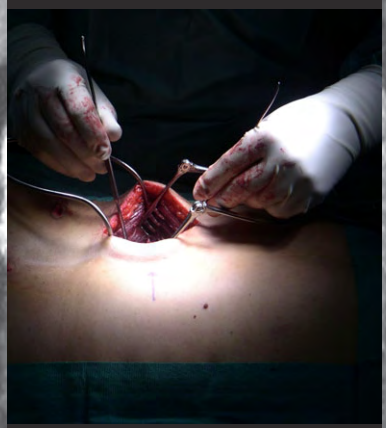
On Lumbar Spinal Stenosis and Disc Herniation Surgery

by

Karl-Åke Jansson



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Cover shows a spine surgeon performing a spine procedure, to the left MRI of a lumbar spinal stenosis and to the right MRI of a disc herniation.

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CONTENTS

1 LIST OF ABBREVIATIONS

CDR	Cause of Death Register
CFR	Case Fatality Rate
CI	Confidence interval
CT	Computed Tomography
EpC	Epidemiologiskt Centrum
EQ SDQ	Euroqol Standard Set of Demographic Question
EQ-5D	The 5-dimensional scale of the Euroqol
EQVAS	Euroqol visual analogue scale
EuroQol	European Quality of life questionnaire
HR	Hazard ratio
HDR	Hospital Discharge Register
HRQOL	Health Related Quality of Life
ICD	International Classification of Diseases
LOS	Length of stay
QALY	Quality Adjusted Life Years
MRI	Magnetic resonance imaging
SCB	Statistics Sweden
SD	Standard Deviation
SF-36	Medical Outcomes Study Short Form Survey, 36 items
VAS	Visual Analogue Scale
WHO	Word Health Organization

2 ABSTRACT

Patients with spinal stenosis and disc herniation are most common in spine surgery. Few population based studies of these patients have been made and no studies of their health related quality of life (HRQOL) by the EQ-5D has been published. The aim of this thesis is to analyse incidence, readmission, reoperation and mortality in Swedish patients operated on spinal stenosis or disc herniation in the lumbar spine during 1987-1999 and report the EQ-5D outcome data between 2001-2002. The spinal stenosis cohort and disc herniation cohorts consist of 10,494 and 25,247 patients and the final EQ-5D analysis of 230 and 263 patients. Information from the Swedish Hospital Discharge Register and the Swedish Death Register were linked to analyse the outcomes. A quality register study based on prospectively collected EQ-5D data from the National Swedish Registry for Lumbar Spine surgery was also performed.

The mean annual incidence per 100,000 inhabitants of spinal stenosis and disc herniation surgery during the study period was 10 and 24, respectively. The mean age at surgery for spinal stenosis increased from 60 to 67 years but was constant at 42 years for disc herniation. The 30 day mortality rate was 3.5 and 0.5 per 1 000 operations, respectively. The mortality rate declined despite ageing spinal stenosis patients. The length of stay after surgery was reduced to half. Patients operated on for spinal stenosis and disc herniation have a risk of being reoperated after one and ten years of 2-3 %, and 10-11 %, respectively. The reoperation rate decreased over time. During the 13 years, 78 % of the disc herniation patients had only one hospitalisation (the operation). The risk of being readmitted was constant over time. Preoperatively the HRQOL was low, poorer than among previously reported for patients with stroke or depression. Patients operated on for spinal stenosis and disc herniation experienced an improved health related quality of life and their EQ5-D score increased from 0.29 to 0.70 and 0.36 to 0.64 one year after surgery. Four out of ten reported considerable improvement while a similar proportion of patients with high preoperative scores were slightly improved. A third group (20 %) was unchanged with low EQ-5D scores, and 4-5% perceived a decline in their HRQOL. The majority of patients approached but did not reach the level reported by the matched population sample.

The studies indicate factors such as male sex, age over 80, fusion procedure, smoking, hospital stays before surgery or long hospital stays at surgery, severe back pain, long duration of pain, short walking ability were risks for a less favourable outcome.

The EQ-5D instrument increases the awareness of the importance of health related quality of life when considering surgery and when evaluating treatment. Future studies need to elucidate the gender differences, impact of smoking cessation programs and the cost utility of spine surgery.

Key words: spinal stenosis, disc herniation, surgery, spine surgery, discectomy, population based, epidemiology, mortality, length of stay, reoperation, readmission, health related quality of life, EQ-5D

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3 SAMMANFATTNING PÅ SVENSKA

Få nationella epidemiologiska studier av operation för spinal stenos och diskbråck har publicerats, trots att de utgör de vanligaste kirurgiska åtgärderna vid ryggkirurgi. Inga analyser om patienternas hälsorelaterade livskvalitet (HRQOL) med EQ-5D har rapporterats.

Syftet med denna avhandling var att analysera patienter med spinal stenos och diskbråck i ländryggen som opererats i Sverige under 1987 -1999 och deras HRQOL med EQ-5D data under 2001-2002.

Spinal stenos- och diskbråcksgrupperna bestod av 10 494 respektive 25 247 patienter och den slutliga EQ-5D analysen genomfördes med 230 respektive 263 opererade fall. Epidemiologiska data erhölls genom länkning av Svenska Patientregistret (HDR) och Dödsorsaksregistret CDR). En kvalitetsregisterstudie genomfördes baserad med prospektivt insamlade data (EQ-5D) från Svenska ländryggsregistret.

Den årliga medel incidensen för kirurgi av spinal stenos och diskbråck var 10 respektive 24 operationer per 100,000 invånare. Medelåldern vid kirurgi av spinal stenos ökade under studietiden från 60 till 67 år medan den var konstant 42 år för patienter med diskbråck. Mortaliteten inom 30 dagar efter operation var 3.5 respektive 0.5 per 1 000 operationer. För båda ingreppen halverades medelvårdtiden. Frekvensen av reoperationer efter kirurgiska åtgärder av spinal stenos och diskbråck inom 1 år var 2-3 % och 10-11 % efter 10 år. Av de diskbråcksopererade hade 78 % endast ett vårdtillfälle. Risken att bli återintagen var konstant över tid.

HRQOL före kirurgi var påtagligt nedsatt, sämre än för patienter med stroke och depression. Patienter som opererades för spinal stenos och diskbråck upplevde en förbättrad HRQOL och deras EQ-5D score ökade från 0.29 till 0.70 respektive 0.36 till 0.64 ett år efter kirurgi. Fyra av tio upplevde en betydande förbättring av HRQOL och en liknande andel av patienter med hög preoperativ EQ-5D score blev något förbättrade. En tredje grupp (20 %) var oförändrade med låga värden och ett fåtal upplevde en försämrad HRQOL. De flesta patienterna närmade sig men nådde inte upp till HRQOL nivån hos en matchad population.

De samlade studierna visade att kvinnligt kön, ålder över 80 år, fusionskirurgi, rökning, tidigare vårdtillfälle för ryggsjukdom före kirurgi, svår ryggsmärta, lång smärtduration och kort gångsträcka var riskfaktorer för sämre resultat efter operation. EQ-5D instrumentet ökar medvetenheten om vikten av att beakta hälsorelaterad livskvalitet såväl inför beslut av kirurgi som vid evaluering av behandling. Det medger även möjligheter till jämförelser med normalpopulationen och patienter med andra sjukdomar.

Framtida studier bör ägnas faktorer bakom könsskillnaden, effekt av rökavvänjning samt relationen kostnad och nytta.

4 LIST OF PUBLICATIONS

This thesis is based on the following studies which will be referred to in the text by their Roman numerals I-V. Content of published material was reprinted with kind permission from the respective copyright holders.

I. **Spinal stenosis surgery in Sweden 1987-1999.**
Jansson K-Å, Blomqvist P, Granath F, Németh G
European Spine Journal 2003;12:535-541

II. **Spinal stenosis reoperation rate in Sweden is 11 % at 10 years. A national analysis of 9 664 operations.**
Jansson K-Å, Németh G, Granath F, Blomqvist P
European Spine Journal, in press 2005

III. **Surgery for herniation of a lumbar disc in Sweden between 1987 and 1999.**
Jansson K-Å, Németh G, Granath F, Blomqvist P
Journal of Bone and Joint Surgery [Br] 2004;86-B:841-847

IV. **Health related quality of life (EQ-5D) before and after lumbar spinal stenosis surgery.**
Jansson K-Å, Granath F, Németh G, Jönsson B, Blomqvist P
Journal of Bone and Joint Surgery [Br], accepted for publication 2005

V. **Health related quality of life (EQ-5D) in lumbar disc herniation surgery patients.**
Jansson K-Å, Granath F, Németh G, Jönsson B, Blomqvist P
Submitted for publication

5 INTRODUCTION

Sweden with 9 million inhabitants has a health care system based on independent county councils, divided into six medical regions and the private health sector is small. Registration and statistics of diseases and surgical treatments, Hospital Discharge Register (HDR) of patients have a long history in Sweden and the Cause of Death Register (CDR) are among the oldest worldwide. After World War II WHO took over responsibility for international co-ordination and the International Classification of Diseases was then adopted. Since 1987 have HDR and CDR covered all public in-patient care in Sweden. The lifetime prevalence of low back pain is 80% and the point prevalence is around 30%, common disorders are spinal stenosis or disc herniation.

During the last decade's introduction of CT, MRI and development of spine surgery has developed. The age distribution has also changed with an aging population. How this affects the incidence of surgical interventions for spinal stenosis and disc herniation is important for clinicians and health care providers to know in order to plan the need for resources for the two most common spinal surgical interventions. Geographic differences and trends could also be used in the different county councils as baseline data for comparisons. Health care has undergone changes. During the last 40-years the number of in hospital beds has decreased by 80 % in Sweden. It is important to find out if this had an impact on length of stay and re-admissions after spinal surgery.

One of the essential outcomes after surgery is reoperation rates. There is, however, no information gathered of national spinal stenosis reoperation rate. In surgical treatment mortality rates are important especially if the patients are elderly. However, no national longitudinal data of incidence and trends or rates of mortality have been published.

The Swedish register for lumbar spine surgery is unique in the world, documenting multiple pre- as well as postoperative variables including health related quality of life (HRQOL). We used this register to assess the HRQOL according to EQ-5D questionnaires. This multidimensional instrument could function as a complement to the conventional outcomes such as complications, reoperations, and also harmonize with disease specific instruments evaluating spine functioning. The two groups of patients studied could also be compared to the general population and patients with other diseases.

The purpose of the thesis was to increase the epidemiological knowledge of lumbar spinal stenosis and disc herniation by using the HDR and CDR. The intension was also to give information about the magnitude and the demand on medical and social resources. An additional purpose was to report the pre- and one year postoperative health related quality of life outcome by the EQ-5D instrument in the two groups of patients operated on for a lumbar disc herniation or a lumbar spinal stenosis

6 BACKGROUND

6.1 DISK HERNIATION

6.1.1 Incidence

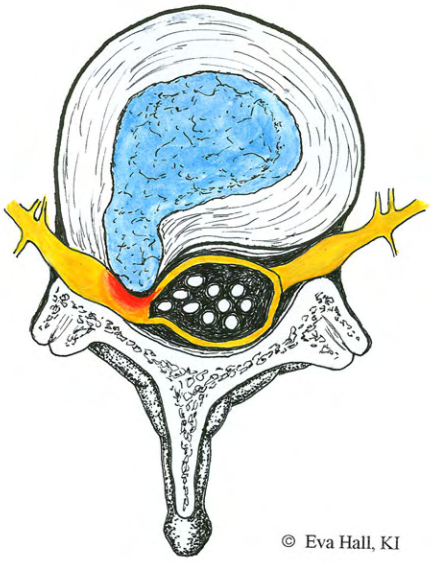
The prevalence of back pain in developed countries is high and is clearly one of the most widespread and costly musculoskeletal problems[139].
One cross-sectional study determined a lifetime incidence of sciatica of about 40 % while lifetime incidence of disc herniation is 1- 2 %[65]. In Sweden, the frequency of operations due to disc herniation has been 20 per 100,000 inhabitants and year from the mid 1950s through 1980[135]. In the UK, the corresponding level was 10 per 100,000 inhabitants and year, in Finland 40, and in the US 70, respectively[82;158].

Regional differences within a country have also been reported, i.e. an eight-fold variation between different regions in the US[23].

6.1.2 Pathophysiology

Disc herniation is a process with rupture of annulus fibres and subsequent displacement of the central mass of the disc into the intervertebral space. The dorsal or dorsolateral aspects of the disc are affected more often than other parts (Fig 1).

