

Evidence-based lumbar spine surgery

The role of national registration

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Lumbar spine surgery has for a long time been mainly authority based but during the last decade, much interest has focused on outcome evaluation, exemplified by a very high number of outcome instruments developed (Zanoli et al. 2000) and this development reflects a paradigm shift within spinal surgery. For lumbar spine surgery to develop and to be based on clinical experience, pilot studies, prospective randomised studies and broad, preferably national, registrations are required. This will be reflected in the following presentation which, however, mainly focuses on problems and benefits with the Swedish National Lumbar Spine Register.

The Swedish Lumbar Spine Register

Background

In contrast to hip and knee arthrosis and hip fracture, disease entities with prosperous registers, degenerative lumbar spine disorders are less well defined. Disc herniation and lumbar spinal stenosis is present in between 20 and 50% of asymptomatic subjects (Boden et al. 1990, Kent et al. 1992), and the findings on MRI or CT do not in any way reflect the pain and disability experienced by the individual patients. Therefore, a significant amount of preoperative data on pain and function has to be gathered for the individual patient. The same is true for the postoperative follow-up and the outcome evaluation. Using reoperation as an endpoint is meaningless and multiple outcome parameters have to be included which is one of the reasons for the many outcome instruments developed recently, described above. The high amount of data that

need to be collected put an increased effort on the patient as well as the surgeons, inducing the risk of incompleteness of data and loss to follow-up. On the other hand, the patient group treated is thoroughly described and a comprehensive description of patient related outcome is obtained.

Historical background

The first version of the register was presented in 1993 at a state of the art meeting on the degenerative lumbar spine in Lund, Sweden (Strömqvist and Jönsson 1993) and was received with great enthusiasm from many spinal surgeons. Funding was obtained from the National Board of Health and Welfare, and the register was classified as one of the national quality registers in Sweden. The protocol was surgeon based and a dedicated computer application was elaborated. The main aim was to prospectively describe the outcome of disc surgery, decompressive surgery and fusion surgery of the lumbar spine. In spite of national enthusiasm among spinal surgeons, however, the register did not take off from the ground during the first 5 years. Therefore some measures were taken: The register was transferred to the Swedish Society for Spinal Surgery and a steering function as well as a supportive function was created. The surgeons in the steering group were available for discussions with the users concerning methodological aspects, and two half-time secretaries were available for registration and administrative purposes as well as practical support meaning that the individual departments with computer problems could receive personal visits and help. Further, the protocol was entirely rearranged and made patient based. One page (Figure 1) was provided for data on the



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

Patient ID _____

Strömqvist/Jönsson

Pain drawing

Pain drawing (1-4)

Diagnosis

Disc herniation

Central spinal stenosis

Lateral spinal stenosis

Spondylolysis/olisthesis

Segmental pain

Other.....

Hospitalization

Date (yy-mm-dd)

Admitted _____

Date of operation _____

Discharged _____

Surgeon (initials) _____

Postoperative complication No

Yes, type

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.....

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.....

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

Reviewer

Reviewer, initials _____

operation and completed by the surgeon. Concerning pre- as well as postoperative data, the patient completes the protocols, if needed, assisted by a nurse, and, if wanted, provided by mail. Finally an improved feedback function on the computer was created. Hitherto, annual reports from the register were provided to the individual departments concerning the national figures totally, and, for the individual departments, their own data. Now, an export function to a statistical program enables every department to continually monitor their own data. A comprehensive algorithm for protocol handling was provided to each participating department.

These undertakings seem to have reversed the negative trend of low participation. During the mid 1990s between 6 to 10 departments out of 45 performing spine surgery in Sweden participated. The participation rate has improved from 12 in 1998 to 27 in 1999 and 32 in the year of 2000. The first year with acceptable participation rate, thus, was 1999 when 2,553 patients were included out of approximately 5,000 lumbar spine operations estimated to be performed in Sweden each year.

In order to facilitate registration, a web-based protocol is under development. This would enable the patient or the department to feed the data directly into the register and minimise work.

The protocol

The data included in the current patient-based protocol preoperatively are age, sex, smoking habits, previous lumbar spine surgery, working capacity, type of work and duration of back and leg pain. Consumption of analgesics and working distance, and back and leg pain on a visual analog scale (VAS) are recorded. A pain drawing is completed (Udén et al 1988), as well as the EuroQol and SF-36 questionnaires (Ware and Sherbourne 1992). The patient usually completes this protocol on the day before surgery.

