling is often recommended as a tool to be physically active in LSS. Long periods of bed rest or inactivity, in the past often mistakenly advocated as a favourable treatment, have no positive long-term effect on clinical outcomes [99]. Epidural injections have shown pain reduction in the short-term perspective, more for LDH than for LSS, but not in the long-term perspective [100, 101]. If there is need of analgesics, the general recommendation is to start with non-opioid analgesics, usually paracetamol, followed by non-steroid anti-inflammatory drugs, with or without medications such as gabapentin for the

neurogenic pain. In the most severe cases, opioid analgesics may be necessary to use for a shorter period to relieve intractable pain. Long-term opioid medication should be avoided as this is associated with a high risk of developing addiction. Several other treatment options have also been postulated, such as traction and manipulation therapy; however, the literature shows limited support for these methods regarding their efficacy and then only in publications with low evidence grade [20, 32, 102].

Surgical treatment

Lumbar disc herniation

Aside from the emergent cases, such as CES, LDH surgery is often considered in patients who do not recover for a period of 2–3 months with analgesics and physiotherapy. In these cases, surgery usually results in instant improvement in the leg pain [3]. When following the recovery pattern after surgery in LDH patients, leg pain is reduced the first day after surgery, back pain diminishes during the first two postoperative weeks and quality of life gradually improves from before to two weeks after surgery [3]. The study also showed that the criteria for successful outcome were already achieved two weeks after the operation. Other studies have also shown that patients with LDH reported faster improvement with surgery than with non-surgical treatment [28]. Discectomy with or without microscopic assistance is the most commonly advocated surgical procedure for this condition. A posterior midline cut through the skin and subcutis is followed by an incision in the facia, release of the extensor muscle followed by a minor laminotomy. A tubular or ordinary retractor are usually used. The ligamentum flavum is exposed and partially removed and the neural structures medialised. The disc material is removed with a rongeur until no mechanical compression remains on the nerve root (Figure 17). Several variants of the procedure exist with varying degrees of soft tissue dissection, using open, minimally invasive, endoscopic, or microscopic techniques. A recent Cochrane review could not identify any clinically relevant differences in outcomes between the different techniques [103].
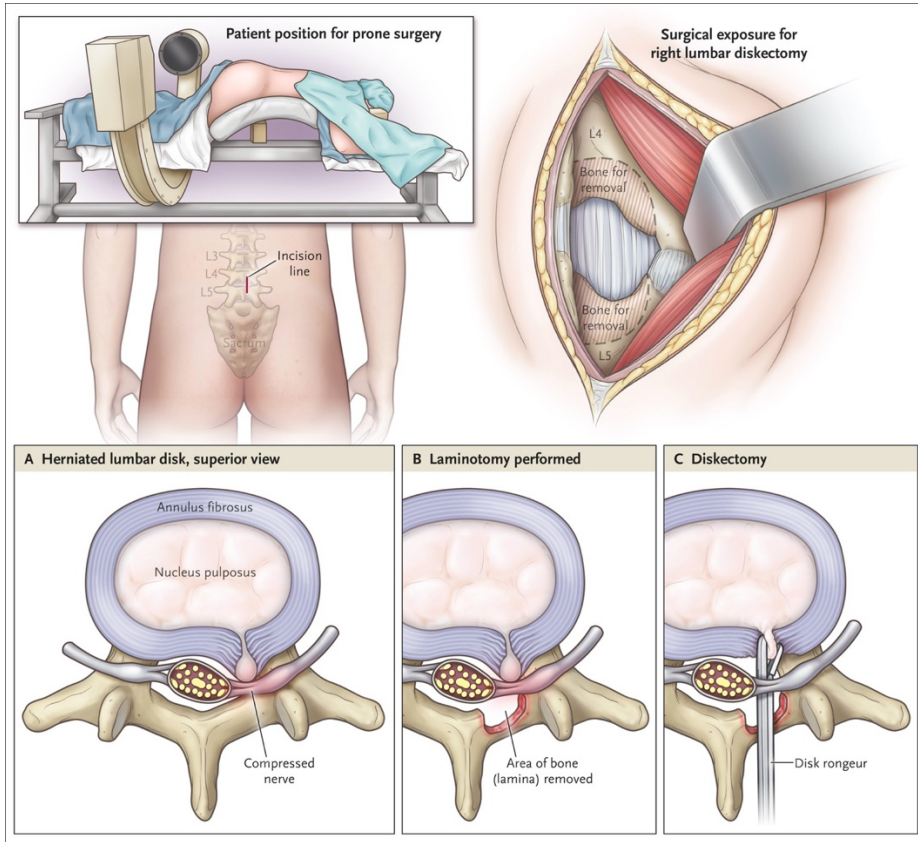
Figure 17. Microdiscectomy. Reproduced with permission from (Deyo et al. Herniated Lumbar Intervertebral Disc, N Engl J Med 2016), Copyright Massachusetts Medical Society.

Recently, Full-Endoscopic Lumbar Discectomy (FELD) has been introduced as a treatment choice for LDH. There are reports that indicate promising outcomes with this technique, although there seems to be a long learning curve [104]. The method is new and still limited in use [105, 106]. Several other surgical methods have also been described [107]. However, apart from patients who have concomitant spinal disorders requiring a specific surgical approach, discectomy is still the gold standard when treating LDH surgically.

Surgical interventions in LDH patients are predominantly performed to alleviate symptoms in the lower extremities. A popular belief is that patients with dominant leg over back pain are good candidates for surgery; this view is supported by reports implying that the surgical outcome of LDH is better in patients without back pain [108]. However, even if a surgical intervention is performed predominantly to alleviate symptoms in the lower extremities, there are reports that support the view that back pain may also be improved through surgical intervention [109, 110].

Lumbar spinal stenosis

In patients with LSS, there is usually a longer period of non-operative treatment before surgery becomes an option. It should be noted that patients with CLSS can also present with severe clinical symptoms that needs urgent decompressive surgery. The recovery pattern after surgery in LSS patients is not known, even if surgery is reported to provide faster improvement than non-surgical treatment [28].

Decompression surgery is the preferred method in patients with LSS who need an operation. The goal of the intervention is to widen the narrowed part of the spinal canal. The decompression can include total removal of the posterior laminar arch (laminectomy), with or without sparing the midline, or just removing half of the posterior arch (hemilaminectomy) (Figure 18). In surgery, a posterior midline cut through the skin and subcutis is followed by an incision in the fascia, in the case of a laminectomy release of the extensor muscle on both sides, which allows the lamina to be removed. Hemilaminectomies, usually followed by less soft tissue exposure, are more often performed when the stenosis, as in LRS or FS, is isolated to one side. The Swespine 2021 report stated that 82% of registered operations for CLSS were laminectomies and 6% were hemilaminectomies [111]. In addition, 9% had fusion done in addition to decompression [111]. It should also be noted that 19% of the patients in this cohort had a previous lumbar spine surgical procedure registered in Swespine [111]. Internationally there are great variations in the proportion of patients who, apart from decompression, are also treated with a lumbar spine fusion [20, 32]. This is especially common if the spinal canal narrowing is associated with a degenerative spondylolisthesis (DS) [20, 32]. In Sweden, however, we question whether decompression should be accompanied by spinal fusion when treating patients with LSS, with or without DS, as the outcomes in RCTs have not been proven to be more effective than decompression alone [29, 34].

Surgical interventions in LSS patients are predominantly performed to alleviate symptoms of neurogenic claudication. The common belief is that LSS patients with dominant symptoms from the lower extremities are also candidates for decompression surgery [29] even if there are some data supporting that even some level of back pain may be improved by the surgical intervention [109, 110].
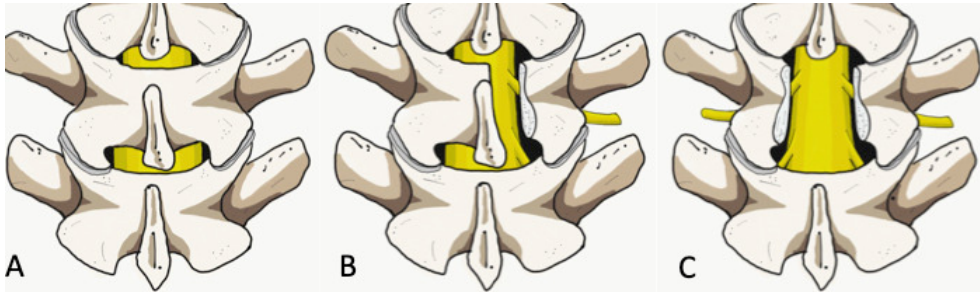
Figure 18. A. Normal. B. Hemilaminectomy (mid line sparing). C: Laminectomy. By: Franco L. De Cicco for Statpearls: Laminectomy.

Factors associated with the surgical outcome

Lumbar disc herniation

Outcomes after LDH surgery are often presented at group level. However, the surgeon who determines if surgery should be offered evaluates a specific patient, then assesses the probability of a successful or unsuccessful outcome. It is therefore of great value to identify factors that are associated with superior and inferior surgical outcomes.

A systematic review by Wilson et al. screened 562 studies that were published between 2000 and 2014 regarding the outcome of LDH surgery. Forty of these studies were deemed to be of high quality [112]. The review concluded that younger age, more severe leg than back pain, and better mental health were associated with superior outcomes in LDH surgery. In contrast, an intact anulus fibrosus, worker's compensation, long duration of sick leave, and greater severity of baseline symptoms were associated with inferior outcomes, while any association with sex, obesity and duration of sciatica were inconclusive [112]. It should also be noted that most included studies in this review were association studies and the majority included fewer than 300 patients [112]. One large study opposes this view regarding the importance of sex, as it reported that the 1-year outcomes after LDH surgery were more inferior in women than in men [113]. It should, however, be noted that the women in this study had an inferior clinical status compared to the men when scheduled for surgery, and that the improvement through the surgery was similar in both sexes [113]. Smoking is another example of a factor that has been associated with inferior outcomes, higher recurrence rates, and more reoperations in patients with LDH [114, 115].

