

The Swedish National Register for Lumbar Spine Surgery

Swedish Society for Spinal Surgery

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The need for documentation is as obvious in spinal surgery as in other medical specialties. New diagnostic tools, such as CT and MRI, have proved better than myelography for making diagnoses. However, these modalities are hampered by a high number of false positive findings; disc herniation, for example, is present in 30–50% of asymptomatic subjects (Weinreb et al. 1989, Boden et al. 1990), and spinal stenosis in about 20% (Kent et al. 1992). This means that a certain morphological diagnosis does not have a definite clinical and diagnostic significance. This, in turn, means that the patient description in lumbar spine surgery should include other variables, subjective and objective, than just the diagnosis. Outcome classification is also difficult, as most procedures aim at pain relief and must be classified into soft data, such as reduction of pain, satisfaction with surgery and so on. Revision surgery as the end point is probably not sufficient for the successful registers of hip and knee arthroplasty in the future, and it would be meaningless in spinal surgery. Registration of functional outcome has to be more complex with more data and, consequently, inherent drawbacks (risk of incomplete data and complicated determination of outcome). However, in today's hard competition for resources, it is mandatory to perform outcome studies on lumbar

spine surgery. Randomized controlled trials can answer specific questions, but broad registrations are important complement and should be carried out on a national or international basis. Today, there is an increasing demand for patient-based data to compare outcomes and the lumbar spine register makes a serious effort to fulfil this demand in a comprehensive way.

Trials and errors

In the mid-1980s, an attempt was made at the Lund University Department of Orthopedics to study surgery for degenerative lumbar spine disorders prospectively. A computer-adapted protocol was designed, and a number of publications on diagnostic aspects (Jönsson and Strömquist 1993b, 1995, Jönsson et al. 1997a) and outcomes of surgery for lumbar disc herniation, spinal stenosis, spondylolisthesis and disc degeneration were published (Jönsson and Strömquist 1993a, 1994a,b, Jönsson et al. 1997b). Encouraged by prospective registers for hip and knee arthroplasty, the idea of making a Swedish register for lumbar spine surgery was born and developed during a meeting on degenerative lumbar spine disorders in Lund 1992. This state-of-the-art conference, among other things, discussed the layout of a protocol for lumbar spine surgery published in 1993 (Ström-

Participating orthopedic departments 1999: Boden, Eskilstuna, Falun, Gävle, Göteborg (Sahlgrenska), Halmstad, Helsingborg, Huddinge, Jönköping, Karlskoga, Karlstad, Lund, Malmö, Mora, Motala, Oskarshamn, Stockholm (Karolinska), (S:t Görans Sjukhus AB), (Södersjukhuset), Sundsvall, Uddevalla, Uppsala (Akademiska), (Elisabethsjukhuset), Väster- vik, Västerås, Örebro, Östersund.

qvist and Jönsson 1993). The protocol consisted of preoperative subjective data and objective evaluation completed by the surgeon, surgical data and a follow-up form, also filled in by the surgeon. The protocol was approved by the Swedish National Board of Health and Welfare as of 1993 and also adopted by the Swedish Society for Spinal Surgery. The register, however, did not achieve wide dissemination, despite the initial enthusiasm of many spinal surgeons. Inter alia, it evolved during a time when resources were diminishing for health care in Sweden, and a certain "registration fatigue" was noted. The main problem, however, was the design of the protocol that created much more work for the spine surgeons. Interesting data emerged from the protocol (Strömqvist and Jönsson 1993), but it did not become widely used. Two measures were therefore taken: first, the protocol was rearranged and designed as a patient-based protocol. Many studies have shown that the objective findings in lumbar spine patients, such as reflex abnormalities and sensory afflictions, are not very important, although the SLR test is of value (Jönsson and Strömqvist 1995). Therefore, in the new protocol, registration of objective findings was omitted and it was entirely patient-based with 13 questions (see Current protocol) and a quality of-life-scale. An entirely new administrative structure was adopted, whereby Sweden was divided into three parts, each of which was made the personal responsibility of two spine surgeons (for the northern part, PF and BEL, for the mid part, OH and BL, and for the southern part BJ and BS). Two part-time secretaries were hired; one for registration and administrative purposes and one for more practical help who could visit departments having computer problems, initiation difficulties or registration problems. An algorithm for the protocol was given to each department and all departments performing spine surgery in Sweden were contacted by mail and personally.

