THEME B:
Outcomes assessment
Chapter 05
Evidence and practice of spine registries
A systematic review and recommendations for future design of registries

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Appendix to Chapter 05 - editorial comment
(after Chapter 06 - page 130-133)

Guest editorial:
Spinal disorders, quality-based healthcare and spinal registers
Fairbank JCT
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Abstract

Purpose: We performed a systematic review and a survey in order to 1) evaluate the evidence for the impact of spine registries on quality of spine care, and with that, on patient-related outcomes, and 2) evaluate the methodology used to organize, analyze, and report the 'quality of spine care' from spine registries.

Methods: To study the impact, the literature on all spinal disorders was searched. To study methodology, the search was restricted to degenerative spinal disorders. The risk of bias in the included studies was assessed with the Newcastle-Ottawa Scale. Additionally, a survey among registry representatives was performed to acquire information about the methodology and practice of existing registries.

Results: 4,273 unique references up to May 2014 were identified and 1,210 were eligible for screening and assessment. No studies on Impact were identified, but 34 studies were identified to study the methodology. Half of these studies (17 of the 34) were judged to have a high risk of bias. The survey identified 25 spine registries, representing 14 countries. The organization of these registries, methods, analytical approaches and dissemination of results are presented.

Interpretation: We found a lack of evidence that registries have had an impact on the quality of spine care, regardless of whether the intervention was non-surgical and/or surgical. To improve the quality of evidence published with registry data we present several recommendations. Application of these recommendations could lead to registries showing trends, monitoring the quality of spine care given, and ultimately improving the value of the care delivered to patients with degenerative spinal disorders.
Evidence and practice in spine registries

Introduction

Lumbar spine disorders are a heterogeneous group of conditions with a lack of diagnostic clarity. Thus, in both surgical and non-surgical spinal interventions there are large variations in practice. The increasing frequency of spine-related interventions with increasing costs has led to a shift towards the delivery of value-based spine care [1]. Here, value is expressed as patient-centred outcomes (safety and effectiveness; quality) divided by the related costs of care or per unit cost [2]. While Randomized Clinical Trials (RCTs) are considered the gold standard for assessing the efficacy of interventions, the difficulties with RCTs, specifically for assessing surgical procedures in spinal disorders, are acknowledged [3]. Some barriers are surgeon preferences, patient selection, patients’ reluctance regarding randomization, difficulties in blinding, high cost, the need for long-term follow up, the often high proportions of loss to follow up, and the problem with crossover. Well-designed observational cohort studies, reflecting daily clinical practice, have been reported to produce as trustworthy and externally valid results as RCTs [4-6], [7-10].

An outcome registry is an organized system that uses observational study methods [11], based on STROBE recommendations [12]. Registries could therefore, be used to describe care patterns, including appropriateness of care and disparities in the delivery of care. Registry data could also be used to understand variations in treatment and outcomes and to identify and select subgroups in the heterogeneous chronic low back pain population, with a probability of successful or poor outcome. The ultimate goal of health services registries is to increase value of delivered care (i.e. outcome per unit cost) [13]. Moreover, it has been suggested that measuring with continuous feedback (audit cycles) of outcomes captured in registries raises the awareness and improves quality of care [14]). However, as yet, little is known about the effect of registries on the quality of spine care and the methods for registering and feedback.

This study had 2 aims: 1) to evaluate the available evidence for the effect and possible impact of introducing and using spine registries on quality of spine care after any intervention and on patient-related outcomes; 2) to evaluate the methodology used to organize, analyze, and report the ‘quality of spine care’ from spine registries.

Methods

We performed a systematic review according to the PRISMA statement for reporting in systematic reviews and meta-analyses [15]. In addition, for the second aim (regarding methodology) a survey among spine registry representatives was performed to acquire information about the current status of existing spine registries. The complete protocol of this study was presented at the preconference meeting of the International Society for the Study of the Lumbar Spine 2014 (ISSLS) [16]. Selection of studies and appraisal of their quality was performed independently by MH and WJ. Discrepancies were discussed during consensus meetings, with mediation by a third author (PW) were disagreements persisted.

Search

A comprehensive search was conducted because terminology in the field of chronic low back pain is not yet standardized, and because we aimed to include both randomized and non-
randomized studies. The search was performed by one of the authors (WJ) on May 12, 2014, using the most common databases: CBRG trials register (up to search date), MEDLINE (from 1966 to search date), EMBASE (from 1980 to search date), and ISI Web of science (up to search date). The search string for MEDLINE is given in Appendix 1 (See Supplementary data) and was adapted for the additional databases. No language or date restrictions were made. References and citation of selected articles were tracked and included in the search.

**Impact of registries on quality of spine care**
Articles were included if they met the following criteria:

**Types of studies**
Studies on spine registries based on results from prospectively acquired data were included. To comply with the definition of patient or outcomes registry, we used the following registry characteristics: inclusion principle, mergeable data, standardized dataset for all consecutively included patients, rules for data collection (i.e. systematically and prospectively collected, including pre-intervention data), knowledge about patient-related outcomes, and observations collected over time (i.e. follow-up assessments) [17]. Studies were included if published between 2000 and May 2014 and written in English.

**Types of spine disorders**
We included patients of all ages with spine disorders who underwent any elective or acute, non-surgical or surgical spinal intervention. The following specific disorders were defined: degenerative disc disease (DDD, ‘non-specific’ and/or chronic low back pain, segmental pain), spinal stenosis, disc herniation, spondylolisthesis/-/lysis (isthmic/degenerative), failed back surgery syndrome, spinal deformities (degenerative deformity: de novo, osteoporotic, idiopathic, neuromuscular, congenital), spinal oncology, spine trauma, and infections of the spine.

**Types of interventions**
Interventions were included that provide a system to register quality of spine care, i.e. outcomes, including a system for feedback: quality improvement strategies [18-20]. These strategies include those targeted: health systems (e.g. team changes), healthcare professionals (e.g. reminders), and patients (e.g. reminders). Specific improvement strategies included: (clinical) audit and feedback, (electronic) patient registries, case management, clinician education, (promotion of) self-management, patient reminder systems, and continuous quality improvement.

**Types of outcome measures**
Quality of care is a multidimensional concept and is defined in many ways, e.g. ‘doing the right thing, at the right time, in the right way, for the right person, and having the best possible results’ [21]. Following this definition, the outcomes of spine interventions are a proxy for quality of care. As measures for quality of spine care we included patient-related outcome indicators: patient-reported outcome measures (PROMs) and clinical outcome measures. PROMs [22] are functional status (e.g. Roland and Morris Disability Questionnaire [RMDQ], Oswestry Disability Index [ODI], Scoliosis Research Society-22 [SRS22]), pain intensity back and leg (e.g. Visual Analogue Scale [VAS], Numeric Pain Rating Scale [NPRS]), and health-related quality of life (e.g. Short Form-36 [SF36], EuroQol 5 Dimensions [EQ5D]). Clinical outcomes
were regarded as re-intervention (i.e. reoperation), complications, and failed back surgery syndrome (FBSS).

The search did not reveal any studies related to the first aim of this study (impact) concerning the effect and possible impact of introducing and using spine registries on the quality of spine care and on patient-related outcomes (Figure 5.1).

**Methodology used in existing spine registries**

**Selection criteria**
The same criteria were used as for the first aim, but they were restricted to include studies with patients with degenerative lumbar spine disorders: degenerative disc disease (DDD, ‘non-specific’ and/or chronic low back pain, segmental pain), spinal stenosis, disc herniation, spondylolisthesis/lysis (isthmic/degenerative), and spinal deformities (degenerative deformity: de novo, osteoporotic).

**Risk of bias assessment**
The included studies were assessed for methodological quality, to get an impression of the quality of published scientific studies based on registries. Quality was assessed with the Newcastle-Ottawa Scale (NOS; Appendix 2, see Supplementary data) for cohort studies[23]. Studies were considered to be of high quality if the total score was 6 or more (75% of the maximum score). The clinical relevance of study results was assessed with 3 questions: 1) ‘Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?’; 2) ‘Are the interventions and treatment settings described well enough so that you can provide the same for your patients?’; 3) ‘Were all clinically relevant outcomes measured and reported?’.

**Data extraction and management**
Using forms already developed, the following data were extracted: authors (affiliation, sponsoring), name and type of registry (i.e. based on exposure: health service, disease/condition and medical devices [11]), setting (nationwide, multicentre), diagnosis, methods (purpose, study design, outcomes, covariates, statistical analysis, patient numbers recruited and included), follow-up response, non-responder analysis, conclusion. MH extracted the data and WJ checked the data; inconsistencies were discussed and PW was consulted if necessary.

**Survey**
A web-based survey, built in the Harvard Business online Qualtrics Survey Software and provided by International Consortium for Health Outcomes Measurement (ICHOM), was performed among spine registry representatives. The survey consisted of 21 questions regarding: 1) organizational structure and financing, 2) methodology used and outcome assessment, 3) procedures concerning response rates and missing data, and 4) approaches for analysis and reporting.