Fig 1. Lumbar disc hernia



A classification scheme based on morphologic criteria is accepted: normal disc, bulging disc and herniation disc[28]. Disc herniation is categorized as; protrusion (contained), extrusion (complete/non contained), and extrusion with disc material (sequestered). These types are correlated to the clinical picture[99;174].

Disc hernia usually occurs as a consequence of degeneration of the disc and the onset of an annular rupture is usually the end point of a gradual disc degeneration [64;130]. It is generally accepted that the etiology of lumbar disc degeneration is multifactorial and related to a variety of factors such as mechanical, chemical, genetical, occupational and social environmental factors[15;75;80;108]. The pathophysiological mechanism of symptomatic lumbar disc herniation has been studied. A mechanical compression of nerves together with chemical irritants from the disc nuclear tissue increases production of cytokines triggering the inflammatory or autoimmune response. This may secondary lead to hypersensitivity and nerve dysfunction. All these factors have been shown to have a cause-and-effect relationship with pain and radicular symptoms[31;107;127;142;160].

6.1.3 Symptoms and signs

Patients with lumbar disc herniation initially report back pain followed by development of pain and parasthesia radiating down to the leg (sciatica). The distribution of leg pain usually follows the nerve root leaving the spinal canal one vertebral level caudal to the disc herniation. The patients may present with a motor weakness or sensory disturbance typical for the nerve root's distribution[51]. Valsalva maneuver or cough may increase the pain in the leg and frequently the patient has a scoliosis due to pain. If the herniation is located more centrally in the spinal canal, the nerve root leaving two levels below will also occasionally be affected. A central herniation may even damage the roots that exit several levels below.

In the cauda equine syndrome, the sacral roots are involved, leading to an emergency condition with flatus incontinence, urinary incontinence, peroneal sensory loss in addition to bilateral sciatica[1;50;51;111;139].

6.1.4 Diagnostics

On physical examination, most patients have a positive straight raising leg test (radicular pain occurs with straight-leg elevation of 60 degrees or less), and may have associated reflex, sensory or motor deficis[51;100]. Laségue´s sign (positive straight raising leg test) is an important predictor for a lumbar disc hernia[7]. A crossed Lasèue test indicates an high incidence of complete disc herniation[51;100;174]. If the patients suffer from disabling sciatica longer than 4-5 weeks, a radiologic examination is recommended. CT or MRI is preferable; however, both have a moderate sensitivity and specificity and asymptomatic disc hernias are also common [24;25;27]. Following introduction of MRI and CT, disc herniation has been diagnosed more frequently than before[109]. The diagnosis of disc hernia is established if radiology confirms an abnormality that corresponds with the physical findings and symptoms[139].

6.1.5 Non-operative treatments

Treatment aims to reduce pain and disability, and restore the premorbid function. The natural course of lumbar disc herniation varies with the different intensity of clinical symptoms, the coexisting pathology, and the psychosocial factors[6;152;161]. The average natural history is based on clinical experience and literature reports[39;77;161;201]. The dominating leg pain is most intensive initially. Commonly the pain weakens to same extent after a few weeks, it then tends to remain at about the same level for approximately one to three months, and disappear in 50% to 78 % of non-surgical cases[77;201].

Conservative therapeutic (non-surgical) options are nomerous, physical therapy, manual therapy, pharmacological therapy i.e. analgesics, and rehabilitation strategies. However, it is

unlikely that this type of intervention will change the natural history of disc hernia with radicular symptoms[135;170;194]. When there are prolonged symptoms, surgical treatment is an option to consider.

6.1.6 Surgical interventions

The primary rationale of any form of surgical intervention for a disc prolapse is to relieve nerve root irritation from compression due to herniated disc material[174]. A few clinical criteria to select surgical candidates have been suggested. These are: Impairment of sacral roots (bowel or bladder), evidence of increasing impairment of root conduction, persisting severe sciatica or increasing pain despite conservative treatment, recurrent episodes of sciatica, positive Lasègue test and a radiologic examination confirming the clinical symptoms and signs[111;123].

Open discectomy, performed with macrotechnique without the use of a microscope, or with an operating microscope, is the most common procedure, but there are a number of other less invasive surgical techniques, these are: Percutaneus discectomy, laser- or ultrasound discectomy[43;48]. Chemonucleolysis, dissolution of the nucleus, by enzyme injection using chymopapain has also been advocated for contained lumbar disc hernia[18;72;84;173].

6.1.6.1 Effect of surgical interventions

There is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc herniation, which fails to resolve with conservative management [136]. In Weber's series, 25 % of patients admitted with documented disc herniation improved after a 2-week hospital stay. However, 25 % remained significantly symptomatic and were surgically treated. The remaining 126 patients in the study were randomized to non-surgical or surgical treatment. At 1 year, good results were found in 90 % of surgically treated patients compared to 60 % in the conservative treatment group. At the 4-and 10-year follow-up the results were similar in the 2 groups.[201] This study has drawbacks. First the 126 patients with proved disc hernia had "uncertain" indication for surgery. Secondly there was no blinding and a crossover of 26 % of the conservative treated group to surgery due to intolerable pain during the first year[21]. Also the reports of pain mechanism due to the neurotoxical contents in the disc may have altered the insight to a more surgically prone therapy[31;139;142;160].

Surgical discectomy provides faster relief from the acute attack than conservative treatment, although any positive or negative effects on the lifetime natural history of the disease disc hernia are unclear. Patients experience improvement after discectomy, in some reports up to 80 to 90 %[47;146;165;201].

The choice of macro- (standard) or microscopic discectomy probably depends more on the training and expertise of the surgeon, and the resources available, than on scientific evidence of efficacy[83;112;191]. There is evidence to support the option of chemonucleolysis as a less invasive, intermediate stage between conservative management and open surgical procedure, although the over-all results are poorer than after primary discectomy[68]. At present percutaneous discectomy, laser discectomy[68] and also ultrasound technique as well as disc prosthesis should be regarded as research techniques under development.

6.1.6.2 Length of stay (LOS)

LOS in hospital is an important indicator of efficiency for in-patient care but it must be adjusted for the case mix of the hospitalized patients. Factors such as age, gender, number of comorbid conditions, and financing have been found to affect the length of stay[8;76;205].

The LOS after disc herniation surgery has been reported to be 4.5 days[119]. The same authors also showed that by adding a fusion, the LOS increased to 7.2 days. Shortened LOS has been shown to not adversely influence the medical or functional outcome from lumbar discectomy[113].

6.1.6.3 Reoperation and readmission

The definition of a reoperation varies in the literature. In this context the definition of a reoperation is repeated surgery for the same diagnoses (disc herniation and spinal stenosis). The rates of reoperation after disc hernia surgery vary from 4 to 25 % after 4 to 10-years (Table 1). There are differences among studies of reoperations with regard to inclusion criteria for surgery, number of patients included, type of surgical interventions and follow-up time.

Table 1. Reoperation after Lumbar Disc Hernia surgery

Author	Country	Year	No. of Pts.	Average Follow-up (yrs)	Reoperation (%)
Österman H[145]	Finland	2003	35 309	1	7.5†
				10	24.9†
Gaston P[67]	UK	2003	993	5.2	4.9
				10	7.9
Morgan-Hough C[132]	UK	2003	531	7	7.9
Atlas S[12]	US	2001	507	5	19.0
Vik A[196]	Norway	2001	211	8.5	3.7
Daneyemez M[46]	Turkey	1999	1072	10	7.9
Malter A[119]	US	1998	3938	5	16.0
Hu R[87]	Canada	1997	2417	4	9.5

†Include discectomy, decompression and fusion operations

6.1.6.4 Mortality

In-patient mortality in the United States after orthopaedic surgery has been reported to be approximately 1 % for all patients and 0.6 % after spine procedures[22]. In an analysis of disc herniation surgery the mortality rate was 0.9 per 1 000 operations[103]. National longitudinal data of the mortality rates have not been reported.

6.2 SPINAL STENOSIS

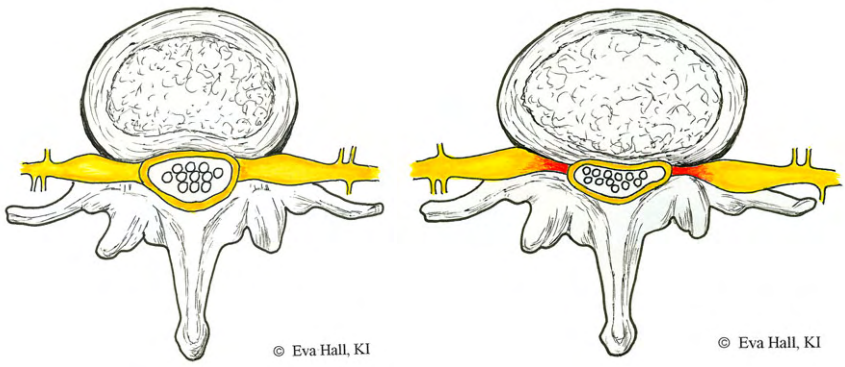
6.2.1 Incidence

Lumbar spinal stenosis is a common cause of low back pain[96;163;195]. The incidence of spinal stenosis in Sweden has been studied previously in selected areas and was reported to be 5 per 100,000 inhabitants and year (1987-1991)[94]. The same study reported a rate of spinal stenosis surgery of more than 3 per 100,000 inhabitants and year. In a report from Geneva in Switzerland the incidence of operations for spinal stenosis was estimated to 11.5 per 100,000 per year[14].

6.2.2 Pathophysiology

Lumbar spinal stenosis is defined as a reduction in the diameter of the spinal canal. The anatomic classification refers to central canal stenosis, lateral recess stenosis or neural foraminal stenosis. The last two may occur with or without central spinal stenosis (Fig 2 a-b)is a common cause of low back pain[96;163;195].

Fig 2a Normal vertebral canal **Fig 2b Spinal Stenosis**



According to Arnoldi et al[10] lumbar spinal stenosis is divided into congenital-developmental or acquired, both with subgroups. This classification is commonly used. In this context the subgroup degenerative spinal stenosis is the major focus. The stenosis may occur as a part of a generalized disease process and involve multiple areas of the canal and multiple levels or, conversely, may be localized or segmental. The reduction in the diameter of the spinal canal or neural outlets may be attributable to bone hypertrophy, ligamentous hypertrophy, disc protrusion or combinations of these elements[26;41]. In these degenerative processes, the spinal canal and/or the nerve root canals narrow, reducing the space available for the nerve roots of the cauda equina. If the dimensions are reduced below critical values, the cauda equina nerve roots will be subjected to mechanical compression. If the pressure developes over an extended period of time, there may be an adaptation of the nerve tissue to the applied pressure. In cadaver experiments it was shown that a critical cross-sectional area of the dural sac was 77 mm^2 [166;167]. This was also found to correlate with a corresponding area computed from CT images in spinal stenosis patients.

There are also well defined changes in spinal nerve root blood flow, nutritional supply via diffusion from the cerebrospinal fluid and impulse conduction occuring at different

experimental pressure levels. These factors correlate to pressures which are likely to act in vivo on the cauda equine in central spinal stenosis[141;144].

A single level central spinal stenosis causes little vascular impairment in contrast to a double level central spinal stenosis at low pressures, which results in considerable blood pooling[149]. Double or multiple nerve root compression induces more pronounced changes in nerve root nutrition and function than single level at corresponding pressure levels [143;188]. This is of clinical significance for clinical symptoms in spinal stenosis patients. In addition longstanding compression or higher pressure may cause fibrosis in the spinal canal[160].

In trunk flexion, the antero-posterior diameter increases in the vertebral canal. With extension, the diameter decreases and the canal narrows. In addition, trunk extension increases the bulging of the ligamentum flavum and intervertebral discs into the spinal canal and thereby compromises the size of the canal additionally, which probably also correlates to patients´ symptoms and dynamics of their clinical signs [63;168].

The compression of the spinal canal via the above mentioned neurophysiological changes causes the major symptoms in spinal stenosis, neurogenic claudication, sensory reduction, motor weakness and pain.

6.2.3 Symptoms and clinical signs

Three major clinical problems are significant. First of al the patient often has a long history of low back pain with or without leg pain. This is probably due to different degenerative pain mechanisms. Secondly, the radiculopathy in the leg, paresthesia, sensory disturbance and/or motor weakness and pain are present according to the specific nerve root distribution. This may occur due to entrapment of the root in the lateral recess of the central canal or neural foramina. It is most common to have bilateral symptoms in the legs due to plurisegmental nerve root impairment. The third symptom is neurogenic claudication. Patients experience pain or discomfort in one or both legs when walking or in prolonged standing, but not present when sitting. The most important aspect of neurogenic claudication is the relationship of symptoms to posture. Symptoms worsen with spinal extension and are relieved in flexion. Patients can walk longer distances with less pain in a forward trunk flexed position,"grocery cart sign". They may bicycle sitting in flexed position and sleep with the trunk in a flexed position. These posture findings have been explained by studies where the spinal canal area increases by 25 % in flexion[168]. Uncommon symptoms are groin, perineal, and genital pain. Those symptoms could be due to a chronic cauda equine syndrome.