This seemed to reverse the negative trend. Of about 45 departments performing spine surgery in Sweden, 12 participated in 1998, 27 were registered in 1999 and 13 more register from the year 2000. Minor compilations of data have been made for 1996 and 1998, but 1999 was the first year when many patients (2,553) were included

(Strömqvist and Jönsson 2000). It is estimated that more than 5,000 operations on the lumbar spine are performed in Sweden each year.

Current protocol

The protocol is patient-based. Before surgery, the patients report their age, sex, smoking habits, previous lumbar spine surgery, working capacity, type of work and the duration of back and leg pain. Consumption of analgesics and walking distance are given and also back and leg pain on a visual analog scale (VAS). A pain drawing is made and divided into one of four categories (Udén et al. 1988): Organic, probably organic, probably non-organic and non-organic. Before surgery the patient also completes the SF-36 questionnaire (Ware and Sherbourne 1992).

Concerning surgical data, one page is completed (Figure 1). Method of diagnosis, diagnosis and type of surgery are reported, as well as level and side. The use of antibiotic prophylaxis is noted as well as duration of hospitalization, name of surgeon and, if applicable, a report on complications. Reoperation as well as date and type are included.

The follow-up protocol, at 3–6, 12 and 24 months postoperatively, contains the following points: back pain, as compared to preoperatively, leg pain, as compared to preoperatively, return to work, duration of sick-leave, type of work, consumption of analgesics and ability to walk. The patient reports if a complication and/or a re-operation has occurred (as a double check concerning this important issue). An overall judgment of the surgical outcome (satisfied, uncertain and dissatisfied) is made and also of back and leg pain on the visual analog scale. At the 12-month follow-up the SF-36 is completed once again.

A computer application has been prepared by Kaj Knutson, Lund University Department of Orthopedics, using the FileMaker Pro-program and the computer register has been simplified greatly (Figure 2). The program also has an export function, enabling its export to programs, such as Statview or SPSS, for statistical evaluation. The possibility of extracting certain statistical data at any time during registration is being evaluated, and the introduction of computer reporting on the Internet is being assessed. The total outcome is published yearly. Data from each department are



SPINAL SURGERY Dpt _____ No: _____

Radiology

Myelography	<input type="checkbox"/> Yes	<input type="checkbox"/> No
CT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Myelo-CT	<input type="checkbox"/> Yes	<input type="checkbox"/> No
MRI	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Diagnostic block	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Pain drawing

Pain drawing (1–4)

Diagnosis

- Disc herniation
- Central spinal stenosis
- Lateral spinal stenosis
- Spondylolysis/olisthesis
- Segmental pain
- Other.....

Operation

- Open discectomy
- Microscopic discectomy
- Percutaneous nucleotomy
- Decompression
- Decompression + posterior fusion, uninstrumented
- Decompression + posterior fusion, instrumented
- Posterior fusion, uninstrumented
- Posterior fusion, instrumented
- Anterior fusion, uninstrumented
- Anterior fusion, instrumented
- Other.....

Type of implant.....

Level operated on (from – to)
 (i.e. nerve root: L4 – L4) Proximal

(i.e. disc: L5 – S1) Distal

Side Right

Bilateral Left

Antibiotic prophylaxis Yes No

Figure 1. Surgical data to be entered in the computer application.

Patient ID _____

Strömqvist/Jönsson

Hospitalization

Date (yy-mm-dd)

Admitted

Date of operation

Discharged

Surgeon (initials)

Postoperative complication No

Yes, type

Reoperation

A new operation on the same side and level or an operation for a postoperative complication following the primary procedure is regarded as a reoperation. Only indication, date and type of procedure is recorded for a reoperation.

Indication for reoperation

Date of reoperation (yy-mm-dd)

Reoperation

- Discectomy
- Decompression
- Decompression + posterior fusion
- Posterior fusion
- Anterior fusion
- Reoperation for complication
- Other.....