Lumbar spinal stenosis

A systematic review by Aalto et al. screened 885 studies that were published until April 2005 and that evaluated outcomes after LSS surgery. Twenty-one of these studies were deemed to be of high quality [116]. The review concluded that depression was related to worse surgical outcomes after decompressive surgery in LSS patients, and that inferior walking capacity before surgery was also associated with inferior walking capacity after surgery [116]. Another study concluded that patient expectations before the operation are associated with the postoperative outcomes [117], where patients with more realistic expectations tend to be more satisfied postoperatively than those with unrealistic expectations [117]. One study found that obesity, but not age, duration of symptoms or sex, was associated with inferior outcomes after LSS surgery [118] and another found that duration of symptoms exceeding 2 years and poor preoperative function were associated with inferior outcomes [119]. In the Spine Patient Outcomes Research Trial, the authors concluded that older diabetes patients have more postoperative complications after LSS surgery than non-diabetic patients [120], that more back than leg pain was associated with inferior outcomes [121] and that in patients with LSS and additional DS, many stenotic levels were associated with inferior outcomes [122]. Finally, smoking has also been strongly associated with inferior outcomes in LSS surgery [123, 124].

Age

One interesting possible risk factor to address in both LDH and LSS surgery is age. Recovery after operations and/or recovery after diseases is usually inferior in the old than in the young patient. However, it is essential to emphasise that age might not be the causal relationship with outcomes. It is also possible that confounders associated with age, such as more comorbidities, may explain inferior outcomes in elderly patients.

Studies have shown that patients of advanced age are referred to LDH surgery with more severe symptoms than young patients [125]. This could be one explanation of inferior postoperative outcomes in older than in younger LDH patients. It is also possible that age influences symptoms and signs of LDH, thereby delaying referrals to surgery [126]. Most studies show comparable favourable outcomes after LDH surgery in young adults and adolescents [127, 128]. The few studies that have evaluated the outcomes in the elderly are retrospective studies that include small sample sizes; these studies show partly inconclusive results [129-133].

Advanced age in LSS surgery is usually reported to be associated with increased risk for perioperative dural lesions, but it is debated whether this influences the final outcomes [134]. Another LSS study concluded that advanced age is associated with inferior postoperative walking ability [135]. However, there are also reports that

conclude that age is not associated with the outcomes after LSS surgery [119, 136]. In summary, there is ongoing debate as to whether age is associated with inferior status after LDH and LSS surgery.

Obesity

Obesity is defined by the World Health Organisation (WHO) as Body Mass Index (BMI) $\geq$30.0 kg/m^2 [137]. Further, obesity is a growing health concern worldwide, with a global tripling of the prevalence of obese individuals since 1975 [138]. Since obesity has a substantial negative impact on health, on many surgical outcomes, and is associated with more anaesthetic complications [139-143], the rising obesity problem in society poses a great challenge to future health care.

Several studies conclude that obesity is associated with inferior surgical outcomes after both LDH [144-146] and LSS surgery [147-149], in comparison with the outcomes in normal-weight patients. In contrast, other studies conclude that obese patients achieve similar outcomes after both LDH [150, 151] and LSS surgery [152-155], in comparison with the outcome in normal-weight patients. This is not totally unexpected when taking the *obesity paradox* into account. This paradox has been proposed after studies showing obesity to be associated with superior outcomes after certain types of cardiac surgeries [156-159].

One problem with most obesity studies is that they evaluate obese patients as a homogeneous group. However, the span in obese patients can be greater than the span among patients with underweight (BMI <18.5 kg/m^2), normal weight (BMI 18.5 to <25.0 kg/m^2), overweight (BMI 25.0 to <30.0 kg/m^2) to obesity (BMI $\geq$30.0 kg/m^2). The minimum BMI span from underweight to obese patients is thus 11.5 kg/m^2. To even the playing field, the WHO has classified obese patients in obesity class I (BMI 30.0 to <35.0 kg/m^2), obesity class II (BMI 35.0 to <40.0 kg/m^2) and obesity class III (BMI $\geq$40.0 kg/m^2); this group often referred to *morbid obesity* or *severe obesity*. And some patients with obesity may reach a BMI in excess of 50 kg/m^2. The BMI span in a group of obese patients may therefore span >20 kg/m^2. The problem when trying to evaluate morbidly obese patients separately is to achieve a sufficient sample size, an almost impossible task in a single centre. National registries such as Swespine may, however, reach sufficient samples for such evaluations.

Patient-Reported Outcome Measure Score (PROM)

When evaluating the surgical outcomes, there is an advantage to using validated patient-reported outcome measures (PROMs). This is the current gold standard when evaluating the patients' perceptions. The Visual Analogue Scale (VAS), the

Numeric Rating Scale (NRS), the Oswestry Disability Index (ODI) and the Short Form-36 (SF-36), EuroQol-5D, and global assessment scales (Likert satisfaction scale (satisfied, uncertain or dissatisfied) are examples of commonly used PROMs when evaluating the outcomes of different types of treatments [160]. Swespine also uses the question '*How is your back/leg pain today as compared to before the surgery*' in the postoperative evaluation.

Visual Analogue Scale (VAS) and Numeric Rating Scale (NRS)

VAS is the most commonly used PROM in spine surgery. It allows patients to rate their pain from 0 (no pain) to 100 (worst imaginable pain). A sliding scale is used to provide visual help for the rating. NRS is another continuous scale that rates pain, but where the patients rate the pain from 0 (no pain) to 10 (worst imaginable pain) (Figure 19). Swespine initially used VAS to evaluate pain levels, but this was later changed to NRS. Studies have shown that they correspond well with each other, but that NRS might be easier to use due to the lower resolution (using only a ten-point scale) that might be associated with better compliance [161, 162].
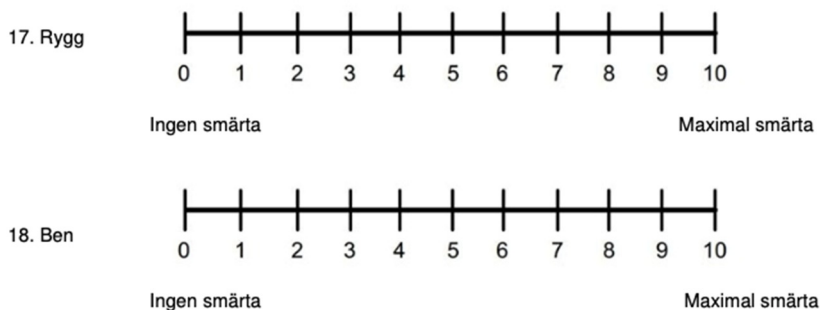
Figure 19. NRS back pain (17) and leg pain (18) in the Swespine questionnaire in Swedish. In the text above the scale, patients are instructed to mark their pain level during the last week. The instructions explain what 0 and 10 mean. 'Ingen smärta' means 'no pain' and 'maximal smärta' means 'maximum pain'. Further instructions state that the patients must select a whole integer value which best represents their pain level.

Short Form 36 (SF-36)

SF-36 is general health PROM. The patient answers a questionnaire with a series of eight questions (36 questions in total). Four of the questions measure physical measures which are calculated to a 'Physical Component Summary Score' (PCS) and four questions measure mental health, which is calculated to a 'Mental Component Summary Score' (MCS). SF-36 is a PROM where the result can be translated into 'Quality-adjusted life years' (QALY). SF-36 has been validated and assessed for cross-cultural health measurement and been translated into many languages, including Swedish [163-165]. The use of SF-36 has been discontinued in Swespine since 2020.

Oswestry Disability Index (ODI)

ODI is the most-used disease-specific PROM in lumbar spine surgery. The questionnaire covers 10 topics: intensity of pain, lifting, ability to care for oneself, walking ability, ability to sit, sexual function, ability to stand, social function, sleep quality and ability to travel. The score is reported as a percentage of the maximum disability, ranging from 0 (no disability) to 100 (maximum disability) [166].

EuroQoL-5D

EQ-5D is a general health PROM. Patient answers a single multiple-choice question of 5 items (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). The EQ-5D exists in two forms, one with 3 alternatives per item (EQ-5D-3L) and one with 5 alternatives per item (EQ-5D-5L), where Swespine uses EQ-5D-3L. The health status is calculated into an index where 1 corresponds to the best possible health status, 0 to a health state equivalent to death and negative values to a status worse than death.

Minimal Clinically Important Difference (MCID)

The use of P values is normally credited to statistician Karl Pearson, although the first to use probabilistic reasoning to reject a null hypothesis was when an English physician in 1710 showed that the higher number of male than female births did not occur by chance [167]. In the early days, statisticians had no way to foresee the creation of national registries when constructing tests to accept or reject the null hypothesis. These modern registries, such as Swespine, may contain over 100,000 patients, with more than 10,000 patients being operated on due to LDH and more than 10,000 operated due to LSS. With such enormous numbers of participants, even a difference so small that it could not be discovered by clinicians in the everyday practice, may reach statistical significance. The inevitable question, then, is whether

a statistically significant improvement detected in Swespine is also of clinical significance (clinical relevance). Due to this concern, the concept of a Minimal Clinically Important Difference (MCID) was introduced, a difference that is regarded as a clinically meaningful improvement for a specific disease and a specific treatment.

MCIDs are often defined as '*the smallest difference in score in the domain of interest which the patients perceive as beneficial, and would mandate, in the absence of troublesome side effects and excessive cost, a change in the patients' management*' [168] or '*the smallest change that is important to patients*' [169]. The MCID is specific for each diagnosis and each treatment option. There are also several ways to define an MCID, either by an anchor-based criterion, or with a sensitivity and specificity-based approach [170]. Specific MCID values have also been established when evaluating treatment effects for LDH and LSS [171-173].

Solberg et al. reported that an MCID for LDH surgery equals an improvement ≥3.5 for NRS leg pain (scale 0–10), ≥2.5 for NRS back pain or ≥20 points in ODI (scale 0–100) [172]. This study also provided excellent receiver operating characteristic curves (ROC) for NRS leg pain and ODI. Another recent study reports similar MCID values for LDH surgery [171], while concluding that the MCID in LSS surgery should be at least 14 points in ODI, at least 28 points in VAS back pain (scale 0–100) and at least 27 points in VAS leg pain.

The MCID could be defined according to absolute changes in the PROM, the relative changes (percent changes), or the end result in the PROM score (follow-up score) following a treatment. One recent study assessed which of the methods would be best to use when evaluating patients with LSS surgery [173]. The study concluded that it was better to use relative improvement (%), or the final outcomes scores, rather than using absolute improvement in the scores when defining MCID. This was also independent of whether leg pain, back pain or ODI was used as the variable to follow. This study further stated that the MCID for patients subjected to LSS surgery was ≥40% improvement in NRS leg pain, ≥33% improvement in NRS back pain and ≥30% improvement in ODI [173].