The sample included participants of the ICHOM Low Back Pain Working Group, representatives of spine registries identified through spine registry websites, and corresponding authors of publications on spine registries as identified in this systematic review. All recipients were contacted by e-mail and asked to participate in an online survey. Subjects who did not respond were sent a reminder after 2 weeks.
Analyses

Results from the included studies in the review were not pooled; instead, we compared and reported on the methods used in these studies. The data from the survey are described and support the results found in the review. The PROMs used were checked with the ICHOM-LBP PROMs criteria [24]: 1) functional status (ODI [0-100] version 2.1a); 2) pain intensity (NPRS [0-10] back and leg; average pain during last 7 days); 3) health-related quality of life (EQ5D-3L and EQ-VAS); 4) timeline assessments included were baseline, 3 and 6 months, and 1, 2, and 5 years after the ‘index event’ (3 months and 5 years assessments were optional). The ‘index event’ was defined as the reported first intervention episode.

Figure 5.1 Flowchart of studies through the different phases of the systematic review.
Results

Impact of registries on quality of spine care

Included studies

4,273 unique references were identified, 1,210 of which were eligible for screening and assessment (Figure 5.1). No studies on the effect of spine registries on quality of care were identified.

Methodology used in existing spine registries

Included studies

34 studies were identified for study of the methodology used to organize, analyze, and report the quality of spine care in degenerative lumbar spine disorders (Appendix 3, see Supplementary data; Table S1). The 34 studies were based on 11 separate registries, representing 7 countries. Indications included were disc herniation (3), spinal stenosis (9), chronic low back pain (5), adult deformity (5), and spinal disorders (7). In 3 studies a mixture of indications (non-specific subacute and chronic neck, back, and low back pain) was included, but these allowed to extract data of methodology used for separate indications.

Risk of bias

Half of the studies were classified as having a high methodological quality (17 of 34; Table 5.1). Although 'selection of the non-exposed cohort' (item 2) scored high quality (i.e. low risk of bias), 21 studies were rated 'n.a.' as these studies did not include a control group. In 20 of the 34 studies, a low risk of bias in 'comparability' (item 5a) was seen, meaning studies controlled for the most relevant case-mix variables (i.e. diagnosis and baseline outcome score). In all studies the 'assessment of outcome' (item 6) was rated 'self-report' (c), and with that scoring low quality. The follow up was long enough for outcomes to occur (item 7; 29 of 34). However, low quality was seen in the adequacy of follow up of cohorts (item 8; 18 of 32). Although in almost all studies the clinical relevant outcomes are measured and reported (31 of 32; 'clinical relevance' [item 3]), in less than one-third of the studies (10 of 32) the description of patients and intervention ('clinical relevance', items 1 and 2) was sufficiently detailed.

Survey

We identified 25 spine registries, representing 14 countries, within the ICHOM Low Back Pain Working Group (ICHOM-LBP WG; 10) through the literature (10; 4 overlap with ICHOM-LBP WG) and through internet searches (9). We were unable to make contact with representatives of 7 of the multicentre registries; the remaining 18 were invited to participate in the survey. 16 of them responded, representing 12 countries and 2 including 'diverse' countries (Spine Tango and European Spine Study Group database [ESSG]). The non-responders were representatives of Russian and Indian registries.

An overview of existing spine registries is presented in Table 5.2: survey responders (16) and searches though internet and literature (6). 3 multi-centre registries in the USA were found through internet searches, but we were unable to obtain relevant information (NASS Spine Registry, SMISS Prospective Data Registry, and Scolisoft Scoliosis Database [see references for websites]); these registries were not included in Table 5.2.
**Organization and Methods used in spine registries**

**Organization (Table 5.2)**

9 of 22 registries are organized on a nationwide basis. Most spine registries started within the last decade. All registries are health services registries, except for Kaiser Permanente which is a device or implant registry and SWISSspine, a device or implant registry with health technology assessment purposes.

**Methods (Table 5.2)**

All registries incorporated the main patient-reported outcome domains. ODI, NPRS back and leg, and EQ5D are mainly used as PROMs. In the majority of the registries clinical outcomes (e.g. complications and reoperations) are also registered. All registries have baseline and 12- and 24-months follow-up assessments, except for NORspine and N²QOD (with only a 12-months follow up). Although 15 registries report on lumbar spine disorders, only 3 fulfil all the ICHOM-LBP criteria for PROMs. The Adult Deformity Outcomes Database registry has the longest follow up (25 years). To improve the response rate, all registries use postal, e-mail or telephone reminders.

**Analyses and reporting**

In the 34 scientific publications, various analytic approaches were used (Appendix 3, see Supplementary data, Table 5.4), varying from descriptive statistics, all studies, to multivariate techniques as mixed linear modelling [25,26] and propensity modelling [27,28]. To evaluate the study purpose all studies used 1 or more PROMs as an outcome measure. In 8 studies secondary clinical outcomes were defined: complications [25,27,29], reoperation [30], BMI [31], adverse events [32], and Bridwell classification for fusion rates [33]. In 5 studies, no adjustment for covariates was performed to explain variation in outcomes [33-37]. In the remaining 29 studies patient characteristics were used as covariates, varying from 17 predefined covariates [38] to adjustment for baseline PROMs only [39]. Adjustment for baseline PROMs was not performed in 8 studies [27,30,32,40-44]. In 8 studies, a dropout analysis was performed to compare baseline characteristics (missing data on assessments) with the remaining cases. To handle missing data, multiple imputation techniques were applied in 2 studies [38,41]. In the remaining studies complete case analysis was performed.

All 16 registries representatives reported in the survey, to describe the population and outcomes using descriptive statistics and to provide feedback reports on a regular basis to all participating institutions and spine societies. Benchmarking is performed against the average value of participating institutions in 10 registries (Table 5.2). The 12-months follow-up responses on PROMs vary from 20% (British Spine Registry) to 88% (Neuroreflexotherapy registry within Spanish National Health Service [NRT en el SNS]).
Discussion

We found a lack of evidence to support or refute the effect that spine registries may have on the quality of spine care and on patient-related outcomes. Nonetheless, the publications that have resulted from the spine registries have yielded relevant evidence on interventions or predictive factors for spinal disorders. We have therefore described the methodology used to organize, analyze, and report the ‘quality of spine care’ from spine registries. To improve the quality of results published with registry data and to study the effects of spine registries in future; we have formulated and included several recommendations, which are summarized in Table 5.3. First of all, the registries should be methodologically well constructed and we need to learn from existing registries so that a more standardized approach to registering and analysis are achieved to allow international collaboration, national and international benchmarking, and to make sure that in future spine care is value-based (Table 5.3; recommendation [rec.] 1).

Quality improvement in spine care

Although we did not find any scientific evidence for an effect of introducing and using spine registries on the quality of spine care, in 16 registries feedback reports are compiled and disseminated on a regular basis to the participating institutions and the spine societies in order to improve the quality of spine care delivered. In general, improvement strategies include (clinical) audit and feedback, (electronic) patient registries, case management, clinician education, (promotion of) self-management, patient reminder systems, and continuous quality improvement [18-20] (Table 5.3; rec. 2).

That registries can have an important effect on quality of health care has, however, been reported in other fields. For example, the Swedish Hip Register has shown that prospectively and systematically collected data decreased revision rates, by describing trends in outcomes adjusted for case-mix factors and early problems [58]. Antibiotic treatment for patients with hard-to-heal ulcers was reduced from 71% before registration to 29% after registration and feedback [59]. A collaborative cohort study of 5 ICUs in the USA showed that an evidence-based intervention resulted in a large sustained reduction (up to 66%) in the rate of catheter-related bloodstream infection, which was maintained throughout the 18-months study period [60]. A study of 13 patient registries in 5 countries demonstrated that these systems have great potential to both improve health outcomes and lower health care costs[13].