6.2.4 Diagnostics

The most important features of the physical signs are the neurological status and palpatory examinations. Many patients demonstrate normal or non-specific findings. Therefore, it is difficult to evaluate the relevance of the clinical examination. Katz et al found that the highest specificity came from no "pain when seated" and "wide-based gait" and the highest sensitivity was "age greater than 65", "pain below the buttocks" and "no pain at trunk flexion"[104]. Others have used treadmill tests, and electrophysiological tests to further evaluate patients symptoms and for differential diagnostic purpose i.e. vascular claudication and peripheral neuropathy[63].

The patients' symptoms of back pain, leg pain and neurogenic claudication should correspond with findings on a confirming radiology, MRI or CT[157]. Since the introduction of MRI and CT, spinal stenosis has been diagnosed more frequently[109]. The cross sectional area

should be less than 77mm^2 to be considered as a significant spinal stenosis[168]. However, it should be emphasized that pathologic findings on CT and MRI indicating spinal stenosis are common and have been reported to occur in 21 to 28% of asymptomatic individuals [25;109].

The diagnose of spinal stenosis is verified, if imaging studies confirm an abnormality at a spinal level that corresponds to the physical findings and symptoms.

6.2.5 Non-operative treatments

The natural history of lumbar spinal stenosis is not well understood. Slow progression appears to occur in all affected individuals. The clinical course varies considerably, and in most patients is chronic and benign[3;4;62;94]. The natural course of lumbar spinal stenosis has only been reported from one study with 32 patients followed for a mean of 49 months. In that study, 70 % of the patients were unchanged, 15 % were improved, and 15 % were worse[96].

Patients with symptoms related to lumbar spinal stenosis will primarily be treated non-operatively because many patients respond well to this therapy[4;138]. Although non-operative treatment is less successful in patients who have more severe pain, higher functional limitations, and neurologic dysfunctions, the non-operative management is recommended because a delay of surgery for some months does not worsen the prognos for these patients[4;13]. Even if rapid symptomatic deteriorations are rare in lumbar spinal stenosis patients, the physician has to keep in mind that changes such as disc herniation or fracture could further compress the spinal canal and an acute cauda equina syndrome may develop. This should be considered as an emergency case and treated as soon as possible[50;111].

The goal of treatment of lumbar spinal stenosis is to affect the pathophysiologic mechanism that causes the patients´ symptoms. Little is known about the efficacy of conservative management (non-operative)[171]. There are many options available i.e. physical therapy, analgesic drugs, transcutaneuous electrical nerve stimulation, lumbar belt (to maintain the spine in flexion), calcitonin (at least in patients with osteoporosis and Paget´s disease)[56]. It is reasonable to use concurrent or overlapping treatments to achieve better results. If prolonged symptoms, surgical treatment is an option to consider[66;86;95].

6.2.6 Surgical interventions

The principle of a surgical procedure for lumbar spinal stenosis is to relieve the nerve root(s) and spinal canal irritation of compression. The clinical criteria for the surgical indication are not yet established. However, there is agreement that surgical intervention should be considered only following adequate conservative treatment[3;11;95;171]. The patients' symptoms, especially the severity of pain is the key factor in the selection of surgical candidates[79]. There has to be a correlation attained between the patients´ symptoms and the radiology images before surgical treatment is considered[24;109]. Lumbar spinal stenosis surgery is generally an accepted intervention when conservative treatment has failed [4;11;105;193].

The most common procedure is standard decompression with laminectomy or laminotomy (fenestration), the latter a more bone saving technique. The decompression could be performed with or without operating microscope. Sometimes an additional fusion is performed with or without instrumentation, usually due to pseudospondylolisthesis. More seldom a fusion without decompression is performed. A new concept with an instrument that keeps the spine in flexion has also been introduced[115].

6.2.6.1 *Length of stay (LOS)*

The LOS after lumbar spinal stenosis has been reported to be 6.8 days[119]. The same authors also showed that by adding a fusion the LOS increased to 8.0 days. During the last decades, the number of beds in Swedish hospitals has decreased by nearly 80 %, from 120, 000 to just over 27, 000[128]. How this decrease in beds has influenced the LOS after lumbar spinal stenosis during late 1980s and 1990s is unclear.

6.2.6.2 *Effect of surgical interventions*

There are two prospective randomize studies showing that the 4 year overall patient satisfaction with surgery for lumbar spinal stenosis was 63 and 80 %, compared to conservative treatment with 42 and 50 % respectively[4;13]. However, regardless of treatment, unsatisfactory outcomes have commonly been reported, 20 to 40 % of patients treated operatively and 50 to 70 % of patients treated non-operatively had unsatisfactory outcome after 4 years[4;13;120;121]. There are few comparisons between different surgical procedures and also heterogeneity of the patient selections. In a prospective randomised study comparing laminectomy with multilevel laminotomy the overall results were similar [151]. Other studies have compared laminectomy with posterolateral fusion, with or without instrumentation and no major differences were noted [30;71;85]. However, in patients with degenerative spondylolisthesis it was found that an instrumented fusion with union was better than a non-instrumented fusion[71;85].

6.2.6.3 *Reoperation and readmission*

The rates of reoperation after spinal stenosis surgery vary from 6 % to 23 % in studies with a 4- to 13-year follow-up (Table 2). There are differences among these studies with regard to inclusion criteria for surgery, number of patients included, type of surgical intervention and follow-up time. Most previous studies of the reoperation rate of spinal stenosis surgery have been based on selected patients groups, either from different regions, hospitals, or patients belonging to certain healthcare insurance programs. No national longitudinal data of the spinal stenosis reoperation rate have been reported.

6.2.6.4 *Mortality*

The characteristics and mortality of operated patients have been reported for elderly patients, based on Medicare data[52;140]. A meta-analysis from 1992 of spinal stenosis surgery reported an in-patient mortality rate of 0.32 %[193]. The median age in the Medicare data study by Oldrigde et al from 1994 was 71 years and they found an in-patient mortality rate of 0.52 %. National longitudinal data of the incidence, trends, or data after discharge of mortality rates have not been reported.

Table 2. Reoperation after Lumbar Spinal Stenosis surgery

Author	Country	Year	No. of Pts.	Average Follow-up (yrs)	Reoperation (%)
Rillardon L[153]	France	2003	141	10	10.6
Hee T[81]	Singapore	2003	68	8	7.4
Atlas S[13]	US	2000	148	4	6.2
Javid M[93]	US	1998	170	5.1	6.5
Malter A[119]	US	1998	1085	5	12.5
Hu R [87]	Canada	1997	805	4	9.5
Jönsson B[97]	Sweden	1997	105	5	18
Katz J[105]	US	1996	88	10	23
Herno A[86]	Finland	1993	108	12.8	9.3
Caputy A[40]	US	1992	88	5	18

6.2.7 Health related Quality of Life (HRQOL)

WHO defines health as a complete physical, mental and social well-being and not merely the absence of infirmity[203]. The definition of quality of life is debated[169] but the WHO defines it as the individuals' perception of their position in life, in the context of the cultural and value system in which they live and in relation to their goals, expectations, standards and concerns[204].

The multidimensional HRQOL concept refers to perceived physical and mental health of a person or a group. The purpose of any HRQOL instrument is to cover the different dimensions of health into a feasible measure that is appropriate for a population. Public health professionals use HRQOL to measure the impact of numerous disorders, short- and long term disabilities, and diseases in different populations. Today it is evident that instruments measuring HRQOL should be used to evaluate health care interventions[69]. The incorporating of HRQOL data will provide additional outcomes in for instance spine surgery interventions. The multidimensional HRQOL measurement acts complementary to the conventional outcome indicators i.e. complications, reoperations, and also harmonize with disease specific instruments evaluating spine function.

The development of HRQOL instruments has during the last decades followed four specific paths, these are:

Domain – specific instruments focus on certain aspects of health. Examples are single items such as walking ability or multi item physical function, Disability rating index (DRI)[162].

Disease – specific instruments focus on a particular health problem. Common validated disease specific instruments for spinal disorder treatment are the Oswestry Disability Index[58], the Million Index[126], the Low Back Outcome Score[70], the Quebec Back Pain Disability Scale[110], and the Roland Morris Disability Questionnaire[154;155] which was developed from the Sickness Impact Profile[19].

Generic – instruments focus on description of health status in dimensions that are more general health profiles that allow comparisons of interventions across different

diseases and populations. Instruments used in spine research are the Nottingham Health Profile[88], the Duke Health Profile[147] and the SF-36[199;200].

Utility – instruments focus on weighing together several dimensions of health into a single index (utility score) as an expression of the health state [190]. Available instruments are the Health Utility Index[189], the Quality of Well-Being[102]and the EuroQol (EQ-5D).[57] The utility score of a specific health state could be multiplied with the number of years of duration of the health state, resulting in the quality adjusted life years (QALYs)[134;202]. When combining the costs of an intervention with the utility score attained, a cost utility analysis provides results expressed as cost per QALY, as an indicator of the socio-economic benefit of medical treatments[134].

There are few reports on cost-effectiveness of the surgical intervention[114;118]. The outhor's knowledge no studies using utility instruments have been performed after disc herniation or lumbar spinal stenosis.

6.2.7.1 EQ-5D Questionnaire

The EQ-5D (EuroQol) is a non-disease specific instrument for describing and evaluating the Health Related Quality of Life (HRQOL). The EQ-5D has a standard set of demographic questions (EQ SDQ) and the protocol is a two part patient self-administered multidimensional questionnaire[32;57]. The EQ-5D score states has 5 dimensions; mobility, self care, usual activities, pain-discomfort and anxiety-depression. Each dimension is divided into three categories: no problem, some (moderate) problem and major (severe) problem, rendering 243 (3^5 +2) health statuses, in addition to death and unconsciousness. These health states have been ranged as EQ-5D index scores by a large UK population sample between 0.00 which indicated worst possible health state (death) and a value of 1.00, indicating best possible health state. It turned out that some states were considered worse than death and they were given negative values (UK index Tariff)[53;54].

The second part of the protocol is a global assessment of the patients' own current state of health on a vertical 20 cm visual analogue scale, the EQ-VAS, where 0 indicates worst imaginable health state and 100 indicates best imaginable health state.

Thus, the EQ-5D provides three types of data for each respondent. A profile indicating the extent of problems in each of five dimensions, a score determined from a population sample based on these health states, and a global health status by a VAS assessment. The EQ-5D has been used in population studies as well as in several clinical trials in different fields of medicine and has been found to have acceptable reliability and validity[29;33;55;89].

In order to estimate HRQOL and QALYs in a population in Sweden a EQ-5D national survey was performed[38]. The National Swedish Register for Lumbar Spine Surgery monitors outcomes after spine surgery in Sweden and since 2001 the protocol includes the EQ-5D questionnaire[184](www.ssu.orthop.gu.se/nrr-default.htm).

7 AIMS

The aim of this thesis is to describe and analyse Swedish patients operated on for spinal stenosis and disc herniation in the lumbar spine with epidemiological methods and to report their health related quality of life.
The specific aims were to assess

- The incidence and the geographic distribution of surgical interventions in patients with lumbar spinal stenosis and disc herniation, the characteristics of these patients and the subsequent development during 13 years. *(Study I, III)*

- The length of stay in patients operated on for lumbar spinal stenosis and disc herniation surgery. *(Study I, II, III)*

- The reoperation rates in patients operated on for lumbar spinal stenosis and disc herniation surgery. *(Study II, III)*

- The readmission rates in patients operated on for lumbar disc herniation surgery. *(Study III)*

- The mortality rate in patients operated on for lumbar spinal stenosis and disc herniation surgery. *(Study I and III)*

- The pre- and one year postoperative health related quality of life outcome by the EQ-5D instrument in cohorts of patients operated on for a lumbar disc herniation and lumbar spinal stenosis. *(Study IV and V)*

- The differences between lumbar spinal stenosis and disc herniation patients in pre- and postoperative health related quality of life measured by the EQ-5D instrument and to compare with a Swedish EQ-5D population survey. *(Study IV and V)*

8 PATIENTS AND METHODS

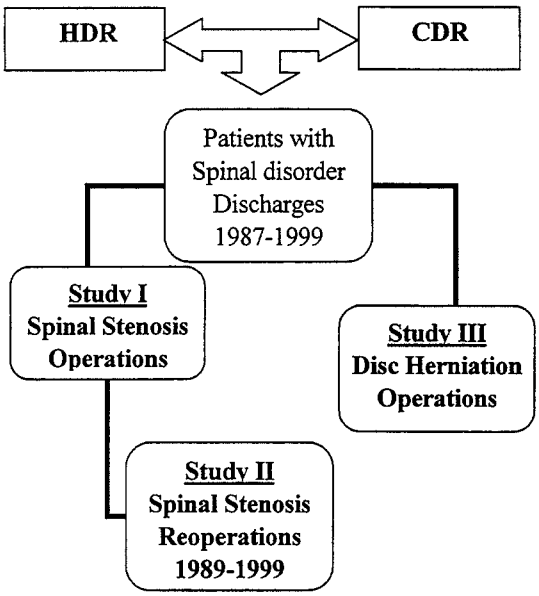
8.1 DATA SOURCES

Three data sources were used. The Swedish Hospital Discharge Register[183], which was linked to mortality data from the Cause of Death Register[182], and The National Swedish Register for Lumbar Spine Surgery[187]. All three registers are described separately in the text.