The Swedish Spine Register–Swespine

Figure 20. Left figure: Swespine, The Swedish Spine Registry.
Right figure: Swedish Society of Spinal Surgeons

The predecessor to Swespine was started as a local registry in 1986 at the department of orthopaedics in Lund. This registry grew so much in the following decade that it was transferred to the Swedish National Society of Spine Surgeons in 1998 (Figure 20) [174]. Since then, Swespine has been considered a national database, since practically all the clinical departments conducting spine surgery report to the registry. In 2018, the annual report from Swespine found that 49 out of 50 clinics that conduct spine surgery reported their data to Swespine, and in 2021 that >95% of all clinics with spine surgery reported to the registry [111]. The completeness of Swespine has varied over the years, being 75–80% in 2018 and 85% in 2021 [111, 175]. The follow-up (evaluated through the 1-year exam) in Swespine has also varied over the years, being 75% in 2018 and 70% in 2021 [111, 175]. The lower proportion in 2021 has often been attributed to changes in the technical platform allowing patients to register their PROMs digitally or send the forms by postal service, as well as the Covid pandemic [19, 111]. Swespine is currently certified to be the highest level of national registries (level 1) by the Swedish Association of Local Authorities and Regions (*Sveriges Kommuner och Regioner, SKR*).

The patients enter their preoperative status in Swespine before the operation. This includes questions in a general questionnaire (age, sex, weight, height, self-estimated walking distance, duration of leg pain and/or back pain, smoking status, analgesics consumption, work ability and type of work). The patients then complete the following PROMs: NRS leg pain, NRS back pain, SF-36, EQ-5D, EQ-VAS, and

ODI). SF-36 was omitted as a PROM in 2020. The surgeons register peri- and postoperative data (diagnosis, type of operation, levels operated on, side if applicable, complications). If the surgery is a reoperation, the surgeon enters all the perioperative details regarding the reoperation. Finally, similar questions and PROMs as preoperatives are sent to the patients 1, 2, 5, and 10 years after the surgery. At the follow-up exams, there is also a global assessment question regarding satisfaction rate rated in a Likert scale (satisfied, uncertain or dissatisfied) and a question regarding the self-perceived improvement after surgery. Swespine has been described in detail in previous publications and the registry has been validated [174, 176]. Data from the registry has been included in more than 130 research publications and several dissertations.

Loss to follow-up

As with all registry studies, attrition bias is a concern that needs to be addressed. A 2018 study compared the 27% of patients lost to the one-year follow-up in Swespine with data from another single centre study with a loss to follow-up of 2% [177]. This comparison found that the lower response rate in Swespine didn't affect the conclusions [177]. Another study addressed the problem by contacting non-responders through questionnaires and/or phone [178]. This study supported the previous study, reporting that the patients lost to follow-up did not have any influence on the conclusions [178]. The Swespine study also concluded that there were no major differences when comparing the postoperative 1- and 2-year data [177]. These researchers concluded that the 1-year data in Swespine represented the final outcomes [177], a conclusion supported in another report [171]. Additionally, studies from both Norway [179] and Denmark [180] support the notion that the lack of data in individuals lost to follow-up do affect the inferences when evaluating lumbar spine surgery.

Another attempt to address whether the loss to follow-up in Swespine influenced the findings was done through merging Swespine with other registries, in order to assess baseline characteristics in responders and non-responders and use the baseline characteristics to predict the PROM values in non-respondents [181]. This study found that after LDH surgery, 78.7% of responders achieved successful outcomes while the proportion with successful outcomes in non-responders was predicted to be 75.4%. The similar data in LSS surgery was 58.2% for responders and 53.9% for non-responders [182]. It must be emphasised that these proportions are only estimates, as the use of other registries introduced a variety of confounders to the prediction of outcomes in non-responders.

Swespine – Oswestry Disability Index and Short Form 36

In December 2022, Swespine published a paper that reported that the scoring algorithms used in Swespine for Oswestry Disability Index (ODI) were underestimated by approximately 1 out of 100 units. The matter was covered in detail in the paper, and they contacted researchers who had accessed these data. The scoring was described, and they explained that the consequences seem minimal and not clinically relevant. We used ODI in Papers I–IV. Since the underreporting concerns all patients, it is therefore just as common in both baseline scores as it is in follow-up scores. It is also as common in any group compared in our large datasets. We agree with the Swespine board and draw the conclusion that the minor underreporting of ODI has no meaningful effect on our comparisons or conclusions.

In January 2023, the research group was in contact with Swespine concerning the Short Form 36 (SF-36) Mental Component Summary (MCS) and Physical Component Summary (PCS). Swespine is currently investigating if MCS and PCS values were interchanged during a transfer of the database in 2005. We were urged to reanalyse our data. We found that their assumption seems to be correct. This data error could have consequences. We used MCS and PCS in Paper I, and MCS in Paper II. Hence, we recalculated all MCS and PCS scores from scratch and performed new analyses.

The effect on Paper I was minor, only affecting our multivariate values in the second decimal place, and one nonsignificant value in the first decimal place, however it remained not significant. Baseline values were basically interchanged for PCS and MCS. No significances were changed. No conclusions were changed.

The effect on Paper II was similar, affecting our values in the second or third decimal place. However, SF-36 MCS changed from a nonsignificant RR of 1.00 (95CI 0.99–1.00), to a significant RR 1.005 (95CI 1.002–1.007) in table 3, and from a nonsignificant RR of 1.00 (95CI 1.00–1.00), to a RR of 1.000 (95CI 1.000–1.005) in table 4. This did not alter any other significances.

This does not alter our main conclusions, however; MCS will have an association with achieving improvement equal to or above MCID, both in leg pain and back pain. This was somehow reassuring due to, as discussed in the introduction, preoperative mental health being associated with the outcome in spine surgery. The values used in this dissertation were corrected compared to the original Paper II. We will provide erratum when Swespine has published the data error.

Aims of the thesis

Paper I

In patients aged ≥65 years with LDH surgery

- Evaluate the 1-year outcomes
- Identify factors associated with superior and inferior satisfaction

Paper II

In patients aged 20–64 years with LDH surgery

- Evaluate the 1-year outcomes in leg and back pain
- Evaluate the proportion of patients who improve ≥MCID
- Identify factors associated with an improvement ≥MCID

Paper III

In patients aged 20–64 years with LDH surgery

- Evaluate the 1-year outcomes in non-obese and obese grade I to III patients.
- Evaluate the proportions of non-obese and obese grade I to III patients who improve ≥MCID
- Evaluate the rate of complications in non-obese and obese grade I to III patients

Paper IV

In patients aged ≥50 years with CLSS surgery

- Evaluate the 1-year outcomes in non-obese and obese grade I to III patients
- Evaluate the proportions of non-obese and obese grade I to III patients who improve ≥MCID
- Evaluate the rate of complications in non-obese and obese grade I to III patients

Paper V

In patients >50 years with decompressive CLSS surgery

- Evaluate the recovery pattern in back pain, leg pain, and quality of life, from before to 2 weeks after surgery

Research Questions

Paper I

In patients aged ≥65 years undergoing LDH surgery

- What are the 1-year outcomes?

- Which factors are associated with superior and inferior outcomes?

Paper II

In patients aged 20–64 years undergoing LDH surgery

- What are the 1-year outcomes?

- Which factors are associated with improvement ≥MCID?

Paper III

In patients aged 20–64 years with LDH surgery

- What are the 1-year outcomes in non-obese and obese grade I to III patients?

- What proportion of patients improve ≥MCID among non-obese and obese grade I to III patients?

- What is the rate of complications in non-obese and obese grade I to III patients?

Paper IV

In patients aged ≥50 years with CLSS surgery

- What are the 1-year outcomes in non-obese and obese grade I to III patients?

- What is the rate of complications in non-obese and obese grade I to III patients?

- What proportion of patients improve ≥MCID among non-obese and obese grade I to III patients?

Paper V

In patients >50 years with decompressive CLSS surgery

- How is the recovery pattern in back pain, leg pain, and quality of life from before to 2 weeks after surgery?

Data Collection

In **Papers I to IV** all data was retrieved from Swespine. **Papers I and II** include patients registered 2000–2016, **Paper III** patients registered 2006–2016, and **Paper IV** patients registered 2005–2018 (Swespine started to register height and weight in 2005).

In **Papers I to IV** we report perioperative data and then compare the preoperative data with the 1-year outcomes. In **Papers III and IV** we also report rate of complications.

In **Paper V** data was retrieved from 50 patients operated with decompression due to CLSS in March 2020–January 2022 at Ängelholm County Hospital in Sweden. In this paper we compared preoperative PROMs Swespine data with postoperative outcomes, i.e., PROMs data day 1, 7 and 14 days after surgery. The postoperative data was collected through interviews.

Flow charts

Figure 21. Flow chart of patients in **Paper I** (2,095 patients aged ≥65 years with LDH surgery).

Patients with preoperative data

(n = 2,623)