Type of implant.....

Reviewer

Reviewer, initials

Run #	Social sec. #	Name	Delete	Pre	SF1	Op	4m	12m	SF2	24m	Reop	mo	Dead	Valid
LUN 1	000000-0000	Doe, John	<input type="checkbox"/>	OK	OK	OK	OK	OK	call	call				OK
LUN 2	000000-0000	Doe, Jane	<input type="checkbox"/>	OK	OK	OK	OK	unf	reop	reop	OK	18		OK

Figure 2. Computer application. Starting page with flip-top head.

Table 1. Age and sex distribution in relation to diagnosis

	n	Mean age	% men	Mean duration of pain (year)
Disc herniation	1,276	44	59	1
Central spinal stenosis	714	67	56	2.5
Lateral spinal stenosis	192	59	52	2.5
Spondylolisthesis	157	44	41	4.5
Segmental pain	214	45	34	4

Table 2. Distribution of diagnoses (%) in university, central and county hospitals

Diagnosis	University hospital	Central hospital	County hospital
Disc herniation	34	54	60
Central stenosis	33	28	25
Lateral stenosis	9	7	10
Spondylolisthesis	11	5	2
Segmental pain	12	4	2
Other	1	2	1

returned to that department, but are not published officially.

Cervical spine protocol

A protocol for cervical spine surgery has been developed with similar data, but adapted to the cervical spine. This protocol is still in the early stages of development and the computer application is under construction. Far fewer departments perform cervical spine surgery than lumbar spine surgery in Sweden. Therefore this registration should be less difficult to implement.

Results

The following presentation refers to the 1999 material. At the time of compilation of data, a total of 23 departments had registered 2,553 patients who had undergone surgery for degenerative lumbar spine disorders.

Most operations concerned disc herniation followed by central spinal stenosis (Table 1). It is noteworthy that most surgical treatment of spondylolisthesis and segmental pain had been given at university hospitals (Table 2).

Outcome

The following figures relate to 4- and 12-month follow-ups. Since these patients were operated on in 1999 and reported in the spring 2000, follow-up data are available concerning 30–45% of the patients.

Disc herniation

For disc herniation, 75% reported complete or almost complete pain relief at 4 months postoperatively, 14% improvement, 7% were unchanged and 4% deteriorated. The figures at 12 months were similar. The leg pain (sciatica) was reduced to a large extent (Figure 3).

Before surgery, 52% of the patients reported regular consumption of analgesics. This figure was reduced to 14% and 18% at 4 and 12 months postoperatively.

The SF-36 score showed that the patients with lumbar disc herniation had a very poor quality-of-life before treatment, and that they improved in all physical and mental domains after surgery (Figure 4).

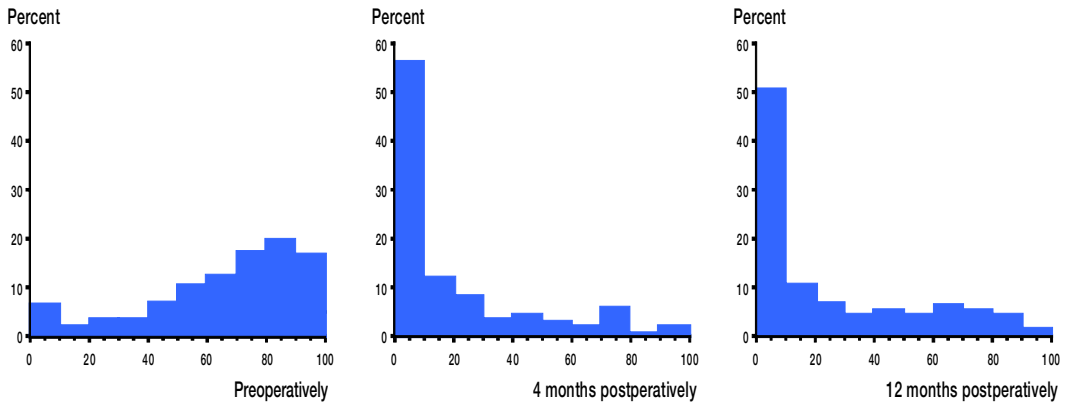


Figure 3. Leg pain, according to the visual analog scale, in patients before and after surgical treatment of disc herniation (%).