Recently, reports from Sweden indicate that spine registries have a positive effect on health care, i.e. on patient-related outcomes, by the SweSpine registry (complying with the recommendations in Table 3). For example, the national mean length of stay (LoS) for surgery in lumbar disc herniation today is 2 days, with a range of 0-4 days. After introduction of new routines the LoS in 1 university hospital was reduced from 4 to 2.5 days, giving the same patient-related outcomes at lower costs [61]. Another example is a change of surgical procedure in elderly with lumbar spinal stenosis (LSS). 2-year registry data on 8,785 elderly patients showed that surgery can be limited to an invasive procedure of decompression alone, in order to avoid unnecessary complications associated with fusion procedures [62]. These registry findings have recently been confirmed with a multicentre RCT among 229 elderly patients with 1- or 2-level LSS. After 2 years, no benefit from adding fusion to decompression surgery was found, which means that in this population a less invasive procedure of decompression can reduce the number of complications and costs for society [63].
Quality of studies based on registry data
In the present study, only half of the publications could be regarded as having a low risk of bias, as assessed on the Newcastle-Ottawa Score (NOS). The main weaknesses of the included studies were the inaccurate descriptions of the patients and interventions studied, and the lack of long-term assessment of the outcome. We therefore recommend to use the STROBE guidelines for reporting observational studies [12] (Table 5.3; rec. 3). Moreover, as it is known that during the first year after spine surgery changes in patient-related outcomes are seen [6,27,64,65], a minimum follow-up period of 1 year is recommended (Table 5.3; rec. 4). As stability of patient-reported outcome measures (PROMs) results is seen between 2 and 4 years [6,27] longer follow-up periods are desirable. Another weakness causing high risk of bias according to NOS is that the assessment of outcomes in all studies was performed by PROMs. As PROMs are self-report measures, these measures are assessed as low quality by NOS (Appendix 2, see Supplementary data). Although of lower quality methodologically, PROMs are the recommended outcome measures in spine surgery [22], as there is no valid biomedical measure currently available to evaluate recovery after a spinal intervention. Although they are usually defined as clinical patient-related outcomes, reoperation and complications are in fact process measures for a complicated course to an endpoint defined by PROMs.

Methodology of studies based on registries
Although all 34 studies met the 6 inclusion criteria for registry characteristics [17] (Table 5.3; rec. 5), we found various analytical approaches. Thus, we cannot give the best approach to use when comparing institutions in the search to identify best practices. In measurement of patient-based outcomes, the PROMs used should ideally fulfill the criteria of good measurement properties [66]. Recently, consensus was reached within the ICHOM collaboration on which PROMs should be recommended for the evaluation of outcomes of interventions for degenerative lumbar spinal disorders (Oswestry Disability Index [ODI], Numeric Pain Rating Scale [NPRS] back and leg, and EuroQol 5 Dimensions [EQ5D]; [24]; Table 5.3; rec. 6). Although as yet only 3 lumbar spine patient registries (SweSpine, Dutch Spine Surgery Registry and Spine Tango) use the specific ICHOM PROMs, every other studied registry already evaluated functional status, pain intensity, and quality of life with PROMs, but the assessment used other tools.

To prevent selection bias [67] and to explain real differences in outcomes between institutions multivariate approaches with adjustment for covariates (corrections for differences in characteristics of patients treated in hospitals; ‘case-mix adjustments’) and correction for chance variation (reliability adjustments) are needed [64,68-70] (Table 5.3; rec. 7). A shortcoming of these techniques is that they only account for known covariates. In this systematic review we found that a large variety and number of covariates are included in different registries. A recently published study showed that a large number of patient characteristics (biomedical, psychosocial and health-related indicators) could influence the outcome of interventions of lumbar spinal disorders or maintain the complaints [71]. Within the ICHOM collaboration consensus was reached to use a minimum set of factors: age, sex, education level, work status, duration of sick leave, smoking status, comorbidities, BMI, duration of back/leg pain, morbidity state, diagnosis and indication surgery, need for continuous analgesic use, prior intervention, and baseline patient-reported disability, back and leg pain baseline, and health-related quality of life [24] (Table 5.3; rec. 7). Currently, none of the registries collect data of all of these recommended factors. Within the countries influenced by the SweSpine registry format
Evidence and practice in spine registries (Sweden, Norway, Denmark, and the Netherlands), consensus has been reached to implement all these factors in the registry, to allow them to be used as covariates in future benchmark analyses. When benchmarking across centers, it has been suggested that together with these patient-related covariates, center-specific characteristics might also influence the outcome of surgery in degenerative lumbar spine disorders [64].

In the registries, the 12-months follow up on PROMs varied from 20% (British Spine Registry) to 88% (NRT en el SNS). A suggested rule of thumb is that a loss to follow up larger than 20% would probably lead to bias in results, whereas a rate of less than 5% would not [72,73]. A recently performed study on Norwegian registry 2-year follow-up data on 633 patients showed that a loss to follow up of 22% would not alter conclusions about the outcome of interventions [74]. Efforts should be made to increase 12- and 24-months follow-up responses to 60-80% (Table 5.3; rec. 8). Although patients are 3 times more likely to respond when invited for follow-up visits [74], it is too demanding for all parties involved to arrange long-term follow-up visits in large patient registries [75]. Solberg et al. [74] found that forgetfulness is the most important reason for not responding, which could possibly be prevented by modern communication techniques as text messages and email (Table 5.3; rec. 9). To handle missing data in most registries only analyses are performed on complete cases. To understand potential sources of bias, a non-responder analysis on baseline characteristics should be provided (Table 5.3; rec. 10). Statistical sensitivity techniques are available to test whether there is bias present. When missing at random, indicating that the missing data are related to other observed or documented patient data but not to unobserved outcomes, we recommend multiple imputation techniques (Table 3; rec. 11). The major advantage of this method over single imputation techniques or ‘complete cases only’ is that it does not underestimate variability [76,77].

Strengths and Limitations
To evaluate the risk of bias in the studies included, as a quality assessment, we defined a cutoff value (total score ≥6 [75%]) for the Newcastle-Ottawa Scale (NOS) for cohort studies. However, research is needed to identify whether this is the correct tool for assessing risk of bias in patient registries. Another limitation is that selection bias might be present in the spine registries identified. We identified 2 types of registries: national and institutional. The national registries are in most cases part of an obligatory, government or insurer driven need for quality control and/or audit. The multicentre institutional registries carry the risk of selection bias (e.g. many institutional registries include premier spine institutes with selected patients) and even more when they are sponsored by industry (ESSG, SWISSspine, Canadian Spine Outcomes, and Research network; Indian Spine Registry) or by membership (SSE Spine Tango, British Spine Registry, National Spine Network Spine Outcomes Registry). Although we performed a profound search and gained an overview of 25 large registries for degenerative spinal disorders we cannot rule out that more spine registries exist.

The main strength of this study was that we adopted a systematic approach, including a systematic search and an appraisal of quality. In addition, we conducted a survey among representatives of all the known registries to add information to that found in the literature. To increase the response, we contacted (successfully) all the representatives of the spine registries to complete our data.
Conclusions
Currently, despite there being some evidence in other fields of healthcare, there is a lack of evidence to either support or refute the impact that spine registries may have on the quality of spine care and, with that, on patient-related outcomes. To improve the quality of results published from registry data, we have formulated several recommendations. With the first indications of the effects of the SweSpine registry already known (e.g. improved outcomes after feedback on length of stay and no patient-related benefit from adding fusion to decompression surgery), we believe that application of these recommendations could lead to spine registries demonstrating trends and outcomes, monitoring the quality of spine care delivered, resolving controversies in the management of degenerative spinal disorders, and ultimately improving the value of the care given to our patients.

Acknowledgements
The authors thank members of the ICHOM Low Back Pain Working Group and all participants who completed the spine registry survey. Particular thanks are to Caleb Stowell (ICHOM) for his support in building and managing the survey in the Harvard Business' Qualitrics online web-application and to Serge Stommels for his support in translating Russian texts in relation to the Russian Spine Registry.

Supplementary data
Appendices 1-3 are available at Acta’s website (www.actaorthop.org), identification number 8170.
### Table 5.1: Risk of bias assessment according to Newcastle-Ottawa scale (NOS)

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<tr>
<td>Stromqvist et al. (2012)</td>
<td>SweSpine</td>
<td>a</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>Berg et al. (2010)</td>
<td>SSE Spine Tango</td>
<td>b</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>a</td>
</tr>
<tr>
<td>Grob and Mannion (2009)</td>
<td>SSE Spine Tango</td>
<td>a</td>
<td>n.a.</td>
<td>d</td>
<td>b</td>
<td>no</td>
</tr>
<tr>
<td>Porchet et al. (2009)</td>
<td>SSE Spine Tango</td>
<td>c</td>
<td>a</td>
<td>d</td>
<td>a</td>
<td>*</td>
</tr>
<tr>
<td>Aghayev et al. (2012)</td>
<td>SWISSspine</td>
<td>a</td>
<td>*</td>
<td>b</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>Aghayev et al. (2010)</td>
<td>SWISSspine</td>
<td>b</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>d</td>
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<tr>
<td>Schluessmann et al. (2009)</td>
<td>SWISSspine</td>
<td>a</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
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<tr>
<td>Zweig et al. (2010)</td>
<td>SWISSspine</td>
<td>a</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>McGregor et al. (2013)</td>
<td>NQOD</td>
<td>a</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>d</td>
</tr>
<tr>
<td>Deer et al. (2000)</td>
<td>Nat Outc Reg</td>
<td>b</td>
<td>*</td>
<td>n.a.</td>
<td>c</td>
<td>a</td>
</tr>
<tr>
<td>Taylor et al. (2000)</td>
<td>Comp outc m study</td>
<td>b</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>b</td>
</tr>
<tr>
<td>Bridwell et al. (2007)</td>
<td>A D O Database</td>
<td>b</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>Glassman et al. (2009)</td>
<td>A D O Database</td>
<td>b</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>Glassman et al. (2007)</td>
<td>A D O Database</td>
<td>b</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>a</td>
</tr>
<tr>
<td>Kasliwal et al. (2012)</td>
<td>A D O Database</td>
<td>b</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>d</td>
</tr>
<tr>
<td>Schwab et al. (2008)</td>
<td>A D O Database</td>
<td>a</td>
<td>*</td>
<td>n.a.</td>
<td>d</td>
<td>b</td>
</tr>
<tr>
<td>Adqwa et al. (2014)</td>
<td>Multicenter reg</td>
<td>a</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>d</td>
</tr>
<tr>
<td>Seng et al. (2013)</td>
<td>Singapore GH Reg</td>
<td>b</td>
<td>*</td>
<td>a</td>
<td>*</td>
<td>c</td>
</tr>
</tbody>
</table>