Patients with missing postoperative data

n = 528

Patients with pre- and postoperative data

n = 2,095
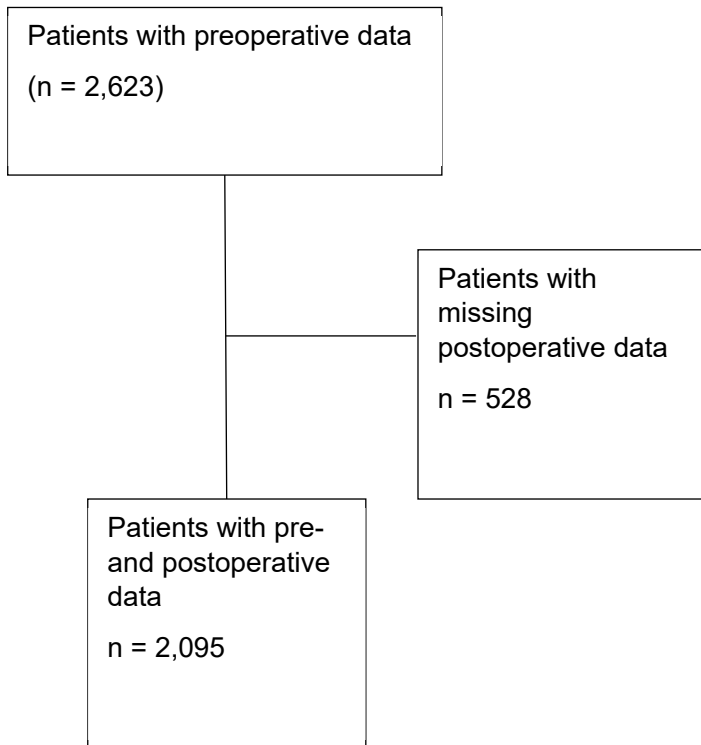
Figure 22. Flow chart of patients in **Paper II** (14,097 patients aged 20–64 with LDH surgery).
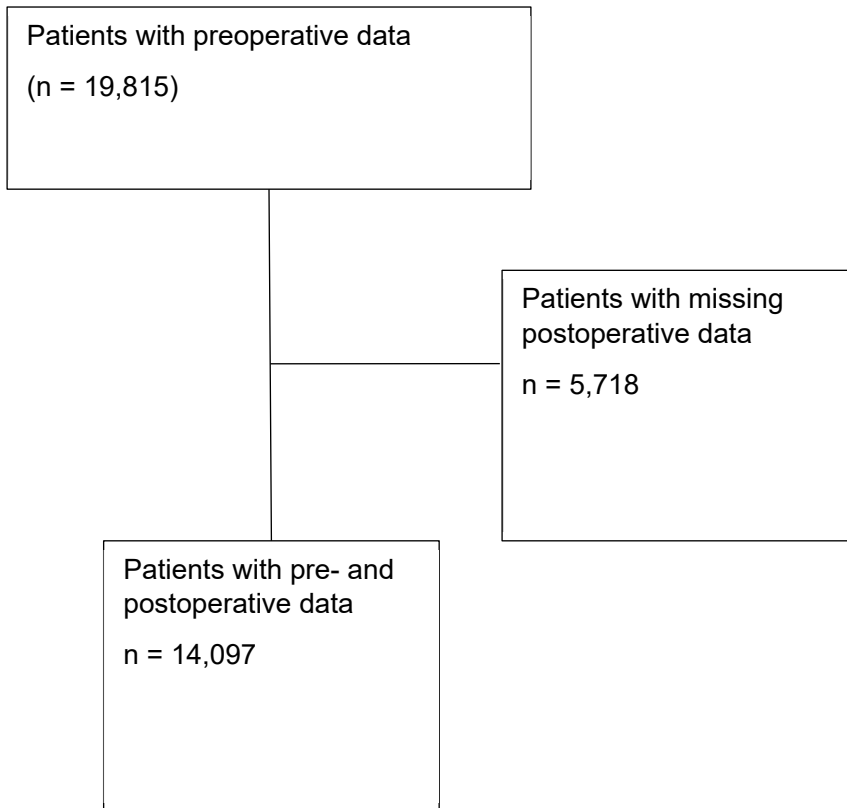
Figure 23. Flow chart of patients in **Paper III** (9,979 patients aged 20–64 with LDH surgery).

Patients who underwent surgery for LDH in 2006–2016 and participated in preoperative PROMs questionnaire (n=17,165)

Excluded (n = 3024)

- Age not available, i.e. foreign ID (n = 4)

- Age <20 or ≥65 (n = 1952)

- Missing data for height and/or weight (n = 932)

- Height <140 cm or >210 cm (n = 26)

- Weight <40 kg or >200 kg (n = 12)

- BMI <18.5 kg/m^2 (n = 98)

Patients meeting inclusion criteria at baseline (n = 14,141)

Patients who did not participate in the one-year follow-up (n = 4,162)

Patients who participated and answered questions regarding at least one PROM at the one-year follow-up (n = 9,979)

Figure 24. Flow chart of patients in **Paper IV** (14,984 patients aged ≥50 with CLSS surgery).

Patients who underwent surgery for LSS 2005–2018 and participated in preoperative PROMs questionnaire (n = 29,237)

Excluded (n = 10,566)

- Gender information missing (n = 41)
- Age <50 (n = 1,527)
- Missing data for height and/or weight (n = 2,345)
- Height <140 cm or >210 cm (n = 79)
- Weight <40 kg or >200 kg (n = 28)
- BMI <18.5 kg/m^2 (n = 134)
- Underwent other type of surgery than decompression (i.e. instrumentation) (n = 2,271)
- Surgery type missing (n = 153)
- Had previous lumbar surgery (n = 4,580)

Patients meeting inclusion criteria at baseline (n = 18,079)

Patients who did not participate in the one-year follow-up (n = 3,095)

Patients who participated and answered questions regarding at least one PROM at the one-year follow-up (n = 14,984)

Figure 25. Flow chart of patients in **Paper V** (50 patients aged >50 with CLSS decompression surgery). All invited accepted participation.

Patients aged >50 who underwent surgery at Ängelholm County Hospital and answered preoperative questionnaire (n = 50)

Interviewed postoperative day 1 (n= 50)

Interviewed postoperative day 7 (n= 50)

Interviewed postoperative day 14 (n= 50)
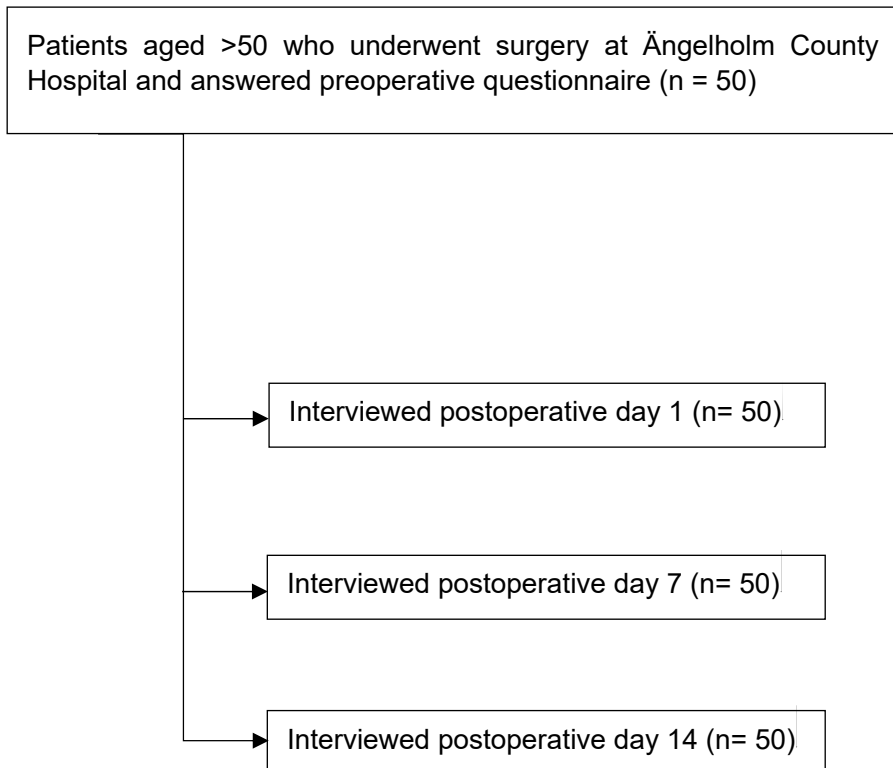
Ethics

Swespine is a certified national quality registry. Patients are informed about the intent of the registry and how the data will be processed before the patient is included and preoperative data registered. The patient approves when they accept to be included that their data can be used for research purposes. The patients are further informed that they may refrain from participation with no change in their clinical treatment, that they can at any time have their information erased, get information about the stored data, get a copy of the data, and/or get information about who has received approval of access to data and when this was done.

The data can only be used to secure and improve the quality of spinal surgery, and for research purposes. The latter previously required an ethical review board approval from the university where the study was initiated. Nowadays, ethical approval is granted by the Swedish Ethical Review Authority. Our studies are also approved by the board of Swespine. The data care and processing follow the General Data Protection Regulation (GDPR).

As with most registry studies, the patients have not given consent to our specific studies. The party responsible for consent for a specific study was previously the different ethical review boards, currently the Swedish Ethical Review Authority. Upon approval, the data is pseudonymised with removal of personal identification numbers so that a specific individual cannot be identified in the working files. The data in Paper V was also pseudonymised. Only the researchers have access to the data in the studies. Further, the data is only presented at group level with no individual results revealed.

All studies in this thesis are approved by the Lund regional ethical review board. (Papers I, II, III, IV reference number Dnr LU2017/158 and for Paper IV, also Dnr LU 2020-03112. Paper V was approved with reference number Dnr 2016/159).

Patients give no specific written consent when being included in Swespine (Papers I to IV). Patients in study V gave written consent after receiving written and verbal information about the study.

Statistical analysis

All statistical analysis in **Papers I–IV** was done with SPSS (IBM Corp., Armonk, NY, USA) in different iterations depending on the year the analysis was done (**Papers I and II**: SPSS 26, **Paper III**: SPSS 27, **Paper IV**: SPSS 28). In **Paper V** Statistica version 12 (Stat Soft) was used.

Data is reported as means ± standard deviations (SD), means (ranges) or proportions (%). In Paper I, baseline pain is presented as means with 95% confidence intervals (95% CI). Inferential statistics are reported as means with 95% CI.

In all papers, group comparisons of continuous variables were tested using Student's t-test between means or between pairs if there were repeated measurements. In the case of comparison of continuous data in several groups, Analysis of Variance (ANOVA) was performed. Proportions were compared with the Chi-square test or Fisher's exact test. Paired categorical testing was performed with McNemar's test. For all papers we used an alpha value of 0.05.

Multivariate analysis was used in **Papers I-IV.** In **Papers III–IV**, covariates were chosen after dialogue within the research group. In **Paper I**, variables with p-values below 0.10 were included in the multivariate analysis. In **Paper II,** previously identified predictors (in the literature) were included in the multivariate analysis. Logistic regressions were performed for dichotomous outcomes. Analysis of covariance (ANCOVA) was used for adjusted analyses of continuous variables. Negative binomial regression analysis was performed in **Paper II**, and we used linear regression in **Papers III and IV**.

In the logistic regression models, data was tested for goodness of fit with the Hosmer–Lemeshow test. Also, the method of adding and subsequently removing each of the selected covariates (stepwise) was tested to ensure that the model would not change drastically. The model assumptions for linear regression were assessed with residual plots with no signs of heteroscedasticity. In **Papers II and III** we used Q-Q plots assessment and the Shapiro–Wilk test for ANOVA in **Paper III**. In **Paper IV** we used Kolmogorov–Smirnov.

Missing Data, Implausible values, and Loss to follow-up

All registry studies must address the problem of missing data. Data could be missing at baseline or have implausible values. Further, a proportion of data is missing at follow-up. The methodological issue of attrition bias was discussed in the introduction. On the basis of this, we do not believe that missing data would affect our results in a clinically relevant manner.