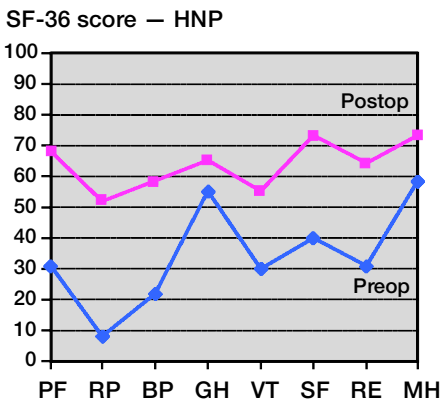


Figure 4. SF-36 scores (mean) before and 12 months after surgery in patients operated on for lumbar disc herniation. Abbreviations: PF physical function, RP role-physical, BP bodily pain, GH general health, VT vitality, SF social function, RE role-emotional, MH mental health.

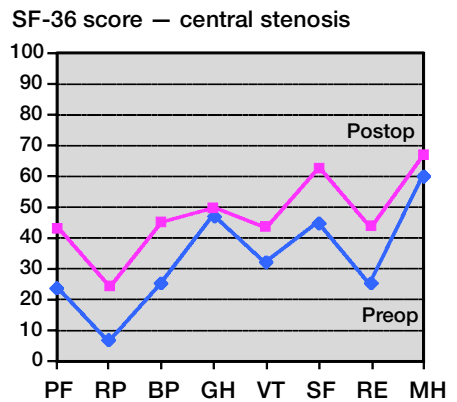


Figure 5. SF-36 scores (mean) before and 12 months after surgery in patients operated on for central spinal stenosis. Abbreviations: see Figure 4.

Central spinal stenosis

Among patients with central spinal stenosis, 59% reported almost complete or complete pain relief at 4 months postoperatively and 50% at 12 months. 20% were improved, 16% unchanged and 5% deteriorated. Findings concerning leg pain on the visual analog scale were similar to those of disc herniation and regular consumption of analgesics was reduced from 51% preoperatively to 27% 4 months after surgery. Patients with central stenosis had a preoperative SF-36 score similar to that of patients with a disc herniation, but showed less marked improvement afterwards (Figure 5).

Lateral spinal stenosis

In these patients the results were not so good, 52% were almost or completely pain-free at 4 and 12 months postoperatively and 9% and 10% of the patients, respectively, deteriorated. Pain showed a widespread pattern on the postoperative VAS scores, but they had very high values preoperatively (Figure 6). Consumption of analgesics was regular in 47% preoperatively and 32% 12 months after surgery. The SF-36 score showed improvements in all domains (Figure 7).

Spondylolisthesis

In patients with spondylolisthesis, the main preoperative complaint was back pain and a poste-

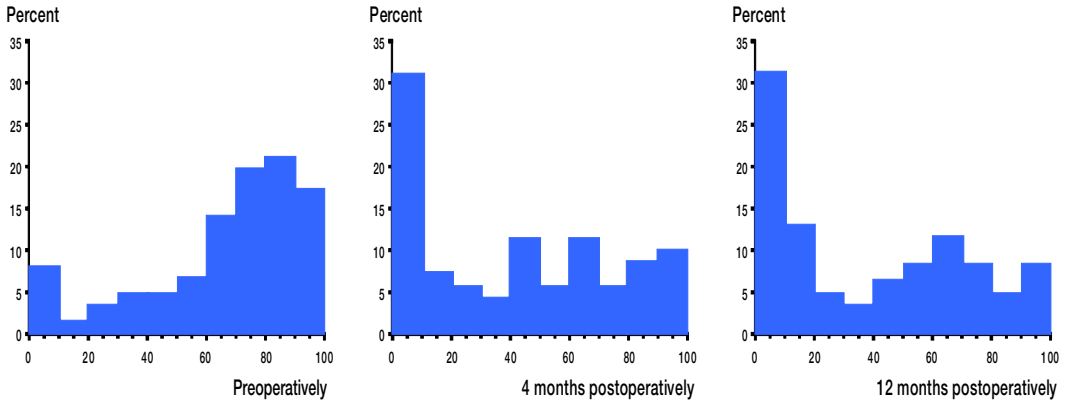


Figure 6. Leg pain before and after surgery, according to the visual analog scale (%), graded by patients operated on for lateral spinal stenosis.