Percentage with *, a or yes: 94 92 17 86 59 71 0 85 33 50 31 31 97

**Explanation**: NOS, including description of items and method of scoring, is given in Appendix 2.

- **Selection**: 1 representativeness exposed cohort; 2 selection non-exposed cohort; 3 ascertainment exposure; 4 outcome not present at start study.
- **Comparability**: 5a and 5b Comparability cohorts on the basis of design/analysis; 6 outcome assessment.
- **Outcome**: 7 follow up long enough; 8 adequacy follow up.

- *Score*: a high quality; b n items, considering n.a.; c National Outcomes registry; d Community outcomes management study; e Adult Deformities Outcomes Database; f Multicenter registry for lumbar spine surgery; g Singapore General Hospital Spine Outcomes Registry.

**Direction of Risk of Bias (NOS)**

- Selection: 1-2
- Comparability: 5a-5b
- Outcome: 6-7

- *Clinical relevance*: 1 are the interventions and treatment described well enough so that you can provide the same for your patients? 2 are the outcomes of the study measured and reported well enough so that you can judge their relevance for your practice? 3 are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
<table>
<thead>
<tr>
<th>Registry name</th>
<th>Location</th>
<th>Setting</th>
<th>Since (year)</th>
<th>Location spine</th>
<th>Outcomes Lumbar spine</th>
<th>PROMs assessment</th>
<th>ICHOM LBP PROMs criteria</th>
<th>Benchmark</th>
<th>Scientific publication</th>
<th>NOS Risk of Bias score</th>
</tr>
</thead>
<tbody>
<tr>
<td>SweSpine</td>
<td>Sweden</td>
<td>N</td>
<td>1998</td>
<td>L; C; D; T; M</td>
<td>ODI; VAS &amp; L &amp; B; SF36; EQ5D</td>
<td>B; P: 12; 24; 0,3y</td>
<td>Yes</td>
<td>average &amp; individual centers</td>
<td>Yes; 12</td>
<td>5 (2-7)</td>
</tr>
<tr>
<td>NORspine</td>
<td>Norway</td>
<td>N</td>
<td>2006</td>
<td>L; D</td>
<td>ODI; NRS B &amp; L &amp; EQ5D</td>
<td>B; P: 3; 6; 12; 24; O, 5y</td>
<td>No</td>
<td>average</td>
<td>Yes; 2</td>
<td>4.5 (2-7)</td>
</tr>
<tr>
<td>DaneSpine</td>
<td>Denmark</td>
<td>N</td>
<td>2009</td>
<td>L; C; D; T; M</td>
<td>ODI; VAS &amp; L &amp; EQ5D</td>
<td>B; P: 3; 12</td>
<td>No</td>
<td>average</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Dutch Spine Surgery Registry</td>
<td>The Netherlands</td>
<td>N</td>
<td>2014</td>
<td>L; D (mainly); C; T; M</td>
<td>ODI; NRS B &amp; L &amp; SF36; EQ5D</td>
<td>B; P: 2/6; 12; 24*</td>
<td>Yes</td>
<td>average &amp; individual centers (planned)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>British Spine Registry</td>
<td>UK</td>
<td>N</td>
<td>2012</td>
<td>L; C; D; T; M</td>
<td>ODI; VAS &amp; L &amp; EQ5D</td>
<td>B; 3; 12; 24; O,5y</td>
<td>No</td>
<td>average &amp; individual centers (planned)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>NRT en el SNS</td>
<td>Spain</td>
<td>N</td>
<td>2002</td>
<td>L; C</td>
<td>RM-DQ; NRS B &amp; L &amp; not meas.</td>
<td>B; P: 3; O, each 3mo #</td>
<td>No</td>
<td>only own data</td>
<td>Yes; 4</td>
<td>4.0 (2-6)</td>
</tr>
<tr>
<td>SWISSspine</td>
<td>Switzerland</td>
<td>N</td>
<td>2005</td>
<td>L; C; D; T; M</td>
<td>NASS; COMI; NRS B &amp; L &amp; EQ5D</td>
<td>B; P: 3; 6; 12; 24; O, 5y</td>
<td>No</td>
<td>average</td>
<td>Yes; 4</td>
<td>5 (5-6)</td>
</tr>
<tr>
<td>SSE Spine Tango</td>
<td>Diverse</td>
<td>M</td>
<td>2002</td>
<td>L; C; D; T; M</td>
<td>OD1; COMI; COM &amp; NRS B &amp; L &amp; EQ5D</td>
<td>B; P: 6w; 3; 12; 24</td>
<td>No</td>
<td>average</td>
<td>Yes; 3</td>
<td>3–1.5 (2–5)</td>
</tr>
<tr>
<td>Canadian a</td>
<td>Canada</td>
<td>N/M</td>
<td>2012</td>
<td>L; C; T</td>
<td>OD1; VAS &amp; L &amp; SF22; EQ5D</td>
<td>B; P: 3; 12; 24</td>
<td>No</td>
<td>average</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Singapore b</td>
<td>Singapore</td>
<td>N/I</td>
<td>2001</td>
<td>L; C; D; T; M</td>
<td>OD1; NASS; NRS B &amp; L &amp; SF36</td>
<td>B; 1; 3; 6; 24</td>
<td>No</td>
<td>only own data</td>
<td>Yes; 1</td>
<td>5</td>
</tr>
<tr>
<td>Neuro Fondation</td>
<td>Australia</td>
<td>I</td>
<td>2010</td>
<td>L; C</td>
<td>OD1; RMDQ; NRS B &amp; L &amp; SF2; future EQ5D</td>
<td>B; 6w; 3; 6; 12; 24</td>
<td>No</td>
<td>only own data</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Texas Back Institute</td>
<td>USA</td>
<td>I</td>
<td>New</td>
<td>L; C; D; T; M</td>
<td>ODI; VAS &amp; L &amp; SF2; future EQ5D</td>
<td>B; 3 %</td>
<td>No</td>
<td>only own data</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Kaiser c</td>
<td>USA</td>
<td>M</td>
<td>2009</td>
<td>O, instrumented procedures</td>
<td>n.a.</td>
<td>n.a.</td>
<td>n.a.</td>
<td>P</td>
<td>No</td>
<td>only own data</td>
</tr>
<tr>
<td>N²QOD d</td>
<td>USA</td>
<td>M</td>
<td>2012</td>
<td>L; C; D</td>
<td>OD1; NRS B &amp; L &amp; EQ5D</td>
<td>B; 3; 12</td>
<td>No</td>
<td>average</td>
<td>Yes; 1</td>
<td>4 ^0</td>
</tr>
<tr>
<td>Schön-Clinics Spine Registry</td>
<td>Germany</td>
<td>M/I</td>
<td>2010</td>
<td>L; C; D; T; M</td>
<td>OD1; VAS &amp; L &amp; EQ5D</td>
<td>B; P: 3; 12; 24</td>
<td>No</td>
<td>average &amp; individual centers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>European Spine Study Group</td>
<td>Diverse</td>
<td>M</td>
<td>2010</td>
<td>D</td>
<td>OD1; SRS 22r; COMI; NRS B &amp; L &amp; SF36</td>
<td>B; P: 6w; 6; 12; 24</td>
<td>n.a.</td>
<td>n.a.</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Registry Name</td>
<td>Country</td>
<td>Year</td>
<td>Setting</td>
<td>Location</td>
<td>Functional Status</td>
<td>Pain</td>
<td>Quality of Life</td>
<td>PROMs at</td>
<td>NOS Risk of Bias Score</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------</td>
<td>------</td>
<td>---------</td>
<td>----------</td>
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<td>------</td>
<td>----------------</td>
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<td></td>
</tr>
<tr>
<td>Russian Spine Registry</td>
<td>Russia</td>
<td>2012</td>
<td>M</td>
<td>L</td>
<td>ODI, VAS, SF36</td>
<td>No</td>
<td>Not found</td>
<td>B; P; not reported</td>
<td>11.8 (11-12)</td>
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</tr>
<tr>
<td>Indian Spine (Surgery) Registry</td>
<td>India</td>
<td>M; future</td>
<td>Plan.</td>
<td>L; C</td>
<td>ODI, SF36, SF8</td>
<td>Not found</td>
<td>Not found</td>
<td>B; P; 12, 24</td>
<td>11.8 (11-12)</td>
<td></td>
</tr>
<tr>
<td>National Spine Network</td>
<td>USA</td>
<td>M</td>
<td>1995</td>
<td>C</td>
<td>ODI, SF12, SF8</td>
<td>Not found</td>
<td>Not found</td>
<td>B; P; 12, 24</td>
<td>11.8 (11-12)</td>
<td></td>
</tr>
<tr>
<td>Multicenter registry</td>
<td>USA &amp; Canada</td>
<td>M</td>
<td>2003</td>
<td>L</td>
<td>ODI, SRS-22, ODI</td>
<td>Not found</td>
<td>Not found</td>
<td>B; P; 12, 24</td>
<td>11.8 (11-12)</td>
<td></td>
</tr>
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<td>ADO Database</td>
<td>USA Spine Deformity Study Group</td>
<td>M</td>
<td>2002</td>
<td>D</td>
<td>SRS-22, ODI, VAS &amp; L</td>
<td>Not found</td>
<td>Not found</td>
<td>B; P; 12, 24</td>
<td>11.8 (11-12)</td>
<td></td>
</tr>
<tr>
<td>ATSD Database</td>
<td>USA International Spine Study Group</td>
<td>M</td>
<td>2010</td>
<td>D</td>
<td>SRS-22, ODI, VAS &amp; L</td>
<td>Not found</td>
<td>Not found</td>
<td>B; P; 12, 24</td>
<td>11.8 (11-12)</td>
<td></td>
</tr>
</tbody>
</table>