8.1.1 Selection of patients - Study I, II, III

A retrospective cohort from the Swedish Hospital Discharge Register[183] (HDR) and Death Cause of Death Register (CDR)[182]was selected, 234, 000 discharges of spinal disorder during the years 1987 through December 1999 were included (Fig 3).

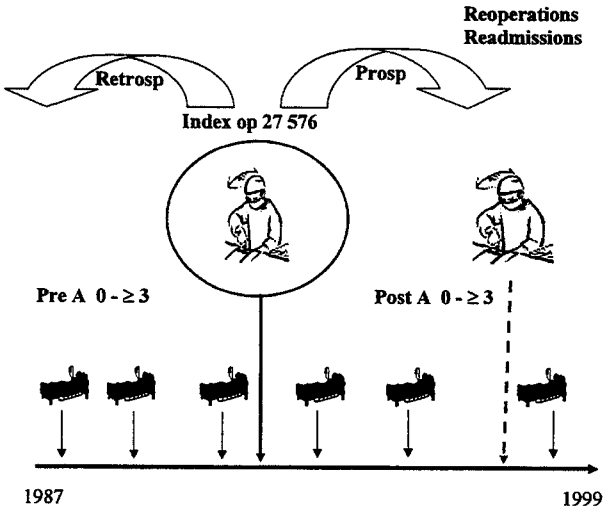
Fig. 3 Study design



Only patients with a primary diagnosis of spinal stenosis (Study I and II), and patients with a primary diagnosis of lumbar disc herniation (Study III), were selected according to the ICD 9 and ICD 10 classifications[176;178]. Operations were coded according to the Swedish classification of operations and major procedures, 6th edition[177], and classification of surgical procedures 1997 [179]. In order to minimize the risk that the index operation was actually a reoperation of an index operation performed before 1987, only operations from January 1, 1989 trough December 31, 1999 were included in Study III. The secondary analysis of data left 9, 664 patients who had undergone surgery for spinal stenosis in Study II. To analyze the risk of dying among those operated on, we linked information on date of death and underlying cause of death from the Cause of Death Register to the Hospital Discharge Register using the personal identification number. Underlying causes of death were coded by the ICD 9 and ICD 10 classifications. For each patient undergoing operation for disc

herniation (Study III), all pre- and postoperative admissions for spinal pathology (ICD) 720-724, ICD 10 M46 –M50) were also merged (Fig 4).

Fig 4. Pre- and postoperative admissions



In Study I and III the characteristics of the patients, incidence, trends, geographic distribution and mortality rate were calculated. In Study II and III the characteristics of patients who were reoperated, length of stay and in Study III also readmission were analysed.

8.1.1.1 The Swedish Hospital Discharge Register (National Inpatient Register)

Since 1964, the Swedish National Board of Health and Welfare has compiled data on individual hospital discharges in the Swedish Hospital Discharge Register[183] (HDR), and since 1987 the register has covered all public in-patient care in Sweden. Information to HDR is delivered once a year to the Centre of Epidemiology at the Swedish National Board of Health and Welfare, Epidemiologiskt Centrum –EpC (www.sos.se/epc) from each of the 21 county councils in Sweden.

Information on the patients' sex, age and place of residence are reported. Data on the county council, hospital and department are given. Each discharge also contains administrative data including length of stay, surgical procedures performed and diagnoses at discharge. The register is approved by the Swedish Data Inspection Board and based on the 10-digit identification number unique for all Swedish inhabitants, which makes it possible to identify each individual and to perform computerised linkage between registers.

The quality of data of the total number of drop-outs reported for the somatic short-time care for the period 1987-1991 has been estimated to be less then 2 per cent. For all records reported to HDR, a data control is performed. A check is made that compulsory variables are reported, e.g. personal identification number, hospital and primary diagnosis. A check is also made that codes for different variables and dates have valid values. Some obviously incorrect data are corrected in connection with the quality controls. Number of stays with missing personal identification number (PIN) was 0.4 % in 2001. In the same year the

primary diagnoses were missing in 0.9 per cent of the hospital stays reported. The missing primary diagnoses are concentrated to a few county councils. The information in HDR for 1964-2000 whether the patient was deceased or alive at discharge has been compared with the date of death from the Swedish Cause of Death Register (CDR)[182]. Of the total number of 42 million discharges during the years it has been possible to compare 95.5 % per cent. For the remaining 4.5 % either the personal identification number or the variable "discharged" or the date of death in CDR was missing. For 99.91% of the discharges, the information in HDR corresponded to that in CDR.

8.1.1.2 The Swedish Cause of Death Register (CDR)

The attending physician reports with the compulsory death certificate, the date, underlying cause of death and contributory causes of death to the National Causes of Death Register of the National Board of Health and Welfare[182]. To analyse the risk of dying among those who are operated upon, it is possible to link information on date of death and underlying cause of death from the Swedish Death Register to the Swedish Hospital Discharge Register by using the unique personal identification number. Statistics on causes of death have annually been published between 1911-1993 by Statistics Sweden (SCB). General statistics are available to the public on the Internet (www.scb.se). The National Swedish Board of Health and Welfare has been responsible for publication since 1994. Statistics Sweden, however, is entrusted by the National Swedish Board of Health and Welfare with the actual compilation of the statistics.

The diagnoses are recorded by the Swedish version of ICD-10, described in detail in International Statistical Classification of Diseases and Related Health Problems (10^{th} revision, volume 3, Geneva 1993). The main source of the statistical unreliability is the examinations made to define the underlying causes of death. According to WHO the underlying cause of death must be taken from the death certificate to be included in the annual statistics. The underlying cause of death is defined as a) the disease or injury that initiated the chain of diseases that finally resulted in death or b) the circumstances involving the accident or the act of violence that caused a lethal injury.

The most comprehensive method to establish the cause of death is to perform an autopsy. The autopsy frequency has decreased in Sweden. A decrease in the number autopsies performed might lead to inaccurate statistics. Reasons for the decrease are new regulations that give relatives the right to deny autopsies, changed rules of financial compensation for clinical autopsies, and changed directives for forensic autopsies. The proportion of autopsies has decreased from about 50 % at the beginning of the 1970s to about 15 % in 2001. The yearly statistics on causes of death comprises all deaths during the year, covering Swedish residents, whether the person in question was a Swedish citizen or not and irrespective of whether the deaths occurred in Sweden or not. The quality of the statistics varies, due to the examinations made to define the underlying cause of death or the changes in the classification system or the processing methods.

The main variables included in the register are; social security number, home district, sex, date of death, underlying cause of death, contributory causes of death, and a marker if operated within four weeks before death. The number of deaths in Sweden in 1998 amounted to 93, 628 of which 46 788 were women and 46, 840 men. To facilitate comparison with other years and regions age standardizing is used. In this report, the mean population of 1995 is used for both women and men as the standard population. The most common causes of death both for women and men are cardiovascular diseases. Almost half of the deceased population had such a disease as the underlying cause of death (49 % in women, 47 % in

men). The second most common cause of death is malignancy, 22 % for women and 25 % for men.

8.1.2 Selection of patients - Study IV, V

From the National Swedish Register for Lumbar Spine Surgery[185;187] we included 343 patients with a primary operation for disc herniation and 285 patients with a primary lumbar spinal stenosis procedure. We selected all patients with operations performed between April 2001 and June 2002, who completed the EQ-5D questionnaire[32;57]. One year after the operation, 263 (77 %) of the disc herniation patients and 230 (80 %) of the lumbar spinal stenosis patients, responded to the follow-up questionnaire. Calculations of the five EQ-5D dimensions were performed on 245 (71 %) of the disc herniation patients and 226 (79 %) of the spinal stenosis patients with uniquely identifiable dimensions.

We also compared patients older than 20 years of age (n=237) from the disc herniation and all the 230 of the spinal stenosis patients to a Swedish population survey with 3, 069 persons assessing the EQ-5D[36;38].

We performed a dropout analysis of the non-responders 80 (23 %) of the disc hernia patients and 55 (19 %) of the spinal stenosis patients. These patients were also compared to the 13-year Swedish national studies of all lumbar disc herniation and lumbar spinal stenosis surgery patients based on the Swedish Hospital Discharge Register (Study I, II)[92]

Data were collected on the patients' characteristics. HRQOL data were obtained by the EQ-5D, a patient self-administered questionnaire[33]. We analysed the profiles of the extent of problems in each of five dimensions, the score determined from a population sample based on these health state, and the global health status by a VAS measurement. Data were also collected of the patients´ age, gender smoking habits, pain intensity in the lower back and in the legs (VAS-visual analogue scale, graded between 0-10 where 0 denotes no pain and 100 worst conceivable pain), duration of pain (months), and walking ability (<100 m, ≥100m-<500m, ≥500m -<1000m, ≥ 1000m) The patients´ postoperative evaluations of back pain and leg pain compared to their preoperative pain were characterised as improved or worse. The patients' satisfaction with the outcome of surgery was given as satisfied, uncertain or not satisfied.

8.1.2.1 The National Swedish Register for Lumbar Spine Surgery

The purpose of the National Swedish Register for Lumbar Spine Surgery is to monitor outcome from spine surgery in Sweden[184;187]. The aims of the register are:

- To enable analysis of the indications of the different lumbar spine diagnosis, the trends and regional distribution of surgery.
- To offer the major results and perform quality assurance of all lumbar spine surgery procedures performed in Sweden.
- To identify inferior surgical techniques and implants.
- To document and report the outcome of new implants.
- To reports the incidence of complications.

The register started in 1993, partly founded by the National Board of Health and Welfare, and is now kept by the Swedish Society of Spine Surgeons. In 1998 a revised version of the protocol was introduced and the current development includes the establishment of a web based register version (www.ssu.orthop.gu.se/nrr-default.htm).

Today approximately 85 % of the units performing lumbar spine surgery in Sweden participate on a voluntary basis. The reporting on internet was gradually introduced in late

of 2002 and today the registry is web based for reporting, aggregating, storing and analyzing data. The web version also has the possibility of presenting results in real-time. The protocol has been gradually changed through the years in order to optimize information and since 1999 all data except the surgical report are patient based.

Data are collected preoperatively and at 1, 2, 5 and 10 years after surgery on patients' characteristics, pain and functional impairment. In 2004 the protocol contains the validated questionnaires (SF-36, Oswestry Disability Index and EQ-5D). The surgical report includes the diagnosis at surgery, type of operations performed and type of implant. Reporting of complication is performed by the surgeon as well as by the patient at follow-up.

The 2002 reports[187] with aggregated data have showed important demographic data and surgical outcomes. The patient follow-up rate has been acceptable. All patients have significant improvement regarding back pain as well as leg pain on a VAS scale and also in the SF-36 domains but with significant variation.

8.2 STATISTICAL ANALYSIS

8.2.1 Study I-III

Descriptive analyses of patients' characteristics considering age, gender, discharge diagnoses, time period and length of stay was performed. In Study I and III each patient's underlying cause of death case within 30 and 90 days after admission was analysed. We did not include contributory causes of death (multiple causes of death). Exact 95 % confidence intervals for the overall case fatality rate were calculated. Case fatality rate (CFR) per 1,000 spinal stenosis operations was computed by categories of age, gender, number of surgical interventions, time period and in study I also type of surgery. Multivariate analysis was performed in Study I of the 90 day mortality by Cox' regression. The covariates included number of spine surgical interventions as a time dependent variable, and the variables age, gender, complexity of surgery and time period[156;164].