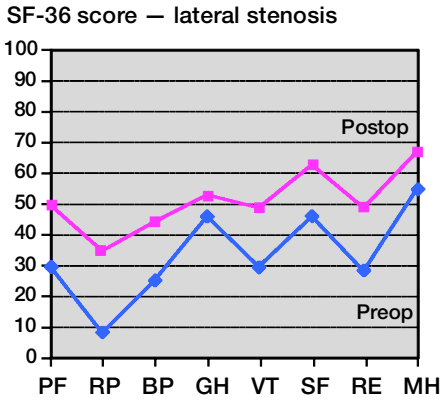


Figure 7. SF-36 scores (mean) before and 12 months after surgery in patients operated on for lateral spinal stenosis. Abbreviations: see Figure 4.

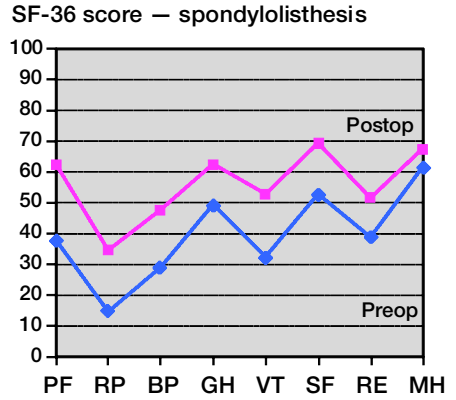


Figure 9. SF-36 grades (mean) before and 12 months after surgery in patients operated on for spondylolisthesis. Abbreviations: see Figure 4.

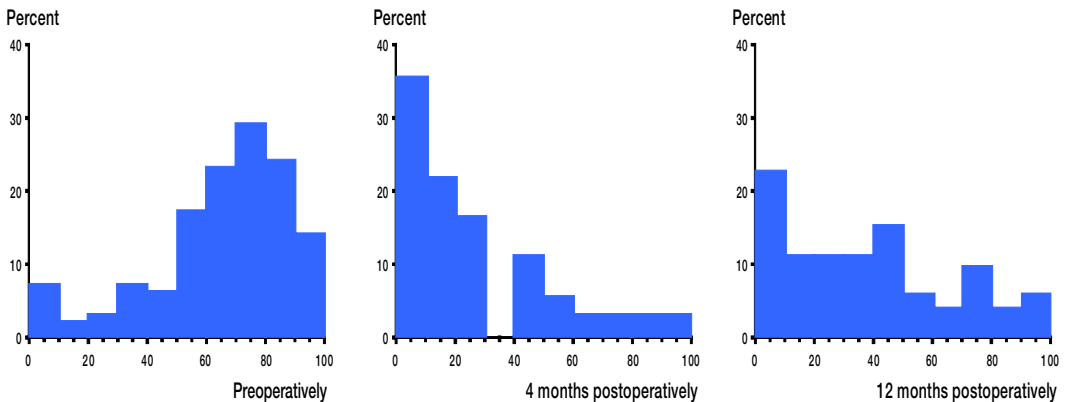


Figure 8. Back pain before and after surgery, according to the visual analog scale (%), graded by patients operated on for spondylolisthesis.

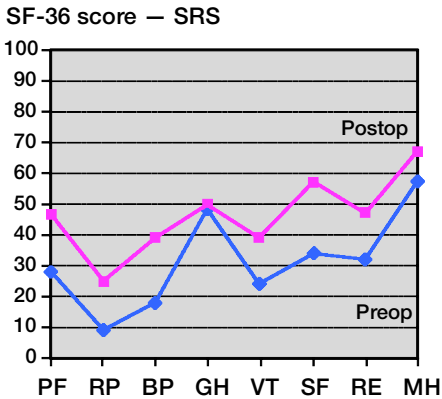


Figure 10. SF-36 grades (mean) before and 12 months after surgery in patients operated on for segmental pain. Abbreviations: see Figure 4.

rior or anterior, uninstrumented or instrumented, fusion was performed. A decompressive procedure was also added in a few cases. 4 months after surgery, 65% of the patients had become pain-free or almost pain-free, but at 12 months only 51% remained so. This corresponds well to the back pain score on the visual analog scale (Figure 8). Patients with spondylolisthesis also improved in all physical and mental domains at 12 months after surgery (Figure 9).