Missing data at baseline were addressed differently in the included studies. In **Paper I**, a simple inclusion and exclusion criterion was presented. In **Paper II** we gave more information on variable completeness. In **Paper III** we tried to overcome some limitations to inclusion and exclusion in registry studies by coding optional exclusion criteria (patients could have some complete and some incomplete follow-up values). The database, in **Papers I-III,** was assessed for irregularities before the data preparations were made, i.e. patients with missing sex information (always less

than 1%) were treated as incomplete registry inputs, and then treated as missing values. Hence, all included patients had gender information at baseline.

In **Paper IV**, which was the most recent Swespine database output to be analysed, the same optional inclusion and exclusion criteria were adapted with the addition of stepwise transparent exclusion, i.e., 41 (0.14%) patients had missing sex information out of 29,237. This is more unusual in registry studies, but also more transparent. The advantage to this in **Papers III and IV** is that less data is missing, however, the tables become crowded with numbers (n=) in every row and column to report the actual numbers that had answered this question.

In **Papers III and IV**, we further excluded patients with implausible values for height (<140 cm or >210 cm) and weight (<40 kg or >200 kg), as we believe there is a higher probability that these values represent wrongful inputs that would skew the statistical calculation.

We conducted no statistical testing of the baseline values in **Papers I to V**, as we had no hypothesis to test regarding baseline differences. Such testing is often seen, but usually regarded as statistically unsound [183]. Instead, we present descriptive data in participants and non-participants, so that the readers could evaluate whether there were any differences of clinical relevance between the groups.

Summary of papers

Paper I

A total of 2,095 patients aged ≥65 years who underwent LDH surgery from 2000–2016, and had preoperative and 1-year data on satisfaction (satisfied, uncertain or dissatisfied) were identified in Swespine (Figure 21). Of these, 76.9% had undergone open discectomy with or without microscope. Logistic regression analysis was used to assess the odds ratio (OR) of preoperative factors associated with satisfactory and uncertain/dissatisfactory outcomes (the 1-year satisfaction rate was dichotomised).

One year after surgery, 71% of patients were satisfied, 18% were uncertain and 11% were dissatisfied.

Among the patients with a discectomy, 73% were satisfied compared to 67% in patients with a decompression. Factors that were associated with a subjective satisfactory outcome were younger age, shorter preoperative duration of leg pain, more leg than back pain, and better SF-36 mental component summary (MCS) (all $p < 0.01$). In contrast, higher age, longer duration of leg pain, and inferior SF-36 MCS and PCS scores were associated with subjective unsatisfactory outcome (all p <0.01).

81% of patients with preoperative leg pain ≤3 months were satisfied compared to 57% of patients with leg pain >2 years ($p < 0.001$). Among patients with registered complications, 56% were satisfied, 23% uncertain and 21% dissatisfied. The corresponding proportions in patients with no complications were 73%, 18% and 10%, respectively (p<0.001).

We conclude that only one out of ten individuals ≥65 years was dissatisfied with the outcome of LDH surgery. Age, preoperative duration of leg pain, preoperative SF-36 score, and as regards satisfaction, also dominance of back over leg pain, are factors associated with subjective outcome after LDH surgery in elderly patients.
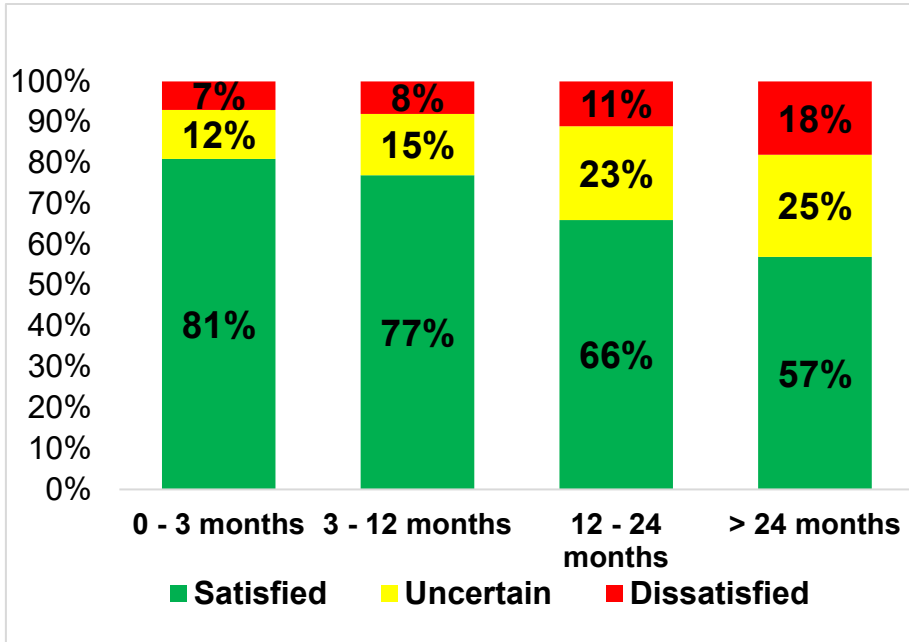
Figure 26. Proportion (%) of satisfied, uncertain, and dissatisfied patients one year after surgery in relation to duration of perioperative leg pain.

Paper II

A total of 14,097 patients aged 20–64 years who underwent LDH surgery 2000-2016, and had preoperative and 1-year postoperative data on back pain registered were identified in Swespine (Figure 22). Of these, 87% had had open discectomy with or without microscope.

The minimum clinically important difference (MCID) was defined as an improvement ≥3.5 for NRS leg pain, ≥2.5 for NRS back pain and ≥20 in ODI [172]. A regression model was used in patients with baseline pain of at least MCID (that is having a hypothetical possibility of improving by at least MCID) to assess preoperative factors associated with achieving improvement ≥MCID.

Mean improvement from before to one year after LDH surgery was 4.5 for NRS leg pain (95% CI 4.5–4.6), and 2.2 for NRS back pain (95% CI 2.1–2.2). Among patients with preoperative pain ≥MCID, 79% of the patients achieved improvement ≥MCID in leg pain and 60% in back pain. Smoking, lower SF-36 MCS and long duration of preoperative pain were associated with lower probability of achieving improvement ≥MCID for both leg and back pain. Old age was also associated with lower probability of reaching improvement ≥MCID in leg pain.

We conclude that LDH surgery improves both leg pain and back pain, and that among patients with clinically significant pain, 79% experience improvement ≥MCID in leg pain and 60% in back pain. Smoking and long duration of pain are associated with inferior recovery in both leg and back pain.

Paper III

A total of 9,979 patients aged 20–64 years who underwent LDH surgery 2006–2016 operation and had preoperative and 1-year postoperative data registered were identified in Swespine (Figure 23). We also identified perioperative complications (death, dural tear, injury of a nerve root, postoperative hematoma, urinary retention, urinary tract infection, pulmonary embolism, wound infection, Cauda Equina Syndrome and thrombosis). A variable was created where patients who had any complication (including several) were merged into "any complication" (coded dichotomous). The same limits for MCID were used as in Paper II.

Patients were divided into weight groups according to WHO [138]: normal weight (BMI 18.5–24.9 kg/m^2), overweight (BMI 25.0–29.9 kg/m^2), obesity class I (BMI 30.0–34.9 kg/m^2), obesity class II (BMI 35.0–39.9 kg/m^2), obesity class III (BMI ≥40.0 kg/m^2). Outcomes in the groups were compared in multivariate analysis in two ways. First, a comparison between outcomes in normal weight, overweight and obese patients, and secondary the outcomes in obese class I, II and III patients.

One year after surgery, 80% of normal-weight, 77% of overweight and 74% of obese patients (class I–III evaluated aggregated) were satisfied (p<0.001). This should be compared to 75% in obese class I patients, 71% in obese class II patients, and 75% in obese class III patients (p=0.43).

NRS leg pain improved in normal-weight patients by 4.8 (95% CI 4.7–4.9), in overweight by 4.5 (95% CI 4.5–4.6) and in obese by 4.3 (95% CI 4.2–4.4). This should be compared to 4.4 (95% CI 4.3–4.6) in obese class I patients, 3.8 (95% CI 3.5–4.1) in obese class II patients and 4.6 (95% CI 3.9–5.3) in obese class III patients.

ODI improved in normal-weight patients by 30 (95% CI 30–31), in overweight by 29 (95% CI 28–29) and in obese by 26 (95% CI 25–27) (p<0.001). This should be compared to 29 (95% CI 28–29) in obese class I patients, 25 (95% CI 22–27) in obese class II patients and 27 (95% CI 22–32) in obese class III patients (p<0.01).

All groups improved in mean by ≥MCID in both NRS leg pain and ODI.

3.0% normal-weight, 3.9% overweight and 3.9% obese patients suffered complications (p=0.047). This should be compared to 3.8% in obese class I patients, 4.4% in obese class II patients, 3.5% in obese class III patients (p=0.90).

We conclude that LDH surgery also in patients with morbid obesity in general is associated with favourable outcomes and few complications.
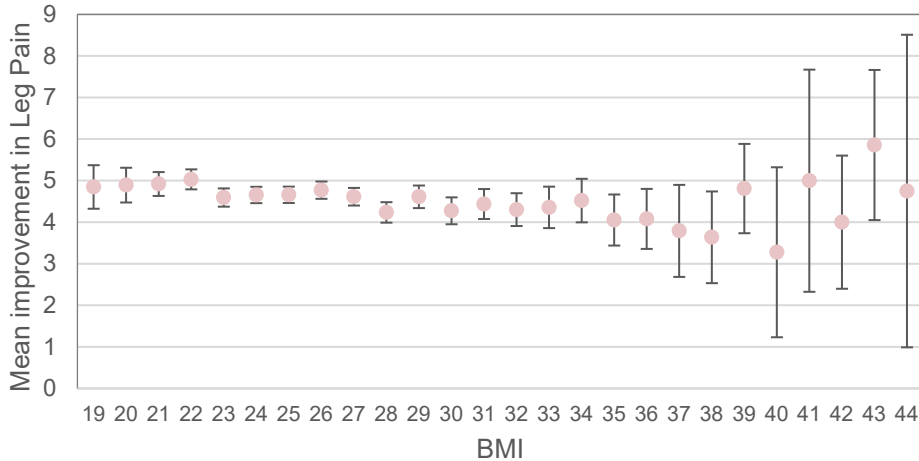
Figure 21. Improvement in Numeric Rating Scale (NRS) leg pain in relation to body mass index (BMI; kg/m^2) from before to one year after LDH surgery. Data is shown as means with 95% CIs.