Annual number of operations performed for lumbar spinal stenosis and disc herniation surgery in Sweden, and the regional distribution of operations per 100,000 inhabitants was correlated to the total population of Sweden 1987-1999[180;181].

In Study II the absolute risks for a reoperation and in Study III also back disorder-related readmission were assessed using the Kaplan-Meier estimator. Cox' regression analyses were performed for the time to first reoperation and time to first readmission. Results are presented as hazard ratios with 95 % confidence intervals and likelihood ratio tests for the overall significance for each of the variables included in the model are given. All analyses were performed using the Statistical Analysis (SAS®) package system[164].

8.2.2 Study IV, V

A multivariate analysis of the preoperative score was performed by analysis of variance (ANOVA) with age, gender, smoking status, type of surgery, duration of leg and back pain, intensity of leg pain (measured by pre-VAS) and preoperative walking distance as covariates. Intensity of leg pain was used as a continuous variable. The 12 month postoperative score was analysed by the same variables but the preoperative score was introduced as a continuous covariate. The final models included all significant variables (i.e. $p<0.05$) after a backward selection. We calculated the observed and expected fraction of patients reporting moderate or severe problems in the five different dimensions[37]. The relative differences pre- and postoperatively compared to the population survey were

calculated. The corresponding confidence intervals were calculated based on the binomial distribution of the observed frequencies. The statistical uncertainty in the expected values was not accounted for.

8.3 ETHICS

All papers were approved by the Ethical committee North at Karolinska University Hospital (Dnr: 03-295 paper I and II, Dnr: 03-294 paper III and Dnr: 03-293 paper IV and V).

9 RESULTS

9.1 INCIDENCE (STUDY I, III)

The lumbar spinal stenosis cohort and lumbar disc herniation cohorts consist of 10,494 and 25,247 patients with 11,283 and 27,576 operations during the years 1987 to 1999. The mean follow-up time was 4.5 and 6.0 years. The overall mean age at surgery for spinal stenosis was 64 years. Over the study period, the mean age increased from 60 to 67 years and the gender distribution was almost even. Disc hernia patients were younger, the mean age was 42 years throughout the study period and a slight male predominance was found (58 %).

The most common surgical procedure for lumbar spinal stenosis was laminectomy (89 %) followed by laminectomy and additional fusion in 11 % of the patients admissions.

The mean annual rate of lumbar spinal stenosis operations was 9.7 per 100,000 inhabitants. The incidence of surgery increased from 4.7 per 100,000 inhabitants per year at the end of the 1980s, to 13.3 per 100,000 inhabitants and year in 1993 (Fig 5). Lumbar disc herniation surgery was almost four times more common than spinal stenosis surgery in the late of 1980s (18 per 100,000 inhabitants per year) and increased to 32 per 100,000 inhabitants in 1993, and then fell to 20 per 100,000 in 1999. The mean incidence over the studied period was 24 per 100,000.

The geographic distribution for lumbar spinal stenosis ranged from 6 per 100,000 inhabitants in the northern part of Sweden to 13 in the south east part of the country. For disc herniation operations the geographical differences were smaller (20%)(Fig 6).

Fig 5. Number of operations performed for lumbar spinal stenosis and disc herniation in Sweden 1987 to 1999 per 100,000 inhabitants.

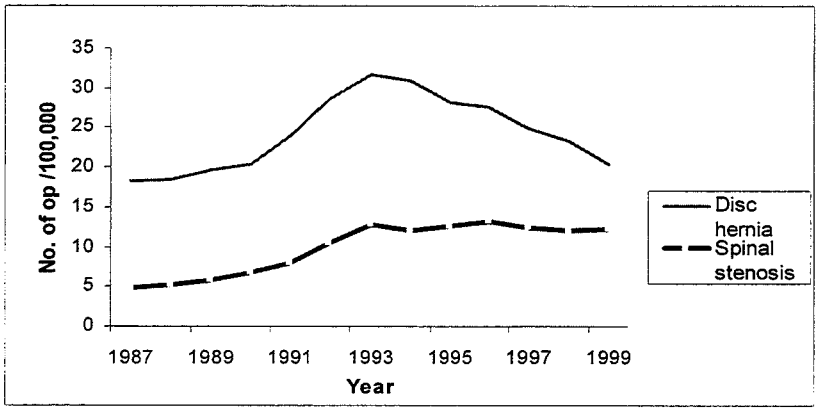
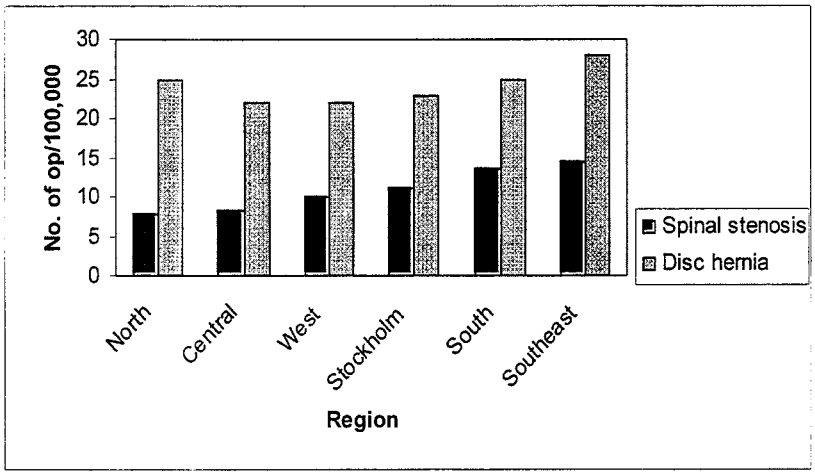


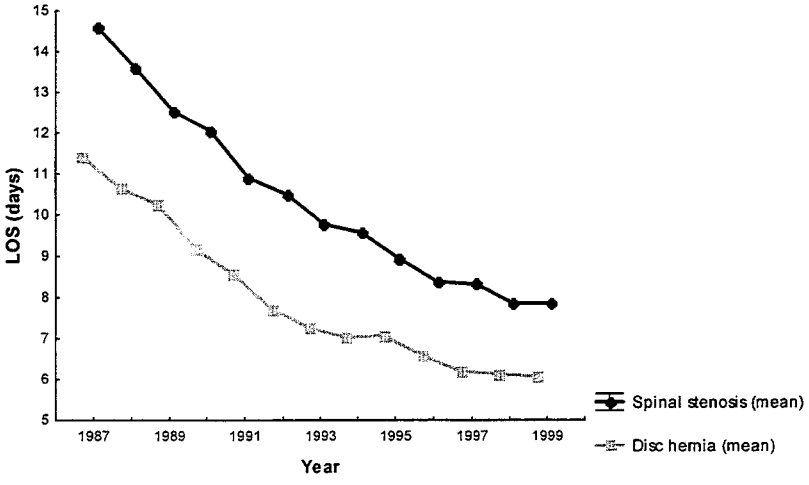
Fig 6. Number of operations performed per 100,000 inhabitants 1987-1999 in different regions in Sweden.



9.2 LENGTH OF STAY (STUDY II, III)

The mean length of stay after spinal stenosis surgery and disc herniation decreased from 15 and 11 days 1987 to 8 and 6 days in 1999, respectively (Fig 7). The standard deviation also decreased, 50% during the study period.

Fig 7. Length of stay after lumbar spinal stenosis and disc herniation surgery in Sweden 1987-1999.

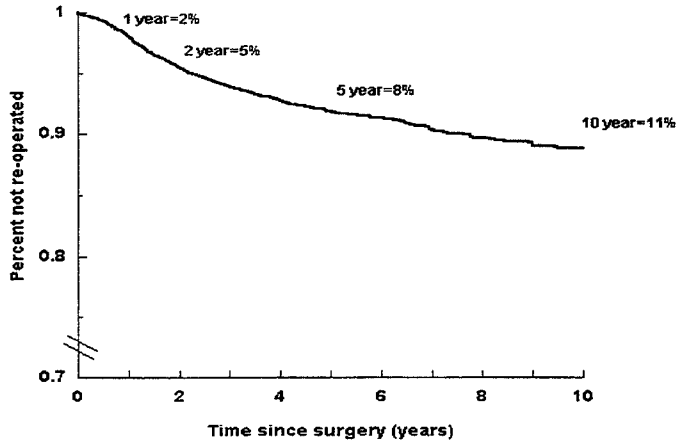


9.3 READMISSIONS AND REOPERATIONS (STUDY II, III)

Within 30 days after the first spinal stenosis operation 14 patients (0.15 %) were re-operated. The one, two, five and ten-year reoperation rates were 2 %, 5 %, 8 % and 11 % respectively (Fig 8).

The risk of being re-operated was higher among women although not significantly. Age brought a decreased risk but only among patients older than 80 years of age. The risk was slightly lower although not significantly after a high complexity operation (fusion with or without instrumentation). The risk of reoperation lowered significantly during each time period, and was 31 % lower at the end of the study period.

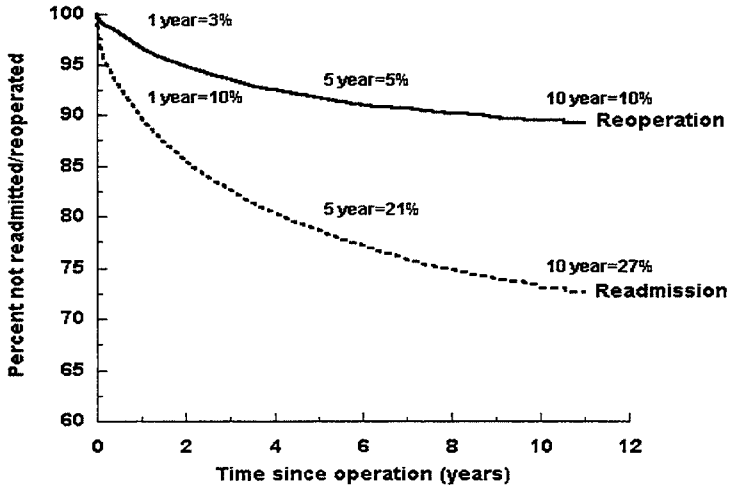
Fig. 8 Spinal Stenosis surgery in Sweden 1989-1999. Reoperation rates over time.



For disc herniation surgery the reoperation frequencies were similar to those of spinal stenosis surgery. The one, two, five and ten-year reoperation rates were 3 %, 5 %, 8% and 10 %, respectively (Fig 9).

In the analyses of the risk of reoperation or readmission considering age, gender, time period, length of stay we found that the risk was 15 % higher among women and a third higher for patients with a length of stay shorter than four days. The risk of a reoperation was 40 % lower at the end of the study period. Patients who had been previously admitted for back diseases were not at an increased risk of being reoperated.

Fig. 9 Reoperation and readmission after lumbar disc herniation surgery in Sweden 1989-1999.



In the risk analysis cohort 78 % of the patient has only one hospitalisation (the operation). The one, five and ten year readmissions rate due to disc herniation was 10 %, 15 % and 27 %, respectively (Fig 9).

The strongest risk factor for being readmitted after disc herniation surgery was a pre-operative hospital admission for back diseases. For these patients the risk increased significantly with the frequency of earlier hospital care for spinal disorders. In patients with more than one earlier admission >1 the risk increased with 50 %, for those with ≥ 2 by 80 %, and for those with ≥ 3 admissions by 330 %. Women had a significantly increased risk, RR 1.15 (CI 1.07-1.23). The risk also varied with the length of stay of the index operation. If the patient stayed in the hospital after a disc herniation surgery more than one week, the risk of readmission for a spinal disorder increased by 40 %. If the length of stay was more than two weeks, the risk of readmission was increased by 80 %. The risk of being readmitted was constant during the study period.

9.4 MORTALITY

The case fatality rate within 30 days after spinal stenosis surgery and disc herniation was 3.5 and 0.5 per 1,000 operations respectively.

Cardiovascular diseases were the most common causes of death (46 %) after surgery for spinal stenosis, followed by tumors (30 %). Distribution of the other causes of death was very heterogeneous. A high proportion of spinal disorder as cause of death (31 %) was noted, while deaths due to infections were uncommon (3 %). The most common underlying causes of death within three months after the operation for disc herniation were also cardiovascular diseases (7/25), followed by accidents or suicides (6/25). A high proportion of spinal disorders (7/25) as cause of death was apparent, but only two patients died from infections. Other causes of death were chronic obstructive bronchitis, diverticulitits, and lymphoma.