n.a not applicable
1 Registry names: 2 Canadian Spine Outcomes and Research Network; 3 Singapore General Hospital Spine Outcomes Registry; 4 Kaiser Permanente Spine Implant Registry; 5 National Neurosurgery Quality and Outcomes Database (N²QOD); 6 National Spine Network Spine Outcomes Registry (SpineChart); 7 Multicenter registry for lumbar spine surgery; 8 Adult Deformity Outcomes Database; 9 Adult Thoracolumbar Spinal Deformity Database
2 Setting: N National, M Multicenter, I Institutional
3 Location: L Lumbar spine; C Cervical spine; D Spinal Deformity; T Spine Trauma; I Spinal Infections; M Spinal metastases; O Other
4 Functional status: ODI Oswestry Disability Index; RMDQ Roland and Morris Disability Questionnaire; NASS North American Spine Society lumbar spine outcome scale; COMI Core Outcome Measures Index; SRS22 Scoliosis Research Society 22 questions
5 Pain: VAS Visual Analogue Scale; NPRS Numeric Pain Rating Scale
6 Quality of Life: SF8, SF12, SF36 Short Form 8 or 12 or 36 questions; EQ5D EuroQol 5 Dimensions (including EuroQol VAS)
7 PROMs at: B Baseline; P Peri-operative; 6w 6 weeks; 1 1 month; 3 3 months; 6 6 months; 12 12 months; 24 24 months; O Other; ... * 2 months in hernia/stenosis; # until discharge; $ at least 1 follow up; % variabel: when patient returns to clinic
8 n: according to Appendix 2; Table 1
9 NOS Risk of Bias score Newcastle-Ottawa scale – total score; median (range) according to Table 1
10 high quality
11 Shevelev et al. [79]; 12 See references for websites
13 Adogwa et al. [27]; 14 e.g. Kasliwal et al. [28] (see Table 1); 15 Scheer et al. [78]
### Table 5.3 Recommendations to improve the quality of study results published from registry data

**Organization and Method**

1. Use a standardized approach to registering in design, methodology, and analysis to allow international collaboration, to achieve benchmark purposes, and to make sure that in future spine care is value based.

2. Study and incorporate strategies to improve quality of care, e.g. continuous feedback and audit cycles of results collected in spine registries of delivered spine care.

3. To increase the quality of registry studies the population needs to be well defined, in terms of diagnosis and indication for surgery. Both in the developmental stage of a registry and when reporting on registry data follow the STROBE guidelines.

4. Include a minimum follow-up period of 1 year for surgically treated patients.

5. To meet the definition of a patient registry all registry characteristics should be present ([17]. This means an inclusion principle, mergeable data, standardized dataset for all consecutively included patients, rules for data collection (i.e. systematically and prospectively collected, including pre-intervention data), knowledge about patient-related outcomes, and observations collected over time (i.e. follow-up assessments))

**Patient-related outcomes**

6. Patient-reported outcome measures for degenerative lumbar spine disorders are PROMs with good measurement properties and as recommend by ICHOM. Although often defined as clinical patient-related outcomes (i.e. re-operation, complications, and Failed Back Surgery Syndrome), these indicators are in fact process measures for complicated course.

**Analyses and Report**

7. To explain differences in outcomes with advanced multivariate analytical techniques, include a reliability adjustment and an adjustment for covariates. For degenerative lumbar spine disorders the recommended factors in ICHOM could be used as covariates.

8. To reduce bias in results a 60-80% 12-months follow-up response is recommended.

9. To increase PROMs response at follow up reminders by text messages or email could be sent.

10. To understand potential sources of bias a non-responder analysis on baseline characteristics should be provided, including a quantitative sensitivity analysis in order to evaluate to which extent the results are affected by bias.

11. Multiple imputation techniques are recommended for sensitivity analysis when missing data are randomly divided.

**Practical issues**

12. Linkage between electronic medical records and registry data to avoid double data entry and to enhance routine in daily practice.

13. Participating departments should have direct access to their own data and should have real-time comparisons with other departments and if available, with the national mean.

14. After approval, analyzed results corrected for case mix should be presented for public on open web pages in order to increase credibility and to make adequate and relevant comparisons.

---

* not discussed in this study
Appendix 1: Search strategies

**MEDLINE - Pubmed**


AND

(“low back pain”[tiab] OR "back pain"[mesh] OR "back pain"[tiab] OR “intermittent neurogenic claudication”[tiab]

OR "intermittent claudication”[mesh] OR "intermittent claudication”[tiab]


AND


Within Reference manager on all fields (indexed and non-indexed)

Appendix 2: NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE for COHORT STUDIES

Note: A study can be awarded a maximum of one star (*) for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Selection
1) Representativeness of the exposed cohort (dependent on the diagnostic group)
   a) truly representative of the average case in the community *
   b) somewhat representative of the average case in the community *
   c) selected group of users eg nurses, volunteers
   d) no description of the derivation of the cohort

2) Selection of the non-exposed cohort
   a) drawn from the same community as the exposed cohort *
   b) drawn from a different source
   c) no description of the derivation of the non-exposed cohort

3) Ascertainment of exposure
   a) secure record (e.g. surgical records) *
   b) structured interview *
   c) written self-report
   d) no description

4) Demonstration that outcome of interest was not present at start of study
   a) yes *
   b) no

Comparability
5) Comparability of cohorts on the basis of the design or analysis
   a) study controls for the most relevant case mix variables (1. Diagnosis and 2. Baseline outcome score) *
   b) study controls for any additional factor *

Outcome
6) Assessment of outcome
   a) independent blind assessment *
   b) record linkage *
   c) self-report
   d) no description

7) Was follow-up long enough for outcomes to occur
   a) yes (select an adequate follow up period for outcome of interest) *
   b) no