Paper IV

A total of 14,984 patients aged ≥50 years who underwent CLSS surgery 2005–2018 and had preoperative and 1-year postoperative data registered were identified in Swespine (Figure 24). We also identified perioperative complications as in Paper III, and the patients were categorised in the same weight classes as in Paper III. MCID was defined as an improvement of >40% for NRS leg pain, an improvement of >33% for NRS back pain and an improvement of >30% for ODI [173]. Outcomes in the groups were compared in multivariate analysis as in Paper III.

One year after surgery, 69% of normal-weight, 67% overweight and 62% of obese patients (class I–III evaluated aggregated) were satisfied (p <0.001). This should be compared to 62% in obese class I patients, 60% in obese class II patients and 57% in obese class III patients (p=0.70).
NRS leg pain improved in normal-weight patients by 3.5 (95% CI 3.4–3.6), in overweight by 3.2 (95% CI 3.1–3.2), and in obese by 2.6 (95% CI 2.5–2.7). This should be compared to 2.8 (95% CI 2.7–2.9) in obese class I patients, 2.5 (95% CI 2.2–2.7) in obese class II patients and 2.6 (95% CI 2.0–3.2) in obese class III patients.

ODI improved in normal-weight patients by 19 (95% CI 19–20), overweight by 17 (95% CI 17–18), and in obese by 14 (95% CI 13–15). This should be compared to 16 (95% CI 15–17) in obese class I patients, 14 (95% CI 13–16) in obese class II patients and 14 (95% CI 11–18) in obese class III patients.

8.1% of normal-weight, 7.0% of overweight and 8.1% of obese patients suffered complications (p=0.04). This should be compared to 8.1% in obese class I patients, 7.0% in obese class II patients and 17.0% in obese class III patients (p<0.01).

We conclude that CLSS surgery also in patients with morbid obesity in general is associated with favourable outcomes, even if satisfaction rate is inferior, compared to in normal-weight patients. Morbidly obese patients have more complications than patients with lower BMI.
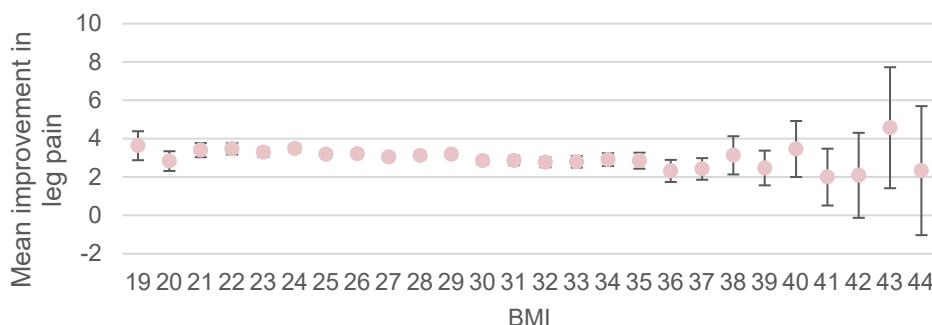
Figure 28. Improvement in Numeric Rating Scale (NRS) leg pain in relation to body mass index (BMI; kg/m^2) from before to one year after CLSS surgery

Paper V

Fifty patients, 25 women with a mean age of 72 years (range 55–85) and 25 men with a mean age of 66 years (range 51–82), with decompressive surgery due to CLSS, performed at Ängelholm County Hospital March 2020–January 2022, were followed from before through 14 days after surgery (Figure 25). The patients had CLSS on 1–4 levels confirmed by MRI, had decompression surgery without fusion, had no cognitive impairment, and sufficient knowledge in Swedish to be able to answer the questions. All but one patient had neurogenic claudication preoperatively, one patient had only back pain. Pre- and perioperative data was retrieved from Swespine. In the postoperative period the patients were followed up with structured telephone interviews on days 1, 7 and 14 after surgery where we registered NRS back pain, NRS leg pain, EQ-5D-index, EQ-5D-VAS, and pain medication. MCID thresholds for back and leg pain were defined as in Paper IV.

NRS leg pain was reduced from preoperative to first postoperative day by mean 5.2 (95% CI 4.3, 6.1) while no further improvement was found from postoperative day 1 to 7 or day 7 to 14. NRS back pain did not improve from preoperative to first postoperative day but from postoperative day 1 to 7 by NRS 0.6 (95% CI 0.03, 1.2) and from day 7 to 14 by 0.7 (95% CI 0.2, 1.3). The EQ-5D index increased from preoperative to first postoperative day by 0.09 (95% CI 0.06, 0.13), and from day 1

to 7 by 0.05 (95% CI 0.02, 0.08) with no further significant change to day 14. EQ-5D VAS from preoperative to first postoperative day by 13.7 (95% CI 9.1, 18.3) and from day 1 to 7 by 6.0 (95% CI 2.0, 10.0) with no further significant change to day 14. Two weeks after surgery 51% of the patients had improved ≥MCID in back pain and 71% ≥MCID in leg pain.

We conclude that decompression due to CLSS is followed by improvement in leg pain within one day of surgery, that back pain improves day 1 to 14 after surgery and that quality of life improves from preoperatively to day 7 after surgery. The majority of patients already within 2 weeks after surgery achieve a clinically relevant improvement.
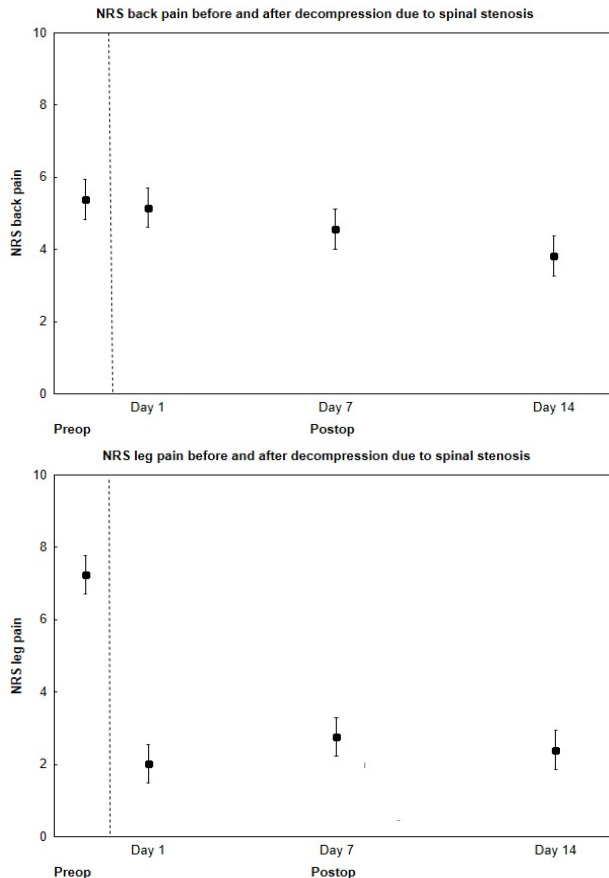
Figure 28. NRS back pain and leg pain, before and 1, 7, and 14 days after surgery in 50 patients aged 51–85 years who underwent decompression due to central lumbar spinal stenosis (CLSS). Data is shown as mean with 95% confidence intervals (95% CI).

General discussion

Outcomes of lumbar disc herniation surgery in the elderly

In **Paper I**, we showed a high satisfaction rate in individuals aged ≥65 years after LDH surgery. The preoperative factors in **Paper I** that were associated with a satisfactory outcome resemble those that were reported in the literature to be associated with a satisfactory outcome in middle-aged adults [112, 114, 115]. Higher age, lower quality of life (Short Form-36 score), and dominant back over leg pain have in middle-aged adults previously, and now also in our cohort, been shown to be associated with a lower probability of satisfactory outcome [112, 114, 115]. However, in patients ≥65 we could not find that smoking was associated with inferior outcome, in contrast to most data in middle-aged adults [112, 114, 115]. This could however be due to our criteria of selection for multivariate analysis (factors with bivariate p <0.1 were included). Another study with the threshold of p <0.2 came to a similar conclusion as regard smoking [184].

In **Paper I**, a short duration of the preoperative leg pain was associated with satisfactory outcome and the improvement was only slightly inferior to the reported improvement in middle-aged adults [185-187]. The reason why those with longer duration of preoperative leg pain had inferior outcomes is unclear. We speculate that central sensitisation of the pain might be one factor. Another possible factor is selection bias in those with a long duration of symptoms. This group of patients may more often have had a long patient delay before seeking medical help, unclear radiology, unclear clinical symptoms, and/or other factors that contradict a successful surgical result, making the surgeon (or patient) more likely to avoid or postpone surgery. Due to the study design in **Paper I**, our inferences could only be regarded as hypothesis generating, and we cannot conclude any causality regarding duration of symptoms. We are also unable to provide recommendations regarding the best timing of LDH surgery in this age group in relation to duration of symptoms.

One concern in **Paper I** is that the study cohort may include not only patients with LDH but also, as the patients are elderly, also cases of spinal stenosis. We speculate that this could be a possibility as the reported proportion of decompression of 15.6% is higher than reported in middle-aged adults [111, 188]. Since CLSS patients are generally less satisfied with the surgical result than LDH patients [111], this ought to, if anything, underestimate the effect of LDH surgery. This view is supported by our data, showing that when stratifying the cohort in **Paper I** into those who underwent discectomy alone and those who underwent decompression, 73% of

patients with discectomy were satisfied compared to 67% of patients with decompression.

Back pain in LDH surgery

In **Paper II**, in patients aged 20–64 with LDH surgery, we found that both leg and back pain improved through the surgical procedure, leg pain more than back pain. Furthermore, among patients with preoperative pain ≥MCID (that is, patients with a theoretical possibility to improve above MCID), leg pain improved ≥MCID in 79% of the patients and back pain improved ≥MCID in 60% of the patients.

The preoperative factors in **Paper II** that were associated with back pain reduction ≥MCID resembled those that were associated with leg pain reduction ≥MCID. There are speculations that this may be the result of common pathogenic mechanisms behind both leg and back pain, which could possibly be associated with the disc. A herniated disc may put pressure on nerve structures and thus provoke leg pain. Some also suggest that pathology in the affected disc may result in back pain. This view is controversial. The common belief prior to the 1980s was that discs lack nerve supply [189]. The timeline of the scientific consensus could therefore be described in the following captions. In the 1980s the view was that *'discs cannot hurt'*. Studies then showed that discs actually have a nerve supply [189]. The general belief changed to '*discs can but do not hurt'* to the often advocated view today, that '*discs can hurt, but it is not diagnosable'*. There are studies trying to address this issue, such as one from 2015 that reported back pain in 87% of patients who, on MRI, had both a high-intensity zone (HIZ) (indicating an anulus tear), and a moderately degenerated disc [95]. Such research will need to continue and will be of great interest if in the future it will be possible to find explanatory mechanisms for back pain and/or if it will be possible to foresee who will benefit from surgery (and possibly also type of surgery) in respect to reduced back pain.