We calculated the relative risk of dying within 90 days of admission, taken into consideration the combined effect of sex, age, surgical complexity, and time period. For spinal stenosis patients the risk was significantly lower in women than in men, and overall the risk was 30% lower at the end of the study. Age over 80 years brought a fourfold risk, and adding a fusion procedure almost doubled the risk compared to laminectomy alone. After disc herniation surgery the risk was lower among women than men (RR 0.60, 95% CI 0.51-0.70).

In some patients, the underlying cause of death is a disease that normally is not considered fatal, e.g. spinal disorders. Analysing only the underlying cause of death could be misleading. Contributory causes of death are also recorded in the death certificates and in the Cause of Death Register. The order of rank of underlying and contributory causes of death is not always apparent. For instance this may explain our finding that seven of the patients who died within 30 days after disc herniation surgery had a spinal disorder as an underlying cause (Table 3). However in a separate analysis of all causes of death according to the ICD 9 codes 7220 and 7222 (lumbar disc herniation) in Sweden during 1987 to 1996, we also included the contributory death causes, (Table 4). No deaths with ICD10 codes of disc hernia 1997 to 1999 were found.

Nine patients had underlying causes of death due to lumbar disc herniation and seven out of them were reported to have undergone an operation. In only one case a complication with relation to treatment was noted in the death certificate. The mean age at death was 74 years and 5 out of 7 were men. On average there were 3 contributory causes to the death reported. All patients had fatal contributory causes of death.

Table 3. Lumbar Disc herniation surgery in Sweden 1987-1999 Underlying causes of deaths in patients within 90 days after operation. n=25

Underlying Causes of Death	No.
Spinal disorders	7
Cardiovascular diseases	7
Accidents/suicide	6
Infections	2
Others(chronic obstructive bronchitis, diverticulitis and lymphoma)	3

Table 4: Causes of Death according to ICD 9 codes 7220 and 7222(lumbar disc herniation) in Sweden during 1987 to 1999, n=7

Contributory Causes of Death (multiple causes)	No.
Complication without relation to treatment	6
Complication with relation to treatment	1
Mean age (range)	72(55-84)
Gender (male: female)	5:2
Number of contributory death causes (mean per patient)	22(3)
Contributory death causes:	
Cardiovascular disease	5
Infection	3
Sequelae after paraplegia/weakness in leg	3
Pulmonary disease	2
Other unknown cause of death	2
Local wound complication due to surgery	2
Others (Diabetes, autoimmune disease, senility, Sequelae after hip fracture and poor nutrition)	5

9.5 HEALTH RELATED QUALITY OF LIFE, EQ-5D (STUDY IV, V)

9.5.1 Patients characteristics

In Study IV and V the final analyses consisted of 230 spinal stenosis and 263 disc hernia patients, with a mean age of 42 and 66 years respectively. One out of five (19 %) of the spinal stenosis patients and one out of four (26 %) of the disc hernia patients were smokers.

In the spinal stenosis group of patients conventional decompression (macro) was performed in 52 % of the patients, micro-decompression in 25%, decompression and fusion in 16 % and fusion only in 5 %. In the remaining 2 % a variety of other procedures were performed. In half of the patients (47 %) the disc hernia was operated by macro discectomy, 42 % was operated by microdiscectomy and in one out of ten the disc hernia was operated by other procedures.

Before the operation leg pain with a duration longer than three months was common (95 and 84 %) and mean duration was 30 and 11 months respectively. Mean rating of leg pain by VAS improved by 28 and 29 % one year postoperatively. After surgery, 77 % of the spinal stenosis patients reported improvement of their leg pain, 10 % were unchanged or have worse pain. In comparison the disc hernia patients reported after surgery an even higher improvement in their leg pain (90 %) and only 10 % was unchanged or had worse pain.

Back pain with a duration of more than three months was reported by 94 % of the spinal stenosis patients, and more than half of the patients had suffered from back pain two years or longer prior to surgery (mean duration 44 months). Before surgery the disc hernia patients had shorter duration of pain than spinal stenosis patients, still more than half of them had suffered from back pain longer than 6 months prior to surgery (mean 14.9 months). Spinal stenosis patients' back pain intensity by VAS lowered from 58 to 39 (32 %) while disc hernia patients lowered slightly more, from 46 to 24 (39 %). Postoperatively back pain mirrored leg pain according to the patients' global perceived pain reduction. Disc hernia patients reported higher percentage of improvement (85 %) compared to 76 % of the spinal stenosis patients.

Spinal stenosis patients had lower ability to walk than disc hernia patients. Just one out of four (27 %) of the spinal stenosis patients could walk longer than 500 m before the operation compared to 65 % one year later. Before the disc hernia operation, only 17 % of the patients could walk longer than 1 km compared to 76 % one year later. The patients reported similar improvement in walking ability after spinal stenosis and disc herniation operations. Three out of four were satisfied, one out of six was uncertain as to the benefits, and one out of ten was dissatisfied.

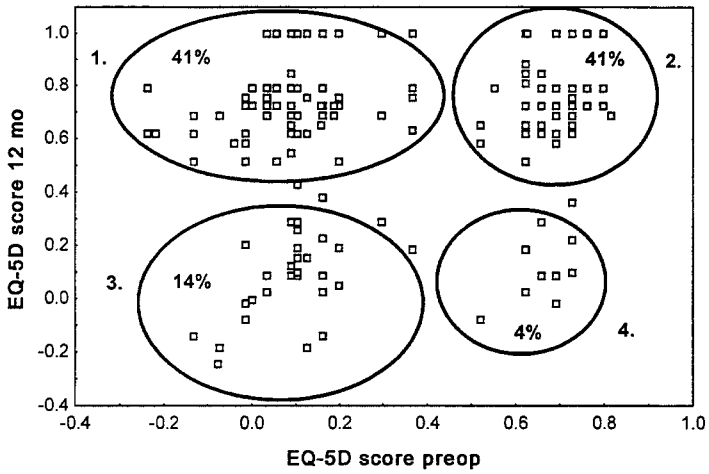
9.5.2 EQ-5D

The lumbar spinal stenosis preoperative mean EQ-5D score improved from 0.36 to 0.64 and the EQ-VAS increased from 50.2 to 65.2 one year after surgery. In comparison the disc herniation patients preoperative mean EQ-5D score improved even more from 0.29 to 0.70 and the EQ-VAS was also better and increased from 46.8 to 70.4 postoperatively.

Preoperatively, the EQ-5D score had a bimodal distribution around 0.1 and 0.7 for both spinal stenosis and disc herniation disorders. One year later, the majority of the patients had scores in the range of 0.7-1.0, and four major groups of patients had emerged (Fig 10 and 11). The first group of patients (50 and 41 %) had experienced great improvement (upper left ellipses), while a second group of patients (25 and 41 %) with high preoperative scores slightly improved (upper right ellipses). A third group (20 and 14 %) with low EQ-5D scores

preoperatively was unchanged (lower left ellipses), and a fourth small group (5 and 4 %) perceived a decline in it's HRQOL (lower right ellipses).

Fig. 10 EQ-5D in lumbar spinal stenosis surgery. Preoperative and 12 month postoperative EQ-5D scores, n=230.



Before the operation for lumbar spinal stenosis women had 0.14 ($p<0.01$) lower scores than males, and one year after operation their score was still 0.08 lower. Longer walking distance was associated with higher preoperative EQ-5D score. Patients with 500 meter walking ability before the operation had 0.13 ($p<0.0001$) higher score than those with shorter walking distance. High score before operated on for lumbar spinal stenosis was, in contrast to operations on disc hernia patients, a significant predictor ($p<0.0005$) for better quality of life 12 months after surgery.

We further analysed the five dimensions and a significant difference was found in the patients' ratings of back pain. Patients who reported severe preoperative pain (48%) had 0.16 ($p<0.007$) lower postoperative score than patients who reported no or moderate pain. We explored this finding further by evaluating the preoperative pain intensity in the back and in the leg measured by VAS (0-100). Pain rating ≥ 70 predicted a 0.15 ($p<0.0001$) lower EQ-5D score postoperatively compared to lower ratings. However, leg pain rating above 70 was not significantly associated with lower EQ-5D score one year after surgery ($p<0.08$).

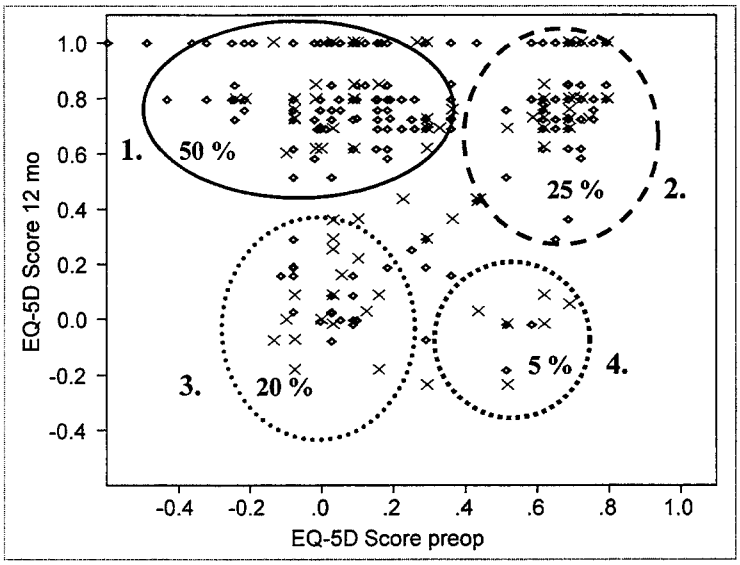
Disc hernia patients who were smokers experienced lower levels at 12 months than non-smokers, 0.57 and 0.75, respectively. In addition, a high proportion of these smokers did not improve at all at 12 month follow-up (Fig. 10). No major differences were noted between non-smokers and smokers in the spinal stenosis patients.

The bimodal distribution of the disc hernia patients preoperative EQ-5D scores could be explained by the preoperative variables walking distance, duration and intensity of leg pain. Patients with a walking distance shorter than 1 km had 0.16 ($p<0.0001$) units lower scores than patients able to walk longer than 1 km. Those who had experienced leg pain less than 6 months prior to surgery had 0.14 ($p<0.0001$) units lower score than those with longer pain duration, and the preoperative score decreased by 0.06 ($p<0.0001$) units per ten VAS units leg pain. Age, smoking, type of surgery, and duration of back pain were factors not significantly associated with the preoperative score.

We found that the preoperative score did not influence the 12 month score. Significant

predictors for poorer quality of life 12 months after surgery were short preoperative walking distance, smoking and long duration of back pain. Patients with a preoperative walking distance shorter than 1 km had 0.11 (p=0.008) units lower score than patients able to walk longer than 1 km. Those who had suffered from back pain more than 6 months prior to surgery had 0.11 (p=0.003) units lower score than those with short duration. Finally, smokers had 0.16 (p=0.0003) units lower score than non-smokers.

Fig. 11 Health related quality of life (EQ-5D) in lumbar disc herniation surgery. Preoperative and 12 month postoperative EQ-5D scores, n=263. Cross bars indicate smokers and rhomb bars indicate non-smokers.



For spinal stenosis and disc hernia patients a detailed analysis of the five EQ-5D dimensions comparing the severity of problems perceived before the operation to one year later showed that the majority of patients had experienced an improvement.

The patients reporting moderate or severe problems in the EQ-5D dimensions were compared to the scores obtained from a Swedish population EQ-5D survey (Fig. 12 and 13). A majority of patients reported improvement but did not reach the level reported by the population with similar age and sex distribution. The mean negative difference 12 months after lumbar spinal stenosis surgery and disc herniation surgery was 0.18 and 0.17 respectively. Before the operation, the relative risk of having moderate or severe problems in the five dimensions was between 1.8 to 7.7 higher for for spinal stenosis patients and between 2.3 to 22.7 higher in disc hernia patients compared to the reference population. One year later these risks were still higher but had decreased to between 1.3 and 7.1.

Fig. 12 Health related quality of life (EQ-5D) in lumbar spinal stenosis surgery. The distribution of the difference between the 12 mo post-operative EQ-5D score and the reference population survey.