Segmental pain

This patient group mainly suffered from back pain and they underwent posterolateral uninstrumented fusion (8%), posterolateral instrumented fusion (29%), anterior instrumented fusion (29%), PLIF (7%), decompression + instrumented fusion (17%) and other procedures (10%). 66% of these patients reported a complete or almost complete pain relief at 4 months postoperatively, but only 45% at 12 months. Their regular consumption of analgesics, however, was reduced from 61% preoperatively to 36% at 4 and 12 months postoperatively. The im-

Table 4. Results concerning leg pain 4 months after surgery for disc herniation in relation to type of hospital (%)

	University hospital	Central hospital	County hospital
Pain-free	31	33	37
Almost pain-free	44	36	38
Improved	17	23	11
Unchanged	5	7	8
Deteriorated	3	1	6

provement on the SF-36 score was less marked in patients with segmental pain (Figure 10).

Outcome related to diagnosis

1 year after surgery, patient satisfaction varied in the different diagnostic categories; it was best after surgery for disc herniation and worst after surgery for segmental pain (Table 3).

Outcome of disc herniation related to type of hospital

The outcome after disc surgery at 4 months regarding leg pain was similar in the three types of hospitals (Table 4).

Complications

Short-term complications were reported in 138 cases (5%) ranging between 0 and 30% in the types of different hospitals. Complications were slightly more frequent in central hospitals (8.6%) than in university (4.9%) and county hospitals (3.6%).

The 4 commonest complications were: urinary retention, requiring catheterization (29), dural tear (22), wound infection (17) and postoperative hematoma (10). Dural tears were commonest in spinal stenosis—i.e., 15 of 22 cases.

Complications were commonest after the combined procedure of decompression and instru-

Table 3. Patient satisfaction in relation to type of operation (%)

	Disc herniation	Central stenosis	Lateral stenosis	Spondylo- listhesis	Segmental pain
Satisfied	74	56	61	67	55
Uncertain	16	27	24	27	24
Dissatisfied	10	17	15	6	21

Table 5. Incidence of complications in relation to type of surgery

	%
Conventional discectomy	2.7
Microscopic discectomy	5.8
Decompression	5.2
Decompression + posterolateral fusion	8.5
Decompression + instrumented fusion	13
Posterolateral fusion	8.1
Posterolateral fusion with instrument	8.9
Anterior fusion with instrument	9.2

mented fusion (Table 5).

The wide range in the incidence of complications probably reflects differences in criteria and, in some hospitals, an underestimation.

Pain measured with the Visual Analog Scale

In a sample of 755 patients from Lund (Zanoli et al. 2001), some interesting facts were found on the visual analog scale concerning pain. For example, the relative difficulty of patients to recall previously described pain (Linton and Melin 1982). Of various statistical relations investigated, the closest correspondence was found between the subjective change in pain and the exact VAS pain noted at follow-up. The postoperative course after decompressive surgery can be described comprehensively by using the VAS (Figures 3, 6, 8).

Conclusion

A national protocol for degenerative lumbar spine surgery in Sweden has been developed including its use for computers and a system for registration with feedback to each department. It is now being used more frequently and from the beginning of the year 2000, more than 80% of all operations on the spine performed in Sweden are expected to be included. With an ambitious support system, all departments performing spinal surgery in this country will have been approached and offered help with registration and continuous back-up concerning computer technical problems. A protocol for cervical spine surgery is also being developed. The need for documenting outcomes of spine surgery is obvious and more variables are needed for a spine surgery protocol than in arthroplasty registers. This permits outcome evaluation focusing on pain relief and function.

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