Even if we found in **Paper II** that back pain also was reduced through LDH surgery, this data must be interpreted with care when addressing an individual patient, as the data in **Paper II** represents the outcomes at group level. Furthermore, the data in **Paper II** cannot be used to support the idea that back pain should be an indication for LDH surgery. The data can only be used when informing the patient that with current indications of LDH surgery, there is a good chance that back pain will also be reduced through surgical intervention. Further studies should therefore assess whether certain subgroups of patients with back pain benefit from surgery, and whether back pain in these groups can be an indication for surgery.

The role of overweight and obesity in relation to LDH and CLSS surgery

In **Paper III** and **Paper IV**, we found that with current indications of LDH and CLSS surgery, not only normal-weight, overweight and those with a lower level of obesity, but also morbidly obese patients in general are satisfied with their outcomes.

To our knowledge, **Paper III** and **Paper IV** are the largest studies that have evaluated the association between BMI classes and the outcomes of LDH and CLSS surgery. The relatively large sample sizes provided an opportunity to evaluate the outcomes in obese patients within different classes, also in morbidly obese patients. To our knowledge this has not been done with such a large sample size before.

The outcome of LDH surgery in obese patients is debated. The largest previous study (before ours) is a retrospective analysis of the SPORT trial [144]. This study concluded that 336 patients with obesity (BMI $\geq$30 kg/m^2) had statistically significant inferior outcomes after LDH surgery compared to 854 non-obese patients (BMI <30 kg/m^2). In this study, ODI improved from before to one year after surgery in the obese group by 35.2 ± 1.2 (mean $\pm$ SD) compared to 38.5 ± 0.8 in the non-obese patients (p=0.02) [144]. Therefore, it has been questioned whether such a small difference could be regarded as a clinically relevant difference [144]. Furthermore, other end-point variables had similar or even greater treatment effect in the obese group of patients [144]. This, in conjunction with the possibility in **Paper III** to evaluate the different obesity classes separately, makes us conclude that, as most morbidly obese patients are also satisfied after LDH surgery, this procedure ought to continue to be an option not only in class I and II obese patients, but also in morbidly obese patients.

Conclusions regarding the outcome in obese patients after LSS surgery are also debated. The largest previous study (before ours) that evaluated this was a study by Knutsson et al. using Swespine data and assessing the 2-year outcomes after LSS surgery in 606 obese (BMI >30 kg/m^2), 1,208 overweight (BMI 25–30 kg/m^2) and 819 normal-weight patients (BMI <25 kg/m^2) [149]. This study included patients with previous surgery, patients scheduled for fusion surgery and all patients with LSS that is, probably also those with only foraminal and lateral recess stenosis. The researchers in this study reported that 67% of patients with normal weight, 64% overweight and 57% obese were satisfied with the 2-year outcome. Furthermore, the mean improvement in each weight group was $\geq$MCID, which is a clinically relevant improvement. This should be compared to the data in **Paper IV**, in which 69% of patients with normal weight, 67% of overweight patients and 62% of obese patients were satisfied with the 1-year outcomes. The discrepancies between the studies are thus small, possibly explained by the different inclusion criteria and different follow-up time. The conclusions in both the cited study [149] and **Paper IV** were that surgery should not be withheld from obese patients. In **Paper IV** we were able to further substantiate this recommendation by concluding that CLSS surgery had predominantly satisfactory outcomes not only in class I and II obese patients, but also in morbidly obese patients, albeit with significantly more dural tears.

However, we acknowledge that the conclusions, both in **Paper III** and **Paper IV**, must be drawn with care, due to possible selection bias in the higher obesity classes.

Patients with high BMI might be selected extra carefully and only undergo surgery if the symptoms and clinical findings are absolutely clear. It is also possible that the hospital prepares more attentively, with more experienced surgeons, anaesthesiologists, and personnel for this group of patients. Further, there is a possibility of information bias. The surgeons might have the preconceived notion that obese patients should expect more complications and a less successful outcome, thereby possibly giving the patients lower expectations than more normal-weight patients.

We must also acknowledge that complications in **Paper III** and **Paper IV** might be underreported. This view is supported in one study when cross-referencing the patients' complication data in Swespine to an insurance company [190]. However, we have no reason to believe that any underreporting of complications would be dependent on the patients' BMI.

The short-term outcome in decompressive CLSS surgery

In **Paper V** we found that the recovery pattern after CLSS decompression surgery is clinically relevant during the first week, and the recovery pattern in leg pain, back pain and quality of life have different temporal patterns. To our knowledge this has not been previously reported. There is one study that reports follow-up 6 weeks after LSS surgery [27], while most others conduct the initial follow-up after 3 months or more [35, 191, 192]. There is one further study that evaluated the recovery pattern the first two weeks after LDH surgery [3], a study that reported leg pain already improved the first postoperative day, that back pain improved gradually during the two first postoperative weeks as did quality of life (EQ-index). That is, as shown in **Paper V**, the recovery pattern after CLSS decompression surgery resembles the recovery pattern after LDH surgery.

The importance of the recovery pattern in the immediate postoperative period after CLSS and LDH surgery might previously have been overlooked. Studies have focused on the median and long-term outcomes, and/or differences between surgical and nonoperatively managed patients. But there is also a great informative value of assessing the improvement in the immediate postoperative period, as to be able to provide patients with realistic information regarding recovery, need for analgesics, rehabilitation rate, and ability to return home. Improved knowledge about the postoperative period improves our ability to give adequate and thorough preoperative patient information. Currently, 54% of patients with degenerative LDH surgery report that they are dissatisfied with the preoperative information [193]. This is surprising, as inadequate information is associated with inferior surgical outcomes and less satisfied patients [117, 194, 195]. The improved knowledge regarding the recovery pattern after CLSS surgery provided in **Paper V** would therefore not only provide realistic expectations and improved ability to optimise aftercare planning and pain medication, but possibly also contribute to more satisfied patients.

One concern in **Paper V** is the small sample size (n=50). However, as the baseline values regarding NRS leg and back pain, age, and sex distribution mimic those seen nationally in Sweden [196], this indicates that our results can be generalised. The use of independent observers in **Paper V** not participating in the care of the patients and not aware of the radiological, clinical, or perioperative findings minimises the risk of an interviewer effect in the postoperative interviews. We must however also acknowledge that the close personal contact with a doctor before and after the operation (regardless of the doctor not participating in the care) may be a source of bias, as close personal contact has been shown as a possible way to influence the response as compared to form-based responses [197].

Other limitations and strengths in the registry-based studies

In **Papers I to IV**, we used the term *predicto*r in the headline, a term that is frequently used in studies of similar composition. The term is correct from a technical perspective but only in the models performed on the same observational cohort. The term can be misleading if one would assume that the same would apply in an actual clinical situation. For example, in **Papers I to IV** in our statistical models we found that long duration of preoperative pain symptoms gives greater odds of having an inferior outcome. However, with the study design in **Papers I to IV,** we could not state whether this was caused by long duration of nerve structure compression, or if the group who underwent surgery after a long duration of pain were exposed to selection bias. The risk of selection bias in different groups is inevitable in registry studies, including our studies on Swespine data. The patients are selected for surgery by the individual surgeon, based on several factors, many of which are not registered in Swespine. We can only use registered variables and traits, such as diagnosis, baseline variables and demographics, when trying to estimate if there is selection bias between groups. It would, of course, have been of value to also have radiological assessments and deeper medical histories of the patients. However, no such data is included in Swespine. The obvious risk of selection bias in registries is why it is more accurate to use the expression '*factors associated with*' than '*factors that predict.'*

Therefore, in our view the registry studies as reported in **Papers I to IV** should be classified as evidence level III (*Definition Level III according to the Journal of Bone and Joint Surgery: Retrospective cohort study; Case-control study; Non-consecutive included patients*). But there is also controversy regarding this. Several reviewers of **Papers I to IV** questioned whether the studies should not be classified as level II studies (*Definition Level II according to the Journal of Bone and Joint Surgery: Prospective cohort study).* The confusion arises as Swespine collects data prospectively. However, when conducting research studies, the data is assessed retrospectively. If the hypothesis is formed after the data has been collected, in our view the study is retrospective, even if the data was collected prospectively. However, we are aware that retrospective studies with prospectively collected data,

both in registry and other cohort studies, are reported with a higher level of evidence (level II) in many publications. One example is the aftermath of the SPORT trial, where several retrospective analyses were performed in the cohort years after the initial RCT was published. These were then predominantly graded as level II studies, sometimes also as a level I study (*Definition Level I according to the Journal of Bone and Joint Surgery: Randomized controlled trial; RCT*). However, the same inherent limitations as discussed above apply to these studies, as the hypotheses were generated after the data was collected.

Another weakness in **Papers I to IV** is the risk of selection bias due to large proportions of non-responders or patients being lost to follow-up. This has already been discussed in detail in the previous chapter, 'Swespine', in this thesis. However, several previous studies concluded that loss to follow-up of magnitudes as in Swespine will probably not alter any conclusions [171, 177, 178]. Despite this, we will recognise that loss to follow-up is a concern in all register-based studies.

'With great power comes great responsibility' is a phrase most often attributed to the Spider-man comic. We are of the opinion that same ought to be applied to large registry-based studies, as in **Papers I to IV**. The size of the study population provides more than enough power for conducting most statistical calculations. These may result in statistically significant, yet very small, clinically insignificant group differences (or improvements). This is the reason why the use of MCID is important in studies that include a large sample size. For the clinician it is probably of more interest if a difference achieves clinical relevance than if the statistical difference is found with a p-value of $p<0.05$, $p<0.01$ or $p<0.001$.

Furthermore, in studies with many variables and a large sample size (making it possible to conduct sub-group analyses), the researcher should avoid more tests than necessary for testing the primary and secondary hypotheses. This will minimise the risk of type I errors. This is the reason why we in most cases avoided conducting a variety of post-hoc tests between groups in **Papers I to IV**, and instead used different multivariate analyses.