The surgical data registered on one page (Figure 1) contain method of obtaining diagnosis, diagnosis and type of surgery, side and level. The time for hospitalisation is recorded as well as the first surgeon (optional). The use of antibiotic prophylaxis and the occurrence of complications and type are included. If a reoperation is performed (except for complications), the reoperation represents a new index operation.

The follow-up protocol is completed at one and two years after surgery and our aim is to repeat it five years postoperatively. Back and leg pain as compared to preoperatively are reported by the patient as well as return to work, duration of sick leave, type of work, consumption of analgesics and walking distance. In order to double check the occurrence of complications, also the patient receives a question on complication and reoperation. The patient gives an overall estimation of the surgical outcome (satisfied, uncertain, dissatisfied), and the back and leg pain on the visual analog scale is completed as well as the EuroQol and SF-36.

The computer application, prepared by Kaj Knutson, MD, PhD, Lund University, Department of Orthopedics, uses the FileMakerpro program and includes an export function to the Statview or SPSS programs for statistical evaluation. A yearly report is produced by the steering group (Strömquist et al. 2001) containing data for the whole of Sweden, and, also, divided into three categories: University hospital, central hospital and county hospital. Data from the individual department are not published.

Yearly compilation

Data on the 1999 results of the register was presented recently (Strömquist et al. 2001) and the following are examples of data possible to extract from the register. At the time of the compilation of data, 23 departments had registered 2,553 patients having undergone surgical treatment or a degenerative lumbar spine disorder such as disc herniation, central or lateral spinal stenosis, spondylolisthesis, segmental pain or other. Fifty percent of the operations were performed for disc herniation (Table 1) and 8% for segmental pain, whereas when sub division into type of hospital was performed, it was obvious that surgery for segmental pain was mainly performed at university hospitals. Bearing in mind the dispute around fusion surgery today, this seems a logical finding, and the majority of these patients are parts of prospective studies on the value of fusion.

The results of surgery can be presented for example as figures on visual analog scale pain (Figure 2) or SF-36 scores (Figure 3). Patient satisfaction varies significantly between the diagnoses

Table 1. Indication for surgery, degenerative lumbar spine disorders

	n	Mean age	% men	Pain (year) ^a
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

^a Mean duration of pain (year)

for surgery (Table 2) and also the complication rate which was in mean 5%, (range 0–30 %). The most common surgical complications were dural tear (1%), (mainly occurring in spinal stenosis surgery), wound infection (0.8%) and postoperative hematoma (0.4%). The complication rate varied between 2.7 and 13% for various types of surgery, the highest rate being noted in combined procedures with decompression and instrumented fusion.

Prospective randomised study

The register study thus showed the least positive results and the highest complication rate when fusion surgery was performed especially for segmental pain. A prospective randomised study comparing surgical and non-surgical treatment in patients with segmental pain and longstanding symptom has been performed by the Swedish lumbar spine study group (Fritzell et al. 2001). This study which was given the Volvo Award 2001

Table 2. Patient satisfaction related to diagnosis for surgery (%)

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

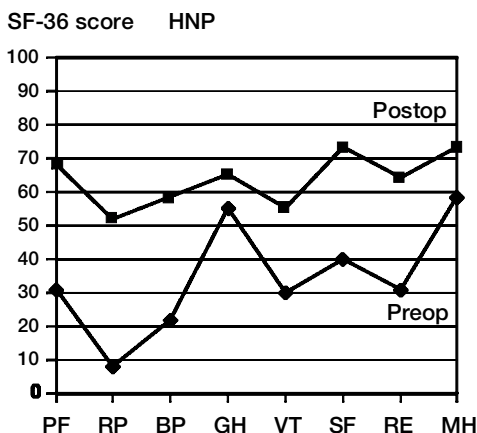


Figure 3. SF-36 scores pre- and postoperatively for patients operated on for lumbar disc herniation.

showed fusion surgery to be superior to non-operative treatment ($p < 0.0001$ regarding back pain) and with an outcome two years postoperatively using an independent observer, demonstrating 60% of the surgically treated patients as much better or