8) Adequacy of follow up of cohorts
a) complete follow up - all subjects accounted for *
b) subjects lost to follow up unlikely to introduce bias - small number lost → 20%; 80% response *
c) follow up rate < 80% (select an adequate %) and no description of those lost
d) no statement

| Total score (n stars) | 0.5 |
Appendix 3: Table S1. Study characteristics

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Name Registry</th>
<th>Study purpose</th>
<th>Indication</th>
<th>Outcomes</th>
<th>PROMs</th>
<th>Secondary PROMs</th>
<th>Statistics</th>
<th>N</th>
<th>Clinical covariates</th>
<th>Methods Mising data</th>
<th>Study characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerland et al., 2014</td>
<td>Norwegian Registry for Spine Surgery</td>
<td>To study the equivalence of changes in functional outcomes</td>
<td>Lumbar spinal stenosis</td>
<td>PROMs: ODI v.2.0</td>
<td>EQD</td>
<td></td>
<td>Descriptive statistics</td>
<td>25</td>
<td>Adjustments for numbers of levels operated (one or two), age, BMI, baseline ODI value</td>
<td>Complete case analysis</td>
<td>Controlling for postoperative complications, duration of surgical procedures, length of hospital stay</td>
</tr>
<tr>
<td>Solberg et al., 2013</td>
<td>Norwegian Registry for Spine Surgery</td>
<td>To estimate cut-off values for success</td>
<td>Lumbar disc herniation</td>
<td>PROMs: ODI v.1</td>
<td>EQD</td>
<td></td>
<td>Descriptive statistics</td>
<td>39</td>
<td>Adjustment for baseline scores: ODI v.1, NPRS (0-10) back pain intensity, NPRS (0-10) leg pain intensity</td>
<td>Treatment effect: Paired Students t-tests, Subgroup comparison: one-way ANOVA, Relationship Global Perceived change and change scores: Spearman rank correlation coefficient, Cut-off values for success: ROC analyses and AUC</td>
<td></td>
</tr>
<tr>
<td>Coroll et al., 2006</td>
<td>Registry within Spanish National Health Service</td>
<td>To describe the implementation of Neuroreflexotherapy and the audit results</td>
<td>Non-specific subacute and chronic neck, back, and low back pain</td>
<td>PROMs: VAS (10cm) pain intensity of local and referred pain, RMDQ</td>
<td></td>
<td></td>
<td>Descriptive statistics</td>
<td>34</td>
<td>Not reported</td>
<td>Multiple imputation analysis (n=5 imputed datasets)</td>
<td></td>
</tr>
<tr>
<td>Kovacs et al., 2012</td>
<td>Registry within Spanish National Health Service</td>
<td>To explore the feasibility of implementing a registry in routine practice and to develop predictive models to quantify the likelihood that a given patient experiences a clinical relevant improvement</td>
<td>Acute and chronic low back pain with or without leg pain</td>
<td>PROMs: VAS, RMDQ, NRS (0-10) back pain intensity, VAS (10cm) leg pain intensity</td>
<td></td>
<td></td>
<td>Descriptive statistics</td>
<td>41</td>
<td>Independent variables in model: age, gender, duration of current pain episode (acute, subacute, chronic), employment status, education, current status of back surgery, previous back surgery, current spine diagnosis, duration of current spine episode because of Failed Back Surgery Syndrome, Diagnostic procedure/tests, Current spine complaint</td>
<td>Multiple imputation analysis (n=5 imputed dataset)</td>
<td>Multiple imputation analysis (n=5 imputed dataset)</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Registry</td>
<td>Setting</td>
<td>Objective</td>
<td>非特异性亚急性及慢性颈部、背部及下背部疼痛</td>
<td>PROMs</td>
<td>Independent Variables</td>
<td>Analysis Method</td>
<td>Missing Data Analysis</td>
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<tr>
<td>Kovacs et al., 2007 [48]</td>
<td>NRT en el SNS Registry within Spanish National Health Service Spain - Balearic Islands</td>
<td>To identify prognostic factors for clinical outcome.</td>
<td>Non-specific subacute and chronic neck, back, and low back pain.</td>
<td>PROMs: RMDQ (10cm) local pain intensity VAS (10cm) referred pain intensity</td>
<td>Independent variables in model: Reason for referral (neck, back) Gender Age Baseline PROMs Number of days with implanted surgical staples Duration of current pain episode (classified) Duration since first diagnosis (classified) Failed previous surgery for current episode</td>
<td>Descriptive statistics Multivariate logistic regression models using backward strategy</td>
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<tr>
<td>Royuela et al., 2013 [38]</td>
<td>NRT en el SNS Registry within Spanish National Health Service Spain</td>
<td>To assess the feasibility of using a registry in routine practice. To develop models predicting the probability of improvement</td>
<td>Non-specific subacute and chronic neck, back, and low back pain.</td>
<td>PROMs: RMDQ for LBP / NDI for neck pain VAS (10cm) local pain intensity VAS (10cm) referred pain intensity</td>
<td>Independent vars in model: Reason for referral (neck, back LBP) Gender Age Baseline PROMs Number of days with implanted surgical staples Duration of current pain episode (classified) Duration since first diagnosis (classified) Employment status Type of pain Diagnosis of fibromyalgia Other comorbidities Involvement in employment claims Involvement in litigation Diagnostic tests before Neuroreflexotherapy (NRT) Imaging findings History of spine surgery Treatments before NRT</td>
<td>Descriptive statistics Improvement based on Minimal Clinical Important Change Multivariate logistic regression models Nomograms to illustrate results of models Methods Missing data: Multiple imputation analysis (n= 10 imputed datasets)</td>
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<td>Fritzell et al., 2014 [57]</td>
<td>SweSpine Swedish National Spine Register Sweden</td>
<td>To compare PROMs between primary LDH and recurrent LDH. To determine risk factors for worse outcomes.</td>
<td>Lumbar disc herniation</td>
<td>PROMs: VAS (10cm) leg pain intensity VAS (10cm) back pain intensity ODI EQ5D Satisfaction and Global assessment of change in leg pain</td>
<td>Adjustments for: Age Gender Smoking Baseline value of analysed PROM</td>
<td>Descriptive statistics Comparison baseline characteristics between groups: independent Students’ t-test continuous variables, Chi-square test ordinal data. In outcome calculation ANCOVA was used. Multivariate logistic regression analysis</td>
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<td>Study Authors</td>
<td>SweSpine</td>
<td>Swedish National Spine Register</td>
<td>Sweden</td>
<td>Study Objective</td>
<td>Lumbar Condition</td>
<td>PROMs</td>
<td>Covariates</td>
<td>Analysis</td>
<td>Additional Details</td>
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<td>Forsth et al., 2013 [62]</td>
<td>SweSpine</td>
<td>Swedish National Spine Register</td>
<td>Sweden</td>
<td>To compare satisfaction after decompression alone and following decompression and fusion.</td>
<td>Lumbar spinal stenosis in one or two levels, with and without pre-operative spondylolisthesis</td>
<td>VAS (10cm) leg pain intensity, VAS (10cm) back pain intensity, ODI EQ5D, Satisfaction and Global assessment of change in leg pain</td>
<td>Adjustments for: Age (continuous), Gender, Smoking, Duration of symptoms, Previous spinal surgery, Baseline analgesic use</td>
<td>Descriptive statistics</td>
<td>Adjusted means were estimated using Students’ t-tests Multivariate logistic regression analyses</td>
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<td>Jansson et al., 2005 [49]</td>
<td>SweSpine</td>
<td>Swedish National Spine Register</td>
<td>Sweden</td>
<td>To report the health-related quality of life outcome in Lumbar Disc herniation. To compare the results with the Swedish population.</td>
<td>Lumbar disc herniation</td>
<td>EQ5D</td>
<td>Covariates: Age, Gender, Smoking status, Type of surgery, Duration of back and leg pain, PROM: baseline VAS leg pain, Pre-operative walking distance, PROM: baseline EQ5D</td>
<td>Descriptive statistics</td>
<td>MANOVA, adjusted for covariates.</td>
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<tr>
<td>Jansson et al., 2009 [50]</td>
<td>SweSpine</td>
<td>Swedish National Spine Register</td>
<td>Sweden</td>
<td>To report HRQoL outcome in a Lumbar Spinal Stenosis cohort. To compare the findings with the Swedish population.</td>
<td>Lumbar spinal stenosis</td>
<td>EQ5D score and EQ-VAS</td>
<td>Covariates: Age, Gender, Smoking status, Type of surgery, Duration of back and leg pain, Pre-operative walking distance, PROM: baseline EQ5D</td>
<td>Descriptive statistics</td>
<td>MANOVA, adjusted for covariates.</td>
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<td>Knutsson et al., 2013 [31]</td>
<td>SweSpine</td>
<td>Swedish National Spine Register</td>
<td>Sweden</td>
<td>To determine the association between BMI and outcome of lumbar spine surgery.</td>
<td>Lumbar spinal stenosis</td>
<td>VAS (10cm) leg pain intensity, VAS (10cm) back pain intensity, ODI, EQ5D, Satisfaction 3-point Likert scale, Clinical outcome: Height &amp; weight (BMI)</td>
<td>Adjustment for: Age, Gender, Smoking, Use of analgesics, Previous back surgery, Duration of symptoms, PROMs: Baseline values</td>
<td>Descriptive statistics</td>
<td>General linear models (GLM), Restricted cubic-spline logistic regression analysis</td>