Strengths with nationwide registry studies are the use of nationwide data that is prospectively collected to achieve an unselected population (with knowledge that patients with no or foreign IDs and/or difficulties understanding Swedish may be excluded). That is, the outcomes in **Papers I to IV** reflect outcomes in the regular health care system compared to single-centre studies that often report what is possible to achieve in highly-specialised health care centres with highly skilled surgeons, or RCTs that usually use selective inclusion criteria.

Another advantage in registry studies is that some hypotheses are practically possible to evaluate only in registries. For example, evaluation of the surgical outcomes in rare subgroups, such as the morbidly obese patients evaluated in **Paper III** and **Paper IV**, could hardly be done with a sufficient sample size in single-centre studies (or even multicentre settings) in Sweden. In fact, even if we included more

than 10 years of nationwide surgical treatment in **Paper III** and **Paper IV**, we barely collected a sufficient number of morbidly obese patients to be able to (with acceptable power) assess the outcomes in this group of patients.

Future perspectives

The early Swedish hip and knee arthroplasty registries are global forerunners of orthopaedic registries. Swespine follows as the counterpart in spinal surgery. Swespine has improved data-driven health care in Sweden, with the recently introduced dialogue support further enhancing the preoperative assessment [198]. In the future, the introduction of artificial intelligence (AI), such as deep learning, will possibly enhance data analysis as well as provide better predictive tools in our national registries.

Another developing branch in spine research is cross-referencing different registries, such as combining Swespine with regional and national health care registries and national prescription registries. A future utopia (in the author's opinion) would be to create a 'mother registry' where all registries and charts are automatically cross-referenced into one encrypted nationwide registry. Such a behemoth of a registry is, of course, fascinating, offering almost endless possibilities of data analysis. However, the path to this is arduous and must regard several aspects including ethics, data protection, legislative measures, and coordination between academia, health practitioners, legislative and governmental institutions. The public opinion of such a registry is also of greatest relevance. It should be noted that when Swedish physicians and orthopaedic professors Göran Bauer founded the knee-arthroplasty registry in 1975, and Peter Herberts the hip-arthroplasty registry in 1979, they initially met fierce resistance [199] from other Swedish orthopaedic surgeons, who called it '*a flagrant intrusion on personal and professional integrity*.'

Another development in the national registries is to create registry-based randomised controlled trials (RCTs). Such studies could be done in rare diseases and conditions, where patients are randomised at their home clinic, with a majority of clinics in Sweden (or preferably all) being involved in the study. Such an approach will, within an acceptable time limit, reach sufficient numbers of patients, also including rare diseases (or treatments). The outcomes will then be followed through the national registry. Such studies are already ongoing in the Swedish arthroplasty registry and Swedish Fracture Register (SFR).

Another interesting use of Swespine is the newly implemented web-based form, where the patients can report the data in their own computers directly to Swespine. Time will tell if this improves loss to follow-up by making patient entry more convenient.

Another possibility in the future would be robotic process automation (RPA). Some RPA systems are currently under development. Region Halland in Sweden has started working with RPA to automate administrative tasks, leaving valuable time for health personnel to do other things. Similar RPA may hypothetically be included in Swespine, to aid the surgeon with the entry of perioperative data.

Conclusions

Paper I

In patients ≥65 years undergoing LDH surgery,

- most patients are satisfied with the surgical result

- only one out of ten is dissatisfied

- longer duration of symptoms, higher age, worse preoperative physical and mental health are associated with greater odds of experiencing postoperative dissatisfaction

- shorter duration of symptoms, younger age, better preoperative physical and mental health, and more leg than back pain are associated with greater odds of experiencing postoperative satisfaction

Paper II

In patients aged 20–64 years undergoing LDH surgery,

- there is in general a clinically relevant reduction in both back and leg pain

- the reduction in leg pain is generally more obvious than the reduction in back pain

- 60% of the patients with preoperative clinically significant back pain experience a reduction in the back pain by ≥MCID

- 79% of the patients with preoperative clinically significant leg pain experience reduction in the leg pain by ≥MCID

- duration of symptoms, mental health and smoking are associated with improvement ≥MCID in back pain in patients with preoperative clinically significant back pain

- age, duration of symptoms, mental health and smoking are associated with improvement ≥MCID in leg pain in patients with preoperative clinically significant leg pain

Paper III

In patients aged 20–64 years with LDH surgery,

- obese patients in general achieve inferior outcomes compared to normal weight patients, but with minor or no clinical relevance

- obese class III patients in general achieve similar outcomes as obese class I patients

- obese patients in general have more complications than normal-weight patients

- obese class III patients in general have no more complications than obese class I patients

- more than half of all patients with preoperatively clinically significant deterioration achieve improvement ≥MCID

Paper IV

In patients ≥50 years with CLSS surgery

- obese patients in general achieve inferior outcomes compared to normal weight patients, but with minor or no clinical relevance

- obese class III patients in general achieve similar outcomes as obese class I patients

- obese patients at group level have no more complications than normal-weight patients

- obese class III patients in general have more complications than obese class I patients

- more than half of the patients with preoperative clinically significant pain achieve a reduction in pain ≥MCID irrespective of their pre-operative BMI (except for leg pain in obese class III patients where 49% improved ≥MCID)

Paper V

In patients >50 years with decompressive CLSS surgery,

- leg pain in general improves from preoperative to day 1 after surgery

- back pain in general improves from day 1 to day 14 after surgery

- quality of life in general improves from preoperative to day 7 after surgery

- a majority of patients achieve a clinically relevant improvement within 2 weeks

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Appendix

Best Presentation, Annual Meeting of Swedish Orthopedic Society (SOF) 2022.

Best National Paper, Annual Meeting European Federation of Trauma and Orthopaedics (EFORT) 2023 (invited abstract)

BÄSTA FRIA FÖREDRAG

Obesitas
– ingen kontraindikation för diskbråckskirurgi

Vi har genomfört en studie med 9979 patienter 20-64 år gamla från Svenska ryggregistret, Swespine. Syftet var att jämföra resultat samt komplikationer hos patienter med normalvikt, övervikt samt olika grad av obesitas, samt att jämföra andelen patienter inom varje viktkategori som i uppnår förbättring överstigande "Minimal ClinicallyImportant Difference" (MCID)

Vi fann följande bland patienter som opererats för lumbalt diskbråck:

· De flesta är nöjda oberoende av grad av obesitas

Niyaz Harenis föredrag "Favorable Outcome of Lumbar Disc Herniation Surgery Also in Morbidly Obese Patients" mottog utmärkelsen "Bästa fria föredrag" under Ortopediveckan.

· Förbättringen av bensmärta är något sämre bland obesa jämfört med normalviktiga, men vi finner ej skillnad mellan obesa klass III patienter och obesa klass I patienter

· De flesta når en förbättring överstigande MCID oberoende av BMI-klass

· Överviktiga drabbas av fler komplikationer än normalviktiga men vi finner ingen skillnad mellan obesa klass III och obesa klass I-patienter.

Demografi - preoperativt

	Normal vikt BMI 18.5 - <25.0	Övervikt BMI 25.0 - <30.0	Obesitas I BMI 30.0 - <35.0	Obesitas II BMI 35.0 - <40.0	Obesitas III (Morbid obesitas) BMI ≥40.0
	N = 4156	N = 4063	N = 1384	N = 317	N = 59
Ålder	42 ± 11	44 ± 10	45 ± 10	43 ± 10	41 ± 11
Kön (Man/Kvinna)	45%/55%	64%/36%	56%/44%	44%/56%	42%/58%
Rökare	16%	14%	16%	19%	19%
NRS bensmärta	6.7 ± 2.4	6.7 ± 2.5	6.7 ± 2.4	7.0 ± 2.5	6.8 ± 2.2
ODI	47 ± 19	47 ± 18	50 ± 17	53 ± 19	51 ± 17

Medelvärde ± SD
Proportioner (%)

LUNDS UNIVERSITET

Förbättring bensmärta per enhet BMI i relation till MCID

Förbättring >MCID

Medelvärde med 95% konfidensintervall
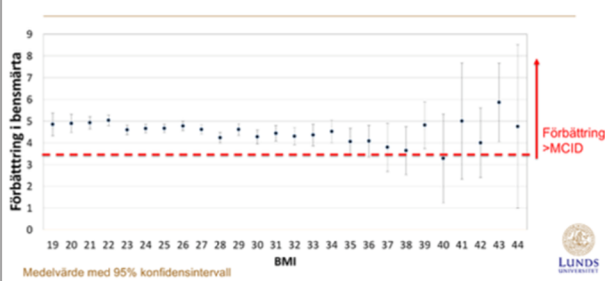
LUNDS UNIVERSITET

I forskargruppen ingår även Fredrik Strömqvist, Björn Rosengren och Magnus Karlsson. Samtliga vid ortopediska klinikerna vid Hallands Sjukhus, Varberg och Skånes Universitetssjukhus, Malmö.

Editorial Acta Orthopaedica (co-editor Bart Swierstra), Newsletter, December 2022

Selected Highlights

A comparison study on patient-reported outcome between obese and non-obese patients with central lumbar spinal stenosis undergoing surgical decompression: 14,984 patients in the National Swedish Quality Registry for Spine Surgery

Niyaz Hareni, Kari Gudlaugsson, Fredrik Strömqvist, Björn E Rosengren, and Magnus K Karlsson

Decompressive surgery for central lumbar spinal stenosis (CLSS) is advocated when disability persists despite conservative therapy. Hareni et al. tried to find an answer for the commonly encountered clinical dilemma whether clinical outcomes are inferior, and risks for complications higher, in obese than in non-obese patients with data of 14,984 patients in the National Swedish Quality Registry for Spine Surgery.

They found improvement in pain and disability after laminectomy due to CLSS in patients of normal weight, those who were overweight, and obesity classes I–III, but in general obesity and improvement were inversely associated. Most obese patients were satisfied, even if satisfaction rate was inferior compared with normal-weight patients. There was no statistically significant difference in satisfaction rate among patients in different classes of obesity, as the group with morbid obesity was small. The morbidly obese had more complications than patients with lower BMI. The authors conclude that decompression due to CLSS ought to remain a treatment option also in patients with overweight and classes I–III obesity. The main strength of this study is that it includes nationwide prospectively collected data, i.e., outcomes in an unselected national population undergoing CLSS surgery. The results are thus applicable to general healthcare and not only, as in many other studies, to highly specialized spine units with certain inclusion criteria. For spine surgeons the results of this study will be useful in their preoperative shared decision-making process, particularly in the morbidly obese patients (BMI > 40) who were satisfied in only 57% at the cost of 17% complications (compared to 69% satisfaction and 8% complications in the normal weight patients).

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