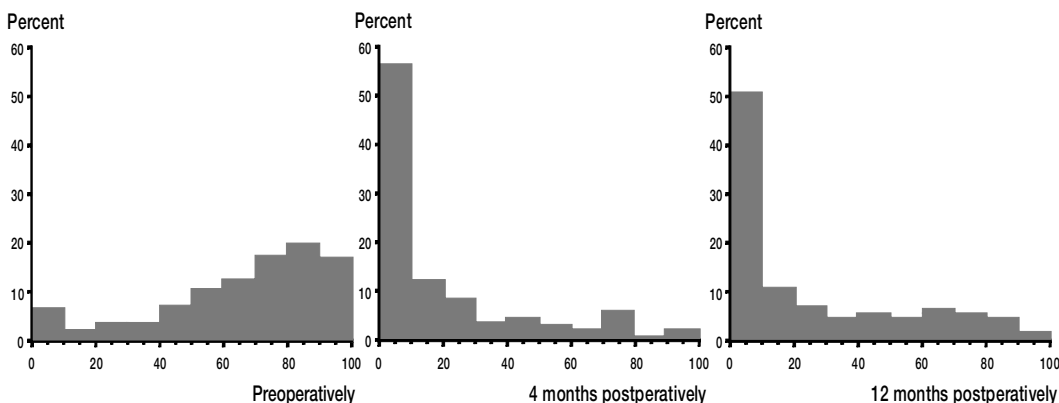


Figure 2. Leg pain on the visual analog scale (VAS) for patients operated on for lumbar disc herniation preoperatively, 4 and 12 months postoperatively.



Figure 4. External pedicular fixation ad modum Magerl.

better compared to 33% of the non-surgically treated patients. There was however no significant difference regarding return to work. Three fusion techniques were used, posterior, uninstrumented and instrumented fusion, and 360° fusion. The two more demanding techniques (instrumented and 360° fusion) consumed significantly more resources with the respect to operation time, blood transfusions and hospitalisation time and the early complication rate was 6.16 and 31 % in the respective groups. Thus, an RCT has proven the scientific value of fusion surgery for chronic low back pain but the results reported demonstrate that there are pronounced margins for improvement.

Improving patient selection for fusion by an external test fixation

A pilot study

Although surgical treatment of the patients described in the study above gave better outcome than non-surgical treatment, a better patient selection seems desirable. In a pilot study (Axelsson et al. 2002), 26 patients were evaluated before fusion by the external fixation test ad modum Magerl. Shantz screws were inserted in the pedicle of the suspected symptomatic level under general anaesthesia and the Magerl frame was applied externally on the day after surgery (Figure 4).

During the fixation period, the patients rated their grade of improvement subjectively and it was also objectified by a functional test. The test period lasted for 7–10 days. Based on the outcome of the tests, 20 of the 26 patients were suggested to undergo spinal fusion which was performed two months later. Thus, 20 patients were operated on with posterolateral fusion, in 15 of the cases augmented by pedicular screw and plate fixation. Nineteen of the 20 patients demonstrated fusion healing at two years and one patient non-union. Of the 19 patients with fusion healing, 14 (74%) had a good to excellent two-year outcome. This pilot study, thus, yielded a better two-year outcome than the prospective randomised study presented above, although the study sample was too small to yield statistical significance, and it seems logical to evaluate the selection by external test fixation in a large comparable patient material in the future.

Discussion

The three studies described in presentation partly overlapped regarding time of conduction so the historical aspect is not entirely correct. The idea, however, is to illustrate the interrelation between the three types of studies, registration, RCT and pilot studies. The register identifies areas for further analysis, the RCT can demonstrate the superiority of one technique as compared to another, and a pilot study may give the incitement to further studies, if the results are promising and so on.

Surgery for degenerative lumbar spine disorders is improving, shows pronounced regional variations (Taylor et al. 1994) and is debated by many. (Nachemson 1999). On the other hand, scientific documentation is improving in quality as well as quantity as exemplified by the multitude of outcome instrument developed for lumbar spine surgery during recent years (Zanoli et al. 2000). When leaving the old authority based spinal surgery and entering the époque of evidence based medicine, three components should be included for spinal surgery to have a good scientific basis still to continue to develop. National registers for giving a base line, enabling regional comparisons and monitoring outcome are needed. New techniques should be thoroughly tested in biomechanical as

well as in animal studies before introduced into humans. Thereafter, focused pilot studies and efficacy studies are needed followed by RCTs comparing new techniques to golden standards as well as the natural course. In the other end the national register may determine whether implementation of the new techniques in general use is successful. If we can adhere to these basic principles, spine surgery will be a good exponent for evidence based medicine in the future but without inducing the risk of suppressing the evolution of new techniques and new concepts. Validated outcome instruments will enable comparison also between different surgical techniques and also between different parts of the world, and the ongoing trend towards less complex instruments will facilitate their use.

Conclusion

Spinal surgery is gradually changing from an authority-based speciality to an exponent for evidence-based medicine. Agreement on suitable outcome instruments is mandatory. Pilot studies, prospective randomised studies and broad (preferably national) registers will contribute and will enhance the ongoing developments in spinal surgery.

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