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<td>Study</td>
<td>Registry</td>
<td>Population/Settings</td>
<td>Methodology</td>
<td>Outcomes</td>
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<td>Robinson et al., 2013 [26]</td>
<td>SweSpine Swedish National Spine Register</td>
<td>To compare the 2-year results of 3 methods of lumbar fusion (UIF, IPF, and TLIF/PLIF).</td>
<td>Degenerative disc disease</td>
<td>PROMs: VAS (10 cm) leg pain intensity VAS (10 cm) back pain intensity ODI EQ5D</td>
<td>Adjustment for: Age Gender Smoking Use of analgesics Previous back surgery Duration of symptoms PROMs: Baseline value under study Year of surgery: as 2 of the methods were unevenly distributed over study period. In many hospitals 1 surgical method predominated.</td>
<td>Descriptive statistics PROC MIXED and Kenward-Roger method, adjusted means Modified Poisson regression approach</td>
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<td>Sanden et al., 2011 [55]</td>
<td>SweSpine Swedish National Spine Register</td>
<td>To determine the relation between smoking status and disability after surgical treatment.</td>
<td>Lumbar spinal stenosis</td>
<td>PROMs: VAS (10 cm) leg pain intensity VAS (10 cm) back pain intensity ODI Walking distance (categorized) SF36 EQ5D</td>
<td>Adjustment for: Age Gender Smoking Use of analgesics PROMs: Baseline value under study</td>
<td>Descriptive statistics General Linear Models (GLM), adjusted means Multivariate logistic regression</td>
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<tr>
<td>Sigmundsson et al., 2012 [42]</td>
<td>SweSpine Swedish National Spine Register</td>
<td>To determine predictive factors of surgical outcome.</td>
<td>Lumbar spinal stenosis</td>
<td>PROMs: VAS (10 cm) leg pain intensity VAS (10 cm) back pain intensity ODI Walking distance (categorized) EQ5D</td>
<td>Controlled for: Age Duration of back and leg pain MRI: Multilevel stenosis and spondylolisthesis MRI: Central dural sac area? PROMs: baseline values Walking distance, Back and Leg pain</td>
<td>Descriptive statistics Paired Students’ t-test; Mann Whitney U, Kruskall Wallis Multivariate regression analysis MANOVA for variation in PROMs.</td>
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<td>Sigmundsson et al., 2013 [37]</td>
<td>SweSpine Swedish National Spine Register</td>
<td>To determine how different constellations of back and leg pain influence preoperative health related quality of life.</td>
<td>Lumbar spinal stenosis</td>
<td>PROMs: VAS (10 cm) leg pain intensity VAS (10 cm) back pain intensity ODI Walking distance (categorized) SF36 EQ5D</td>
<td>Not reported</td>
<td>Descriptive statistics Parametric tests: Satterthwait t-test Non-parametric tests: Mann-Whitney test, test for trend (Chi-square)</td>
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<td>Study</td>
<td>Spine Register</td>
<td>Setting</td>
<td>Objective</td>
<td>Lumbar Spinal Stenosis</td>
<td>Outcomes</td>
<td>Risk Factors</td>
<td>Analysis</td>
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<td>Sigmundsson et al., 2014</td>
<td>SweSpine Swedish National Spine Register</td>
<td>Sweden</td>
<td>To evaluate outcome of surgery and to explore the role of spinal fusion in predominant back pain and predominant leg pain.</td>
<td>PROMs: VAS (10cm) leg pain intensity VAS (10cm) back pain intensity ODI Walking distance (categorized) SF36 EQ5D Satisfactory with operation (categorized)</td>
<td>Adjustments for: Age Gender Duration of Leg and Back Pain Comorbidity Smoking Baseline PROM score</td>
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<td>Descriptive statistics Linear regression analysis. Cox proportional hazard model (Robust) Outcomes compared with unadjusted nonparametric tests, test for trend (Chi square), Mann Whitney U test.</td>
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<td>Stromqvist et al., 2012</td>
<td>SweSpine Swedish National Spine Register</td>
<td>Sweden</td>
<td>To elucidate the incidence of dural lesions in decompressive surgery, to identify risk factors and effect on postoperative outcome.</td>
<td>PROMs: VAS (10cm) leg pain intensity VAS (10cm) back pain intensity ODI SF36 EQ5D Satisfactory with operation (categorized)</td>
<td>Risk factors: Age Gender Smoking Work Consumption of analgesics Walking distance Clinical risk factors: Dural lesion Number of levels decompressed</td>
<td>Risk factors: Age Gender Smoking Work Consumption of analgesics Walking distance Clinical risk factors: Dural lesion Number of levels decompressed</td>
<td>Descriptive statistics Logistic regression analysis</td>
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<td>Berg et al., 2010</td>
<td>SweSpine Swedish National Spine Register</td>
<td>Sweden</td>
<td>To determine whether a registry can provide the same information as an RCT.</td>
<td>PROMs: Global rating scale for improvement of back and leg pain</td>
<td>Not reported</td>
<td>Complications Reoperations Work status Medication</td>
<td>Descriptive statistics Two-tailed Mann-Whitney U; Wilcoxon rank sum tests Students’ t test; Spearman r, Fisher exact; Chi-square tests</td>
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<td>Study (Year)</td>
<td>Registry</td>
<td>Countries</td>
<td>Purpose</td>
<td>PROMs</td>
<td>Secondary PROMs</td>
<td>Statistical Methods</td>
<td>Findings</td>
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<td>Grob and Mannion, 2009</td>
<td>SSE Spine Tango Surgery Registry Switzerland</td>
<td>To investigate the occurrence of post-surgical complications from the patient's perspective.</td>
<td>Spine surgery for different pathologies of the cervical and lumbar spine</td>
<td>PROM: COMI Occurrence / nature of postop complications</td>
<td>Not reported</td>
<td>Descriptive statistics to evaluate group differences: Chi-square tests for proportion differences</td>
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<td>Porchet et al. 2009</td>
<td>SSE Spine Tango Surgery Registry Switzerland</td>
<td>To compare outcome after lumbar disc excision with and without the use of the microscope.</td>
<td>Lumbar/ lumbosacral degenerative disorders</td>
<td>PROM: COMI, incl. - NPRS (0-10) Back pain intensity - NPRS (0-10) Leg pain intensity</td>
<td>Gender - Age categories (&lt;60; &gt;60) - Health insurance (Private; Basic obligatory) - Comorbidity (ASA score)</td>
<td>Descriptive statistics Unpaired Student's t tests Contingency analyses (Chi-square tests)</td>
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<tr>
<td>Aghayev et al. 2012</td>
<td>SSE Spine Tango Surgery Registry SWISS spine Registry Switzerland</td>
<td>To compare back and leg pain alleviation after total disc arthroplasty and ALIF stratified by implant and surgeon from the SWISS-spine and Spine Tango registries.</td>
<td>CLBP - Degenerative disc disease</td>
<td>PROM: NASS, used - VAS (10 cm) Back pain intensity - VAS (10 cm) Leg pain intensity - EQ5D</td>
<td>Covariates: Implant, Surgeon, Depression, Age, Gender, Follow-up interval, Length of stay (LoS)</td>
<td>Descriptive statistics First step: univariate logistic regression Second step: generalized linear model (GLM), adjusted</td>
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<tr>
<td>Aghayev et al. 2010</td>
<td>SWISS spine Registry Switzerland</td>
<td>To evaluate the outcomes of all single-level Dynardi TDA s compared with all other prostheses in the SWISS spine data pool.</td>
<td>CLBP - Degenerative disc disease</td>
<td>PROM: NASS, used - VAS (10 cm) Back pain intensity - VAS (10 cm) Leg pain intensity - EQ5D</td>
<td>Covariates: Device used, Gender, Age (categorized), Surgical volume of center of intervention, Pharmacologically treated depression, Preoperative PROM scores (pain and EQ5D; categorized)</td>
<td>Descriptive statistics Wilcoxon rank-sum test Chi-square tests Multiple logistic regression models; backward elimination</td>
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<td>Reference</td>
<td>Registry Name</td>
<td>Country</td>
<td>Aim</td>
<td>Outcomes Measured</td>
<td>Methods</td>
<td>Analysis</td>
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<td>Schluessmann et al. 2009 [54]</td>
<td>SWISSspine Registry</td>
<td>Switzerland</td>
<td>To report the methodology and implementation of the SWISSspine registry and early results of the cases with TDA.</td>
<td>Not reported</td>
<td>Lumbar Total Disc Arthroplasty (TDA)</td>
<td>PROM: NASS, used - VAS (10 cm) Back pain intensity - VAS (10 cm) Leg pain intensity EQ5D</td>
<td>Covariates: Prosthesis used, Gender, Age, Surgical volume of center of intervention (categorized), Pharmacologically treated depression, Preoperative PROM scores (pain and EQ5D)</td>
<td>Descriptive statistics, Wilcoxon rank-sum test, Chi-square test, Multiple logistic regression models, backward elimination</td>
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<td>Zweig et al. 2011 [48]</td>
<td>SWISSspine Registry</td>
<td>Switzerland</td>
<td>To prove that preoperative nucleus pulposis status and presence or absence of radiculopathy has an influence on clinical outcomes in patients with mono-segmental lumbar total disc replacement.</td>
<td>Not reported</td>