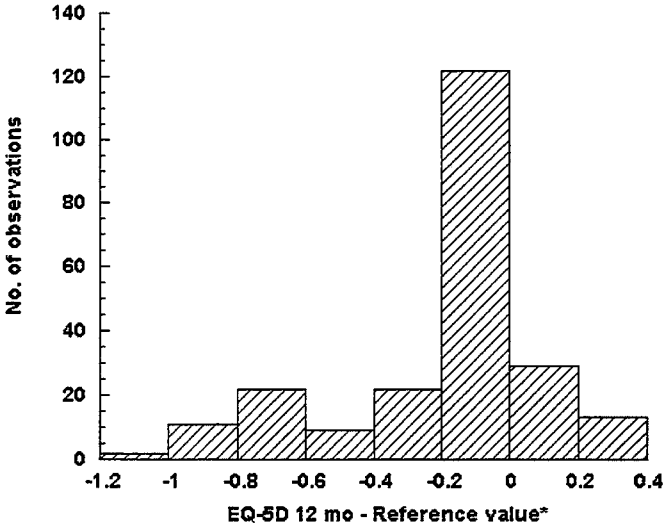
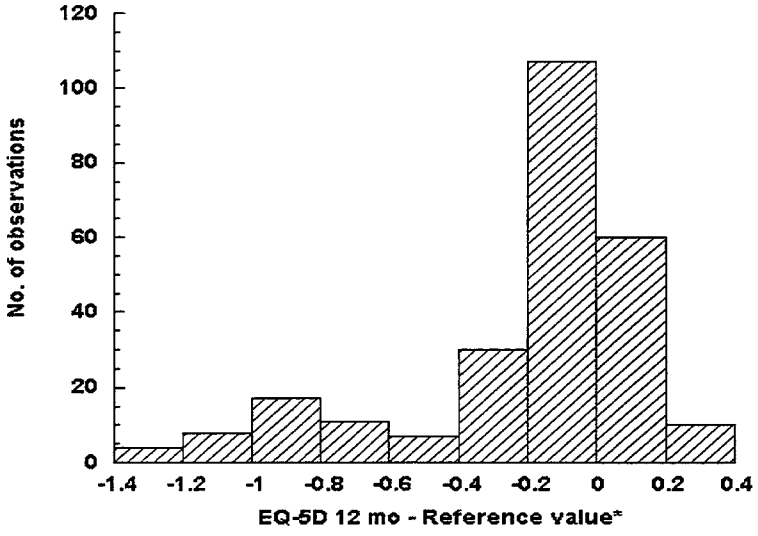


Fig. 13 Health related quality of life (EQ-5D) in lumbar disc herniation surgery. The distribution of the difference between the 12 mo post-operative EQ-5D score and the reference population survey.



10 DISCUSSION

10.1 LIMITATIONS

Our study design has several limitations since the studies are retrospective follow-up investigations of patients operated on, not prospective randomized controlled trials comparing surgery to non-operative treatment of patients with spinal stenosis or disc herniation. However, lumbar disc surgery is an evidenced base and established intervention[136;137] and lumbar spinal stenosis surgery is an generally accepted intervention when conservative treatment has failed[4;13;105].

We had no information on the patients' co-morbidities. Only 20 % of the patient records contained secondary diagnoses, making an analysis of co-morbidity unfeasible. Had this information been available, additional risk factors for deaths, reoperations and readmissions might have been revealed. There are contradictory reports of the impact of the patients' co-morbidities on the outcome of lumbar spinal stenosis surgery[2;5;9;42;106;150;151;172;175]. The most common co-morbidities reported in earlier studies were diabetes neuropathy, arteriosclerosis, osteoarthritis and depression. However, neither the severity of these diseases nor the types of treatments were reported. This might be one explanation for the divergent findings regarding the influence of co-morbidity. If and how co-morbidity might have influenced the outcome in our studies remains unclear since this specific information was lacking.

10.2 HOSPITAL DISCHARGE REGISTER

10.2.1 Incidence

Our data indicate that the annual rate of spinal stenosis surgery increased threefold from the year 1987 to 1993, and remained stable at 12/100,000 inhabitants and year. The mean operation rate during the study period was 9.7 per 100,000 inhabitants/year. The incidence of spinal stenosis in Sweden has been studied previously in selected areas and was reported to be 5 per 100,000 inhabitants and year (1987-1991) [94]. In the same study a rate of spinal stenosis surgery of more than 3 per 100,000 inhabitants and year was reported. Our findings indicate a surgical rate more than two times higher. However, their findings were based on local data and from a different time period whereas our study used data from comprehensive national registers. In a Swiss study the incidence of operations for spinal stenosis was found to be 11.5 per 100,000 per year, a rate similar to our findings[20].

The incidence of disc herniation surgery increased during the late 1980s to a peak in 1993 (31 per 100,000). After that the incidence decreased to 20 per 100,000 in 1999. According to Nachemson[135], the incidence of disc herniation surgery in Sweden has not changed since the mid 1950s, 20 patients per 100,000 inhabitants and year. The increase of disc herniation surgery in the end of 1980s and the early 1990s might be a result of an increased number of trained spinal surgeons, new imaging methods, and introduction of new spinal surgery techniques.

We noted a more than twofold geographic variation in the rate of spinal stenosis surgery among the six Swedish medical regions but only 20 % differences in the rate of disc herniation surgery. The moderate regional differences in Sweden may be due to the discussion of indications, and treatment programs promoted by the Swedish Society of Spine Surgeons. This may be compared to a nearly 12-fold difference in the rates of surgery between different US states[23]. Medicare beneficiaries data reported an eightfold increase in

the rate of spinal stenosis surgery from 1979 to 1992[44].

10.2.2 Length of stay, reoperations and readmissions

The length of stay after spinal stenosis and after disc herniation surgery decreased substantially from two weeks to one week and from eight days to five days, respectively. Atraumatic surgery and improved perioperative care, more effective hospital routines, together with a decreased number of hospital beds may explain this.

We defined a reoperation as a new operation for spinal stenosis and disc herniation in all first three studies not considering the exact level of the spinal stenosis. Information of the level of the encroachment in the spinal canal could not be extracted from the inpatient register which is a limitation in our studies. The ICD 9 classification did not distinguish between disc herniation in the thoracic spine and the lumbar spine, while the ICD 10 classification has a specific code for each anatomical region. Procedures on the thoracic spine are rare in Sweden. It is therefore unlikely that inclusion of these would have had a major impact on our results.

Another limitation is that we could not assume that all operations performed after 1987 were actually first time operations. In order to minimize the risk that the assumed first operation was actually a reoperation of a first operation, we did not include the two first years (1987-1989) available in the data base. By doing this the risk of misclassification of first operations will be reduced because the majority of reoperations are performed early (5 % within two years for lumbar spinal stenosis and disc herniation respectively). Still, there could be a few patients who were operated before 1987 who we actually defined as first time operations during 1989-1999.

The 10 year reoperation rate for lumbar spinal stenosis and disc herniation surgery were 11 and 10 % respectively. Reoperation rates for decompressive surgery have been reported to vary from 6 % to 23 %[13;40;81;86;97;105]. Reoperation rates for disc herniation surgery vary between 3 and 25 %[12;46;67;87;131;145;196]. Our spinal stenosis rates may be compared to a US study by Katz et al[105] that presented a 23 % reoperation rate eight years after surgery. This high rate may be due to different indications for surgery or that the operations were performed with other techniques. The patients in Katz cohort were operated on during 1983-1986 compared to our study period 1987-1999. During the same period as the Katz study, Caputy and Luessenhop[40] also reported a comparable high reoperation rate of 18 % after five years. In a cohort from 1991-92, Hansray et al[78] found only 5 % reoperations after five years.

During our study period the reoperation rate decreased for both lumbar spinal stenosis and disc herniation by 30 and 40 %. This may be due to several factors. The indications for surgery have been more clearly defined and spinal surgeons have better predictors when choosing operation as a treatment option. The etiology of the diseases had been more or less established which may have influenced the indications for surgery[122;166]. The decrease in reoperation rate may also be due to improvement of postoperative diagnostics. Awareness has increased about the different mechanisms behind persistent radicular pain, i.e neuropathic pain[142;159]. Improved diagnostic tools, i.e. CT and also MRI have been developed [109]. Examinations by MRI can more accurately detect and quantify postoperative phenomena, i.e. scar tissue, which in turn has become a more questionable indication for reoperation after disc herniation[98]. Last but not least, development of improved and standardised operative techniques may had an impact on the reoperation rates[16;17].

In our spinal stenos study, 11 % of the patients had a fusion added to the decompression surgery, and there was a tendency towards a lower risk of being re-operated if the patient had undergone fusions. This may be compared to a Swedish hospital based case series of 96

patients operated on for spinal stenosis surgery[45]. A high proportion, 61 %, had undergone fusion surgery. Among patients with instrumental fusions, 25 patients had undergone a reoperation to remove the osteosynthes material. The indication for removing the hardware was, however, not mentioned, but the clinical outcome in patients who were operated on by fusion and those who were operated on but not fused did not differ significantly.

Previous studies have reported that fusion operations have more complications than non-fusions[52;184]. In our study an added fusion seemed to lower the risk of a reoperation. We could not ascertain the reasons for fusions in our study, and therefore this finding must be interpreted with caution. A few controlled prospective randomized trials comparing fusion to non-fusion operations have been performed[59;61;71]. However, long-term analyses of the differences in reoperations rates are still lacking.

Most of the disc herniation patients (78.7 %) had only one hospitalisation (the operation, see fig.9), a small group of patients accounting for the majority of readmissions. A Finnish population based study[206] concluded that lumbar disc diseases leading to hospitalizations develop early. In our study, the small subgroup of patients seems to have different prognosis. The patients with several hospitalisations preoperatively probably have other pathophysiological mechanisms involved which may bring an increased rate of readmissions.

In Sweden the in-hospital beds have decreased by 30 % during the study period and still the readmission rate has not decreased during the period. The risk also varied with the length of stay of the index operation. Patients with long lengths of stay had a higher risk of readmission. This may be an indicator of other diseases or risk factors other than the spinal stenosis disease.

10.3 CAUSE OF DEATH REGISTER – MORTALITY

In some patients, the underlying cause of death was a disease that normally is not considered fatal, a spinal disorder. We obtained data on causes of death but we only considered the underlying cause. In Sweden, contributory causes of death are also recorded in the death certificates and in the National Death Register. The order of rank of underlying and contributory causes of death is not always apparent. This may explain our finding that one out of four of the patients who died within 90 days had a spinal disorder as an underlying cause. Moreover, the autopsy rates in Sweden are low, and decreased during the study period.

The low median age of 42 years in the disc herniation patients is an important factor behind the low 30 days case fatality rate of 0.5 per 1,000 operations. Our spinal stenosis patients had a case fatality rate of 3.5 per 1,000 operations. This may be compared to 2.9 per 1, 000 operations in a study of total hip joint replacement[148]. The authors of the latter study concluded that age brought a significantly increased risk in patients above 70 years. In our study, the risk increased significantly with age, but only in patients above 80 years. This group constituted less than seven 7 % (spinal stenosis) and 0.3 % (disc herniation) of all patients.

Many died of cardiovascular diseases. Some of these cardiovascular deaths may have been caused by the trauma of anesthesia and surgery on patients in a poor physical condition, following high age or co-morbidity. Oldrigde et al[140] reported a significantly higher one year cumulative mortality in men than in women operated on for lumbar spine surgery. Another study also showed increased postoperative mortality with age, and high comorbidity[44].

The case fatality rate following spinal stenosis surgery in our study is among the lowest that have been reported. During the study period, the mean age of surgically treated spinal stenosis patients increased by almost eight years, still we could see a decline in the mortality

rate. This might have been due to more careful patient selection, a healthier population or improved perioperative care. In a study of mortality rates after elective hip arthroplasty, high age, male sex, and a history of cardiorespiratory disease were found to contribute to death within 30 days after the operation. This study also reported a significant decline of the 30 day mortality rate after hip arthroplasty[148].

Our studies are the largest national population based analyses reported on spinal stenosis and disc herniation surgery so far. Contrary to other studies, we also included all deaths after these procedures. The study design, with linkage of the Hospital Discharge Register to the Swedish Cause of Death Register, has the advantage of including all discharges after disc herniation surgery in Sweden during a period of 13 years. It also allowed a complete follow-up, both of dates of death and underlying causes of death, also after the patients were discharged from hospital.

The death rate after spinal stenosis surgery is related to age, gender, and type of procedure. A fusion procedure was associated with an almost twofold increase in the rate of death compared to decompression surgery alone. In previous studies it was found that patients operated on by fusions had more complications[52;186]. However, compared to operations without fusions no differences in mortality rates were reported.

Misclassification of the date of death is unlikely, as the reporting to the Swedish Cause of Death Register is almost complete, and of high quality[182].

10.4 NATIONAL SWEDISH REGISTER FOR LUMBAR SPINE SURGERY

The register only mails one follow-up questionnaire to the patients and no reminders. This is probably the major reason for a loss of 19 % of lumbar spinal stenosis patients, and of 23 % of disc herniation patients, initially included (study IV,V). In our drop-out analysis, we found no differences in the preoperative EQ-5D scores or the EQ-VAS values between responders and non-responders. However, in study IV, responders tended to be older, more often smokers, and with higher proportion of leg pain longer than six months. Thus, the responders more often had risk factors, rendering our results to be a conservative interpretation.