<td>mono-segmental TDR surgery for Degenerative disc disease, Hernia nucleus pulposis - no radiculopathy, Hernia nucleus pulposis - radiculopathy</td>
<td>PROM: NASS, used - VAS (10 cm) Back pain intensity - VAS (10 cm) Leg pain intensity EQ5D</td>
<td>Adjustment for covariates: Gender, Age, Preoperative pain medication, Intervertebral level of intervention, Pharmacologically treated depression, Type of work, Working activity level</td>
<td>Descriptive statistics, Univariate logistic regression or ANOVA, General linear modelling (GLM), Bonferroni-Holm adjustments for multiple testing</td>
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<td>McGirt et al. 2013 [40]</td>
<td>N2QOD</td>
<td>USA</td>
<td>To provide an overview of the aims, registry design and methods of the N2QOD pilot year lumbar module.</td>
<td>Lumbar spinal disorders: - symptomatic lumbar disc herniation - symptomatic recurrent lumbar disc herniation - lumbar stenosis - lumbar adjacent segment disease</td>
<td>Perioperative measures: Blood loss, Length of Stay, Need for inpatient rehabilitation or skilled nursing, 90-day morbidity, readmission, reoperation, Occasional outcome (return to work, capacity)</td>
<td>PROMs: Patient satisfaction, NPRS (0-10) back and leg pain, ODI, EQ5D</td>
<td>Patient characteristics and demographic factors for risk-adjustment</td>
<td>Descriptive statistics, Risk-adjusted models, Complete cases analyses</td>
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<td>Deer et al. 2004 [32]</td>
<td>National Outcomes Registry for LBP</td>
<td>USA</td>
<td>To obtain data on patient demographics, clinical practices, and long-term outcomes for patients with CLBP treated with implantable drug-delivery systems.</td>
<td>CLBP - intrathecal Drug Delivery (IDD)</td>
<td>PROMs: NPRS (0-10) back and leg pain, ODI vs.0, Secondary Return to work, Satisfaction with IDD (recommend IDD to others, and quality of life) Adverse events</td>
<td>Patient characteristics: age, gender, underlying cause of pain, type of pain, previous pain treatments, use of systemic opioids, work status, trialing site, trial duration, type of medical insurer, previous psychological evaluations, implant location, type of system.</td>
<td>Descriptive statistics, Chi-square tests and Paired t-tests treatment effect, Repeated measures ANOVA outcomes over time</td>
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<td>Study</td>
<td>Database/Study Design</td>
<td>Study Aim</td>
<td>Study Details</td>
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<td>Taylor et al. 2000 [53]</td>
<td>Community outcomes</td>
<td>To examine factors associated with favourable self-reported outcomes 1 year after elective surgery.</td>
<td>Lumbar spinal disorders: - degenerative changes - herniated disc - instability (incl. Spondylolisthesis) - spinal stenosis Patient-reported questions: - back surgery changed quality of life - functioning better/worse than before surgery - rate of overall treatment of back problem - bothersomeness back pain - bothersomeness leg pain - interference of physical health in activities - most strenuous level of physical activity</td>
<td>Age Gender Smoking habits Duration of symptoms Clinical signs Diagnosis Surgical procedure Previous surgery Work status Workers’ compensation Seeing attorney Baseline scores on patient-reported questions</td>
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<td>Bridwell et al. 2007 [30]</td>
<td>Adult Deformity</td>
<td>To prospectively analyse the responsiveness of the SRS-22 to change 1 and 2-years following primary surgery.</td>
<td>Adult deformity PROMs: SRS-22 ODI SF12 Age (categorized) Curve type (major curve location)</td>
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<td>Glassman et al. 2009 [44]</td>
<td>Adult Deformity</td>
<td>To examine outcomes after adult deformity surgery. Do 1-year outcomes predict 2-year outcomes?</td>
<td>Adult deformity PROMs: SRS-22 ODI NPRS (0-10) for back and leg pain SF12 (physical and mental component scores) Subgroup analyses based on: Diagnosis Curve type</td>
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<td>Glassman et al. 2007 [53]</td>
<td>Adult Deformity</td>
<td>To determine whether perioperative complications alter clinical outcomes.</td>
<td>Adult deformity Clinical: Complications PROMs: SRS-22 ODI NPRS (0-10) for back and leg pain SF12 (physical and mental component scores) Three defined complication cohorts were matched: Age (categorized) Diagnosis Baseline PROM SRS-22 total score Distal fusion level Sagittal balance at 1-year post-operation</td>
<td>Descriptive statistics Propensity modelling. Analysis: 1-way and repeated measures ANOVA.</td>
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<td>Kasliwal et al. 2012 [28]</td>
<td>Adult Deformity</td>
<td>To assess differences in surgical parameters (e.g. Surgical time, blood loss), complication rates, and outcomes in adults undergoing spinal deformity correction who either did or did not have a history of a short-segment spinal procedure.</td>
<td>Adult deformity PROMs: SRS-22 ODI v1 NPRS (0-10) for back and leg pain SF12 (physical and mental component scores) Patients with/without prior surgery were matched: Age (categorized) Baseline PROM ODI score Cobb angle Sagittal Vertical Axis (SVA)</td>
<td>Descriptive statistics Propensity modelling. Wilcoxon signed-rank or Fisher exact tests used to compare outcomes.</td>
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<td>Study</td>
<td>Database/Registry</td>
<td>Country</td>
<td>Objective</td>
<td>PROMs/Outcomes Measures</td>
<td>Diagnoses and Surgical Procedures</td>
<td>Methodology</td>
<td>Description</td>
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<tr>
<td>Schwab et al. 2008 [29]</td>
<td>Adult Deformity Outcomes Database</td>
<td>USA</td>
<td>To determine if models for predicting outcome and complications can be constructed.</td>
<td>Adult deformity</td>
<td>SRS-22, ODI, NPRS (0-10) for back and leg pain, SF12 (physical and mental component scores)</td>
<td>Clinical: Complications</td>
<td>Descriptive statistics. Two approaches were used to determine factors predicting successful surgical outcome: 1. Binary logistic regression models were built to examine how factors combine and interact. 2. Multiple linear regression analyses using backward stepwise techniques were used to eliminate redundant predictive factors. Subsequently, binary logistic regression to predict a reported complication.</td>
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<td>Adogwa et al. 2013 [27]</td>
<td>Multicenter registry for lumbar spine surgery</td>
<td>USA &amp; Canada</td>
<td>To assess the effect of incidental durotomies on the immediate postoperative complications. To investigate the patient-reported outcomes at longer-term follow up following lumbar fusion.</td>
<td>Lumbar spinal disorders: Degenerative disc disease, Grade spondylolisthesis with central foraminal stenosis</td>
<td>VAS Back pain, VAS Leg pain, ODI, Clinical: Postoperative complications</td>
<td>Patients with durotomy and controls were matched using propensity modelling (1:2) based on: Age, Gender, Comorbidities, Other relevant surgical factors</td>
<td>Descriptive statistics. Student t-test, Mann-Whitney U test and Chi-square tests. Propensity modelling to stratify risk.</td>
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<tr>
<td>Seng et al. 2013 [33]</td>
<td>Singapore General Hospital Spine Outcomes Registry</td>
<td>Singapore</td>
<td>To compare midterm clinical and radiological outcomes of minimal invasive surgery (MIS) versus open transforaminal lumbar interbody fusion (TLIF)</td>
<td>Lumbar spinal disorders</td>
<td>ODI, Neurogenic Symptom Score (NSS) SF36, VAS Back pain, VAS Leg pain, Clinical: Bridwell classification</td>
<td>Not reported</td>
<td>Pearson Chi-square, Student's t-test to compare differences in characteristics. ANOVA to evaluate differences in PROMs. Independent Students' t-test to compare differences between groups.</td>
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1 PRO, M Patient-reported outcome measure; ODI, Oswestry Disability Index; RMDQ, Roland and Morris Disability Questionnaire; NPRS, Numeric Pain Rating Scale; VAS, Visual Analogue Scale; NASS, North American Spine Society lumbar spine outcome scale; COMI, Core Outcome Measures Index; SF36, SF 12, Short Form 36 or 12 questions; EQ5D, EuroQol 5 Dimensions (including EQ VAS); SRS-22, Scoliosis Research Society 22 questions.
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63. Forsth P. No benefit from fusion in decompressive surgery for lumbar spinal stenosis. Two-year results from the Swedish spinal stenosis study. A multicenter RCT of 229 patients. In: 2014 EuroSpine conference; Lyon, France

79. Shevelev IN, Kornienko VN, Konovalov NA, Cherkashov AM, Molodchenkov AI, Votkins RG et al. [Working results of the electronic "on-line" version of the Spine Registry for Degenerative Lumbar Spine Diseases and study of its synchronization capacity with the electronic case history.]. Zh.Vopr.Neirokhir.Im N.N.Burdenko 2013;77:57-64

Guest editorial: Spinal disorders, quality-based healthcare and spinal registers
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