We also compared our patients to the Swedish Hospital Discharge Register studies (studies I-III) of 11,283 operations for lumbar spinal stenosis and 27,576 operations for lumbar disc herniation. The distribution of sex and age, and also the reoperation rates were similar[90-92].Thus we consider our study to be representative of Swedish patients operated on for lumbar spinal stenosis. The annual number of spinal stenosis operations and disc herniation in Sweden 1999 is around 1, 200 and 2, 400 respectively. Our studies were based on only 230 and 263 cases, still these are the largest series reporting on health related quality of life according to EQ-5D on patients with spinal surgery so far.

We reported the one year surgical outcomes and had no information of the long term results. In a long-term prospective follow-up study[93] there were no statistical differences in outcome between 1-year and 11-year follow-up in patients operated on for lumbar spinal stenosis. At least for these patients the results might also reflect the long term outcome.

10.4.1 Health related quality of life, EQ-5D

The low preoperative lumbar spinal stenosis and disc herniation EQ-5D score of 0.36 and 0.29 could be fully explained by the patients' reported problems in the quality in life dimensions. Pain was reported by 99 and 100 %, impaired mobility in 90 and 83 %, problems performing usual activity in 73.5 and 88 %. Surprisingly, a high percentage

reported problems with anxiety/depression 50.5 and 63 %, whereas fewer felt problems with self care12 and 30 %.

Before spinal stenosis and disc herniation surgery nine out of ten patients had moderate or severe problems with pain and this is among the highest proportion reported[35;124]. After surgery, 8 and 10 % of the patients still reported severe problems. There was a considerable improvement of pain or discomfort and only 14 % of spinal stenosis patients and 11 % of disc hernia patients still reported severe problems. Nevertheless 68 % of the patients with spinal stenosis reported severe (14 %) or moderate (54 %) pain or discomfort one year after surgery. In a Swedish population survey, 63 % of the population in the age interval 60-69 reported that they suffered from pain[36;37]. The pain reduction in our studies is, however, encouraging since more than five out of six patients had reported having pain lasting longer than 3 months (chronic pain) before surgery. Patients with severe chronic pain may need additional therapy after surgery. Often multidisciplinary pain analysis and psychological intervention have to be added[60;133;192].

Anxiety or depression was surprisingly common with more than half of the patients reporting moderate or major problems. This may be compared to patients suffering from stroke where this proportion is 31 % or those with depression with a rate of 82 %[35]. Almost one third of the patients in our study felt lower anxiety or depression after surgery but 10 % reported worse symptoms. In patients with low scores in the anxiety/depression dimension, surgery alone is probably insufficient. Cognitive functions and affective symptoms have to be evaluated and attended to[101;117;125;198].

For the disc herniation patients, the preoperative EQ-5D score did not influence the postoperative HRQOL. Other more specific prognostic predictors may have to be used, before a patient may be considered for disc herniation surgery[197]. We found that predictors for a lower postoperative EQ-5D score were smoking, short preoperative walking distance, and long duration of back pain. Ongoing randomized clinical trials of pre- and postoperative smoking cessation are important to further clarify this risk and the impact of interventions[116;129]. Chronic low back pain has been related to lower HRQOL and our result supports those from Burström et l[35]. For lumbar spinal stenosis patients, however, preoperative severe pain was a strong predictor for a low postoperative score. This has to be considered when obtaining history from these patients who are older than the disc hernia patients.

The classification of the severity of lumbar spinal stenosis and minimal spinal canal diameter may influence the outcome[73;74;97]. However in a recent study none of these factors had a statistically significant impact[175].

The results of different operation types have been reported. Fusion procedures in patients with lumbar spinal stenosis were associated with a doubled rate of death compared to decompression surgery alone[91]. Other studies have also reported an increased complication rate in patients operated on by fusion[52;185]. However, we found no differences in EQ-5D scores in patients operated on by fusions when compared to patients operated on by other procedures. Number of operated spinal levels is a variable generally thought to be clinically relevant as predictor for a successful surgical outcome[74;175]. In our study, we did not find that the number of operated spinal levels influenced the EQ-5D scores.

Although the majority of patients felt an improved quality of life, still the preoperative EQ-5D scores of 0.36 in patients with spinal stenosis, and 0.29 in patients with disc hernia are among the lowest reported in the literature so far. In a large Swedish population-based EQ-5D survey patients with low back pain scored 0.55, patients with stroke 0.43 and those with depression 0.38[37].

Before the operation, the distribution of EQ-5D score indicated two major groups of patients for both spinal diseases. The first group had a low preoperative score and therefore also had high potential for improvement. A subgroup of the first group improved considerably and their EQ-5D score increased by two thirds. Another subgroup of patients, 20 %, did not perceive any improvement at all and had low postoperative scores. This could be due to factors such as co-morbidity, not yet diagnosed disorders, life style or other confounding factors rather than an unsuccessful operation. The second group of patients had high preoperative scores. Postoperatively, the majority of them still scored high and only 5 % reported lower EQ-5D values.

10.5 GENDER DIFFERENCES

We found an even gender ratio in our studies of spinal stenosis surgery. A Swiss study reported a male predominance[20]. The Swedish National Register for Lumbar Spine Surgery has also reported a higher proportion of males in spinal stenosis surgery[185]. Their study was based on data from about 80 % of all lumbar spinal stenosis surgery performed in Sweden during the year 1999, compared to our 13-year national study. Male gender was more common in disc herniation surgery where nearly six out of ten patients were men (58 %). This proportion has also been confirmed by the Swedish National Register for Lumbar Spine Surgery[186].

Women had a 15 % higher risk of being reoperated for disc herniation. We also saw the same tendency for women with lumbar spinal stenosis. The reasons are not known. Women also had a 15 % higher risk of readmission after disc herniation surgery.

Women had a 40 % lower risk of dying from the operation. There are other reports of a significantly higher one year cumulative mortality in men than in women operated on for lumbar spine surgery[52;140]. The gender differences in our study could be due to confounding factors. Males might have more co-morbidity or several other risk factors such as smoking. Unfortunately, we could not extract this information from our data set.

In a previous national EQ-5D survey women had significantly lower scores than men in the age group 60-69 years[36]. Women suffered more from anxiety or depression and felt more pain or discomfort. In our spinal stenosis study women had preoperatively 0.14 lower EQ-5D score as compared to men. Also in women with disc herniation the scores were 0.07 lower. Female disc herniation patients selected for surgery were found to have significantly worse physical status than men[49].

10.6 GENERALIZATION

Our study is the largest population based analysis reported of spinal stenosis surgery reported so far. The study design, with linkage of the National Inpatient Register to the Swedish Death Register, had the advantage of including all discharges after spinal stenosis surgery in Sweden during a period of 13 years. It also allowed a complete follow-up both of dates of death and underlying causes of death, also after the patients were discharged from hospital. Misclassification of the date of death is unlikely, as the reporting to the Swedish Death Cause Register is almost complete and of high quality[182;183]. Register studies have several advantages, notably virtually complete coverage and unbiased prospective collection of data. We therefore conclude that the incidence of surgical intervention and death rates are representative for Sweden during the last decade of 1900.

With the changing panorama of spinal stenosis therapy in industrialized countries, our results have implications for health care providers. Both lumbar spinal stenosis and disc herniation are associated with low case fatality rates within 30 days after surgery. It is possible that the surgical trauma itself may pose a risk among patients who undergo surgery for spinal stenosis. Avoiding or postponement of surgery by making a correct preoperative diagnosis, and minimization of the surgical trauma by proper timing of the operation, with preoperative optimization of physiological conditions, may therefore be important to reduce the death rate further. Non-surgical treatment may also be considered in selected patients[171].

The decreased length of stay after spinal stenosis and disc herniation surgery represents a major change in health care during the study years. The number of hospital beds has decreased but in spite of this twice as many lumbar spinal stenosis were performed in Sweden. Continued education and research in patient care, development of atraumatic surgery and improved perioperative care, teamwork between disciplines and professionals, and last, but not least involvement of patients´ and patient organizations have contributed to the evolution in total patient care during the 1990s.

Our analyses of the reoperation rates in the current study were performed on all spinal stenosis patients and disc herniation patients. However, in clinical decision making one has only the individual patient to consider. Thus, results of the reported reoperation rates should be put in the patient's perspective with considation of all present individual factors.

Preoperative hospitalizations for spinal disorders before surgery bring a significant higher risk of readmissions. This is an observation to keep in mind when taken history from patients with disc herniation. This group of patients might have lifestyle risk factors or co-morbidities[170] which also must be evaluated and treated.

The health related quality of life (EQ-5D) adds information on to what extent the lumbar spinal stenosis and disc herniation influences patients life. The majority of patients felt an improved quality of life, still the preoperative EQ-5D score of 0.36 and 0.29 is among the lowest reported health state in the literature so far. Mild health problems are more often considered acceptable than severe problems. The acceptability of health states is related to the quality of life score of these states, i.e., worse state is considered less acceptable[34]. This has implications for the allocation of limited health care resources.

The EQ-5D is a feasible health related quality of life instrument in clinical practise that may increase the patient's awareness, cooperation and also facilitate rehabilitation. The doctor and patient will maybe even have a broader and perhaps more realistic view of the prognosis, before they share the decision of surgical treatment.

11 SUMMARY

The mean annual surgical incidence per 100,000 inhabitants was 10 for lumbar spinal stenosis and 24 per 100,000 for disc herniation. The geographic distributions varied between the medical regions. During the study period the mean age increased from 60 to 67 years for spinal stenosis patients but was constant, 42 years, for disc hernia patients. The gender distribution for spinal stenosis patients was almost even but for disc hernia patients a male (58 %) predominance was seen. The length of stay after an operation was reduced by 50 % from 1987 to 1999.

Patients operated on for lumbar spinal stenosis and disc herniation have a risk of being reoperated after one, two, five and ten year of 2-3 %, 5 %, 8 %, and 10-11 % respectively. The reoperation rate decreased by 31 and by 40 % between 1987 and 1999. After disc herniation surgery, females had a 15 % higher risk of a reoperation.

Patients operated on for lumbar disc herniation had a risk of a readmission after 1, 5 and 10 year of 10 %, 21 % and 27 %. In the risk analysis cohort of disc herniation during 13 years 78 % of the patients had only one hospitalisation (the operation). The risk for being readmitted after disc herniation was 15 %, higher for women, patients with more than one earlier hospital admission (50 %), and a length of stay >7days (40 %). The risk of being readmitted was constant over time.

The case fatality rate within 30 days after spinal stenosis surgery was 3.5 per 1, 000 operations and 0.5 per 1, 000 operations for disc herniation surgery. In spinal stenosis patients the risk of dying was doubled for males and after fusion surgery, and four times higher in patients older than 80 years. The mortality declined over time despite older patients operated on.

Patients operated on for spinal stenosis and disc herniation experienced an improved health related quality of life. Their EQ5-D score increased from 0.36 to 0.64 in patients with spinal stenosis and from 0.29 to 0.70 in disc herniation. Predictors for lower postoperative score after disc herniation were smoking, short preoperative walking distance and long duration of back pain. For spinal stenosis was preoperative severe pain a predictor for a low postoperative score. Four out of ten patients reported considerable improvement while a similar portion of patients with high preoperative scores were only slightly improved. A third group (20 %) were unchanged with low EQ-5D scores, and a few percentages (4-5 %) perceived a decline in their HRQOL.

12 CONCLUSION AND FUTURE PERSPECTIVES

We have highlighted factors for less favourable outcome after spinal stenosis and disc herniation surgery and we think that these have to be taken into consideration in the clinical setting. We found that women, patients over 80 years of age, fusion procedures, smoking, hospital stays before surgery or long hospital stays at surgery, severe back pain, long duration of pain and short walking ability are risk factors and a yellow flag should be raised and addressed for the individual case.

Health related quality of life assessment and utility instruments like EQ-5D give the possibility to compare the spinal stenosis and disc herniation patients to the rest of the population and to those with other diseases. Health care providers have a possibility to allocate resources in order to equalize health. The use of EQ-5D is also the first step in order to perform cost utility studies which are helpful in a system of increased needs for interventions but simultaneously decreased of resources.

Based on the findings of this thesis, future studies of patients with spinal stenosis and disc herniation could focus on:

- The impact of smoking cessation interventions.
- Risk factors behind the less favourable outcomes in women.
- Clinically relevant EQ-5D score changes.
- Long term health related quality of life outcomes.
- Cost effect and cost utility studies.

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